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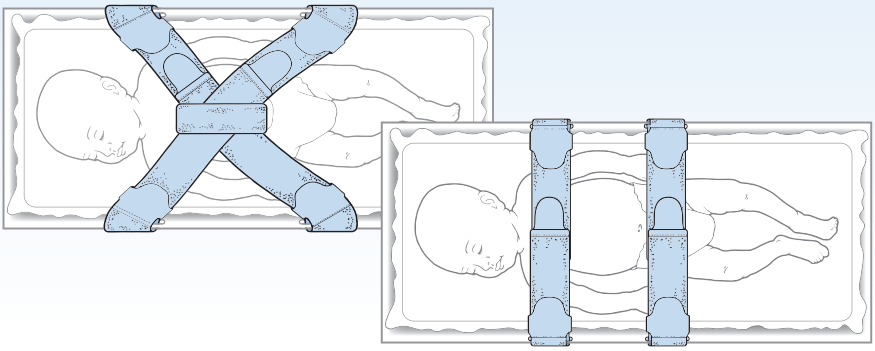

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News

■ Winter 2026

Significant Publication Urging Action on Hemolysis

Werfen announced their commendation for the recent publication of a significant, multi-author Special Report, underscoring the urgent need to address the risks of undetected in vitro hemolysis, a preanalytical error with the potential to negatively impact patient care. The Company congratulates the authors on this important and timely publication. Published in the Journal of Applied Laboratory Medicine (JALM)—an international, peer-reviewed publication—the Special Report, "Handling Hemolytic Blood Samples from High-Risk Clinical Areas: A Call to Action," advocates for a coordinated, hospital-wide approach to better detect, prevent, and manage in vitro hemolysis, particularly in high-risk settings, such as emergency departments and intensive care units. The report highlights hemolysis as a significant cause of preanalytical error, with the potential to cause misinterpretation of critical results, most notably potassium. "This important publication highlights the prevalence and risks of undetected hemolysis in whole blood samples, which can impact test results throughout the hospital," said Annie Winkler, MD, Chief Medical Officer at Werfen. "With innovative technology that detects hemolysis at the point of care in seconds, we can help hospitals expedite decision-making, enhance efficiency, and most importantly, improve patient management." As the number one source of preanalytical error, hemolysis accounts for up to 70% of all such errors. Despite its prevalence throughout the hospital, it can often go unrecognized. Hemolysis is the disruption of red blood cells, triggering the release of hemoglobin and other intracellular components into plasma or serum. This can cause an elevation in potassium results, of up to 152%. In samples impacted by hemolysis, low potassium levels can appear normal and normal levels can appear high. At the point of care, this can lead to inappropriate patient management, longer length of stay, unnecessary sample recollection and increased costs, among other consequences. In neonatal intensive care units, nearly half of whole blood samples have been found to be hemolyzed, while in emergency departments, up to 20% may be hemolyzed. This Special Report reinforces the problem of in vitro hemolysis, emphasizes the need for hemolysis detection in whole blood and provides six recommendations as a call to action to address this significant preanalytical error. Last year, Werfen introduced the GEM Premier 7000 with iQM, the first blood gas testing system that detects hemolysis at the point of care in just 45 seconds, helping to inform appropriate patient management decisions and enhance patient care. The GEM Premier 7000 with iQM3 also helps improve operational efficiency and reduce cost. For decades, Werfen has been a worldwide leader in Specialized Diagnostics. The Company remains committed to innovation, rooted in real-world collaboration with front-line emergency medicine physicians, ICU clinicians, anesthesiologists, and operating room teams. Incorporating feedback from these integral voices has helped shape solutions that directly address clinical needs and support safer, more effective care, such as blood gas testing that detects hemolysis at the point of care in seconds. The GEM Premier 7000 with iQM3 system is part of Werfen's integrated and comprehensive ACD product portfolio—helping clinicians and laboratorians achieve better patient outcomes, lower total cost of care, assure accreditation compliance and improve operational efficiency in hospital acute care settings. For Whole Blood Hemostasis testing, ROTEM viscoelastic testing systems, the GEM Hemochron 100 system, and the VerifyNow platelet-reactivity testing system inform key clinical decisions regarding transfusion, bleeding risk and heparin dose adjustment during surgical and interventional procedures along with a clinical assessment of the patient's condition and

other laboratory tests. For Blood Gas testing, the GEM Premier systems, including GEM Premier 7000, 5000 and 3500 systems, and the Avoximeter 1000 portable CO-Oximeter, simplify POC operations by automating key labor-and skill-intensive tasks, including quality management and system maintenance. From Cardiovascular Operating Rooms and Catheterization Labs, to Intensive Care Units and Emergency Departments, whole-blood, cartridge-based systems with Werfen's integrated data management solutions, help hospitals improve efficiency and enhance patient care.

Resmed Receives FDA Clearance for Personalized Therapy Comfort Settings

Resmed, the leading health technology company focused on sleep, breathing and care delivered in the home, today announced it has received US Food and Drug Administration (FDA) clearance for Personalized Therapy Comfort Settings (PTCS), to be marketed as Smart Comfort. Smart Comfort is the first FDA-cleared AI-enabled medical device that recommends personalized comfort settings to help people with obstructive sleep apnea (OSA) start and stay on CPAP therapy. Smart Comfort will launch in early 2026 in a limited US beta version for new users of myAir, Resmed's consumer sleep companion app, paired with a Resmed AirSense 11 device. It will be followed by a broader US rollout to new myAir users later in 2026. CPAP therapy is not one-size-fits-all. Addressing common therapy issues, like comfort and mask fit, early can promote long-term adherence. Smart Comfort leverages Resmed's proprietary machine-learning algorithms, drawing on more than 100 million nights of de-identified, real-world sleep data and user information, such as age, gender and Apnea-Hypopnea Index (AHI), to recommend individualized comfort settings for CPAP therapy delivered by Resmed's market leading AirSense 11 devices. These include settings that help ease users into therapy, adjust how gradually an AirSense 11 increases pressure and reduce pressure on exhale. Smart Comfort was developed with clinical oversight and ethical data use in compliance with privacy laws, considering quality and patient safety at every stage.

"For people new to CPAP therapy, personalized comfort settings can help them adjust faster and more comfortably, improving confidence and overall health," said Justin Leong, Chief Product Officer at Resmed. "Smart Comfort's FDA clearance marks an important milestone for the future of personalized, data-driven care. It's another example of how we're using technology and real-world evidence to make sleep health more personal, accessible and effective." The FDA submission was supported by retrospective real-world evidence showing that Resmed AirSense 10 and 11 users whose comfort settings matched Smart Comfort recommendations had higher engagement and sustained therapy adherence compared to those using default settings. These findings demonstrate that personalized comfort adjustments can help improve the therapy experience without compromising efficacy. In the US, OSA impacts an estimated 61 million people and is expected to rise to nearly 77 million by 2050. Left untreated, OSA can significantly impact health and quality of life, increasing the risk of high blood pressure, heart disease,

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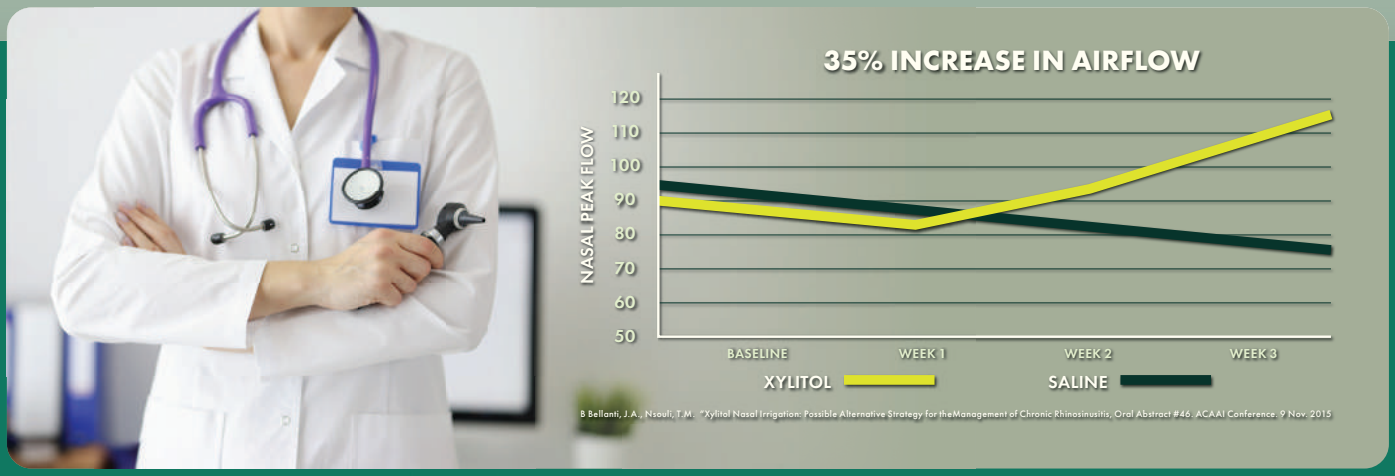

B Bellanti, J.A., Nsouli, T.M. "Xylitol Nasal Irrigation: Possible Alternative Strategy for theManagement of Chronic Rhinosinusitis, Oral Abstract #46. ACAAI Conference. 9 Nov. 2015

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type 2 diabetes and stroke. CPAP therapy, the gold standard treatment for sleep apnea, can significantly reduce the risk of death in people with OSA. For healthcare providers, Smart Comfort offers a solution to help streamline user setup and follow-up and reduce manual adjustments so clinicians can devote more attention to clinical decision-making and patient support. By getting people engaged in their therapy from day one, Smart Comfort helps standardize the comfort settings workflow and builds user confidence that their settings are personalized for them. These non-prescription comfort settings are designed to support CPAP therapy device usage – not alter prescribed therapy settings or therapy efficacy. Smart Comfort is part of Resmed's connected, personalized sleep-health ecosystem – combining AI, cloud-connected Resmed devices and digital tools to help make sleep health more personal and support therapy efficacy. Together with other myAir features, including Dawn, Therapy Control and Streaks, these innovations demonstrate Resmed's commitment to responsible, data-driven innovation that helps more people start and stay on therapy.

New Device May Reduce Hospitalizations of Children With Severe Asthma Attacks

A new bronchodilator delivery device, SOBIstat-F, reduced hospitalization rates and improved clinical outcomes in children with severe acute asthma, according to a randomized clinical trial presented at the European Academy of Paediatrics (EAP) 2025. The study, conducted in two pediatric emergency departments in Asunción, Paraguay, involved 84 pediatric patients treated for severe asthma exacerbations. The children were randomly assigned to receive bronchodilators either via the new SOBIstat-F device (pIDM-SOBx) or through conventional oxygen therapy (pIDM-OxStand). Both groups received standard bronchodilator therapy, but the key difference was in the mode of delivery. The SOBIstat-F integrates continuous oxygen flow with simultaneous bronchodilator administration via a pressurized metered-dose inhaler, which allows for simultaneous oxygen and medication delivery without removing the mask. Conventional care required clinicians to alternate between oxygen and spacers or nebulizers, which potentially affected consistency of medication delivery. Children who were treated with SOBIstat-F vs those treated conventionally had a lower hospitalization rate (9.3% vs 26.8%; P = .036). Clinical improvement in pulmonary scores was noted by 90 minutes (P < .001), and oxygen saturation improved after 60 minutes (P < .001). Lead study investigator Ricardo Iramain, MD, professor of clinic pediatrics at the Hospital de Clínicas at the National University of Asunción, said the findings highlight a practical and affordable advance for pediatric emergency care. "There aren't any barriers for integrating the SOBIstat-F device into emergency department protocols for acute asthma attacks," said Iramain. Iramain said that the product can be reused up to 20 times over a 7-year lifespan, making it "very economical and quite competitive with nebulizers or metered-dose inhaler valve-holding chamber masks used for emergency intervention, which are not reused." Side effects such as increased heart rate and throat irritation

were comparable between the two groups, suggesting that the device is as safe as standard care, the researchers noted. "One of the main advantages of SOBIstat is that it offers a steady flow of oxygen and uniform delivery of the drug into the airways," Iramain said.

Nonin Boosts its Staff

Nonin Medical, a global leader in noninvasive medical monitoring solutions, announced that its Board of Directors has appointed medical device industry leader Todd Austin as the company's next Chief Executive Officer. Austin is a seasoned medical technology executive recognized for driving strategic growth in respiratory diagnostics and medical technology companies. He brings extensive global leadership experience across strategic planning and execution, business development, external partnerships, product portfolio management, marketing, and clinical operations—combined with a proven ability to develop and advance effective business strategies that deliver meaningful results. "Todd's deep expertise in respiratory diagnostics and proven record of strategic leadership make him the ideal person to guide Nonin into its next phase of growth," said Phil Isaacson, Executive Chairman, Board of Directors at Nonin Medical. "His passion for innovation in the respiratory medical device industry and commitment to advancing patient outcomes align perfectly with Nonin's mission and values." Advances in medical technology continue to play a critical role in the heathcare industry. Nonin Medical remains dedicated to delivering dependable noninvasive monitoring solutions designed to support and empower healthcare professionals and patients around the world. The company looks forward to working closely with Austin as he leads Nonin in expanding our global impact and strengthen partnerships across the healthcare ecosystem. "Throughout my 30+ years as a Respiratory Therapist, I've trusted and relied on Nonin's products and technology across nearly every care setting—from bedside and critical care to transport, sleep and cardiopulmonary diagnostics, remote monitoring, and device integration," said Austin. "Nonin has always stood for quality, reliability, and innovation, values that have guided my own career." Prior to joining Nonin Medical, Austin served as President and CEO of MGC Diagnostics, a subsidiary of CAIRE Inc. and Niterra. Prior to that, he held the role of Executive Vice President, Global Marketing, Engineering, and Corporate Strategy at MGC Diagnostics. His career also includes key leadership roles at Angeion, CareFusion, NDD, VIASYS Healthcare, and SensorMedics.

Personalized Self-Management Empowers Patients With Chronic Respiratory Disease, but Global Inequities Persist

The respiratory medical community is increasingly recognizing the importance of involving patients in managing chronic respiratory conditions. As Hilary Pinnock, PhD, professor of primary care respiratory medicine at The University of Edinburgh, Edinburgh, Scotland, pointed out, patients with a condition like asthma spend 120 minutes a year with a healthcare professional, she said. "Have you all worked out how many minutes of the year they're actually managing their own asthma?" Pinnock asked. "Every patient with asthma is self-managing [the disease]. Our role is to support them in what they are doing and to enable them to do it better." But she explained, this is not about handing over responsibility but about forming a partnership. However, for many patients,

Continued on page 29…

VENTILATION ROUNDTABLE

Draeger

What ventilation products does your company offer?
Dräger offers a wide range of ventilators, including those for all patient categories, neonatal/pediatric ventilators, dedicated NIV ventilators, Bubble CPAP, as well as a full line of accessories and service programs.

What are the new features?
Visit us at booth #1007 to discover what's new from Dräger—from airway protection to lung protection tools and educational resources.

Tell us about your company's current or recent R&D efforts.
Dräger continuously invests in R&D projects that help improve patient outcomes, reduce costs, and support clinicians in delivering optimal care. Visit our booth to see the latest efforts in action.

Discuss the training and support services your offer.
Dräger offers flexible clinical education to help healthcare professionals build confidence and use their devices effectively—which can support improving patient care. This includes on-demand learning through Dräger Academy, monthly live Q&A sessions, customized in-person workshops, and virtual reality with our Dräger Virtuo platform.

Where are your products used?
Dräger ventilation products are used in hospitals: including adult, pediatric, neonatal ICUs, ERs, open heart ICUs, and recovery rooms—almost any area that requires mechanical ventilation.

What developments do you foresee for ventilation products and applications?
Dräger is working towards more advancements in device connectivity, workflow efficiency, cost reductions, and technology focused on improving patient outcomes.

React Health

What ventilation products does your company offer?
React Health offers a broad portfolio of invasive and non-invasive ventilators designed to support patient therapy needs across various care settings. Our Solutions include hospital-to-home transition ventilators, configurations with integrated cough therapy, or an all-in-one, five therapy ventilator for pediatric and adult patients. Additionally, we carry bilevels with and without backup rates to support a range of clinical requirements.

What are the new features?
We have added usability enhancements such as Stand-By mode and a simplified pre-use setup process as well improving serviceability by offering extended preventative maintenance options.

Tell us about your company's current or recent R&D efforts.
React Health is actively reinvesting across our sleep and ventilation portfolios to advance product quality, reliability, and usability. We place strong emphasis on incorporating clinician and patient feedback to guide future iterations, improve user experience, and reduce the overall complexity of maintaining and operating our devices.

Discuss the training and support services you offer.
Our ventilation sales team is composed of experienced Respiratory Therapists who partner with clinicians and DMEs daily to help with things like setups/transitions, understanding patient compliance on our Patient Monitoring system, and navigating the current landscape and guideline changes. In addition to this local and in-person team of Ventilation and Clinical specialists, we have Product Support with availability beyond standard business hours for virtual guidance when needed.

Where are your products used? (ie, hospital, home, etc.)
React Health's ventilator portfolio includes devices designed for use in hospital, transport, and home environments. Many of our platforms share similar interfaces and operating principles, helping streamline staff training and support smoother hospital-to-home transitions. Our solutions are used across various patient populations, including pediatric care settings, because of their performance capabilities and ease of operation.

What developments do you foresee for ventilation products and applications?
The recent updates to the NCD RAD guidelines emphasize the importance of ongoing compliance monitoring, making actionable and accessible data increasingly important for therapy support and helping DMEs meet evolving documentation requirements.

In response, we are continuing to advance our Remote Patient Monitoring capabilities to support clinicians and providers with timely therapy insights.

Patient comfort will also remain a key focus in ventilator development. Features such as leak compensation, customizable comfort settings, and expanded therapy modes—including options like High Flow are intended to support a more comfortable and user-friendly therapy experience. Looking ahead, creating opportunities for greater patient engagement and support will also be an important part of ongoing innovation

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- Acute Respiratory Distress Syndrome (ARDS)

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When Machines Write Medicine — The New Challenge for Scientific Integrity

Steve Goldstein

In more than fifty years of publishing in the medical sciences, I have witnessed our field transform from linotype and paste-up to digital composition, from couriered galleys to instant online submission. Yet no technological change has arrived as quickly—or as deceptively—as the entry of artificial intelligence into scientific writing.

Over the past year, a quiet revolution has taken place in manuscript preparation. Authors are turning to AI systems to help draft abstracts, polish grammar, summarize data, and even generate literature reviews. On the surface, this seems like progress: faster publication cycles, improved clarity, and support for non-native English speakers. But beneath that efficiency lies a growing concern for editors, reviewers, and readers alike—**how do we know what is genuinely the author's work, and what has been manufactured by an algorithm?**

Recent reports from across the scientific community are sobering. Investigators have shown that current AI systems can produce full medical research papers—complete with fabricated data, citations, and statistical tables—that appear plausible on first reading. Some are even being submitted to journals, slipping through traditional plagiarism filters because the text is "original" but unverified. Reviewers, often pressed for time, may not spot these subtle fabrications. The result is a creeping contamination of the scientific record.

In medicine, this is not a theoretical problem. If a clinical paper built on AI-generated misinformation reaches publication, it can influence patient care, guideline development, and public policy. A single misleading claim, amplified through digital channels, can spread faster than any correction ever will. For respiratory care—where practice often balances on the interpretation of clinical trials, case series, and evolving technology—credibility is not optional; it is the foundation of our field.

The same dynamic is playing out beyond healthcare. Colleagues in finance, law, and public administration are reporting similar anxieties: AI-generated analyses that sound authoritative but are riddled with inaccuracies, or worse, subtle biases that distort decisions and undermine trust. In both arenas—clinical science and financial reporting—the issue is not simply "bad information." It is the **erosion of accountability.** Machines do not take responsibility; people do.

At *Respiratory Therapy*, we view AI as both a tool and a test. Used responsibly, it can assist in literature searches, translation, or data visualization. Used recklessly, it can corrode the integrity of the peer-review process. For that reason, beginning with our upcoming issues, we are instituting new **author disclosure requirements** regarding the use of artificial intelligence in manuscript preparation. Authors will be asked to specify whether AI tools were used, for what purpose, and under whose supervision. Editors and reviewers will have updated checklists to ensure transparency and validation of all references and data sources.

This is not about resisting innovation; it is about preserving trust. Science has always advanced by building on verified truth, not synthetic certainty. The linotype operators and editors of past generations guarded that standard with blue pencils and steady hands. Today, it falls to us—and to our readers—to uphold it with digital vigilance.

AI may one day become a valued colleague in scientific communication. But until it can share moral responsibility for error, it remains only an assistant. The final judgment, and the final accountability, must remain human.

Steve Goldstein
Publisher, *Respiratory Therapy*
Goldstein & Assoc. Inc., Los Angeles

Steve Goldstein is the Publisher at Respiratory Therapy.

Technologies in Tracheostomy Management: Ensuring Patient-Centered Practice

Gabriela Ortiz, RCP

Tracheostomy management has evolved significantly over recent decades, reflecting advances in surgical technique, airway device design, and multidisciplinary care. Once considered a last-resort intervention, tracheostomy is now part of proactive, long-term respiratory management for patients across all ages and care settings. As technology continues to shape practice, tools like the Passy Muir Valve (PMV) are redefining expectations for recovery, communication, and quality of life.

The concept of early rehabilitation reflects a growing recognition that recovery and quality of life begin well before hospital discharge. Interventions, such as the Passy-Muir Tracheostomy and Ventilator Swallowing and Speaking Valve (PMV), can be introduced early in the care continuum, even while patients remain critically ill. Use of the Valve facilitates communication, swallowing, and participation in therapy. By engaging patients sooner, clinicians promote both physiological and psychosocial recovery, helping to reduce the isolation and dependence commonly associated with prolonged mechanical ventilation.

The Passy Muir Valve was created forty years ago *by a patient, for patients.* Its inventor, David Muir, became ventilator-dependent due to advanced muscular dystrophy and lost his ability to speak following tracheostomy and mechanical ventilation. Determined to communicate again, he designed a Valve that worked with his ventilator and restored airflow to his upper airway. Even as ventilator technology evolves, the Passy Muir Valve remains a key tool in patient-centered care.

Gabriela Ortiz earned her Respiratory Care Practitioner license in 2006. She has extensive experience managing patients at different stages of care, including acute, sub-acute, sleep therapy, and homecare. As the Respiratory Clinical Director and General Manager at a respiratory care provider, Gabriela managed all company operations, including patient assessment and case management for pediatric and adult patient populations. With her clinical knowledge, Gabriela advanced into clinical training and sales for critical care ventilation products for the ICU and PICU within acute and subacute hospitals. Gabriela has combined her clinical experiences to support others through education and is a regularly invited speaker for university programs, Better Breather's Club, and ALS support groups. She has authored and co-authored multiple peer-reviewed papers on respiratory topics such as the progression of ALS, the effects of a tracheostomy in neonates, and respiratory care plans for patients in homecare. Gabriela is currently a full-time Clinical Specialist with Passy-Muir, Inc.

Figure 1. Patient using the PMV007 (Aqua color™) to provide expiratory flow for use of an RMT device

The PMV is well tolerated by both children and adults. In a 2024 study, Huang et al. found that when hospitals used structured protocols to guide patient selection and readiness, speaking Valve trials increased from 75% to 95%, and first-attempt tolerance improved from 60% to 75%. These results underscore the importance of clear protocols and effective teamwork in facilitating safe, early rehabilitation and communication for patients with tracheostomies.[1]

As hospice care becomes more widely accepted, many patients choose to transition home for the remainder of their lives. During this stage, the focus shifts from restoring full function to enhancing comfort, autonomy, and meaningful connection. Use of the PMV allows patients to speak with loved ones, express their needs, and actively participate in care decisions. This helps preserve a sense of identity, dignity, and control at the end of life.

The Evolution of Tracheostomy Management

Surgical vs. Percutaneous Placement

Tracheostomy placement has shifted from exclusively surgical procedures in the operating room to more common percutaneous (bedside) approaches.

- **Surgical tracheostomy** offers direct visualization of the airway and is preferred in complex cases, pediatrics, or when anatomical variations exist.

- **Percutaneous tracheostomy** uses a dilation technique, typically performed in the ICU. It is faster, less invasive, and associated with reduced infection risk and cost.

The Passy-Muir *Instructions for Use* booklet indicates that the Valve may be considered for use 48-72 hours post-tracheotomy. Recent research has demonstrated that patients with percutaneous tracheostomies have tolerated the placement of a speaking Valve in less than 24 hours.[2] Martin et al. (2021) compared "accelerated" (≤ 24 hours) versus "standard" (≥ 48 hours) placements of one-way speaking Valves after percutaneous tracheostomy. The accelerated group had a median placement time of 22 hours after tracheostomy and did not exhibit any adverse events.[2]

Both techniques have unique benefits. The percutaneous approach enables earlier intervention and maintains continuity within the critical care setting, while surgical placement continues to be the preferred option for patients with anatomical challenges or elevated procedural risks.

Changing Expectations: Patient Experience

As technology has advanced, patient and caregiver expectations have also changed. Patients and caregivers may view tracheostomy as a permanent and isolating procedure, but it is now increasingly seen as a temporary step in the rehabilitation process.

Loss of Voice, Loss of Independence

Many patients describe losing independence as one of the hardest parts of living with a tracheostomy. Limited mobility, dependence on equipment, and communication barriers can slow both emotional and physical recovery. The inability to speak is often especially distressing. Today, restoring communication is recognized as an essential part of care. PMV helps patients regain their voice and restore more natural breathing, supporting both healing and human connection.

Earlier Rehabilitation: A Paradigm Shift

Contemporary tracheostomy protocols prioritize early rehabilitation through close collaboration among respiratory therapy, speech-language pathology, and nursing. A dedicated, facility-based tracheostomy team supports patient independence and promotes recovery. Early introduction of a speaking valve enables more natural phonation and breathing, while restoring subglottic pressure to support safe swallowing. Use of the Passy-Muir Valve has been associated with faster progression to oral intake, increased patient engagement, and shorter hospital stays, thus highlighting its role in both functional recovery and ventilatory stability.[3]

Benefits of a Tracheostomy

When managed effectively, a tracheostomy provides several clinical advantages, such as:

- Improved airway access and stability.
- Enhanced secretion clearance.
- Reduced need for sedation and prolonged intubation.
- Facilitation of ventilator weaning.
- Support for long-term respiratory management.

With proper care, patients with tracheostomies can achieve stability and comfort while progressing toward rehabilitation and decannulation.

Quality of Life and the Role of the PMV

The Passy-Muir Valve has become a cornerstone in modern tracheostomy management, promoting both physiological and psychosocial recovery. Its one-way design redirects exhaled air through the upper airway, allowing for speech and restoring natural airway pressures.

Beyond its clinical benefits, the PMV also plays a significant role in hospice care. As hospice care becomes more widely accepted, many patients choose to transition home for the remainder of their lives. During this stage, the focus shifts from restoring full function to enhancing comfort, autonomy, and meaningful connection. Use of the PMV allows patients to speak with loved ones, express their needs, and actively participate in care decisions, helping them preserve a sense of identity, dignity, and control at the end of life.[4]

Key Benefits of PMV Use:

- **Voice and communication:** Enables speech and self-expression, improving emotional well-being.
- **Swallowing, smell, and taste:** Restores subglottic pressure, improving swallowing safety and enhancing taste perception.
- **Airway clearance:** Encourages positive airway pressure for effective cough.
- **Psychosocial recovery:** Reconnects patients with family, caregivers, and everyday activities.

Contemporary Strategies in Ventilatory Support

Non-invasive systems are the first choice for supporting a patient's ventilation. Patients who need higher oxygen levels (O_2) often benefit from high-flow oxygen therapy (HFOT), which can deliver up to 60 L/min of warmed, humidified oxygen. For patients with tracheostomies, HFOT can be used together with a PMV.

The valve helps restore more natural physiological positive end-expiratory pressure (PEEP), which may enhance lung recruitment and improve oxygen saturation (SpO_2).[3] Together, HFOT and the PMV may offer complementary benefits.[5] Patients receiving mechanical ventilation may develop dependence on the ventilator, making weaning challenging. In a study by Sutt et al. (2016), the use of an in-line speaking valve (SV) during mechanical ventilation increased end-expiratory lung impedance (EELI), with this effect persisting up to 15 minutes after Valve removal. During SV use, end-tidal CO_2 ($EtCO_2$) decreased, while SpO_2, respiratory rate, and heart rate remained stable. Importantly, SV use did not cause lung derecruitment during weaning. In actuality, deflating the cuff and restoring airflow through the upper airway via use of the one-way valve facilitated lung recruitment, which may have contributed to faster weaning from mechanical ventilation.[6]

A tracheostomy tube can also reduce the need for sedation, allowing patients to be more awake and interactive. Reducing sedation has been shown to significantly improve patients' ability to communicate and engage with their medical team. When sedation is minimized, patients are more alert and better able to express their needs, preferences, and concerns, allowing clinicians to tailor care more effectively.

When patients require critical interventions, such as extracorporeal membrane oxygenation (ECMO), opportunities for communication often become limited due to the need for invasive airway support. In this state, use of the PMV during

ECMO may be possible in select cases, provided there is careful multidisciplinary assessment and close monitoring. Although patients may still require ECMO support for cardiac and pulmonary function, they may begin to assume more of their own work of breathing. Like patients on conventional ventilation, those on ECMO should meet established selection criteria to ensure they are clinically "stable." Here, stable does not mean "healthy" or "off ECMO," but rather indicates a relative or controlled stability within critical illness, which makes them appropriate for a speaking valve trial. A 2022 study validated safe and effective use in four patients on Veno-Venous ECMO, decreasing their work of breathing and reporting appreciation at being able to speak with family.[7] This level of stability allows clinicians to consider early rehabilitation interventions, such as sedation reduction, physical therapy, or a speaking valve trial, as long as all safety criteria are met and the full multidisciplinary team (RT, SLP, intensivist, ECMO specialist) is present.

Introducing Expiratory Muscle Training (EMT)

Introducing Expiratory Muscle Training (EMT) to patients with tracheostomies and who are ventilator dependent with tracheostomies is best approached using a no-leak speaking Valve. The Valve and EMT can work together to address common deficits in critically ill patients, such as respiratory muscle weakness, reduced cough effectiveness, and impaired airway clearance. Because the PMV restores a closed respiratory system and directs exhaled air through the upper airway, its use during Respiratory Muscle Training (RMT), especially EMT, supports effective airflow and more natural breathing mechanics. The combination of EMT and PMV may help improve swallowing and cough strength, enhance airway protection, and assist in the weaning process from both mechanical ventilation and the tracheostomy itself.[8]

Integration of Artificial Intelligence (AI)

Despite advancements in airway management, deficiencies in provider education, patient instruction, and healthcare access continue to hinder consistency in tracheostomy care outcomes. It has been reported that with AI-assisted monitoring, healthcare teams can detect complications up to 25% sooner, respond more rapidly, and achieve better patient outcomes.[9]

Beyond early detection, AI contributes to patient care through several pathways:

- Predictive analytics help anticipate respiratory decline or secretion buildup before it becomes critical.[10]
- Automated data integration from ventilators, electronic health records, and bedside monitors provides clinicians with real-time insights and trend analysis.
- Personalized education tools can guide both patients and caregivers in tracheostomy care, improving confidence and adherence.
- Workflow optimization reduces delays in communication and intervention, allowing faster collaboration among multidisciplinary teams.

AI-assisted tools in health care now support a wide range of clinical and operational needs. For example, machine-learning algorithms help interpret imaging studies, monitoring systems can optimize ventilator settings, and predict patient deterioration in the ICU. These technologies enhance clinical decision-making, support education, and improve patient safety, while the Passy Muir Valve restores voicing and communication for patients with artificial airways. Together, they exemplify the intersection of technological innovation and compassionate, patient-centered care.

Telehealth and Remote Rehabilitation

As telemedicine continues to expand, the Passy-Muir Valve also has found a natural role within remote tracheostomy management programs. Clinicians remain central to this process, using telehealth platforms to assess whether a patient is an appropriate candidate for PMV use by evaluating airway patency, respiratory stability, and secretion management. Through secure video visits, they can observe PMV trials in real time, guide caregivers in proper placement, cleaning, troubleshooting techniques, and assess patient tolerance from a distance.[11] The PMV itself plays a critical role by restoring voicing, enabling patients to speak and participate in their own care, and helping promote overall quality of life. Together, these innovations extend the reach of multidisciplinary care beyond the hospital, promoting safety, consistency, and confidence for patients and families managing tracheostomy care at home.

Augmentative and Alternative Communication (AAC) Technologies

For patients with communication impairments, AAC may be a consideration. From the use of communication boards to introducing high-tech devices, AAC offers alternative means of communication when the voice is not accessible. For patients with tracheostomies who are unable to tolerate the PMV, AI-powered voice synthesis or augmentative and alternative communication (AAC) devices can help bridge the communication gap. As these patients progress to PMV use, they can transition back to natural speech, demonstrating a seamless continuum of communication supported by enabling technologies.

Conclusion

The Passy-Muir Valve seamlessly fits into next-generation, holistic models of care, linking mechanical ventilation, artificial intelligence, telehealth, and rehabilitation technologies. Its simplicity complements these high-tech systems by restoring human function and communication, bridging the gap between innovation and the patient's lived experience. As medical care continues to advance, ethical standards must evolve alongside technology to ensure patient-centered practice and compassionate care. Tracheostomy management is undergoing a transformation, driven by innovation and an increasing focus on quality of life. The integration of the Passy-Muir Valve into early rehabilitation represents a pivotal step forward, transforming the tracheostomy from a barrier into a bridge toward recovery, independence, and connection. Looking ahead, the ongoing integration of innovative technologies will continue to enhance how clinicians support patients throughout their recovery, from airway management to full participation in daily life.

References

1 Huang, V. W., DeVore, E. K., Kaul, S., Parikh, M., Hayes, M. M., & Teng, S. E. (2025). Valves for the voiceless: Time to speaking valve use in post tracheostomy patients after multidisciplinary initiative. *Otolaryngology, Head and Neck Surgery, 172*(2), 710-716. https://doi.org/10.1002/ohn.1016

2 Martin, K. A., Cole, T.D.K., Percha, C. M., Asanuma, N., Mattare, K., Hager, D. N., Brenner, M.J., Pandian, V. (2021). Standard versus Accelerated Speaking Valve Placement after Percutaneous Tracheostomy: A Randomized Controlled

Feasibility Study. *Annals of the American Thoracic Society*, 18 (10). https://doi.org/10.1513/annalsats.202010-1282oc
3 O'Connor, L. R., Morris, N. R., & Paratz, J. (2019). Physiological and clinical outcomes associated with use of one-way speaking valves on tracheostomised patients: A systematic review. *Heart & Lung*, *48*(4), 356-364. https://doi.org/10.1016/j.hrtlng.2018.11.006
4 Freeman-Sanderson, A. L., Togher, L., Elkins, M. R., & Phipps, P. R. (2016). Return of voice for ventilated tracheostomy patients in ICU: A randomized, controlled trial of early-targeted intervention. *Critical Care Medicine*, *44*(6), 1075-1081. https://doi.org/10.1097/ccm.0000000000001610
5 Egbers, P.H., Sutt, A., Petersson, J.E., Bergström, L., Sundman, E. (2023). High-flow via a tracheostomy tube and speaking Valve during weaning from mechanical ventilation and tracheostomy. *Anaesthesiologica Scandinavica*,*67*(10), 1403-1413. https://doi.org/10.1111/aas.14305
6 Sutt, A., Caruana, L.R., Dunster, K.R., Cornwell, P.L., Anstey, C.M., Fraser, J.f. (2016). Speaking Valves in tracheostomized ICU patients weaning off mechanical ventilation-do they facilitate lung recruitment? *Critical Care 20*(1), 91. https://link.springer.com/article/10.1186/s13054-016-1249-x
7 Martin, A. (2022) The use of the Passy Muir Valve with COVID-19 Veno-Venous Estra Corporeal Membrane Oxygenation patients; a case series. *Journal of the Intensive Care Society*, *23*(1), 173. https://pesquisa.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/resource/pt/covidwho-2043008
8 Opalinski, J., & Hanley, K.M. (2022) No-Leak speaking valves and Respiratory Muscle Training: A perfect pairing for early intervention in the ICU. *Aerodigestive Health*, *5* (2).
9 Pandian, V. & Brenner, M. (2025). Tracheostomy in the digital age: How artificial intelligence and immersive technologies are redefining airway care. *Tracheostomy*, *2* (1), 5-14. https://doi.org/10.62905/001c.133583 .
10 Badawy, M., Ramadan, N., & Hefny, H. A. (2023) Healthcare predictive analytics using machine learning and deep learning techniques: a survey. *Journal of Electrical Systems and Information Technology*, *10* (40). https://link.springer.com/article/10.1186/s43067-023-00108-y
11 Li, L., Jo, S., Kawai, K., Yacovone, L., & Jackmin, M. (2022) Utility of telemedicine in tracheostomy-dependent children. *Larygoscope Investigative Otolaryngology*, *7* (6). https://doi.org/10.1002/lio2.937

From Zoomer to Boomer: Bridging Varied Learning Paths Through a Blended Approach to Clinical Education

Winnie Sywulak, BS, RRT, RRT-NPS

Effective clinical education is critical to high-quality healthcare delivery.[1] Whether it is training a team of respiratory therapists (RT) on ventilator features that support safe and efficient weaning or educating a neonatal intensive care unit (NICU) team on thermoregulation strategies, the application of knowledge and skills can enhance patient care and safety.

Central to clinical education success is the acknowledgment that individuals vary in their learning styles and the way they learn changes as they age. Research has found adults learn quite differently from children.[2] Learning styles can also differ from one generation to the next — from Zoomers to Boomers.[3]

Therefore, it is beneficial to take a blended approach to clinical education, with a broad range of modalities designed to meet the diverse needs of critical care clinicians wherever they are in their learning journeys.

Why clinical education must evolve

Clinicians in a hospital environment span a wide range of ages and experience levels, from the newly graduated to those nearing retirement. "It's very possible that we now have more generational diversity in our workforce than ever before," stated the authors of a Harvard Business article on generational workforce diversity and learning styles. They added: "In many companies, almost every team or unit will have at least some multigenerational diversity."[4]

On a personal level, clinicians have their own learning preferences, whether that's in-person training, e-learning courses, another modality, or a mix of several different ones. Therefore, educators are challenged to train these individuals on evidence-based standards and guidelines when no standard learning path exists.

Given the variation in learning styles and preferences, clinical education should not be viewed as a one-size-fits-all solution but rather as a continuum of offerings that meet the needs of varied learners. Researchers recommend a blended approach that includes traditional modalities combined with "more engaging and interactive methods for teaching."[5]

Winnie Sywulak is the Senior Marketing Manager, Head of Clinical Education for Dräger in North America, an international leader in the fields of medical and safety technology.

In the journal of the European Respiratory Society (ERS) Breathe, respiratory medicine specialists Dr Emer Kelly and Professor Richard Costello explored continuing education from both content and delivery perspectives, noting how "optimization of both elements improves the depth of learning achieved."[6]

They wrote: "Capturing quality content, to meet the learning needs of those working in all fields of respiratory medicine and delivering it in a palatable, accessible format is challenging but paramount."[7]

A study on the efficacy of different digital and blended learning modalities published in the BMC Medical Education journal found, "the integration of traditional and innovative digital teaching methods appeared to provide the most comprehensive learning experience." The researchers noted how "hybrid learning opportunities may meet the needs of diverse groups," including "learners who value in-person collaboration and networking, as well as those who value flexibility."[8]

> "The challenge then is to achieve a balance between the flexibility and convenience of online and the need for personal interaction and engagement that is a strength of in-person engagement. Clearly, there is no one-size-fits-all solution."[9]

Meeting clinicians' needs along the learning pathway

There are several different modalities clinical leaders can employ to address their staff members' varied learning styles. When a medical device manufacturer offers these options as a complete blended learning package, clinical leaders and individual staff members can select the course modalities that best meet their needs.

In-person learning

Research on continuing professional development (CPD) in healthcare supports the notion that clinicians still value aspects of face-to-face learning with their peers. For example, published survey findings revealed how health professionals view CPD "in its broadest sense as offering not just access to information but to supportive professional networks that provide professional and personal enrichment." They "clearly identified benefits from attending in-person events for networking and developing collaborations."[10]

On-demand learning

While in-person educational opportunities have been shown to provide value, clinicians working in today's digital, on-demand environment have expressed the desire for 24/7 access to learning that fits their schedule.

In the same survey on CPD in healthcare cited earlier, respondents reported "many benefits" to accessing online education opportunities, "including saving travel time and reduced cost." During interviews with the survey respondents, researchers noted "much positivity about the access the online medium afforded to a wealth of CPD opportunities that would otherwise have been inaccessible."

Clinical leaders too can benefit from the flexibility and convenience of on-demand learning. With in-person training, a manager is typically tasked with planning the courses around their team members' schedules, identifying/reserving space to hold them, and taking steps to try to ensure everyone on their team gets the education they need.

Conversely, the accommodating nature of on-demand learning alleviates leaders of much of this logistical burden. They assign the e-learning courses or recorded webinars to their teams, and it is the responsibility of the individual team members to manage when and where they take them.

Researchers have found that "online learning platforms can be a valuable complement to traditional clinical education, offering flexible, engaging, and potentially more cost-effective training options." Online modules and courses may also improve knowledge retention "particularly when compared to traditional lecture-based methods."[11]

Live-streamed learning

Virtual education presented live combines the convenience of online learning with the collaborative and interactive elements of in-person courses. Clinicians can participate from the convenience of their workplaces, homes or other settings.

Online, including live-streamed learning, has been shown to be particularly beneficial for upskilling the rural health workforce by offering "relevant, up-to-date practical guidelines and more institutional support and training" that healthcare professionals in rural settings might not have access to otherwise.[12]

Data from the American Community Survey reveals how the rural registered nurse (RNs) workforce has steadily grown in numbers at a rate comparable to urban RNs, pointing to the potential need for additional e-learning options.[13]

Micro-learning

While in-depth learning modalities have their place in clinical education, as in cases when a team is learning how to use a new technology or technique, clinicians are increasing requesting micro-learning options to efficiently fill in knowledge gaps.

Whether it is a listicle of top things to know about a topic or a brief video to supplement a training, these quick hits of digital information hold value for today's healthcare providers.

In their study of large-scale education in respiratory medicine, researchers noted how the "challenge of delivery is to package content into easily accessed, bite sized, snappy formats to facilitate mass distribution and generate further interest and transmission of the information."[15]

> "A three-year study on medical education found there was "no difference in learner engagement level between in-person or livestreamed" courses."[14]

Virtual reality (VR) learning

Clinicians born into the late Millennial and Gen Z generations are typically familiar with the digital gaming culture, including VR gaming modalities. As a result, clinical education has expanded into the VR realm, offering a multi-dimensional learning experience.

"The emergence of serious games and gamification provides alternative approaches for educators to improve the medical teaching process," stated researchers in an article on game-based learning in medical education. "Developing effective GBL (game-based learning) modalities has the potential to bring immersive experiences for medical students and improve their study outcomes."[16]

While younger clinicians come to mind when thinking about VR learning, it is important to consider that age alone doesn't determine an individual's preferred learning path. Many would assume a clinician in their early 20s would gravitate toward VR training, but it could be just as likely that a more experienced clinician in their late 50s would embrace this type of advanced technology.

An intergenerational pilot project on learning in the virtual space sought to answer the question of, "whether baby-boomers and X and Y generation learners accept, understand and perceive the digital form of learning with VR glasses as beneficial for their learning."

Researchers developed a VR course with the goal of teaching the anatomy of the heart by immersive visualization, offered it to participants of different ages, and followed up with a questionnaire to "determine how the use of VR glasses influenced participants' learning, acceptance, understanding and cognitive load." Based on the results, the researchers concluded "that age-heterogeneous groups present no obstacle for new innovative teaching methods, such as the use of VR glasses."[17]

Conclusion

Effective clinical education is essential for high-quality healthcare delivery, and its success depends on recognizing the diverse learning styles and preferences of clinicians across generations. As the healthcare workforce continues to evolve, so too must clinical education, embracing a blended approach that incorporates in-person, on-demand, live-streamed, micro-learning, and even virtual reality modalities.

By offering flexible, engaging and personalized learning experiences, blended clinical education programs empower healthcare professionals to enhance their skills, improve patient care, and stay at the forefront of medical advancements.

References

1 Mueller, M.R., Croghan, I.T., Schroeder, D.R. et al. Physician

preferences for Online and In-person continuing medical education: a cross-sectional study. BMC Med Educ 24, 1142 (2024). https://doi.org/10.1186/s12909-024-06046-1
2 Andragogy, Adult Learning Theory, University of New Hampshire, https://extension.unh.edu/sites/default/files/migrated_unmanaged_files/Resource004496_Rep6406.pdf
3 Generational Learning Practices, My American Nurse, December 2021, https://www.myamericannurse.com/wp-content/uploads/2021/12/an12-Generational-learning-1201.pdf
4 Unlocking the Benefits of the Multigenerational Workplace, Harvard Business Publishing, https://www.harvardbusiness.org/wp-content/uploads/2020/08/Unlocking-the-Benefits-of-Multigenerational-Workforces_Aug-2020.pdf
5 Stephenson CR, Yudkowsky R, Wittich CM, Cook DA. Learner engagement and teaching effectiveness in livestreamed versus in-person CME. Med Educ. 2023 Apr;57(4):349-358. doi: 10.1111/medu.14996. Epub 2022 Dec 12. PMID: 36454138.
6 Kelly E, Costello RW. Large-scale education in respiratory medicine: content *versus* delivery. Breathe (Sheff). 2024 Oct 1;20(3):230218. doi: 10.1183/20734735.0218-2023. PMID: 39360024; PMCID: PMC11444494.
7 Kelly E, Costello RW. Large-scale education in respiratory medicine: content *versus* delivery. Breathe (Sheff). 2024 Oct 1;20(3):230218. doi: 10.1183/20734735.0218-2023. PMID: 39360024; PMCID: PMC11444494.
8 McGee, R.G., Wark, S., Mwangi, F. *et al.* Digital learning of clinical skills and its impact on medical students' academic performance: a systematic review. *BMC Med Educ* 24, 1477 (2024). https://doi.org/10.1186/s12909-024-06471-2
9 Cassidy, Dara BSocSc (Hons), MA, EdD; Edwards, Gareth BA (hons.), PGCE, PGDip, MA; Bruen, Catherine BA, MLitt, MSc, Phd (c); Kelly, Helen M.Phil, Applied Linguistics, PhD(c); Arnett, Richard BSc, HDip, PhD; Illing, Jan BSc (hons), MPhil, PhD. Are We Ever Going Back? Exploring the Views of Health Professionals on Postpandemic Continuing Professional Development Modalities. Journal of Continuing Education in the Health Professions 43(3):p 172-180, Summer 2023. | DOI: 10.1097/CEH.0000000000000482
10 Cassidy, Dara BSocSc (Hons), MA, EdD; Edwards, Gareth BA (hons.), PGCE, PGDip, MA; Bruen, Catherine BA, MLitt, MSc, Phd (c); Kelly, Helen M.Phil, Applied Linguistics, PhD(c); Arnett, Richard BSc, HDip, PhD; Illing, Jan BSc (hons), MPhil, PhD. Are We Ever Going Back? Exploring the Views of Health Professionals on Postpandemic Continuing Professional Development Modalities. Journal of Continuing Education in the Health Professions 43(3):p 172-180, Summer 2023. | DOI: 10.1097/CEH.0000000000000482
11 McGee, R.G., Wark, S., Mwangi, F. *et al.* Digital learning of clinical skills and its impact on medical students' academic performance: a systematic review. *BMC Med Educ* 24, 1477 (2024). https://doi.org/10.1186/s12909-024-06471-2
12 Evans A, Priestly J, Suthern M, Whelan M, Robertson S, Kelly O, Omar SH, Preddy J. Practical recommendations for planning and running live online education workshops for the rural health workforce. Aust J Rural Health. 2023 Feb;31(1):144-151. doi: 10.1111/ajr.12863. Epub 2022 Apr 16. PMID: 35429355.
13 Yates MC, Auerbach DI, Staiger DO, Buerhaus PI. Characteristics of rural registered nurses and the implications for workforce policy. J Rural Health. 2023 Jan;39(1):240-245. doi: 10.1111/jrh.12707. Epub 2022 Aug 15. PMID: 35970812.
14 Mueller, M.R., Croghan, I.T., Schroeder, D.R. et al. Physician preferences for Online and In-person continuing medical education: a cross-sectional study. BMC Med Educ 24, 1142 (2024). https://doi.org/10.1186/s12909-024-06046-1
15 Kelly E, Costello RW. Large-scale education in respiratory medicine: content *versus* delivery. Breathe (Sheff). 2024 Oct 1;20(3):230218. doi: 10.1183/20734735.0218-2023. PMID: 39360024; PMCID: PMC11444494.
16 Xu M, Luo Y, Zhang Y, Xia R, Qian H, Zou X. Game-based learning in medical education. Front Public Health. 2023 Mar 3;11:1113682. doi: 10.3389/fpubh.2023.1113682. PMID: 36935696; PMCID: PMC10020233.
17 Schlegel C, Geering A, Weber U. Learning in virtual space: an intergenerational pilot project. GMS J Med Educ. 2021 Feb 15;38(2):Doc37. doi: 10.3205/zma001433. PMID: 33763522; PMCID: PMC7958907.

The New MIR Plus Line: Next-Generation Spirometers for Advanced Respiratory Care

Medical International Research (MIR)

Why the Plus Line Matters

Healthcare professionals are facing growing demands for efficiency, digital integration, and precise diagnostics across diverse care environments, from busy hospitals to rehabilitation centers and primary care practices. The MIR Plus Line was engineered to support this flexibility, offering solutions that are preventive, precise, predictive, and personalized.

For over 30 years, MIR has led the way in respiratory diagnostics—from launching the world's first homecare telespirometer to introducing internationally patented disposable turbines. Our mission has always been to empower clinicians with tools that not only meet technical standards but also enhance patient outcomes and streamline workflows. The Plus Line reaffirms this commitment by bringing together advanced technology, user-friendly design, and seamless connectivity to deliver professional-grade spirometry that addresses the everyday challenges of modern healthcare.

Clinical Needs, Met by Design

- **Integrated RFID Tag Reader:** Automatically recognizes the new FlowMIR Plus turbine, reducing setup time and ensuring data integrity.
- **Enhanced Low Flow Sensitivity:** Accurately measures flows as low as 20 mL/s, critical for patients with limited pulmonary function.
- **Modern Ergonomic Design:** Built for usability, durability, and everyday clinical demands.
- **Bluetooth and USB Connectivity:** Streamlines data sharing and Work List import/export from MIR Spiro Software.
- **Environmental Stability:** No calibration required; devices remain reliable across diverse care settings.

Meet the Devices Behind the Plus Line

Spirolab Plus: Ideal for pulmonary function labs and advanced hospital use, this premium desktop spirometer features a 7" high-resolution touchscreen, optional oximetry, storage for 15,000 tests, and full software integration.

Minispir Plus: Designed for multi-site professionals, this compact PC-based spirometer combines portability with robust construction. It ensures speed, accuracy, and seamless digital integration.

Spirobank II Plus: A versatile handheld spirometer, equipped with touchscreen display, Bluetooth connectivity, optional oximetry, and Work List functionality, perfect for mobile testing and community health programs.

Spirobank II Light: A streamlined model for screening and essential monitoring. With touchscreen controls and RFID turbine pairing, it balances ease of use with reliable accuracy at a more accessible level.

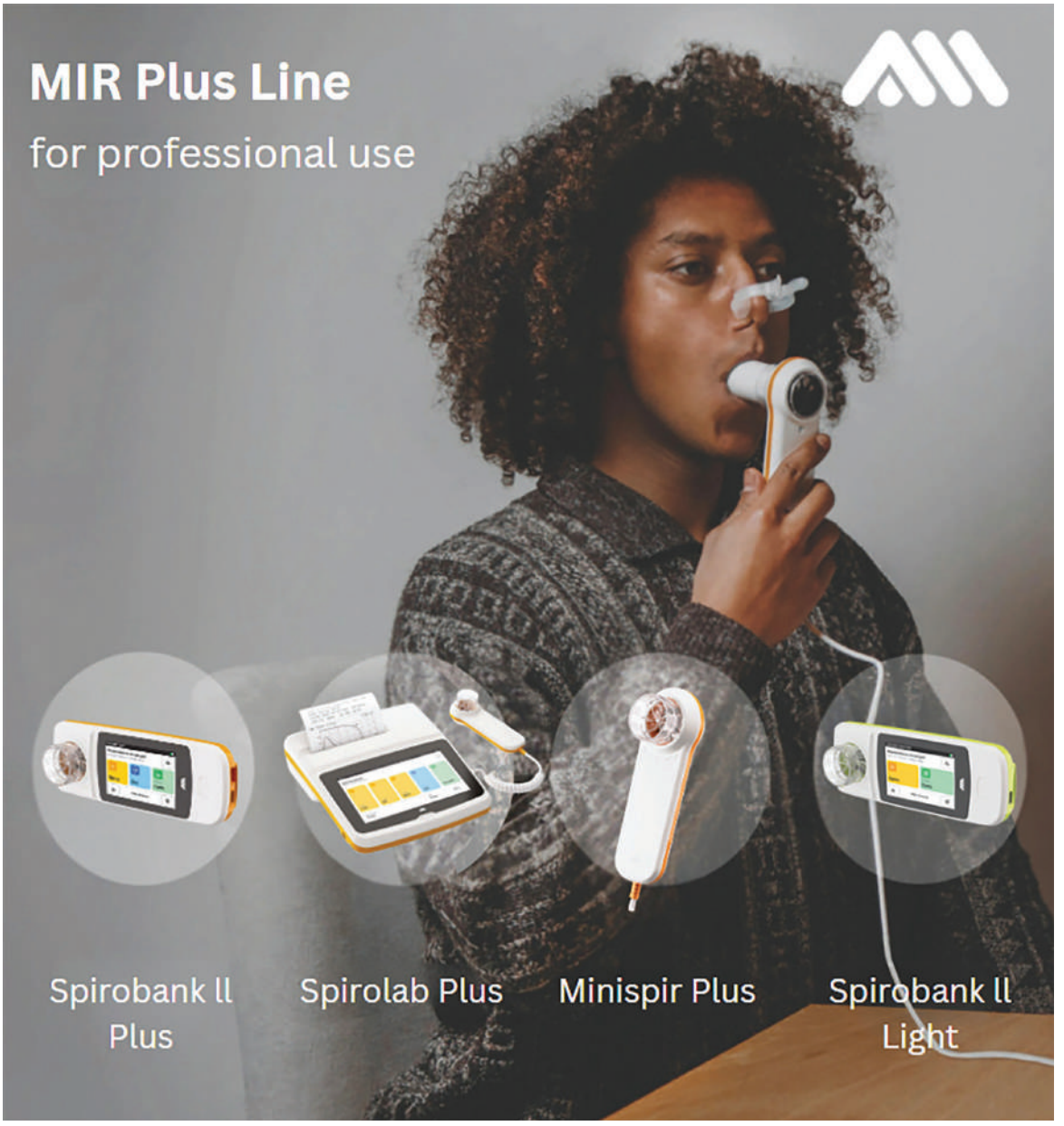
FlowMIR Plus: The Core of Confidence

Every device in the Plus Line is powered by the new FlowMIR Plus turbine, offering:

- Automatic turbine recognition via RFID
- High sensitivity for low-flow accuracy
- No expiration date or special storage needs
- Individually packaged for hygiene
- Fully automated manufacturing for consistency

Validated under ISO 26782 standards using the Spirobank II Plus, FlowMIR Plus demonstrated exceptional accuracy, repeatability, pneumatic impedance, and linearity, confirming its clinical reliability without BTPS correction. Testing included 13 simulated expiratory patterns that mirrored real-world patient profiles, and FlowMIR Plus consistently performed within the tightest error margins required for diagnostic use.

Provided by Medical International Research (MIR)



Proven in Clinical Practice

A pulmonary rehab program recently adopted the Spirobank II Plus for routine spirometry assessments. Clinicians reported:

- Faster onboarding thanks to its intuitive touchscreen interface Reduced invalid tests, improving workflow and patient comfort Greater accessibility for patients with limited mobility
- Streamlined administration through RFID turbine recognition and bidirectional Work List import/export

Combined with FlowMIR Plus, the system ensured that tests were not only accurate but also repeatable and easy to standardize across diverse patient populations.

Powering the Future of Connected Respiratory Care

The Plus Line equips healthcare professionals to deliver high-quality care in any setting, whether managing COPD in the clinic, conducting remote follow-ups, or participating in public. health screening initiatives. With MIR Spiro Platinum software, data can be integrated into EMRs, reviewed remotely, and analyzed in real time.

As models of care evolve, the MIR Plus Line empowers providers to deliver connected, patient- centered care with confidence.

About MIR

Founded in Rome in 1993, Medical International Research (MIR) is a global leader in spirometry and oximetry. With operations in over one hundred countries and local branches in the US, France, and Brazil, MIR continues to shape the future of pulmonary diagnostics through trusted quality, ongoing R&D, and clinician-driven innovation.

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OLE Therapy Moves to a New Level of Performance at Oklahoma Heart Hospital With the Volara System

Overview

The hospital used the **MetaNeb** System to provide Oscillation and Lung Expansion (OLE) therapy since 2014. As those units began to reach end of service, leadership realized they had to explore other options. Their Baxter representative introduced them to the **Volara** System, the next generation to deliver OLE therapy.

"We had a great clinical evaluation period where we were able to look at some clinical results and get some good feedback from our therapists on the machine and the interface," says Justin Rowley, Respiratory Therapy Manager at Oklahoma Heart Hospital. "Being able to show the outcomes and the great versatility was key in being able to get the approval to move to the **Volara** System."

The Transition

Transitioning to a new system is no easy task. "It was a breath of fresh air at the time, in the middle of COVID," Justin says. "This is a big interface to bring into a respiratory department for what it can do and what it could replace. That requires a lot of work and qualifications to support that this is the direction we want to go. Working through those processes, having our Baxter representative there who worked closely with our biomed manager, and getting more units in here when we made the decision to move was critical."

The Performance

Moving to the **Volara** System opened up better ways for Justin and his team to deliver the therapy their patients needed. The **Volara** System has several attributes that help Justin's team treat patients, such as:

- the digital interface on the electromechanical **Volara** System versus the pneumatic **MetaNeb** System, and
- the ability to select manual or automatic modes to deliver precise pressure.

Customizable Care

"It's been very beneficial for our therapists to use the manual mode and adjust to the patient, giving more or less pressure as clinically indicated," says Justin. "And the automatic mode gives physicians the ability to provide a standardized treatment for a specific patient population. It's customizable, so you can go in and make a custom care plan, identifiable by room number or patient name."

Provided by Baxter.

HIGHLIGHTS

Facility
Oklahoma Heart Hospital
Oklahoma City, OK

Profile
- 141 - bed heart hospital on two campuses
- More than 60+ clinics statewide

Partner
Justin Rowley, Respiratory Therapy Manager

Reported Impact
- Expanded clinical treatment options
- Provided versatility to treat specific patient needs
- Helped reduce time on ventilator and ICU length of stay
- Utilization of myVolara App

"As a heart hospital, we see some patients with heart and valve anomalies, or younger patients in that population that sometimes may require more pressure," he says. "Being able to go into the clinical menu and make that happen is a big improvement from the **MetaNeb** System."

Versatility

With its versatility and portability, the **Volara** System is helping the team deliver therapy where it's needed. "The nice versatility of the machine is it can go anywhere in the hospital," says Justin, "although our primary use and protocols are in the ICU and interventional step-down units. We have larger suites or rooms in our ICU, so sometimes the patient is sitting by the window, or they're in a recliner away from the bed. We can still provide that treatment anywhere in the room."

One example of how the **Volara** System is helping the team deliver therapy is in the ICU, where postoperative patients

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References
1. Data on file at Baxter International Inc.
2. Compared to The Vest System Model 105.

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It frees up the clinician to focus more on the patient. You're not focusing so much on the operation of the machine. That's a huge advantage to the patient and therefore, the outcome. You have adjustability and versatility in giving the patient what they actually need to have the desired outcome.
–Justin Rowley
Respiratory Therapy Manager

recover on a ventilator. Justin says, "We see a lot of lobular-specific atelectasis due to manual compression of the lung or patients having thick, retained secretions from being in surgery with dry anesthesia gases in their airways for three hours. Those secretions are sticky and hard to move and it plugs off the lung."

"We use either medication or normal saline in the nebulizer and are able to get those secretions moving with hyperinflation and oscillations," he says. "Within two or three treatments, we're seeing significant chest X-ray improvements off the ventilator. That's now a standard course for many of our postoperative heart patients. Before, we weren't able to get really deep into the airways to actively engage those secretions. Adding that modality with the **Volara** System has been a valuable addition to our immediate postoperative phase for lung function."

Accessible information

Another way the **Volara** System is helping therapists treat patients is by providing easy access to the information they need. "With the **Volara** System, you get a summary about the treatment, an average of your pressures, a total time for all modalities — CPEP, CHFO and your nebulizer. Having that information that the **Volara** System provides is a vast improvement over the **MetaNeb** System as far as pressure delivery."

Ultimately, for Justin and Oklahoma Heart Hospital, transitioning to the **Volara** System came down to two main considerations:

Patient outcomes

"The most important consideration is the outcomes we saw on patients treated with the **Volara** System," he says. "Going through a good clinical evaluation and being able to see the results — that's confirmation it's benefitting the patient."

Ease of use

Close behind that is the ease of use for the respiratory therapists. "When you have staff that are confident and comfortable using an interface, that alone is going to provide a better therapy to the patient," he says. "They're going to be more focused on the patient and what is going on clinically — the pressures and vital signs — instead of just operating the machine."

Technology That Works For People

Any well-designed tool or technology is developed to allow people to do what they do best. In a hospital, that's to make it easier for clinicians to provide the best therapy and care for patients. At Oklahoma Heart Hospital, the **Volara** System is helping the respiratory team to deliver on their mission.

We've had top patient satisfaction awards for 20 years, and it's because we like to offer the best of what's out there to our patients.
–Justin Rowley Respiratory Therapy Manager

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References

1 Oklahoma Heart Hospital South Campus celebrates first anniversary. Oklahoma Heart Hospital. January 13, 2011. Accessed November 7, 2023. https://www.okheart.com/about-us/ohh-news/oklahoma-heart-hospital-south-campus-celebrates-first-anniversary

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COPD Drug Development in 2025: Trouble Ahead?

Heather R Patterson, RRT

Introduction

Few areas of respiratory medicine have faced as much challenge as chronic obstructive pulmonary disease (COPD) drug development. Despite decades of work, COPD remains a leading global cause of death. Over the past ten years, a procession of biologics and novel anti-inflammatory agents advanced to phase 3 only to miss their primary endpoints. Those disappointments have reshaped how we think about COPD and re-centered attention on what reliably improves outcomes: optimized, guideline-directed care.

In 2025 the picture is more nuanced. The first reproducibly positive biologic trials have emerged, and a novel small molecule has been approved. The improvements are impressive but limited to carefully selected patient populations.

The Evolution of COPD Therapeutics

For two decades, progress was steady but incremental. Widespread uptake of long-acting bronchodilators and, later, single-inhaler triple therapy (ICS/LABA/LAMA) reduced moderate–severe exacerbations and likely improved survival in high-risk patients, as shown in IMPACT and ETHOS (Lipson et al., *N Engl J Med* 2018; Rabe et al., *N Engl J Med* 2020). Beyond inhaled combinations, only a few anti-inflammatory add-ons achieved durable clinical impact. Roflumilast benefited patients with chronic bronchitis and severe obstruction but was limited by gastrointestinal side effects (Calverley et al., *Lancet* 2009). Chronic azithromycin reduced exacerbations in frequent exacerbators, tempered by antimicrobial-resistance and QT concerns (Albert et al., *N Engl J Med* 2011).

As biologics transformed asthma, COPD trials shifted toward "treatable traits." The hope was that neutralizing cytokines such as IL-5, IL-33, or TSLP would reproduce asthma's success. The last few years showed how different COPD biology is.

The Wave of Failed Trials

- **Benralizumab (anti-IL-5Rα): GALATHEA and TERRANOVA**
  The twin phase-3 trials GALATHEA and TERRANOVA evaluated benralizumab in >2,500 patients with moderate–very severe COPD and frequent exacerbations on optimized inhaled therapy. Neither reduced annualized exacerbation rate versus placebo; near-complete eosinophil depletion did not translate into fewer events (Criner et al., *N Engl J Med* 2019). Exploratory analyses suggested a delayed effect after an index exacerbation, but AstraZeneca's 2025 update on the follow-on program reported another primary-endpoint miss. The lesson is population-biology mismatch: eosinophil depletion does not address the dominant drivers of most COPD exacerbations and may not fully do so among those patients with high eosinophils (who may have concomitant drivers of disease beyond eosinophilia alone).
- **Tezepelumab (anti-TSLP): Deflating the alarmin hypothesis**
  Despite strong efficacy in severe asthma (Menzies-Gow et al., *N Engl J Med* 2021), tezepelumab failed to significantly reduce moderate/severe COPD exacerbations overall in a phase-2a COPD program when added to background inhaled therapy (COURSE/UPSTREAM; ATS 2024 reporting). Neutral secondary outcomes (lung function, symptoms) reinforced that epithelial alarmin signaling in COPD-especially among current smokers-may not mirror T2-high asthma.
- **Itepekimab (anti-IL-33): The former-smoker paradox**
  Phase-2 work suggested greater benefit among former smokers, consistent with reduced ongoing epithelial injury (Rabe et al., *ERJ Open Res 2024*). The paired phase-3 studies AERIFY-1 and AERIFY-2 in 2025 delivered mixed topline results, one positive, one negative, illustrating how event-rate variability can sway outcomes in large global COPD trials.
- **Repurposing efforts: Misalignment with core pathophysiology**
  Repurposed classes also disappointed. Simvastatin did not prevent exacerbations in patients without cardiovascular indications (STATCOPE; Criner et al., *N Engl J Med* 2014). Metoprolol failed to delay time to first exacerbation and increased severe respiratory events (BLOCK-COPD; Dransfield et al., *N Engl J Med* 2019). Vitamin D supplementation showed no consistent benefit outside profound deficiency (Martineau et al., *Lancet Respir Med* 2015). Modifying comorbidity pathways rarely changes COPD's structural and infectious drivers.

Collectively, these misses do not indict the targets outright; they indict how COPD trials were designed: broad "frequent exacerbator" entry criteria, heterogeneous inflammatory drivers, progressively lower background event rates, and endpoints dominated by infectious and neutrophilic triggers that the tested cytokine axis cannot meaningfully modify.

Heather Patterson, RRT, is the Director of Respiratory Solutions at Apria Healthcare. With 30 years of experience as a registered respiratory therapist, she is committed to advancing respiratory care by integrating emerging technologies, enhancing patient-centered engagement, and implementing longitudinal care approaches that improve outcomes and quality of life.

What finally worked

Amid the disappointments, several successes have reshaped the narrative.

- **Dupilumab (anti-IL-4Rα): A proof of concept**
  By targeting IL-4/IL-13 signaling, dupilumab modulates T2 inflammation. BOREAS and NOTUS showed ~30–34% reductions in annualized moderate–severe exacerbations and clinically meaningful FEV_1 gains in patients with blood eosinophils ≥300 cells/μL on top of optimized triple therapy (Bhatt et al., *N Engl J Med* 2023). In 2024, the FDA approved dupilumab as the first biologic for COPD, specifically for eosinophilic COPD inadequately controlled on standard care.
- **Mepolizumab (anti-IL-5): Redemption via MATINEE**
  Earlier mixed results gave way to the positive phase-3 MATINEE trial in 2025, which reported a 21% reduction in exacerbations versus placebo among eosinophilic COPD patients already on triple therapy (Sciurba et al., *N Engl J Med* 2025). Along with dupilumab, this establishes eosinophilic COPD as a treatable minority phenotype.
- **Ensifentrine (dual PDE3/4 inhibitor): A small-molecule milestone**
  The inhaled dual PDE3/4 inhibitor ensifentrine (Ohtuvayre™) gained FDA approval in 2024 based on ENHANCE-1/-2, which demonstrated consistent FEV_1 improvements (~90–94 mL over placebo) and symptom relief as maintenance add-on therapy, with modest exacerbation signals (Anzueto et al AJRCC). It is the first novel non-steroidal mechanism for COPD in nearly two decades.

Why have so many trials failed?

Five themes recur across empirical discussion.

- **COPD is not one disease.** Molecular and histopathologic profiling reveal overlapping endotypes-neutrophilic, eosinophilic, infection-driven, mucus-dominant, small-airway collapse.
- **Background care keeps improving.** Placebo-arm exacerbation rates have fallen as inhaled therapy, vaccination, and smoking abstinence improve, narrowing the absolute margin for add-on benefit. A meta-regression suggests ~50% decline per decade (Andreas et al., *Respir Res* 2019).
- **Exacerbations are multifactorial.** Many events are infectious and neutrophilic, driven by bacterial/viral dynamics or mucus plugging rather than T2 cytokines; pathway-specific biologics may affect only a subset.
- **Smoking status matters.** Ongoing tobacco exposure sustains epithelial injury and colonization, which can overwhelm cytokine blockade. Signals with anti-IL-33 (and perhaps Ensifentrine) were stronger in former smokers.
- **Endpoints and design.** Annualized exacerbation rate is variable and seasonally sensitive. Structural imaging, severe-exacerbation-weighted endpoints, and trajectories of lung function and health status may better capture pathway effects.

Clinical Implications: The Primacy of Standard of Care

The new precision therapies do not replace fundamentals. In dupilumab and mepolizumab trials, every participant received optimized triple therapy, careful adherence support, and non-pharmacologic measures when available. GOLD guidance continues to emphasize that foundational management yields the largest absolute gains for most patients: correct inhaler selection and technique, single-inhaler triple therapy in high-risk patients, pulmonary rehabilitation, vaccination, smoking cessation, long-term oxygen therapy for chronic hypoxemia, and nocturnal non-invasive ventilation in selected patients with chronic hypercapnic failure.

Device-based therapies can work adjunctively to address physiology directly. Airway-clearance devices reduce mucus burden and V/Q mismatch in secretion-prone phenotypes; home ventilatory support augments alveolar ventilation and lowers $PaCO_2$ in chronic hypercapnic failure; long-term oxygen improves survival in persistent severe hypoxemia. Durable medical equipment partners-including Apria-deliver these elements reliably in the home, close the hospital-to-home gap, and sustain adherence.

Conclusion

After years of disappointment, 2025 finally brings reproducible progress-but only when biology, design, and clinical reality align. The failures of benralizumab, tezepelumab, and others were not wasted; they mapped what COPD is not in the context of clinical trials. The successes of dupilumab, mepolizumab, and ensifentrine reveal what COPD is: heterogeneous disease in which targeted therapy works when anchored to the right biology and layered on top of standard care.

References

1 Lipson, David A., et al. "Once-daily single-inhaler triple versus dual therapy in patients with COPD." *New England Journal of Medicine* 378.18 (2018): 1671-1680.

2 Rabe, Klaus F., et al. "Triple inhaled therapy at two glucocorticoid doses in moderate-to-very-severe COPD." *New England Journal of Medicine* 383.1 (2020): 35-48.

3 Calverley, Peter MA, et al. "Roflumilast in symptomatic chronic obstructive pulmonary disease: two randomised clinical trials." *The Lancet* 374.9691 (2009): 685-694.

4 Albert, Richard K., et al. "Azithromycin for prevention of exacerbations of COPD." *New England Journal of Medicine* 365.8 (2011): 689-698.

5 Criner, Gerard J., et al. "Benralizumab for the prevention of COPD exacerbations." *New England Journal of Medicine* 381.11 (2019): 1023-1034.

6 Menzies-Gow, Andrew, et al. "Tezepelumab in adults and adolescents with severe, uncontrolled asthma." *New England Journal of Medicine* 384.19 (2021): 1800-1809.

7 Rabe, Klaus F., et al. "AERIFY-1/2: two phase 3, randomised, controlled trials of itepekimab in former smokers with moderate-to-severe COPD." *ERJ open research* 10.5 (2024).

8 Dransfield, Mark T., and Daiana Stolz. "Mepolizumab in COPD—If at First You Don't Succeed." *NEJM evidence* 4.6 (2025): EVIDe2500080.

9 Martineau, Adrian R., et al. "Double-blind randomised placebo-controlled trial of bolus-dose vitamin D3 supplementation in adults with asthma (ViDiAs)." *Thorax* 70.5 (2015): 451-457.

10 Bhatt, Surya P., et al. "Dupilumab for COPD with blood eosinophil evidence of type 2 inflammation." *New England Journal of Medicine* 390.24 (2024): 2274-2283.

11 Anzueto, A., Barjaktarevic, I. Z., Siler, T. M., Rheault, T., Bengtsson, T., Rickard, K., & Sciurba, F. (2023). Ensifentrine, a novel phosphodiesterase 3 and 4 inhibitor for the treatment of chronic obstructive pulmonary disease: randomized, double-blind, placebo-controlled, multicenter phase III trials (the ENHANCE trials). *American journal of respiratory and critical care*

medicine, *208*(4), 406-416.
12 Andreas, Stefan et al. "Decline of COPD exacerbations in clinical trials over two decades - a systematic review and meta-regression." *Respiratory research* vol. 20,1 186. 16 Aug. 2019, doi:10.1186/s12931-019-1163-2

News…continued from page 11
especially those in low- and middle-income countries (LMICs), effective self-management remains a significant challenge, hampered by systemic barriers, socioeconomic factors, and a lack of tailored support. The burden of chronic respiratory disease is not evenly distributed across populations. Tanja Effing-Tijdhof, PhD, epidemiologist from the Flinders University, Adelaide, Australia, said 85% of the asthma burden and 96% of asthma deaths occur in LMICs. Similarly, for chronic obstructive pulmonary disease (COPD), the contribution of LMICs is over 85%. Despite this, the vast majority of medical literature and clinical guidelines on self-management comes from high-income countries. This mismatch creates profound challenges:
Health literacy. Factors such as socioeconomic hardship and lower levels of education can significantly affect a patient's ability to manage their condition and adhere to treatment. "A patient's capability for self-management and adherence is directly influenced by their health literacy, which is why we must check and tailor every intervention," Effing-Tijdhof said. She encouraged clinicians to carefully assess a patient's understanding so that educational materials and management plans can be adapted appropriately. **Stigma.** In certain parts of the world, a diagnosis of asthma can cause social isolation and discrimination within communities. Effing-Tijdhof shared a quote from a patient in India who said: "If I cook for my relations and neighbors, they'll hesitate to eat….Those situations affect me very much." This feeling of being perceived differently can lead to discomfort with a diagnosis, or even a reluctance to seek one, and can negatively affect treatment adherence, she explained.
Adherence. Self-management is influenced by cultural beliefs and a simple misunderstanding of the treatment plan, but is also influenced by poverty, which affects the affordability and accessibility of medications. "We need a combination of making drugs affordable and accessible, and that requires action from both pharmaceutical companies and governments," Effing-Tijdhof said. Active patient involvement in care is not always recognized or encouraged in LMICs, with some doctors thinking that self-management means being set aside, Effing-Tijdhof explained. Adding to this, she said, there is a lack of locally tailored clinical guidelines. Effing-Tijdhof said that only 22% of LMICs have their own national guidelines for chronic respiratory conditions, and these are often just "copy-paste" versions of global ones. "Ideally, you should have national guidelines that are adapted to local means and local resources," she said. This focus on high-income settings also skews research priorities. Because the vast majority of research happens in wealthy nations, potentially useful treatments for LMICs are overlooked. For instance, research on cheaper, albeit less effective, drugs, such as oral beta agonists like oral salbutamol or terbutaline, has been abandoned in the high-income world. However, these medications could still be highly beneficial in resource-limited settings where the alternative is no treatment at all.

Asthma Management in Children Gets a Boost With Telemedicine

The Telemedicine Enhanced Asthma Management-Uniting Providers (TEAM-UP) program, which involved preventive medication for asthma and telemedicine visits with specialists, increased the number of symptom-free days and reduced school absenteeism in children with moderate-to-severe asthma. The program also showed promise in reducing emergency visits and hospitalizations. Researchers conducted a prospective randomized trial from 2018 to 2024 involving 325 children
Continued on page 41…

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Fisher & Paykel AIRVO 3 with OptiFlow High-Flow Therapy System

The Editors of Respiratory Therapy

Introduction: A New Benchmark in High-Flow Therapy

High-flow nasal therapy has become one of the most relied-upon tools in modern respiratory care, not because it is a technological novelty, but because it consistently proves its clinical value. Over the past decade, the OptiFlow system from Fisher & Paykel has played a central role in defining how high-flow therapy is delivered, monitored, and incorporated into respiratory treatment pathways. Now, with the introduction of the AIRVO 3, the company sets a new standard—one that reflects the evolving clinical environment, rising patient acuity, and the real-world workflow challenges respiratory therapists face every day.

The AIRVO 3 arrives at a critical moment. Emergency departments are overextended, ICUs are operating at near-constant surge levels, and non-ICU medical floors are managing increasingly complex respiratory cases. In this environment, clinicians need respiratory support systems that are faster to set up, easier to run, more intuitive to adjust, and more reliable through long stretches of therapy. The AIRVO 3 addresses all of these demands with a technological and operational refinement that feels less like an incremental upgrade and more like a strategic reinvention of the platform.

This Relevancy Report examines why the AIRVO 3 matters right now, what its enhancements mean for respiratory therapy departments, and how it can influence patient management, workflow efficiency, and clinical outcomes moving forward.

Therapy Without Friction: What's Changed in the AIRVO 3

One of the most immediate impressions clinicians notice with the AIRVO 3 is how much more fluid the therapy process becomes. Even the initial setup—often a friction point during peak admissions—is noticeably streamlined. The redesigned chamber, simplified circuit connections, and intuitive startup sequence shorten the time from equipment retrieval to therapy initiation, reducing delays in stabilizing a deteriorating patient.

The user interface is now larger, clearer, and built around a more logic-driven structure. Touchpoints are more responsive, menu layers are fewer, and visual cues guide the clinician rather than overwhelm them. Navigating settings feels easier, especially during urgent adjustments, and the upgraded electronic architecture ensures those changes translate into near-instantaneous shifts in flow and humidification.

These design refinements matter clinically. Respiratory therapists often work in highly dynamic environments where seconds count—during rapid desaturations, unexpected agitation, post-extubation transitions, or the early stabilization phase in hypoxemic respiratory failure. The AIRVO 3 removes delay from the equation, allowing clinicians to focus on the patient rather than the device.

Advancing the Core Strength of OptiFlow Therapy: Humidification

Humidification is the physiological foundation of effective high-flow therapy. It is what preserves mucosal function, improves secretion mobility, reduces airway dryness, and supports patient adherence. The OptiFlow system has always differentiated itself through its humidification consistency, and the AIRVO 3 strengthens that advantage even further.

The refined humidifier responds more quickly to variations in ambient temperature, therapy demand, and circuit conditions. That responsiveness translates into less drift and more stable delivery of warmed, humidified gas—even at high flow rates maintained over long periods. Patients who require extended high-flow therapy, especially those with significant secretion burden or post-extubation airway sensitivity, benefit particularly from this continuous thermal and humidity stability.

From a therapist's perspective, improved humidification also means fewer interruptions. Reduced condensation variability, fewer chamber adjustments, and greater temperature accuracy all lessen the need for constant vigilance and manual correction.

Enhanced Monitoring and Data Visibility

Modern respiratory therapy is increasingly guided by data—not just arterial blood gases or chest imaging, but continuous bedside feedback on how patients are responding moment to moment. The AIRVO 3 enhances that visibility through a redesigned display that communicates status information more clearly and predictably.

Flow rate, temperature, FiO_2 (when connected to a blending system), and system status indicators are now presented in a larger, more readable layout that supports quick assessment during clinical rounds. The streamlined alarm structure—fewer nuisance alarms, more meaningful alerts—reduces alarm fatigue,

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which continues to be a major concern for respiratory and nursing staff alike.

These improvements are especially valuable in departments that have expanded high-flow therapy beyond the ICU to step-down units, ED fast-track areas, med-surg floors, and transitional care units. Facilities report that early high-flow stabilization can reduce the need for noninvasive ventilation or intubation—but only when clinicians have immediate visibility into therapy response. The AIRVO 3's monitoring enhancements support that early recognition and intervention.

Workflow Integration in High-Demand Departments

Beyond clinical performance, respiratory therapy departments increasingly evaluate equipment based on workflow impact. With staffing shortages affecting nearly every institution, any device that consolidates steps, reduces complexity, and limits interruptions contributes to a safer and more efficient unit.

The AIRVO 3 demonstrates notable improvements in this regard:

- Faster turnover: Shorter teardown and cleaning time simplifies patient transitions and improves equipment availability.
- Optimized bedside footprint: A more compact design allows easier positioning near monitors, pumps, and ventilators.
- Therapy continuity: Enhanced system reliability decreases the likelihood of mid-therapy troubleshooting.
- Reduced training burden: A more intuitive interface allows new staff to reach proficiency quickly.

For department managers looking to allocate resources effectively, these workflow upgrades collectively represent significant operational value.

Clinical Relevance Across Multiple Patient Pathways

The AIRVO 3 is not a niche tool. Its design reflects a reality in which high-flow therapy is now used across a broad spectrum of respiratory presentations:

- Early hypoxemic respiratory failure (viral pneumonia, sepsis-related respiratory compromise)
- COPD exacerbations where humidification improves secretion management
- Post-extubation prophylaxis to prevent reintubation
- Post-operative respiratory stabilization
- Palliative and comfort-focused respiratory care
- Emergency department early stabilization to prevent ICU escalation

What distinguishes the AIRVO 3 is its ability to integrate smoothly into each of these care pathways, providing the consistency and responsiveness that clinicians need to titrate therapy effectively.

Why the AIRVO 3 Matters Now

The significance of the AIRVO 3 is not limited to its technological improvements. Its relevance is tied to several broader shifts in respiratory care:

1. Earlier use of high-flow therapy as a first-line intervention rather than a step before NIV.
2. Expansion of therapy beyond critical care, requiring devices that are intuitive and reliable across more units.
3. Growing emphasis on patient comfort as a driver of better adherence and better outcomes.
4. Operational pressure to deliver more care with fewer hands.

In this context, the AIRVO 3 feels less like an optional upgrade and more like a necessary evolution for departments committed to modern, responsive respiratory support.

Final Assessment

The Fisher & Paykel AIRVO 3 with OptiFlow system stands as a substantial advancement in high-flow respiratory therapy. It is not simply a redesign—it is a more responsive, more efficient, and more clinically aligned system that directly addresses the demands of contemporary respiratory care.

For respiratory therapists, the AIRVO 3 offers:

- Improved therapy stability
- Faster and smoother workflow integration
- Greater monitoring clarity
- Enhanced humidification precision
- A therapy experience that prioritizes patient comfort and clinician control

In a care environment marked by rising acuity and diminishing margins for error, the AIRVO 3 provides the reliability and ease of use that therapists need to deliver timely, high-quality care.

Related Articles for Additional Reading

- "High-Flow Nasal Oxygen Therapy for Acute Respiratory Failure: Evidence and Best Practices"
- https://pubmed.ncbi.nlm.nih.gov/32186720
- "Humidification in Respiratory Support: Physiological Impact and Clinical Applications"
- https://pubmed.ncbi.nlm.nih.gov/31478955
- "OptiFlow Therapy Use in Emergency and Critical Care: A Review of Clinical Outcomes"
- https://pubmed.ncbi.nlm.nih.gov/32925346
- "Avoiding Intubation: The Expanding Role of High-Flow Therapy in the ED and Step-Down Unit"
- https://pubmed.ncbi.nlm.nih.gov/33375847
- "High-Flow Nasal Cannula Versus NIV: Updated Evidence in Managing Hypoxemic Respiratory Failure"
- https://pubmed.ncbi.nlm.nih.gov/35900101
- "Impact of Humidification on Secretion Management in COPD Patients Receiving High-Flow Therapy"
- https://pubmed.ncbi.nlm.nih.gov/31204710

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The Clinical Relevance of the Getinge SERVO Ventilator in Today's Evolving Critical Care Environment

The Editors of Respiratory Therapy

Modern critical care is defined not simply by rising acuity, but by a kind of clinical volatility that challenges respiratory therapists in ways that were almost unimaginable a decade ago. The ICU has become a crucible of rapid decision-making, advanced monitoring, unpredictable patient behavior, and constant adaptation. Mechanical ventilation, once seen as a largely technical skill rooted in physiology and pressure control, is now a dynamic practice shaped by subtle interactions between patient and machine. In this environment, the ventilator becomes much more than a device; it becomes a partner whose clarity, consistency, and responsiveness influence outcomes as directly as the clinician's expertise.

The Getinge SERVO ventilator family has maintained its presence in many ICUs not because of loyalty or branding, but because it aligns naturally with the evolving realities of respiratory care. Therapists frequently describe the platform not in terms of features but in terms of feel—how it interacts with the patient, how it presents information, and how it supports rapid interpretation during moments when delays can carry real consequences. This relevance becomes particularly apparent when looking closely at how ventilatory practice has changed and why clinicians gravitate toward systems that give them the feedback they need to prevent complications and support recovery.

One of the defining shifts in respiratory care has been the broad recognition that synchrony between patient and ventilator is not merely a comfort measure but a determinant of multiple downstream outcomes. Poor synchrony can increase sedation requirements, prolong ventilation duration, worsen diaphragm function, raise the risk of ventilator-induced lung injury, and ultimately complicate the weaning process. Many therapists report that SERVO ventilators allow them to identify synchrony issues more quickly because the waveforms and loops are presented with clarity that supports intuitive interpretation. In the busy environment of an ICU, where therapists are often caring for large caseloads, the ability to "read" the patient at a glance becomes an invaluable safety layer.

The relevance of the SERVO platform becomes even more apparent when considering the diversity of patient populations treated in modern hospitals. It is not uncommon for an RT to begin the day caring for adults with ARDS, transition to a pediatric trauma patient by mid-shift, and finish in the NICU supporting premature infants requiring delicate ventilatory strategies. Equipment that remains consistent across these environments reduces mental load, training burden, and the potential for errors during high-stress transitions. Hospitals increasingly favor standardization not only for logistical reasons but because it creates a common language across departments. The SERVO family, with models supporting neonates through adults, is frequently chosen because it minimizes the variation therapists must navigate when moving from one unit to another.

The real test of a ventilator's relevance, however, emerges during those moments when rapid assessment and corrective action become essential. Consider the case of a 71-year-old patient nearing the threshold for intubation after struggling with respiratory failure in the emergency department. Upon arrival to the ICU, the patient exhibits inconsistent respiratory drive, erratic tidal patterns, and pronounced work of breathing. Before even touching the settings, the therapist relies on the ventilator to tell the clinical story clearly: Are the patient's efforts being captured effectively? Do the waveforms suggest early fatigue? Is the patient attempting to overbreathe the machine, or does the pattern reflect insufficient inspiratory flow? The therapist makes dozens of micro-decisions during the first hour of care—adjusting sensitivity, rise time, pressure support, and PEEP—and each adjustment depends on rapid interpretation of feedback.

In units where the SERVO platform is widely used, therapists consistently describe its responsiveness during these initial stabilization periods. They report that the ventilator behaves predictably, presenting data in a way that aligns with their expectations and allows them to differentiate between patient-driven phenomena and mechanical artifacts. This reliability builds confidence during the fast-paced transitions that define early ICU admissions, particularly when dealing with patients whose respiratory drive fluctuates dramatically as sedation is adjusted or as physiological instability resolves.

Because mechanical ventilation is never static, relevance also depends on how well a ventilator supports patients across each phase of their ICU course—from intubation through recovery. Weaning is often one of the most challenging and delicate phases of respiratory care. A patient who appears physiologically stable may still fail a spontaneous breathing trial due to subtle inconsistencies in respiratory effort, early fatigue, or misalignment between the ventilator's triggering and the patient's

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neural drive. Therapists often highlight the SERVO's capacity to reveal these issues before they become failures. Its waveform presentation allows clinicians to inspect breath-by-breath variability, detect early signs of tachypnea or low effort, and adjust support before the patient hits a point of no return.

This ability to identify problems early matters because weaning is not simply a question of readiness—it is a question of trajectory. Patients who exhibit poor synchrony or respiratory muscle strain during weaning are more likely to struggle with extubation, require reintubation, or experience setbacks that prolong ICU length of stay. Therapists who use SERVO ventilators often emphasize that consistent feedback helps them guide the patient through these transitions with fewer surprises.

Another dimension of the SERVO's continued relevance is its adaptability across clinical environments that require different emphases in ventilatory control. In neonatal care, for example, the margin for error narrows significantly. Premature infants have fragile lungs, highly elastic chest walls, inconsistent respiratory drive, and small tidal volumes that must be measured and supported precisely. Platforms used in NICUs must be able to deliver stable, reliable ventilation while providing detailed monitoring without overwhelming the clinician with noise. Many NICUs that use SERVO-n ventilators do so because the interface mirrors that of the adult ICU models, reducing training friction, while still offering the precision required for neonatal lung protection. The ability to transition a therapist who works between adult and neonatal units without requiring a completely different operating paradigm is not a small advantage; it directly influences patient safety.

Within pediatric units, where physiology and pathology differ dramatically from adults, relevance becomes a matter of flexibility. Therapists report that SERVO ventilators allow for the adaptability needed to support both small children with high respiratory rates and adolescents whose ventilatory demands more closely resemble adults. The value here is consistency; therapists do not need to shift cognitive frameworks or relearn interfaces when caring for these populations.

Across all age groups, the SERVO platform's long-standing role also reflects its alignment with core principles that continue to define ventilatory research. If there is a single unifying theme across decades of mechanical ventilation studies, it is the centrality of lung protection. The landmark ARDSNet trial demonstrating the survival benefits of low tidal volume ventilation remains the cornerstone of modern practice. Research on driving pressure, notably the work of Amato and colleagues, continues to highlight the importance of monitoring lung stress and adapting support accordingly. Studies on diaphragm protection show how ventilators that minimize unnecessary mechanical workload can support faster recovery. Investigations into patient–ventilator synchrony, such as those by Thille and Chanques, have illuminated the physiological and clinical consequences of mismatched interaction. Neonatal research, including Keszler's work on volume-targeted ventilation, reinforces the importance of precise, stable support during the earliest stages of life. And across many studies examining weaning, researchers consistently emphasize the role of predictable ventilator behavior in achieving timely extubation.

These bodies of evidence collectively underscore why ventilators that deliver clarity and consistency retain value, even as specific technologies evolve. The SERVO platform aligns with these principles not through branding but through its operational stability and its ability to support clinical reasoning. Therapists trust ventilators that behave predictably under stress, and they continue to rely on systems that reveal patient physiology in a coherent and actionable manner.

Looking to the horizon, mechanical ventilation is poised to shift further toward integrated, data-driven care. Closed-loop systems, automated PEEP titration, respiratory drive monitoring, diaphragm-protective strategies, and AI-assisted decision guidance will increasingly influence bedside practice. Ventilators that can serve as adaptable platforms—capable of interacting with these systems rather than resisting them—are the ones that will remain relevant. Many clinicians view the SERVO family as well suited for this transition because it is already designed around information, not just mechanics.

In the end, what makes the SERVO ventilator relevant today is a combination of trust, clarity, and adaptability. In the unpredictable world of critical care, where small details can shape the trajectory of a patient's recovery, therapists gravitate toward tools that amplify their clinical judgment rather than complicate it. The SERVO platform continues to earn that trust through consistent performance, intuitive monitoring, and a design philosophy aligned with modern respiratory practice. Its longevity in ICUs is not an artifact of habit—it is evidence of continued utility.

The conclusions drawn in this report resonate with much of the modern literature that underpins ventilator practice. The foundational ARDSNet findings on lung-protective ventilation remain essential to understanding the physiological goals of modern ventilator strategy (NEJM, 2000). Research by Thille and colleagues illuminates the pervasive challenge of patient–ventilator asynchrony and its clinical consequences (PubMed ID: 16645176). Studies of diaphragm injury, including those led by Goligher and Dres, reveal how ventilator settings and synchrony influence muscular function and long-term recovery (PubMed ID: 28373370). The work by Amato and Meade on driving pressure reinforces the importance of minimizing lung stress to improve outcomes (PubMed ID: 25562138). Neonatal ventilation research by Keszler highlights the need for precise and responsive volume-targeted support in premature infants (PubMed ID: 26009652). And the evidence supporting structured weaning processes, as reflected in analyses such as those by Blackwood (PubMed ID: 24638862), demonstrates the essential role of reliable feedback during transitions from mechanical ventilation.

Together, these studies form an evidence base that highlights why ventilators capable of delivering clear, stable, and physiologically meaningful feedback remain valuable—and why clinicians continue to find the SERVO platform relevant in an era of ever-changing clinical demands.

The Scleroderma-Pulmonary Hypertension Patient Journey: From Early Fibrosis to PH Diagnosis

Seth Hall MBA, RRT, RRT-ACCS, RRT-NPS

Introduction: Understanding the Connection

Consider a patient in their late forties who first notices their fingers turning white in cold weather. Their primary care physician attributes this to Raynaud's phenomenon. Three years might potentially pass before progressive skin tightening and persistent gastroesophageal reflux lead to a scleroderma diagnosis. Unknown to them and their care team, subtle changes may already be occurring in their pulmonary vasculature. It might take another four years before pulmonary hypertension is finally detected. This pattern of delayed recognition represents the norm rather than the exception for patients living with systemic sclerosis that develop pulmonary hypertension.

Systemic sclerosis (SSc), commonly known as scleroderma, is a chronic autoimmune disease characterized by vasculopathy, immune dysregulation, and progressive fibrosis (Tuhy and Hassoun). The worldwide prevalence is approximately 176 cases per million, with women affected three to four times more frequently than men. Among its many complications, pulmonary hypertension has emerged as a leading cause of mortality, accounting for up to 30% of premature deaths in this population.

The prevalence of pulmonary hypertension among SSc patients is estimated between 5 and 19%, making it the second most common cause of PAH after idiopathic forms (Naranjo and Hassoun). Survival data shows the severity of this complication: patients with SSc-PAH face a threefold increased mortality risk compared to those with idiopathic PAH alone, with 3-year survival rates ranging from 50 to 65%.

Pathophysiology: Blood Vessels Under Siege

Understanding how scleroderma leads to pulmonary hypertension starts with acknowledging the complex interplay between vascular injury, inflammation, and fibrotic remodeling (Tuhy and Hassoun). SSc-PAH is fundamentally an obliterative vasculopathy affecting small to medium pulmonary arterioles. The pathological cascade begins with endothelial cell injury, disrupting the balance between vasodilators (nitric oxide, prostacyclin) and vasoconstrictors (endothelin-1). These imbalances trigger smooth muscle cell proliferation, intimal fibrosis, and plexiform lesion formation. The pulmonary vasculature progressively narrows, increasing resistance. The right ventricle compensates initially through hypertrophy but eventually can fail.

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Autoantibody profiles provide insight into disease trajectory and PH risk. Anticentromere antibodies, anti-U1-ribonucleoprotein antibodies, and nucleolar-pattern antinuclear antibodies are associated with increased SSc-PAH risk, while anti-Scl 70 antibodies correlate with PH due to interstitial lung disease rather than primary vasculopathy (Naranjo and Hassoun). Additionally, specific autoantibodies including angiotensin II type-1 receptor and endothelin-1 receptor type A antibodies may function as inflammatory mediators contributing to vascular remodeling.

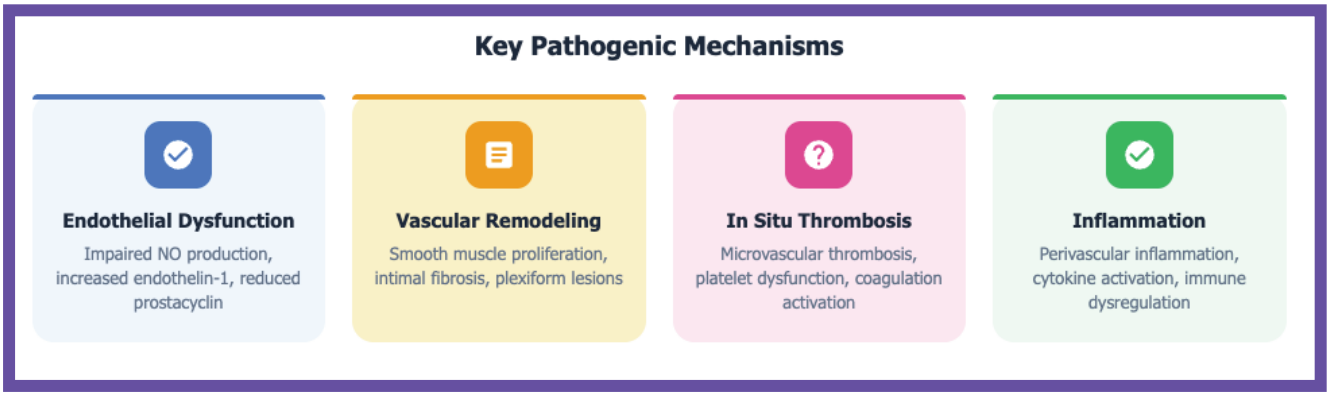
PH in scleroderma can arise through multiple mechanisms: Group 1 PAH from primary vasculopathy, Group 3 PH from interstitial lung disease and hypoxia, or Group 2 PH from myocardial fibrosis causing left ventricular dysfunction (Naranjo and Hassoun). This multiplicity of pathogenic mechanisms explains why careful phenotyping is essential for appropriate management.

Despite similar baseline hemodynamic profiles, patients with SSc-PAH consistently demonstrate worse outcomes than those with idiopathic PAH. Survival data from the REVEAL registry show 3-year survival of 61% for SSc-PAH compared to 80% for non-SSc connective tissue disease-associated PAH (Naranjo and Hassoun). Independent prognostic factors include sex, age over 60 years, DLCO below 50% predicted, pericardial effusion, and right atrial pressure exceeding 20 mmHg. These findings show the importance of aggressive screening and early intervention in the scleroderma population.

Updates from the 7th World Symposium on Pulmonary Hypertension

The 7th World Symposium on Pulmonary Hypertension, held in Barcelona in 2024, brought important updates to our understanding of PH in connective tissue diseases, particularly for patients with concurrent interstitial lung disease. A key development was the updated Group 3 PH classification, which now includes separate categories for ILD-PH, combined pulmonary fibrosis and emphysema (CPFE) with PH, and COPD-PH (Shlobin et al.). This separation provides better phenotyping of pulmonary diseases that lead to pulmonary hypertension and assists with subsequent therapeutic choices. For CTD patients, defining the clinical phenotype is critical to understanding pathophysiology and evaluating potential therapeutic strategies.

Among connective tissue diseases, systemic sclerosis carries the strongest association with PH, with PH-ILD described



in up to 24% of SSc patients (Shlobin et al.). The symposium proceedings describe two distinct clinical phenotypes of CTD-ILD-PH with a spectrum of disease in between. The respiratory phenotype represents an adaptive phenomenon in which PH development is a surrogate marker of advanced fibrotic lung disease; these patients have more severe restrictive physiology, DLCO decreased in proportion to lung volume abnormalities, and more advanced fibrotic changes on imaging. They generally demonstrate mild elevation in mean pulmonary artery pressure and PVR with preserved cardiac output. In contrast, the vasculopathic phenotype represents a maladaptive phenomenon in which PH has developed from discrete pathophysiological changes independent of ILD severity. These patients have mild restriction with DLCO decreased out of proportion to lung volumes, mild fibrotic changes on imaging, but severe hemodynamic compromise and significant right ventricular dysfunction. This vasculopathic phenotype, which has special significance in CTD-PH-ILD patients, may be more responsive to specific PH therapies. Cluster analyses of SSc patients with precapillary PH have identified four homogenous phenotypes depending on ILD and PH severity, with clusters showing either extensive ILD or severe PH demonstrating the highest mortality rates.

Importantly, up to 25% of SSc-ILD patients demonstrate mean pulmonary artery pressure exceeding 35 mmHg, suggesting PH that is "out of proportion" to their underlying lung disease and indicating a high probability of coexisting intrinsic vascular disease (Naranjo and Hassoun). This overlap between Group 1 PAH and Group 3 PH-ILD has significant therapeutic implications, as these patients may benefit from PAH-specific therapies despite the presence of interstitial lung disease.

Early Screening and Detection: A Critical Window

The onset of pulmonary hypertension creates significant diagnostic challenges. Patients typically experience a median 4-year delay from first symptoms to formal diagnosis (Saygin and Domsic). Late diagnosis means more severe hemodynamic compromise and distinctly worse survival outcomes.

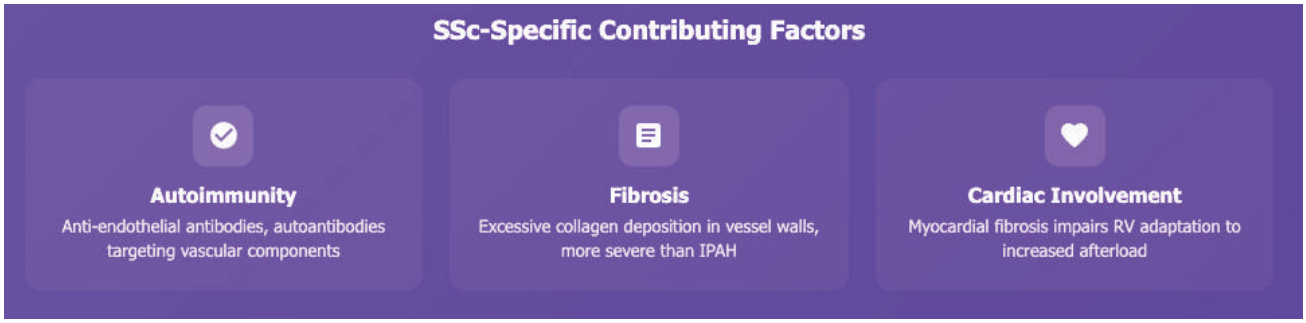
The DETECT algorithm, developed from 466 patients across 18 countries, employs a two-step approach using clinical variables followed by echocardiographic parameters. It demonstrated only a 4% rate of missed diagnoses versus 29% with earlier guidelines. The ESC/ERS guidelines recommend annual echocardiography, while the Australian Scleroderma Interest Group (ASIG) algorithm emphasizes NT-proBNP and pulmonary function tests as initial screens.

Specific biomarker thresholds guide screening decisions. Pro-BNP levels exceeding 240 pg/mL demonstrate 90% specificity for SSc-PAH detection, though elevated values are not specific and require correlation with other findings (Naranjo and Hassoun). On pulmonary function testing, DLCO below 60% predicted or a decline exceeding 20% within one year, particularly in the absence of significant lung volume abnormalities, suggests pulmonary vascular disease. The FVC/DLCO ratio above 1.6 is particularly concerning for vasculopathy. On echocardiography, tricuspid regurgitant jet velocity above 3.4 m/s makes PH likely per ESC/ERS guidelines, while TAPSE below 1.7 cm reflects a nearly fourfold increased mortality risk.

Novel Approaches: The PH-ILD Detection Tool

For patients with concurrent interstitial lung disease, a common overlap in scleroderma, Dr. Raj Parikh, Director of the Pulmonary Hypertension Center at Hartford Hospital, and colleagues developed the PH-ILD Detection tool to address the diagnostic gap. Patients with ILD who develop PH carry extremely poor prognosis, require more supplemental oxygen, and experience significantly diminished quality of life (Parikh et al., 2022).

The PH-ILD Detection tool is a validated 12-point scoring system incorporating multiple clinical and diagnostic variables. In the



original validation study of 154 ILD patients, 48.1% had PH-ILD. A score of 6 or higher was strongly associated with PH-ILD diagnosis, with sensitivity of 86.5% and specificity of 86.3%, yielding an area-under-the-curve of 0.920 (Parikh et al., 2022). The tool was subsequently validated in a multicenter cohort of 161 ILD patients across six facilities, demonstrating 93.3% sensitivity, 90.9% specificity, and an area-under-the-curve of 0.921 (Parikh et al., 2023).

Patients are stratified into low-risk (48.4%), intermediate-risk (33.5%), and high-risk (18.0%) categories. Among intermediate and high-risk patients who underwent follow-up echocardiography, 49.4% had abnormal findings suggestive of PH. Of those proceeding to right heart catheterization, 73.2% were diagnosed with PH-ILD. As Dr. Parikh has emphasized, the tool allows concomitant PH to be diagnosed sooner and more accurately, enabling earlier intervention.

Diagnosis: Confirmation and Classification

Right heart catheterization remains the gold standard for pulmonary hypertension diagnosis. The hemodynamic criteria for pre-capillary PH includes: mPAP greater than 20 mmHg, PCWP of 15 mmHg or less, and PVR of 2 Wood units or greater (Kovacs et al., 2024). Determining the dominant mechanism may involve integration of HRCT for ILD suspicion, pulmonary function testing (DLCO below 55% or FVC/DLCO ratio above 1.6 suggests vascular disease), and six-minute walk testing for functional assessment.

Resources for Patients and Caregivers

Navigating life with scleroderma complicated by pulmonary hypertension requires more than just medical treatment. It demands a network of support, education, and community connection. Below are several resource examples rather than an exhaustive list.

Scleroderma: The National Scleroderma Foundation (scleroderma.org) offers over 100 support groups nationwide, peer mentor programs, educational conferences, and funding for peer-reviewed research. The Scleroderma Research Foundation (srfcure.org) funds innovative research and maintains a directory of specialized treatment centers. The Scleroderma Foundation of Greater Chicago, California, and Greater Washington DC provide resources for patients and caregivers through their spring and fall patient education conferences, advocacy, and regional support groups (stopscleroderma.org).

The Pulmonary Hypertension Association: PHA (phassociation.org) provides patient and caregiver support groups, organized advocacy, early diagnosis awareness programs, specialty care center accreditation, and research funding. PHA offers free membership for patients, families, and caregivers and offers online education.

phaware Global Association: Phaware (phaware.global) was founded by a group of pulmonary hypertension awareness activists dedicated to raising global pulmonary hypertension awareness through its "I'm Aware That I'm Rare" podcast, which features stories from PH patients, caregivers, and medical professionals from around the world. The podcast provides hope and practical insights for those navigating diagnosis and treatment.

Team PHenomenal Hope: Team PHenomenal Hope (teamphenomenalhope.org) combines patient advocacy with research funding. The organization offers programs that remove patients from isolation while advancing scientific understanding. Their annual research symposium brings together experts, young investigators, and healthcare providers to share original research and explore unmet patient needs. The organization provides annual research grants for novel concepts in pulmonary hypertension.

Conclusion

The journey from scleroderma diagnosis to pulmonary hypertension development represents a critical window of opportunity, one that requires vigilance, systematic screening, and timely intervention. For medical professionals, understanding this trajectory enables more effective patient education, early recognition of concerning symptoms, and coordinated care delivery.

With validated screening tools like DETECT and the PH-ILD Detection tool, updated classification systems from the 7th World Symposium, and growing networks of support for patients and families, earlier diagnosis is achievable. The path forward requires continued collaboration between rheumatologists, pulmonologists, cardiologists, nurses, and respiratory therapists working together to improve outcomes for this vulnerable patient population.

References

1 Saygin, Didem, and Robyn T. Domsic. "Pulmonary Arterial Hypertension in Systemic Sclerosis: Challenges in Diagnosis, Screening and Treatment." Open Access Rheumatology: Research and Reviews, vol. 12, 2020, pp. 1-17.
2 Parikh, Raj, et al. "Pulmonary Hypertension in Patients with Interstitial Lung Disease: A Tool for Early Detection." *Pulmonary Circulation*, vol. 12, no. 4, 2022.
3 Parikh, Raj, et al. "The PH-ILD Detection Tool: External Validation and Use in Patients with ILD." *Pulmonary Circulation*, vol. 13, no. 3, 2023.

4 Shlobin, Oksana A., et al. "Pulmonary Hypertension Associated with Lung Diseases." *European Respiratory Journal*, vol. 64, no. 4, 2024.
5 Tuhy, Tijana, and Paul M. Hassoun. "Clinical Features of Pulmonary Arterial Hypertension Associated with Systemic Sclerosis." *Frontiers in Medicine*, vol. 10, 2023.
6 Naranjo, Mario, and Paul M. Hassoun. "Systemic Sclerosis-Associated Pulmonary Hypertension: Spectrum and Impact." *Diagnostics*, vol. 11, no. 5, 2021.
7 Weatherald, Jason, et al. "Screening for Pulmonary Arterial Hypertension in Systemic Sclerosis." *European Respiratory Review*, vol. 28, no. 153, 2019.
8 Kovacs, Gabor, et al. "Definition, classification, and diagnosis of pulmonary hypertension." 7th World Symposium on Pulmonary Hypertension. *European Respiratory Journal*, vol 64, no 4, 2024.

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(mean age, 8.4 years; 60% boys; 58% Black) with moderate-to-severe asthma identified through referrals from elementary schools or primary care or specialist practices. Children were randomly assigned either to the TEAM-UP program (n = 162) or to receive enhanced usual care (n = 163). Directly observed therapy in schools was recommended for all children. Children in the TEAM-UP program received one dose of preventive medication for asthma daily under supervision at school, with additional doses given at home as needed, and telemedicine visits with asthma specialists with assistance from school nurses. Enhanced usual care included recommendations for directly observed therapy and specialist referrals but did not facilitate telemedicine visits. The primary outcome was the mean number of symptom-free days over 2 weeks (days on which the child did not have coughing, wheezing, shortness of breath, or need for rescue medicine for 24 hours). These were assessed at 3, 5, 7, and 12 months after baseline, tracked using symptom diaries. Other outcome measures included school absenteeism and healthcare utilization due to asthma. Children in the TEAM-UP program had more symptom-free days than those receiving enhanced usual care, with a mean difference of 1.32 days (P < .001). Children in the TEAM-UP group vs enhanced usual care group experienced fewer days with symptoms (3.4 vs 4.1 days) and fewer nights with symptoms (1.6 vs 2.3 nights). By 12 months, children in the TEAM-UP group had decreased odds of missing school and requiring emergency visits or hospitalizations due to asthma (odds ratio [OR], 0.70; 95% CI, 0.52-0.96) and (OR, 0.54; 95% CI, 0.31-0.96), respectively. Higher percentages of children in the TEAM-UP group were reported to have used preventive medication for 2 weeks and mild or well-controlled asthma symptoms than children in the enhanced usual care group. Most caregivers believed the program benefited their child and reported they would join again. "This program could serve as a model for the care of children with asthma in communities that are under-resourced," the authors wrote.

Dale Medical Products, Inc. announces the IV Line Manager

Dale Medical Products, Inc., a recognized leader in disposable medical products, is proud to announce its latest innovation, the patent pending IV Line Manager. This device represents Dale Medical's commitment to delivering innovative patient solutions designed to meet the evolving needs of patients and clinicians. The IV Line Manager brings clarity and control to one of nursing's most common safety challenges, IV-line tangling. By securely organizing up to six IV tubing lines into dedicated retention channels, it keeps every line separated, visible, and easy to trace. The result: fewer tangles, less confusion, and greater confidence in every infusion. "We are excited that our new IV Line Manager further broadens our portfolio, specifically within the IV/Vascular securement category. It represents Dale Medical's ongoing commitment to providing unique solutions that support clinician needs and positive outcomes for their patients" said Bob Simpson, Dale Medical President & CEO. The IV Line Manager (product Ref. #630) became available in September 2025 through distributors worldwide. For more information about the IV Line Manager, visit the Dale Medical website at www.dalemed.com. Established in 1961, Dale Medical is recognized as a trusted manufacturer of specialty medical devices that provide high quality, reliable, cost-effective solutions to enhance patient care. As an employee-owned business, we

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Why Flow Direction Matters: Bench Insights into High-Frequency Assisted Airway Clearance

Ashwitha Legala MS, Hattie KenKnight BS, Bruce Rubin MD, MBA, Rob M DiBlasi BS-RT, RRT-NPS, FAARC

Abstract
High frequency assisted airway clearance (HFAC) therapies are widely used to mobilize secretions, recruit lung volume, and support gas exchange in patients who struggle with mucus clearance. Yet in everyday practice, these devices are often grouped together, as if any system that "oscillates" will perform similarly.

The study was conducted using a pediatric ex vivo chimera model to show how therapy delivered from airway clearance systems affect airway pressure and flow patterns, which can have a meaningful impact on mucus movement toward the central airways. The work compared several High-Frequency Airway Clearance (HFAC) delivery systems and found important differences in both their flow patterns and the amount of mucus they mobilized from the lower airways.

This article summarizes that study and explores what its findings might mean for clinicians who select and protocolize HFAC therapies.

Why the mechanics of airflow matter in secretion clearance

The goal of airway clearance therapy is straightforward: move mucus from the distal airways toward the central airways, where it can be coughed or suctioned out. To do that effectively, we need more than just oscillations, we need directional flow that helps "sweep" secretions upward.

Two mechanical concepts are especially relevant:

- Peak inspiratory flow (PIF) – the highest flow rate into the lungs during inspiration
- Peak expiratory flow (PEF) – the highest flow rate out of the lungs during expiration

From these, we can derive:

- Expiratory flow bias (EFB):
  - EFB = PEF – PIF
  - Positive values indicate higher expiratory than inspiratory flow (PEF > PIF)
  - • PIF/PEF ratio:
  - Values < 1.0 indicate expiratory-dominant flow
  - Values > 1.0 indicate inspiratory-dominant flow

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A positive expiratory flow bias and PIF/PEF < 1.0 are thought to favor mucus movement toward the central airways. When flow is more balanced, or biased toward inspiration, secretions may tend to oscillate or "sloshe" without consistently moving upward.

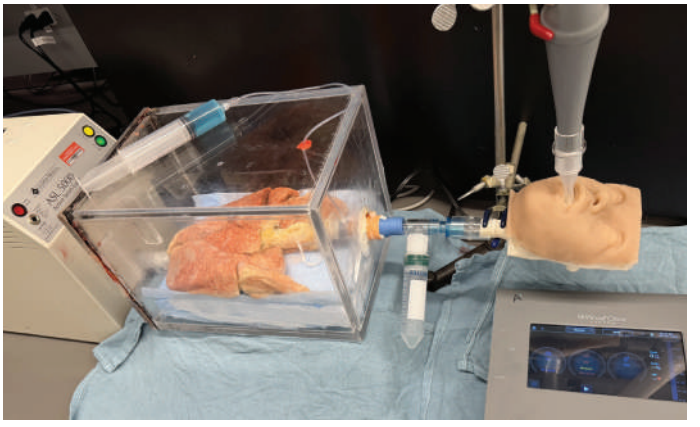
The study summarized here was designed to test that idea directly.

Study overview: a pediatric ex vivo chimera model

The investigators used a pediatric ex vivo chimera model that combined an anatomically realistic upper airway with ex vivo lungs and a mucus simulant. The goal was to approximate a spontaneously breathing child receiving HFAC therapy via mouthpiece.

Breathing model

- Upper airway: A 3D-printed anatomic nose–throat model representing a 25 kg child.
- Lung model:
  - Compliance ~ 55 mL/cmH_2O
  - Resistance ~ 25 cmH_2O/L/s
- Baseline breathing parameters:
  - Respiratory rate: 25 breaths/min
  - Tidal volume:
    - ~145 mL when used to characterize pressure and flow signals
    - ~220 mL when connected to the ex vivo lungs



The model was driven to simulate spontaneous breathing, and all HFAC therapies were delivered via a mouthpiece.

The study compared three HFAC systems, each applied under standardized conditions:

- IPV 1-C (Intrapulmonary Percussive Ventilation)
- Volara® system (oscillating lung expansion system)
- BiWaze® Clear (oscillating lung expansion system)

For the HFAC portion of the testing, devices were set to deliver:

- Peak inspiratory pressure (PIP) of approximately 20 cmH_2O
- Oscillation rate of 230–240 cycles/min (when applicable to the device) via mouthpiece

Ex vivo component and mucus model

In the second phase, the 3D-printed airway model was attached to excised pig lungs (approximately 30 ± 9 kg), enclosed in a chamber and ventilated using the same simulated spontaneous breathing pattern.

- A mucus simulant was instilled into the trachea.
- A collection chamber at the trachea measured the mass of mucus recovered after therapy.
- Mucus recovery was expressed as percentage of the instilled mass.
- Conditions were compared using ANOVA, with $p < 0.05$ considered statistically significant.

The study therefore allowed the team to examine both:

1. Pressure and flow waveforms (including EFB and PIF/PEF) under each HFAC condition, and
2. Resulting mucus mobilization from the lower to the central airways.

What the investigators found: pressure, flow, and mucus movement

Baseline: spontaneous breathing without HFAC

Under spontaneous breathing alone:

- ΔP (pressure amplitude): Low (around 2–3 cmH2O)
- PIF: ~18 L/min
- PEF: ~8–9 L/min
- EFB: Approximately –10 L/min (negative expiratory flow bias)
- PIF/PEF ratio: ~2.0 (inspiratory-dominant)

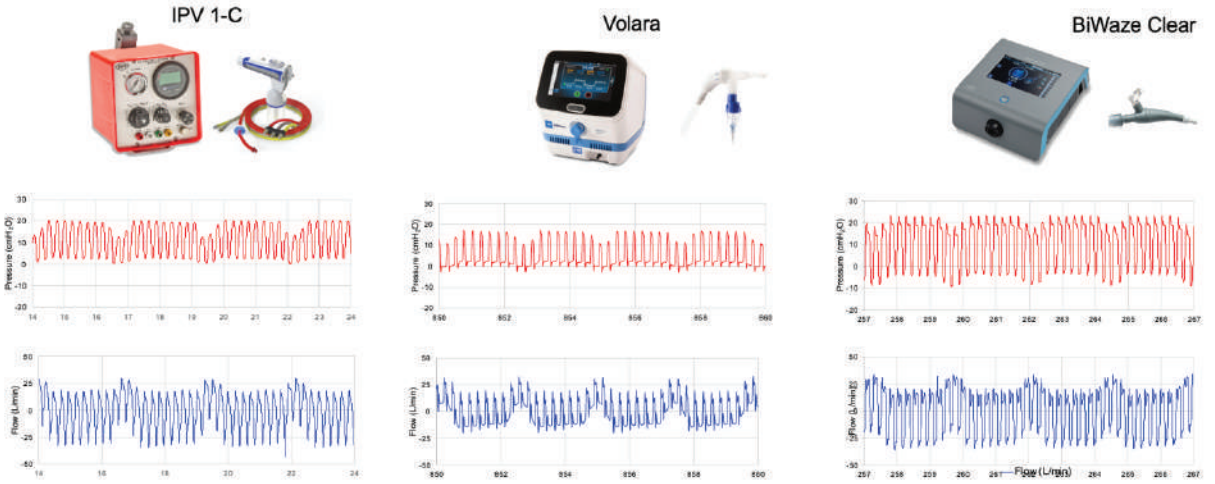
Mucus movement under these conditions represented the baseline against which HFAC-assisted conditions were compared.

Volara: flow pattern similar to spontaneous breathing

- PIF/PEF ratio remained > 1.0, indicating that inspiratory flow still exceeded expiratory flow.
- EFB remained low or negative, similar to spontaneous breathing.

In other words, even with HFAC applied, the flow pattern still favored inspiration rather than expiration. Mucus mobilization from the lower airways was relatively low, similar to or only modestly better than spontaneous breathing alone, and significantly lower than with the other HFAC devices tested.

This suggested that simply adding oscillatory pressure without creating a sustained expiratory flow bias may not be sufficient to optimize mucus clearance in this model.



	No Therapy	IPV	Volara	BiWaze Clear
ΔP (cm H_2O)	2.4 (0.1)	19.2 (2.7)	15.17 (0.74)	24.7 (1.0)
PIF (L/min)	17.6 (0.3)	19.9 (5.6)	29.1 (10.8)	22.8 (7.6)
PEF (L/min)	8.5 (0.9)	26.4 (12.7)	18.8 (8.1)	30.5 (4.4)
EFB (L/min)	-9.8 (0.6)	8.2 (6.9)	-10.7 (11.1)	7.9 (0.5)
PIF/PEF (L/min)	2.07 (0.1)	0.7 (0.1)	1.48 (0.9)	0.8 (0.1)

IPV and BiWaze Clear: positive expiratory flow bias and improved mucus recovery

In contrast, both IPV and BiWaze Clear substantially altered the flow profile:

- Both systems generated positive EFB values (on the order of +8 L/min, depending on condition).
- Both produced PIF/PEF ratios < 1.0, indicating expiratory-dominant flow.

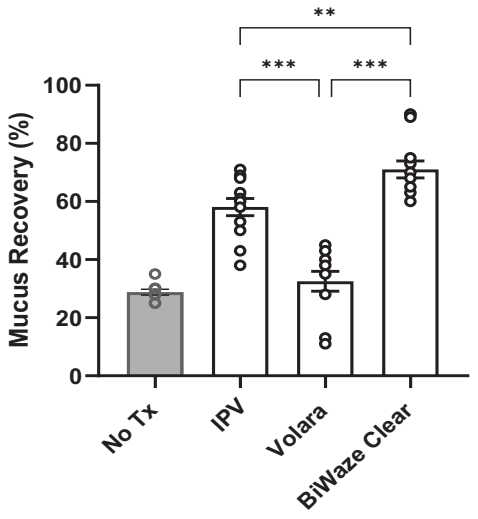
This means that during HFAC:

- Peak expiratory flows were higher than peak inspiratory flows
- The net flow direction favored movement of mucus toward the central airways.

When mucus mobilization was quantified:

- Both IPV and BiWaze Clear mobilized significantly more mucus to the tracheal collection chamber than spontaneous breathing or Volara.
- BiWaze Clear showed a small but statistically significant increase in recovered mucus compared with IPV in this model.

These findings aligned with the study's central hypothesis: HFAC devices that produce a positive expiratory flow bias and PIF/PEF < 1.0 appear to be more effective at mobilizing mucus in this pediatric chimera model.



Clinical implications: what this means at the bedside

Although this is a bench/ex vivo model, the findings raise practical considerations for clinicians:

1. **Not all "high-frequency" therapies are interchangeable**
   In clinical practice, HFAC/OLE devices are sometimes viewed as equivalent—if they deliver pressure oscillations, they're expected to help with mucus clearance. This study suggests:
   - Devices can create very different airway flow patterns, even when set to similar pressures and frequencies.
   - Systems that do not create a sustained expiratory flow bias may provide less secretion mobilization, at least under conditions similar to this model.
2. **Flow direction may be as important as oscillation**
   The key differentiators associated with more mucus movement were:
   - Positive expiratory flow bias (EFB > 0)
   - PIF/PEF ratio < 1.0

For clinicians, this supports the idea that expiratory-dominant flow may be a desirable mechanical target for HFAC devices used to clear secretions.

Key takeaways for practice

- **Flow direction matters.** In this pediatric ex vivo chimera model, HFAC devices that produced a positive expiratory flow bias and PIF/PEF < 1.0 mobilized more mucus toward the central airways than spontaneous breathing or HFAC with an inspiratory-dominant flow pattern.
- **Device choice matters.** IPV and BiWaze Clear generated expiratory-dominant flow and were associated with greater mucus recovery, while Volara's flow pattern was more similar to spontaneous breathing and showed lower mucus mobilization in this model.
- **Ask about mechanics, not just modality.** When evaluating HFAC or OLE systems, consider how the device shapes pressure, flow, and expiratory dominance, not just its frequency or maximum pressure.
- **Bench is not bedside—but it's informative.** These results do not replace clinical data, but they offer a mechanistic rationale for why some HFAC systems may be better suited to secretion mobilization than others in certain patients.

Airway clearance that doesn't just "shake" mucus

BiWaze® Clear SYSTEM

Traditional vest therapy uses external chest vibration to "shake" mucus. BiWaze Clear delivers internal high-frequency oscillations with an expiratory flow-biased waveform to help move secretions toward the upper airways.

3-in-1 airway clearance

for lung expansion, secretion mobilization, and aerosol therapy typically delivered in ~10-minute sessions in both hospital and home settings.

- Bench testing has shown higher aerosol delivery efficiency and modeled lung deposition vs other high-frequency airway clearance systems.[1]
- Expiratory flow biased high-frequency oscillations designed to support movement of mucus toward the upper airways for effective airway clearance.[2]
- Closed breathing circuit includes the Aerogen® Solo nebulizer for aerosol delivery.
- Integrated Aerogen controller within the BiWaze Clear system, no separate controller box to manage the nebulizer.

Scan the QR code or visit abmrc.com to request an in-service and learn more about BiWaze Clear

Website

Videos

References:

1. Kontoudios N, KenKnight H, DiBlasi R. In vitro comparison of aerosol delivery in high-frequency assisted airway clearance devices with integrated nebulizers. Respir Care. 2024;69(10):1221-1230.

2. Data on file

abm RESPIRATORY CARE

A Technology Improvement Using the Smart Trigger on the Panther Ventilator To Reduce Patient-Ventilator Dyssynchrony (PVD) in Ventilated Patients With Air Flow Obstruction

Yuh-Chin T Huang, MD, MHS Professor of Medicine

What is PVD and what are the clinical issues?

Patient-ventilator dyssynchrony is a mismatch between the patient's breaths and ventilator- assisted breaths. It is a common finding in the ICU, occurring in approximately 25% of the sampled breaths in patients on mechanical ventilation.[1] PVD can occur during the three phases of the delivery of breaths: triggering, flow delivery, and breath cycling. Triggering dyssynchrony can occur when the patient's respiratory effort is insufficient to trigger the ventilator. Flow dyssynchrony can be seen in patients who demands an inspiratory flow greater than the maximal flow the ventilator can deliver. The breath cycling dyssynchrony occurs when the cycling off time is too early or too late and does not match the patient's need. PVD increases the work of breathing and contributes to, ventilator weaning failure, prolonged mechanical ventilation, and poor clinical outcomes.[2-4]

What are the effects of PVD and why does this create issues?

Conventionally, the ventilator breaths are initiated using either a pressure or flow trigger mechanism. The sensitivity is typically set high enough (small negative pressure in pressure trigger or a small positive flow in flow trigger) so the patient can trigger a ventilator breath without too much effort. In some situations, however, the patient's effort may not be adequate in triggering the breath, as in cases of neuromuscular diseases or the presence of intrinsic PEEP (PEEPi). The latter situation occurs commonly in patients with airway obstruction whose expiratory time is prolonged and not matched to ventilator setting. This results in air trapping producing positive pressure at the end of the expiration resulting in PEEPi. In this situation, the patient will need to generate enough effort to overcome the sensitivity of the trigger and the PEEPi to initiate a breath from the ventilator. The trigger insensitivity can also be caused by errors in the ventilator's pressure or flow transducer, the ventilator's delay in sampling pressure or flow signals, the duration of time from onset of diaphragm contraction to actual decrease in airway pressure or increase in airway flow, the duration of time from decrease of airway pressure or increase in flow to be sensed by the ventilator, and the duration of time from when the valve is signalled to when flow reaches the airway circuit. These causes can all result in a delayed trigger.

How does Smart Trigger improve the PVD?

Origin Medical has developed the next generation of triggering software in the Panther ventilators based on a new concept known as Smart Trigger.

Figure 1. Passive ventilation showing the air trapping and no simulated trigger. Airflow obstruction and not with any spontaneous breathing. Note the tidal volume does not go back to zero and confirmed as well with the long expiratory time constant (RCexp).

Smart Trigger is now the 3rd type of trigger in the Panther ventilators which has been developed to improve patient/ventilator interaction along with conventional triggers being flow and pressure options.

Smart Trigger analyses the of shape of triggering, i.e., it assesses the patient's effort through changes in the flow/pressure waveform rather than the absolute values. Smart Trigger decreases the missed triggers and has been shown to improve trigger response time in a lung model that simulate patients with airway obstruction with PEEPi.[5] The figures show how Smart Trigger performs differently from the conventional pressure and flow triggers in a ASL 5000 lung simulator with airway obstruction and PEEPi. In the assist/control mode, Smart Trigger decreases missed triggers compared to the pressure or flow trigger.

In this simulation of airflow obstruction, conventional triggering required a drop in baseline pressure to trigger the ventilator often resulting in mis-triggers which increases the WOB and in the case of a patient with moderate to severe COPD more patient/ventilator dyssynchrony.

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Figure 2. Assisted ventilation with pressure/flow triggers. Airflow obstruction with spontaneous breathing with a tandem trigger setting of flow and pressure. Note the mis-triggers (White) and the pressure drop (Red) required to trigger the ventilator.

Figure 3. Airflows obstruction with spontaneous breathing and Smart Trigger activated. Note no missed triggers and many of the breaths were triggered by negative flow (White). Smart Trigger showing the improvement of assisted ventilation when compared to pressure/flow triggers.

The use of Smart Trigger can be the ideal trigger type for obstructive conditions where the patient can trigger from negative flow which in turn improves patient-ventilator interaction. It can be used in combination with other strategies to decrease PEEPi.

The ASL 5000 lung model was set to simulate patients with moderate obstructive lung disease with an inspiratory airway resistance of 25 $cmH_2O/L/S$ and expiratory resistance of 50 cmH_2O. Note that the flow did not return to zero at end-expiratory, indicating the presence of intrinsic PEEP. The Smart trigger tandem setting was at setting 1 and with a pressure trigger of -1.5 cmH_2O. For the Flow/ setting trigger flow was set at 1 LPM and the pressure trigger also at -1.5 cmH_2O.

References

1 Thille AW, Rodriguez P, Cabello B, et al. Patient-ventilator asynchrony during assisted mechanical ventilation. Intensive Care Med. 2006;32(10):1515-22.

2 Elkholy M, Sadek S, Elmorshedy R, et al. Patient ventilator asynchrony as a predictor of weaning failure in mechanically ventilated COPD patients. European Respiratory Journal.56(suppl 64):3726.

3 Docci M, Rodrigues A, Dubo S, et al. Does patient-ventilator asynchrony really matter? Curr Opin Crit Care. 2025;31(1):21-9.

4 De Oliveira B, Aljaberi N, Taha A, et al. Patient-Ventilator Dyssynchrony in Critically Ill Patients. J Clin Med. 2021;10(19).

5 Fujiuchi B, Daoud E. SMART Trigger versus Flow and Pressure trigger performance during auto-PEEP. Journal of Mechanical Ventilation. 2023.

The Unanswered Critique: Why Downgrading Subglottic Secretion Drainage (SSD) Undermines Antimicrobial Stewardship (AS)

Hamid Khosrowshahi,[a] Jerry Gentile,[b] Stanley John[c]

Abstract: The Policy of Unanswered Self-Sabotage

Context: For two decades, Subglottic Secretion Drainage (SSD) was the globally recognized, Essential, Level 1 non-pharmacological intervention for preventing Ventilator-Associated Pneumonia (VAP). This foundational standard was abruptly reversed in the 2020[25,35] and 2022[2] VAP guidelines, downgrading SSD to merely "Moderate."

Thesis Statement: This paper asserts that the SSD downgrade is not a consequence of scientific discovery, but of policy failure, driven by a structurally flawed rationale: penalizing a highly effective non-pharmacological prophylactic tool for failing to achieve a mortality reduction standard it was never powered to meet. This flawed approach actively undermines Antimicrobial Stewardship (AS) efforts and demonstrates a critical failure of evidence-based policy. We reject the philosophy that VAP is an inevitable consequence of critical care; instead, we expose the policy of low expectations that has suppressed structural prevention.

For two decades (2001-2018), as shown in the historical consensus timeline (Figure 1), multiple national guidelines, including those from AHRQ and SHEA, consistently classified Subglottic Secretion Drainage (SSD) as an Essential, Level 1 intervention for VAP prevention. This consensus was driven by a core group of key personnel, including authors affiliated with Johns Hopkins (like Sean Berenholtz and Peter Pronovost) who were essential contributors to these recommendations. This makes the subsequent 2020 and 2022 downgrades to Moderate status particularly striking. The policy shift was justified by AHRQ's document using acknowledged erroneous data and by the SHEA update, which conceded no new evidence supported the change, a reversal overseen by many of the same core authors who initially championed the intervention.

The Flaw

We detail how this policy creates a destructive cycle, achieving institutional hypocrisy by:

1. Imposing an unattainable statistical burden on this non-pharmacological prophylactic intervention, a burden detailed in the unanswered Lichtenthal letters (2023, 2025)[3,7] and the Khosrowshahi (2025) Letter to the Editor.[1]
2. Engaging in selective evidence review—praising VAP bundles that succeeded due to the hidden presence of SSD (the "Pileggi Paradox")[12,32]—while simultaneously minimizing SSD's individual efficacy.
3. Most critically, actively undermining national Antimicrobial Stewardship (AS) efforts by guaranteeing higher VAP rates, thereby ensuring increased reliance on the broad-spectrum antibiotics the AS movement is dedicated to curtailing.

Conclusion: We assert that SSD is the safest and most cost-effective non-pharmacological prophylactic tool. This paper demands the immediate restoration of SSD to its rightful "Essential" status to ensure evidence-based critical care and uphold the policy integrity of antimicrobial stewardship efforts.

I. The Broad Stakeholder Benefit: Who Wins with SSD?

Restoring SSD to its rightful "Essential" status is not just a statistical correction; it is a clinical action that provides clear, measurable benefits across all critical care stakeholders:

- **The Patient:** The most direct beneficiary. Mandated SSD translates directly into a significant reduction in VAP, which minimizes the patient's risk of prolonged mechanical ventilation, increased morbidity, and antibiotic exposure. Preventing VAP in the first place is a primary defense against Post-Intensive Care Syndrome (PICS).
- **The Clinician (Respiratory Therapists and Critical Care Nurses):** SSD provides a reliable, standardized, and proven tool that simplifies care and allows clinical teams to focus on managing the primary illness, thereby reducing the professional burden and moral injury associated with preventable complications.
- **Hospital Finance and Quality:** The Branch-Elliman (2015) meta-analysis decisively identified SSD as the single most impactful intervention for VAP prevention and simultaneously the most cost-effective.[14] The fact that this Harvard-funded study with solid, cost-effectiveness evidence was sidelined in favor of the flawed VAP/VAE strategy, which often fails to capture true clinical VAP incidents, exposes a severe disconnect between economic reality and guideline policy.
- **Antimicrobial Stewardship (AS):** As VAP is the single largest driver of antibiotic consumption in the ICU, the mechanical prevention offered by SSD curtails the need for broad-spectrum empiric antibiotic therapy, directly supporting the core mission of AS.

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Year	Published Guidance/Group	Primary Sponsor/Affiliation	SSD Recommendation Level
2001	Making Healthcare Safer (MHS-I)[33]	AHRQ	Essential, High Level 1
2005	ATS Guidance[53]	ATS	Essential, High Level 1
2009	APIC Guide[52]	APIC	Essential
2009	Safer Healthcare Canada Guide[54]	Canada Patient Safety Institute	Essential
2013	Making Healthcare Safer (MHS-II)[34]	AHRQ	Essential
2014	SHEA Guidelines[55]	SHEA, CDC	Essential
2015	Branch-Elliman (Sharon Wright)[14]	Harvard Clinical and Translational Science Center	Ideal Strategy/Most Cost-Effective Intervention
2016	Systematic Guidance[56]	NIH, AHRQ	Essential
2017	Two State Collaborative[57]	NIH, AHRQ, CDC	Essential
2018	HRET/AHA[16]	CMS/Medicare, AHA	Primary Driver for VAP Prevention
2020	Making Healthcare Safer (MHS-III)[25,35]	AHRQ	Downgrade to Moderate (a)
2022	SHEA Guidelines (Update)[2]	SHEA, IDSA, APIC, TJC, AHA, CDC	Downgrade to Moderate (b)

Figure 1. Historical Timeline: Classification of Subglottic Secretion Drainage (SSD) in VAP Prevention Guidelines (2001 – 2022) – **(a)**- Downgraded primarily based on incorrect data confusing SSD with supraglottic aspiration. AHRQ acknowledged the data error but maintained the Moderate status due to the SHEA 2022 decision. **(b)**- Downgrade was based on no new evidence.

II. Introduction: The Reversal of an Essential Standard and the Unanswered Critique

For nearly twenty years, the use of the endotracheal tube with Subglottic Secretion Drainage (SSD)—a simple non-pharmacological mechanical barrier preventing aspirated secretions from entering the lower airway—was uniformly classified as an Essential, Level 1 practice for VAP prevention. SSD reduces VAP by blocking the primary mechanism of infection: the pooling and subsequent microaspiration of contaminated secretions around the cuff.

The profound efficacy of this non-pharmacological VAP prevention method was consistently demonstrated in a body of evidence including major meta-analyses/reviews since 2005.[4,5,11,13,15,20,37-43] This evidence was recently re-confirmed by the definitive Mastrogianni (2023) meta-analysis of 38 Randomized Controlled Trials (RCTs), solidifying SSD's VAP-reducing efficacy.[11] Critically, this enduring evidence of VAP prevention was the undisclosed basis for the Institute for Healthcare Improvement (IHI)'s successful "Near-Zero VAP" claims, a fact IHI later acknowledged by deleting VAP success stories from its website, as published in a 2024 paper.[36]

This consensus was shattered in the 2020 AHRQ Making Healthcare Safer (MHS-III)[25,35] and subsequent 2022 SHEA guidelines, which downgraded SSD to a "Moderate" or "Additional" approach.[2] This decision was not based on any new evidence challenging SSD's profound VAP-prevention efficacy, but solely on its failure to achieve a secondary, highly specific endpoint: a statistically significant reduction in mortality.

This paper exposes the structural inconsistencies inherent in this decision, arguing that the downgrade represents a failure of statistical rigor and objective reporting. We focus specifically on the flawed philosophy put forth by the guideline authors, a philosophy that remains officially unaddressed despite the rigorous published critique in the Lichtenthal letter to the editor (2023),[3] the subsequent follow-up article (2025),[7] and the most recent Khosrowshahi (2025) Letter to the Editor.[1*]

III. Background on VAP and SSD

VAP is defined as pneumonia developing 48 hours or more after endotracheal intubation. The primary pathogenesis of VAP involves the microaspiration of contaminated secretions that pool above the ETT cuff and below the vocal cords (the subglottic space). The presence of an endotracheal tube (ETT) represents a major risk factor, 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.[8,32] SSD technology was developed to actively and continuously remove these contaminated secretions, effectively disrupting the colonization pathway into the lower airway.

***Footnote 1: Protocol Failure and Safety Violations Undermining the PreVent 2 Trial**

The authors became aware of the publication of the PreVent 2 (2025)[62] trial and the accompanying editorial by Klompas and Branson (2025)[63] after the completion of this manuscript. The trial's findings are non-contributory to VAP prevention efficacy, as they rely on non-specific surveillance metrics (IVAC/PVAP), despite the authors' knowledge and citation of successful SSD trials [Smulders (2002)[64], Lorente (2007)[65]] that used the gold-standard VAP diagnosis. The study is fundamentally compromised by its methodology, reflecting a failure to adhere to established fidelity and safety standards:

1. **Fidelity Protocol Failure (Cuff Pressure):** Successful SSD trials (Lorente 2007[65]; Smulders 2002[64]) achieved VAP reductions of 64.5% to 75% by strictly maintaining cuff pressure with checks every 4 hours—a crucial factor in preventing microaspiration. In stark contrast, PreVent 2 worsened its protocol from Deem (2016)[66] PreVent 1 (8-hour checks) to only "at least" twice daily (every 12 hours). This low-fidelity protocol was virtually designed to fail by ensuring microaspiration, neutralizing any potential benefit of SSD.
2. **Safety Protocol Violation and Mechanism of Failure (CASS Technique):** The decision to use Continuous Aspiration of Subglottic Secretions (CASS)—despite the investigators' awareness of studies (Girou[68], Berra[67]) documenting severe mucosal injury—created a self-defeating mechanism. Nonstop, continuous suction increases the likelihood of tissue being drawn into and blocking the suction port, thereby halting drainage and causing the observed mucosal harm and efficacy failure. Successful SSD trials utilized the safer, more effective Intermittent suctioning to avoid both tracheal wall damage and suction port occlusion. Furthermore, PreVent 2's failure to measure and document the daily volume of secretions removed from the subglottic space means the investigators never verified the functionality of the suction port.

The decision to proceed with PreVent 2—replicating a methodology known to guarantee failure and increase patient risk—provides the logical explanation for the study's dismal outcome. This evidence strongly suggests that the statistically significant increase in post-ICU tracheostomy and laryngeal injury observed in the study group's per-protocol analysis was caused by the unsafe, occluding CASS suction technique, not a failure of SSD itself. This evidence supports the position that CASS suctioning should be banned and never recommended as a secretion drainage technique for SSD.

Early meta-analyses consistently showed that the use of SSD ETTs led to a 40-50% reduction in VAP incidence, leading to its inclusion as an Essential, Level 1 intervention in major VAP prevention guidelines worldwide. The benefit of SSD is mechanical and structural, based on the physical removal of the infectious burden at the point of origin, differentiating it fundamentally from other components of VAP prevention bundles.

IV. The Historical Consensus and The Institutional Data Error (2001–2020)

From the inaugural AHRQ guidance in 2001 Making Health Care Safer (MHS-I)[33] through the 2013 (MHS-II)[34] and to the last major update in 2018 (CMS funded research (AHA/HRET),[16] the use of SSD was universally recognized as the single most critical non-pharmacological mechanical VAP prevention tool. The consensus standard was clear: SSD was Essential and a "Primary Driver" for VAP prevention. In fact, the 2018 CMS funded research specifically recommends to "place SSD-ET in crash carts and emergency intubation supplies, and to engage your ICU leaders and respiratory care leaders to influence the purchase and use of ETT with subglottic suction."[16]

The Doyle/AHRQ Data Error and the "Selective Review Downgrade"

The reversal of this Essential status in the 2020 AHRQ Making Healthcare Safer (MHS-III) guidance[25,35] was triggered by a profound and critical failure of systematic review, known as the Doyle/AHRQ Data Error.

- **The Misleading Secondary Source (Doyle 2011):** The MHS-III authors heavily referenced a flawed data set within the Doyle 2011 systematic review.[27] This data mistakenly categorized the strong, high-quality studies supporting SSD under the heading of "Supraglottic Aspiration."
- **The Correction:** Upon examination, the primary references cited by Doyle to support this section all referred explicitly to the use of Subglottic Secretion Drainage (SSD).
- **The Compounding Error (MHS-III) 2020:** By accepting Doyle's flawed categorization without checking the primary sources, the MHS-III (AHRQ) guidance committed two damaging, simultaneous errors: the SSD Downgrade (as SSD's data was misplaced, leading directly to the downgrade to "Moderate")[25,35] and the Supraglottic Upgrade (as the efficacy of SSD was mistakenly attributed to the much less effective or even non-existent intervention, "Supraglottic Aspiration"). Crucially, even after AHRQ acknowledged this gross error and corrected the text from 'Supraglottic Aspiration' to 'Subglottic Secretion Drainage' in its guidance, it refused to restore the Essential status, choosing instead to retroactively justify the 'Moderate' rating by citing the forthcoming 2022 SHEA guidelines,[2] a profound chronological inconsistency.

This peer-review oversight represents a classic case of "Selective Review Downgrade." This critical oversight, originating from the US Agency for Healthcare Research and Quality (AHRQ), the agency that oversees evidence-based patient safety policies, is structurally unacceptable.

V. The Flawed Rationale: The Impossible Mortality Hurdle and the Institutional Justification

The core of the downgrade is the arbitrary elevation of mortality reduction as the prerequisite for "Essential" status—an impossible standard that is flawed on multiple levels and violates basic statistical principles.

Va. The Leasure (2012), Khosrowshahi (2025), and Gattinoni (2018) Critique

SSD is a non-pharmacological prophylactic measure designed to prevent an infectious complication (VAP) in the first place and at the source. The SHEA 2022 guideline,[2] by prioritizing statistically significant reductions in "hard outcomes," retroactively imposed a philosophical standard of evidence typically associated only with massive, systemic antimicrobial prophylaxis trials.

This statistical hurdle is directly addressed in the Leasure (2012) meta-analysis,[41] which confirmed a significant reduction in VAP with the use of SSD. The authors explicitly explained the lack of a mortality signal, stating, "Individuals requiring mechanical ventilation have underlying medical conditions, which may have a greater impact on mortality rates than the more subtle impact of the use of an ETT with the capabilities for SSD."

Further validating SSD's mechanical efficacy is the Huang (2018) meta-analysis,[43] which provides a critical mechanistic insight: "Less mean volume of SSD daily was observed in VAP group" compared to the non-VAP group. This demonstrates that VAP occurs due to mechanical failure or sub-optimal utilization of the device, not a failure of the concept itself. As Michael Klompas argued in "The Paradox of Ventilator-Associated Pneumonia Prevention Measures" (2009),[18] the failure of VAP risk-reducing measures to show a mortality impact stems from two related issues: the definition captures a "plethora of alternative conditions" which "dilute the signal" from true pneumonias, and "generally low event rates" compound the challenge of detecting significant impacts on outcomes. Penalizing SSD for failing a test that is statistically designed to fail is therefore illogical and unfair.

The Khosrowshahi (2025) Letter to the Editor[1] explicitly argues against this policy, stating that the attributable mortality of VAP is low making the required sample size infeasible. Khosrowshahi further supports this view by invoking the philosophical approach of leading critical care experts: Luciano Gattinoni argued that when evaluating complex critical care interventions, one must "think beyond the conventional endpoint of survival" and focus on how an intervention affects the intermediate physiological or pathological process.[6]

Vb. The Seminal Safdar Contradiction: Attributable vs. Mortality

The severity of VAP is defined by the seminal Safdar 2005 systematic review,[21] which quantified VAP as a deadly and costly infection by confirming its high attributable mortality rate. The philosophical contradiction is stark: The guidelines acknowledge, via Safdar, that VAP is a significant killer. Yet, they simultaneously reject the most effective non-pharmacological intervention (SSD, which reduces VAP

by 55%) because it cannot prove a reduction in all-cause mortality.

Vc. The SDD Contrast: Proving the Mortality Standard is Untenable

The policy-makers who insist that Subglottic Secretion Drainage (SSD) must demonstrate a mortality benefit to retain its "Essential" status fundamentally undermine their own position by comparing a simple, non-pharmacological, single-site mechanical prophylaxis to massive, systemic pharmacological interventions.

The systematic bias against Subglottic Secretion Drainage (SSD) is evidenced by a long-standing practice of misattribution of efficacy within meta-analyses that conflated mechanical and chemical interventions. This practice allowed researchers to validate less-effective bundle components by leveraging the high impact of SSD trials. For example, the Pileggi et al. (2011) meta-analysis,[58] which examined the effect of topically applied antimicrobial agents, reported a high 36% efficacy for antibiotics. This figure was demonstrably inflated by the inclusion of studies, such as the randomized trial by Pneumatikos et al. (2002),[10] which achieved a remarkable 70% VAP reduction using a combined intervention of Selective Decontamination of the Subglottic Area (SDD) plus SSD. By folding this SSD-driven success into a meta-analysis focused on chemical agents, Pileggi et al. effectively obscured the primary, mechanical cause of the VAP reduction.

The only VAP prophylaxis shown to consistently impact all-cause mortality is Selective Decontamination of the Digestive Tract (SDD) or Oropharyngeal Decontamination (SOD). The Difference: SDD/SOD is a highly complex, multi-site pharmacological intervention designed to reduce colonization across the entire digestive and respiratory tract, which necessarily impacts the entire bacterial load and subsequent risk of sepsis, thus achieving a mortality signal.

The Questionable Statistical Power

The most damning evidence against this mortality standard comes from the massive trials of SDD, where a combined approach (all-cause mortality, ventilated and non-ventilated, SDD without and SDD with Intravenous Antibiotics, and SOD) was needed to reach total patient power. For example, the Hammond (2022) review[17] attempted a maximal effort to demonstrate a statistically significant mortality signal by pooling data from 30 RCTs (24,034 patients). Crucially, this massive effort included the earlier Pneumatikos (2002) study,[10] which achieved its best results {70% VAP reduction and a substantial, albeit possibly underpowered, mortality reduction (23% to 16%)} by combining SDD (pharmacological) with SSD (mechanical prophylaxis). Artificially boosting a pharmacological intervention's signal by including a mechanical one exposes the intellectual deception of the statistical hurdle.

Hammond 2022, In-depth Analysis Demonstrates the Following:

- The top 3 largest studies, representing 76% of the total patients (18,335/24,034), collectively do not reduce mortality at all and in fact show a trend toward increased mortality.
- All large studies, representing 89% of the total patients (21,293/24,034), collectively do not reduce mortality.
- Only 7 combined studies that used both ventilated and non-ventilated patients and SDD with intravenous antibiotics, representing 34% of total patients (8,088/24,034), resulted in a reduction in mortality.

What this demonstrates

This detailed analysis of the largest pharmacological trials proves the statistical hurdle imposed on SSD is untenable. Even when maximizing power by pooling studies, including non-ventilated patients, and adding systemic antibiotics to a pharmacological prophylaxis (SDD/SOD), the overwhelming majority of large-scale evidence fails to consistently meet the mortality standard. This confirms that demanding a simple mechanical prophylaxis (SSD) achieve this same standard is an impossible, structural policy flaw.

The SDD Mortality Failure: Additionally, despite this maximal effort, the most recent largest systemic trial, the SuDDICU Trial (Cuthbertson 2025),[28] which studied thousands of patients, failed to reach statistical significance for the crucial all-cause 90-day mortality endpoint.[28] If a highly complex, systemic pharmacological intervention (SDD), which often includes Intravenous Antibiotics (IA) to increase patient power, cannot consistently demonstrate long-term mortality benefit, it is indefensible to demand that a simple mechanical, zero-AMR-risk device (SSD) meet that same standard. Furthermore, the implementation of SDD/SOD introduces the direct, massive risk of increased Antimicrobial Resistance (AMR),[30] a trade-off that SSD completely avoids.

The practice of masking the structural benefit of SSD continues today, mirroring the historical IHI/Pileggi pattern. The work of Landelle et al. (2018)[59] and the 7-year follow-up by Büchler et al. (2025)[60] is the most recent and definitive example, demonstrating an over 80% sustained VAP reduction relative to the pre-intervention period.

In this case, the significant structural impact of the SSD Endotracheal Tube was masked by a methodological structure that ensured only Selective Oropharyngeal Decontamination (SOD) could be individually assessed. This systematic bias elevated the pharmacological intervention (SOD) while sidelining the non-pharmacological structural intervention (SSD), even though both studies achieved their extraordinary success because of the inclusion of SSD.

The irony of this narrative control is profound: the Mastrogianni (2023) meta-analysis—the most recently published study to confirm the effectiveness of SSD—actually used the Landelle (2018) paper[59] as one of its 38 RCTs to demonstrate why SSD plays the single most critical role in any VAP prevention strategy.[11]

The Policy Failure: By demanding that the mechanical, non-pharmacological, single-site intervention (SSD) meet the same all-cause mortality standard achieved only by the pharmacological, systemic, multi-site intervention (SDD/SOD), the guidelines set an unattainable bar. Penalizing the simple, non-pharmacological intervention for failing a test that is statistically designed to fail, while tacitly acknowledging that only a massive pharmacological

intervention can pass, is therefore illogical and constitutes a structural failure of evidence-based policy.

Vd. The HOB Paradox and The Oropharyngeal Route Imperative

The guidelines' decision to retain practices like Head of Bed (HOB) elevation as "Essential"—despite being supported by Very Low-Quality Evidence (VLQE)[9,32] and being difficult to maintain in a busy ICU—while penalizing the most impactful and cost-effective mechanical tool, demonstrates a clear failure of evidence-based policy.

While HOB elevation is a mechanically sound intervention for mitigating gastric reflux via gravity, the difficulty in maintaining consistent, controlled elevation introduces a significant patient safety trade-off: uncontrolled patient slippage is a leading cause of preventable pressure ulcer injury, a 'never event' in patient safety, a critical risk that the 2022 SHEA guidelines fail to acknowledge. The study most often cited to support HOB efficacy is deeply flawed.[26]

This policy is further contradicted by the seminal work of Bonten (1994),[29] which demonstrates that oropharyngeal colonization is a more potent source of VAP (80%) than gastric reflux (20%). This evidence validates the mechanical barrier of SSD at the subglottic space as the most critical and effective point of VAP prevention.

Ve. The VAE Paradox: Institutional Justification and the Surveillance Obfuscation

The VAP to VAE (Ventilator-Associated Event) switch was conducted primarily among US clinicians without full collaboration or agreement from the rest of the world (ROW). The 2022 SHEA guidance[2] operates under the shadow of the 2013 VAP to VAE switch.

The Lethality Fallacy. To provide institutional justification for the VAE framework, the guidance document immediately undercuts the severity of VAP by claiming: "Patients with VAEs are ~50% more likely to die compared to similar patients with VAP."[2,22] The purpose of this quote is to functionally elevate the surveillance metric (VAE) as the more "important" outcome, thereby providing a rationale for downgrading primary VAP prevention efforts like SSD.

The Surveillance Obfuscation. This claim is factually misleading. The Fan (2016) study,[22] which originated this quote, concluded that VAE surveillance was non-specific, that it missed many cases of true clinical VAP, and that the population identified by the two surveillance paradigms differed significantly. By prioritizing a non-specific surveillance metric (VAE) over a true infectious disease endpoint (VAP), the guidelines effectively prioritize measurement convenience over patient outcome.

The Next Iteration (HOS). Furthermore, the recent proposal to shift surveillance entirely to Hospital-Onset Sepsis (HOS)[46] represents the next iteration of this institutional surveillance failure. This proposed move is designed to further obscure true hospital-acquired infection incidents like VAP in favor of a non-specific, post-event metric. This continuous process of prioritizing misleading surveillance metrics over proven VAP prevention interventions like SSD is a fundamental policy failure. Any future shift to HOS must be done with international collaboration and agreement.

Vf. The Pileggi Paradox: Institutional Policy Inconsistency and the Downgrading of SSD

The institutional hypocrisy inherent in the 2022 SHEA guideline authors' position is starkly evident in their selective endorsement of the VAP Bundle narrative, which achieved its success partly due to the undisclosed presence of SSD.

This strategic intellectual bias is starkly reinforced by the conspicuous absence of methodological discussion in papers validating the VAP bundle. Ventilator-Associated Pneumonia is fundamentally a mechanical disease caused by the microaspiration of colonized secretions accumulating above the endotracheal tube (ETT) cuff. This phenomenon necessitates a clear protocol for secretion management. Yet, in major works supporting the bundle approach, such as the Pileggi et al. (2018) meta-analysis[12] on the bundle's effect on mortality, there is a near-total omission of any reference to subglottic, suction/suctioning methodology, aspiration, or secretions. This critical methodological void proves that the bundle's proponents avoided confronting the known mechanical failure of standard ETT care—a failure that SSD, as the true lynchpin, was specifically designed to solve.

A. Selective Credit for Mortality Success. Guideline authors in the 2022 SHEA Practice Recommendation[2] praised the Pileggi et al. (2018) meta-analysis[12] as compelling evidence for the comprehensive VAP bundle's efficacy, explicitly noting its association with a statistically significant reduction in mortality. This endorsement was notably championed by Klompas (2018),[47] who published a paper praising Pileggi's findings for the significant survival outcome achieved by the bundle. Klompas stated: "By choosing mortality as their primary outcome, those investigators neatly sidestepped the ambiguity associated with VAP and tracked a "hard" outcome instead. The investigators reported that implementation of ventilator bundles across 13 studies was associated with a 10% relative reduction in the odds ratio (OR) for death (OR, 0.90; 95% CI, 0.84–0.97)."

B. The Undisclosed Core Mechanism of the Bundle. The flaw in this argument is a persistent and profound omission.

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†Footnote 2: Pattern of Policy Analysis Failure (The Klompas Critique)

The Klompas and Branson editorial[63] accepts the null findings of the PreVent 2 trial[62] at face value, without critically examining the profound methodological flaws detailed in Footnote*. This uncritical assessment aligns with a historical failure in the policy analysis framework used to evaluate SSD: Klompas previously praised the significant mortality reduction observed in the Pileggi meta-analysis,[11,47] yet failed to critically analyze the data to realize that this benefit was overwhelmingly driven by trials utilizing SSD—the very intervention he later advocated against and downgraded[2]. This initial failure to identify the true intervention responsible for the observed benefit in the Pileggi study is repeated in the current uncritical acceptance of PreVent 2's execution-based flaws. Using the flawed PreVent 2 trial to dismiss SSD entirely, concluding it is "Time to pull the plug on subglottic secretion drainage?,"[63] reveals a structural limitation in the policy analysis framework used to evaluate SSD evidence.

The Pileggi (2018) meta-analysis,[12] which involved 13 RCTs based on the IHI ventilator care bundle, achieved its significant VAP and survival outcome because five (5) of those 13 RCTs actually used SSD and reported successful outcomes.[23,24, 48-50] The presence of SSD was the undisclosed Mechanism of the bundle's success.

C. The Policy Inconsistency. The guideline authors, therefore, rely on a mortality signal driven by SSD—the most critical VAP prevention intervention—to justify the bundle approach and its survival benefit, while simultaneously downgrading and sidelining SSD itself to merely "moderate" evidence. This constitutes the height of hypocrisy, where the most important VAP prevention intervention has been silently utilized to achieve successful near-zero VAP rate outcomes, yet is downgraded and sidelined in formal recommendations for unknown reasons. This policy reveals a clear pattern of prioritizing low-expectations surveillance (VAE) over proven, structural prevention (SSD).

D. The Tale of Two Arguments: Manipulation of Evidence. This inconsistency is further exposed by the "tale of two arguments" regarding mortality data: (a) Klompas endorses the Pileggi (2018) VAP bundle mortality outcome (attributed to SSD) because it proves a point about mortality, and later references it in the SHEA 2022 guidance. (b) Conversely, when reviewing the Pozuelo-Carrascosa (2020) meta-analysis, which mistakenly claimed SSD had a statistically significant reduction in mortality, Klompas co-authors the corrected 2022 version[19] (showing no significant reduction) to justify the SSD downgrade. This represents a manipulation of studies and data to achieve policy goals: accepting mortality data when favorable to the bundle narrative, but demanding perfect, replicated mortality data to suppress SSD.[2†]

Vg. The IHI's Own Admission

The seminal work introducing the Ventilator Bundle, Resar, Pronovost, et al. (2005),[45] documented a VAP rate reduction of up to 59% in high-compliance ICUs during the 100K Lives Campaign. Crucially, this paper explicitly lists only four components in the bundle: DVT prophylaxis, PUD prophylaxis, Head of Bed elevation, and Sedation Vacation. Subglottic Secretion Drainage (SSD) was not included. In their discussion, the authors openly admitted the outcome was "very interesting and unexpected" because a "scientific basis for assuming a reductive effect on VAP was present for only two of the elements in the bundle." They concluded that the success reflected a "changed delivery system" and the "all or none" measurement technique, which increased team reliability.

The key to the zero-VAP success stories achieved by IHI's ventilator care bundle and others lies in the synergy between the SSD mechanical intervention and the mandatory checklist compliance. The IHI checklist enforced verification of every step, including ensuring the SSD was functional. The Huang (2018) meta-analysis[43] provides the mechanistic proof for this relationship: VAP was significantly associated with lower collected volumes of subglottic secretions. This means that VAP occurred due to a mechanical or process failure, not a failure of the SSD concept itself. This makes the policy of downgrading SSD due to efficacy failure deeply flawed: the guidelines are actively penalizing a proven, highly effective intervention for issues related to implementation compliance, which the successful bundles, ironically, overcame. The successful bundle study by Youngquist (2007)[51] and the Mastrogianni (2023) meta-analysis[11] also confirm the explicit use of SSD as a component. The focus must be on mandating SSD and enforcing its proper use, not abandoning the device.

Vh. The Policy of 'Choosing Avoidance' (A Policy That Risks Lives to Avoid Failure)

The Choosing Wisely campaign, supported by SHEA in 2024, was developed to promote Antimicrobial Stewardship (AS) and fight AMR by reducing unnecessary antibiotic use. However, its own Recommendation #3 directly promotes a philosophical shift away from structural prevention, telling doctors: "Avoid using essential invasive devices like the breathing tube (ETT) and get them out as fast as possible, because they cause major infections."[31]

This policy embodies a profound and dangerous contradiction:

1. The Goal: The campaign aims to reduce antibiotic use (AS/AMR). Since VAP is the single largest driver of antibiotic consumption in the ICU, the most direct path to reducing AMR is to prevent VAP mechanically.

2. The Institutional Irony: This "Avoiding Devices" recommendation is supported by citing the SHEA 2022 VAP Guidelines[2]—the very document that downgraded the most effective, non-antibiotic structural fix for the ETT (SSD). By downgrading SSD, the 2022 guidelines essentially declared the ETT unfixable; the 2024 CW campaign then formalizes this structural failure by advising against its use.

3. The Perilous Consequence: The ultimate form of device avoidance is to prevent or prematurely stop mechanical ventilation, which for a critically ill patient is the quickest way to increase mortality. In effect, the guidance prioritizes avoiding the risk of infection (VAE/VAP) over addressing the risk of death from respiratory failure. By failing to mandate the structural safety solution (SSD), the policy defaults to a dangerous strategy of low expectations: remove the device, regardless of clinical need, and risk the patient's life.

This focus illustrates an institutional failure: instead of embracing the structural solution (SSD) that makes the ETT safer and reduces antibiotic need, the guidelines settle for a policy of low expectations, preferring to avoid the necessary device and, ironically, increasing the very problems (AMR and mortality) they claim to be fighting.

VI. The Institutional Silence and Conflicted Advocacy (The Tale of Two CVs)

This lack of transparency is amplified by the internal inconsistency observed among the nation's leading patient safety advocates. Dr. Peter Pronovost, the key architect of the IHI's checklist and bundle concepts, served as Co-Principal Investigator for the comprehensive Making Health Care Safer II (MHS-II)[34] report in 2013. The VAP chapter in that report was notably co-authored by Dr. Sean Berenholtz. This placed both prominent Johns Hopkins leaders directly at the center of the evidence base, fully aware of the data supporting SSD as an Essential practice. Yet, Dr. Berenholtz later co-authored the 2022 SHEA

guidelines,[2] joining Dr. Klompas to downgrade SSD for reasons that fundamentally conflict with the data he helped review just nine years prior. Similarly, Linda Green RN, another author of the SHEA 2022 Guidelines,[2] had previously in 2009 published a Guidance paper titled: "Guide to Elimination of Ventilator Associated Pneumonia (VAP)" on behalf of APIC (Association for Professionals in Infection Control and Epidemiology),[32,52] where SSD was considered an essential intervention for VAP prevention. Yet in 2022, Green also joined Klompas to downgrade an intervention that she helped review and publish just 13 years prior. This inconsistency is further highlighted by the economic data: The Branch-Elliman (2015) meta-analysis,[14] which was Harvard-funded, examined 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... 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."

The policy failure to mandate SSD is often excused by its initial acquisition cost. However, the latest systematic review of health economic studies on ETT modifications, conducted by De Vlam (2025),[61] definitively dismantles this rationale. This analysis concludes that the Subglottic Suction ETT is a cost-effective intervention and demonstrates that the low-cost structural tube is both more clinically effective and more cost-effective than the significantly more expensive antimicrobial-coated ETTs reviewed in the literature.[61] This evidence proves the SSD downgrade is an economically unsound policy that prioritizes a minor initial saving over preventing significant healthcare costs from VAP complications. For patient safety leaders to downgrade the most powerful and economically viable non-pharmacological intervention—for failing a flawed statistical test—calls into question their commitment to patient value.

The paradox deepens when considering Dr. Pronovost's contemporary work.[44] He passionately addresses the cultural failures that cause healthcare professionals to accept patient harm as "inevitable," advocating for a leadership culture centered on 'Living and Leading with Love' and shifting focus to the "essential stuff" that drives value. The tragic irony is that SSD represents one of the most rigorously evidenced pieces of 'essential stuff' available to prevent patient harm. For the policy's champions to downgrade or remain silent on an intervention with such irrefutable benefit calls into question the institutional transparency of VAP policy, starkly contrasting the commitment to patient safety Pronovost otherwise champions. The failure of the medical establishment to acknowledge the reasons for the zero VAP rate achieved by the IHI bundles for 20 years, only admitting the role of SSD two years ago, demonstrates a significant lapse in accountability. The systematic deletion of success stories and VAP bundle content from the IHI website,[36] and the continued refusal to restore SSD to its essential status, indicates a prioritization of policy maintenance over patient safety and evidence-based practice. This failure must be challenged to ensure the integrity of future guidelines.

VII. The SSD-SDD Win-Win-Win: A Path to Consensus

The most powerful strategy for VAP prevention is the combined use of the mechanical barrier and the pharmacological control. This dual-pronged approach—pairing Subglottic Secretion Drainage (SSD) with Selective Decontamination of the Digestive Tract (SDD) or Oropharyngeal Decontamination (SOD)—achieves the most significant outcomes. The proof of concept for this superior strategy was demonstrated in early trials, such as the Pneumatikos (2002) study,[10] which achieved its best results (70% VAP reduction and substantial mortality reduction) by combining pharmacological SDD with mechanical SSD. The explicit role of SSD as an essential component in combination trials has also been re-confirmed by the definitive Mastrogianni (2023) meta-analysis of 38 RCTs.[11] This combination works because it addresses both major risk factors simultaneously: SSD acts as the essential mechanical barrier, preventing microaspiration in the first place, while SDD reduces the overall bacterial load at the source of colonization. This powerful, strategic combination guarantees the lowest possible VAP rate, while also mitigating the risk of Antimicrobial Resistance by ensuring the non-pharmacological SSD carries the majority of the prevention burden and reducing the financial burden as SSD is highly cost-effective.[14] This approach should serve as the uncontroversial goal for future research and VAP prevention guidelines, offering a clear path to consensus for both mechanical and pharmacological proponents and achieving the "best overall outcomes" crucial for supporting Antimicrobial Stewardship efforts.

VIII. Institutional Silence and Policy Failure

The policy failure is particularly stark for the leadership at institutions like Johns Hopkins, who were at the epicenter of both the initial evidence-based success and the subsequent SHEA downgrades. This represents a profound failure of accountability. By refusing to reconcile the "zero VAP" era—which they championed for two decades—with the current suppression of the very tool (SSD) that made those results possible, these leaders have prioritized policy maintenance over the integrity of evidence-based practice. This silence must be challenged to restore trust in national guidelines and ensure that patient safety is never again sacrificed for administrative convenience or the preservation of a contradictory policy narrative.

IX. Conclusion: The Necessity of Structural Prevention

The historical evidence is conclusive, and the philosophical contradiction of the downgrading policy is now clear. The current guidelines perpetuate a structural failure born from low expectations that unnecessarily forces a costly and dangerous over-reliance on broad-spectrum antibiotics. We must reject the notion that VAP is INEVITABLE. The continued downgrading of SSD is a failure of leadership, a failure of evidence-based policy, and a disservice to patients. The time for policy to suppress effective, cost-saving structural prevention is over; the immediate restoration of Subglottic Secretion Drainage to its Essential standard is mandatory to restore the integrity of Antimicrobial Stewardship efforts and adhere to the basic principles of health economics, as evidenced by the latest systematic review confirming its superior cost-effectiveness (De Vlam 2025).[61]

Abbreviations

Subglottic Secretion Drainage (SSD), Ventilator-Associated Pneumonia (VAP), Ventilator-Associated Events (VAE), Hospital Onset Sepsis (HOS), Selective Digestive Decontamination (SDD), Selective Oropharyngeal Decontamination (SOD), Head of Bed Elevation (HOB), Antimicrobial Stewardship (AS), Antimicrobial Resistance (AMR), Post Intensive-Care Syndrome (PICS)

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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 Gentile and Stanley John contributed to the review, editing, and final approval of the manuscript.

Reference

1 Khosrowshahi H. Re-evaluate the downgrade of subglottic secretion drainage in VAP prevention guidelines: a call for evidence-based transparency. *Infect Control Hosp Epidemiol* (Letter to the Editor). 2025.

2 Klompas M, Branson R, Cawcutt K, et al. Strategies to prevent ventilator-associated pneumonia, ventilator-associated events, and non-ventilator hospital-acquired pneumonia in acute-care hospitals: 2022 Update. *Infect Control Hosp Epidemiol* 2022;43:687–713.

3 Lichtenthal PR Response to Society for Healthcare Epidemiology (SHEA) recommendations for ventilator-associated pneumonia (VAP). *Infect Control Hosp Epidemiol* 2023;44:522. https://doi.org/10.1017/ice.2022.278.

4 Caroff DA, Li L, Muscedere J, et al. Subglottic secretion drainage and objective outcomes: a systematic review and meta-analysis. *Crit Care Med* 2016;44:830–840.

5 Pozuelo-Carrascosa DP, Herráiz-Adillo Á, Alvarez-Bueno C, et al. Subglottic secretion drainage for preventing ventilator-associated pneumonia: an overview of systematic reviews and an updated meta-analysis. *Eur Respir Rev* 2020; 29:190107 https://doi.org/10.1183/16000617.0107-2019.

6 Gattinoni L, Marini, JJ. Time to rethink the approach to treating acute respiratory distress syndrome. *JAMA* 2018;319:1877–1878. https://doi.org/10.1001/jama.2018.3967.

7 Lichtenthal P, Borg U. Ventilator-associated pneumonia-endotracheal tubes the real culprits. A review. *Med Res Arch* 2025;13(3):e6454. https://doi.org/10.18103/mra.v13i3.6454.

8 Alves D, Grainha T, Pereira MO, Lopes SP. Antimicrobial materials for endotracheal tubes: A review on the last two decades of technological progress. *Acta Biomater*. 2023;158:32-55. doi:10.1016/j.actbio.2023.01.001.

9 van Nieuwenhoven CA, Vandenbroucke-Grauls C, van Tiel FH, et al. Feasibility and effects of the semirecumbent position to prevent ventilator-associated pneumonia: a randomized study. *Crit Care Med*. 2006;34(2):396-402. doi:10.1097/01.ccm.0000198529.76602.5e.

10 Pneumatikos I, Koulouras V, Nathanail C, Goe D, Nakos G. Selective decontamination of subglottic area in mechanically ventilated patients with multiple trauma. *Intensive Care Med*. 2002;28(4):432-437. doi:10.1007/s00134-002-1238-1.

11 Mastrogianni M, Katsoulas T, Galanis P, et al. The impact of care bundles on ventilator-associated pneumonia (VAP) prevention in adult ICUs: a systematic review. *Antibiotics (Basel)*. 2023;12(2):227.

12 Pileggi C, Mascaro V, Bianco A, Nobile CGA, Pavia M. Ventilator bundle and its effects on mortality among ICU patients: a meta-analysis. *Crit Care Med*. 2018;46:1167-1174.

13 Muscedere J, Rewa O, McKechnie K, et al. Subglottic secretion drainage for the prevention of ventilator-associated pneumonia: a systematic review and meta-analysis. *Crit Care Med*. 2011;39:1985-1991.

14 Branch-Elliman W, Wright SB, Howell MD. Determining the ideal strategy for ventilator-associated pneumonia prevention: cost-benefit analysis. *Am J Respir Crit Care Med*. 2015;192:57-63.

15 Dezfulian C, Shojania K, Collard HR, et al. Subglottic secretion drainage for preventing ventilator-associated pneumonia: a meta-analysis. *Am J Med*. 2005;118:11-18.

16 Health Research & Educational Trust. Preventing Ventilator-Associated Events (VAE) Change Package: 2018 Update. Health Research & Educational Trust; 2018.

17 Hammond NE, Myburgh J, Seppelt I, Garside T, Vlok R, Mahendran S, et al. Association between selective decontamination of the digestive tract and in-hospital mortality in intensive care unit patients receiving mechanical ventilation: a systematic review and meta-analysis. *JAMA* 2022;328:1922.

18 Klompas M. The paradox of ventilator-associated pneumonia prevention measures. *Crit Care*. 2009;13:315.

19 Pozuelo-Carrascosa DP, Klompas M, Alvarez-Bueno C, et al. Correction to subglottic secretion drainage for preventing ventilator-associated pneumonia: an overview of systematic reviews and an updated meta-analysis. *Eur Respir Rev*. 2022;31:220013.

20 Mao Z, Gao L, Wang G, et al. Subglottic secretion suction for preventing ventilator-associated pneumonia: an updated meta-analysis and trial sequential analysis. *Crit Care*. 2016;20:353.

21 Safdar N, Dezfulian C, Collard HR, Saint S. Clinical and economic consequences of ventilator-associated pneumonia: a systematic review. *Crit Care Med* 2005;33:2184–2193.

22 Fan Y, Gao F, Wu Y, Zhang J, Zhu M, Xiong L. Does ventilator-associated event surveillance detect ventilator-associated pneumonia in intensive care units? A systematic review and meta-analysis. *Crit Care* 2016;20:338.

23 Hawe CS, Ellis KS, Cairns CJ, Longmate A. Reduction of ventilator-associated pneumonia: active versus passive guideline implementation. *Intensive Care Med* 2009;35:1180–1186.

24 Marra AR, Cal RG, Silva CV, Caserta RA, Paes AT, Moura DF Jr, dos Santos OF, Edmond MB, Durão MS. Successful prevention of ventilator-associated pneumonia in an intensive care setting. Am J Infect Control. 2009 Oct;37(8):619-25. doi: 10.1016/j.ajic.2009.03.009. Epub 2009 Jun 25. PMID: 19559503.

25 Witgert B, Watson A. Section 5.5 PSP: Minimizing Exposure to Invasive Devices and Reducing Device-Associated Risks. In: Making Healthcare Safer III: A Critical Analysis of Existing and Emerging Patient Safety Practices. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ); 2020.

26 Wang L, et al. Head-of-bed elevation for preventing ventilator-associated pneumonia in critically ill patients: a systematic review and meta-analysis. *Crit Care*. 2016.

27 Doyle JS, Buising KL, Thursky KA, et al. Epidemiology of

infections acquired in intensive care units. *Infect Dis Clin North Am*. 2011.
28 Cuthbertson H, et al. Selective Decontamination of the Digestive Tract in the Intensive Care Unit: The SuDDICU Randomized Clinical Trial. *JAMA*. 2025.
29 Bonten MJ, et al. Selective decontamination of the digestive tract in mechanically ventilated patients: A randomized, controlled trial. *N Engl J Med*. 1994.
30 Global Burden of Disease (GBD) Study Group. Antimicrobial resistance and deaths: A global analysis. *The Lancet*. 2022.
31 SHEA. 5 Things Medical Professionals Should Question for Infection Prevention and Antimicrobial Stewardship (Choosing Wisely). *Infect Control Hosp Epidemiol*. 2024.
32 Khosrowshahi H, King J. Subglottic Secretion Drainage (SSD): The Lynchpin of Ventilator-Associated Pneumonia (VAP) Prevention; *Respiratory Therapy* Vol 20 Number 4 Fall (2025) p.72-84 https://respiratorytherapy.ca/pdf/RT-20-4-Fall-2025-web.pdf.
33 MHS-I Making Healthcare Safer – I, Shojania KG, Duncan BW, McDonald KM, et al. Making health care safer: a critical analysis of patient safety practices. *Evid Rep Technol Assess (Summ)*. 2001;(43):i-x, 1-668.
34 MHS-II Making Healthcare Safer - II, Shekelle PG, Wachter RM, Pronovost PJ, et al. Making health care safer II: an updated critical analysis of the evidence for patient safety practices. *Evid Rep Technol Assess (Full Rep)*. 2013 Mar;(211):1-945.
35 MHS-III, Hall KK, Shoemaker-Hunt S, Hoffman L, et al. Making Healthcare Safer III: A Critical Analysis of Existing and Emerging Patient Safety Practices [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2020 Mar.
36 Lorente L, Sabater-Riera J, Rello J. Surveillance and prevention of healthcare-associated infections: best practices to prevent ventilator-associated events. Expert Rev Anti Infect Ther. 2024;22(5):317-332. doi:10.1080/14787210.2024.2345877.
37 Sanaie S., Rahnemayan S., Azizi S. et al., Comparison of subglottic vs. non-subglottic secretion drainage in prevention of Ventilator Associated Pneumonia: A systematic review and meta-analysis, *Trends in Anaesthesia and Critical Care*, 2022.
38 Frost SA, Azeem A, Alexandrou E, et al. Subglottic secretion drainage for preventing ventilator associated pneumonia: a meta-analysis. *Aust Crit Care*. 2013;26(4):180-8.
39 Rahimibashar F., Farsi Z., Danial Z., et al., Subglottic Secretion Drainage to Prevent Ventilator-Associated Pneumonia in Mechanically Ventilated Adult Patients: A Systematic Review and Meta-Analysis. *Trauma Mon*, 2019; 24(4): 1-12.
40 Wang R., Zhen X., Yang B., et al., Subglottic secretion drainage for preventing ventilator associated pneumonia: A meta-analysis, *Chinese Nursing Research*, 2015; 2(2–3): 55-60.
41 Leasure AR, Stirlen J, Lu SH. Prevention of ventilator-associated pneumonia through aspiration of subglottic secretions: a systematic review and meta-analysis. *Dimens Crit Care Nurs*. 2012;31(2):102-17.
42 Wang F, Bo L, Tang L, et al. Subglottic secretion drainage for preventing ventilator-associated pneumonia: an updated meta-analysis of randomized controlled trials. *J Trauma Acute Care Surg*. 2012;72(5):1276-85.
43 Huang XA, Du YP, Fu BB, Li LX. Influence of subglottic secretion drainage on the microorganisms of ventilator associated pneumonia: A meta-analysis for subglottic secretion drainage. *Medicine (Baltimore)*. 2018;97(28):e11223.
44 Pronovost P. Living and Leading with Love: Transforming Healthcare through Mutual Respect and Accountability. *Innovations: Technology, Governance, Globalization* 2025;14(1-2):32–54.
45 Resar R, Pronovost P, Haraden C, et al. Using a Bundle Approach to Improve Ventilator Care Processes and Reduce Ventilator-Associated Pneumonia. *J Quality and Patient Safety* 2005;31(5):243–248.
46 Manzoor F, Rhee C, Klompas M. Advancing Surveillance of Health Care-Associated Infections - Targeting Hospital-Onset Sepsis. *N Engl J Med*. 2025 Oct 16;393(15):1452-1454.
47 Klompas M, Kalil AC. Rethinking Ventilator Bundles. Crit Care Med. 2018 Jul;46(7):1201-1203. doi: 10.1097/CCM.0000000000003173. PMID: 29912107.
48 Pérez-Granda MJ, Barrio JM, Muñoz P, Hortal J, Rincón C, Bouza E. Impact of four sequential measures on the prevention of ventilator-associated pneumonia in cardiac surgery patients. Crit Care. 2014 Mar 26;18(2):R53. doi: 10.1186/cc13799. PMID: 24667011; PMCID: PMC4056787.
49 DeLuca LA Jr, Walsh P, Davidson DD Jr, et al. Impact and feasibility of an emergency department-based ventilator-associated pneumonia bundle for patients intubated in an academic emergency department. Am J Infect Control. 2017 Feb 1;45(2):151-157. doi: 10.1016/j.ajic.2016.05.037. Epub 2016 Sep 21. PMID: 27665031.
50 Dubose J, Teixeira PG, Inaba K, et al. Measurable outcomes of quality improvement using a daily quality rounds checklist: one-year analysis in a trauma intensive care unit with sustained ventilator-associated pneumonia reduction. J Trauma. 2010 Oct;69(4):855-60. doi: 10.1097/TA.0b013e3181c4526f. PMID: 20032792.
51 Youngquist P, Carroll M, Farber M, et al. Implementing a ventilator bundle in a community hospital. Jt Comm J Qual Patient Saf. 2007;33(4):219-225. doi:10.1016/s1553-7250(07)33026-2.
52 Greene LR, Sposato K, Association for Professionals in Infection Control and Epidemiology (APIC). Guide to Elimination of Ventilator-Associated Pneumonia. APIC; 2009.
53 American Thoracic Society; Infectious Diseases Society of America. Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. Am J Respir Crit Care Med. 2005 Feb 15;171(4):388-416. doi: 10.1164/rccm.200405-644ST. PMID: 15699079.
54 Bell M, Muscedere J, VAP Getting Started Kit. Canadian Patient Safety Institute; 2009.
55 Klompas M, Branson R, Eichenwald EC, et al. Strategies to prevent ventilator-associated pneumonia in acute care hospitals: 2014 update. Infect Control Hosp Epidemiol. 2014;35:915-936.
56 Speck K, et al. A systematic approach for developing a ventilator-associated pneumonia prevention bundle. Am J Infect Control. 2016;44(6):652-656. doi:10.1016/j.ajic.2015.12.020.
57 Rawat N, et al. Two-state collaborative study of a multifaceted intervention to decrease ventilator-associated events. Crit Care Med. 2017;45(7):1208-1215. doi:10.1097/CCM.0000000000002463.
58 Pileggi C, Bianco A, Flotta D, et al., Prevention of ventilator-associated pneumonia, mortality and all intensive care unit acquired infections by topically applied antimicrobial

or antiseptic agents: a meta-analysis of randomized controlled trials in intensive care units. Crit Care. 2011 Jun 24;15(3):R155. doi: 10.1186/cc10285. PMID: 21702946; PMCID: PMC3219029.
59 Landelle C, Nocquet Boyer V, Abbas M, et al. Impact of a multifaceted prevention program on ventilator-associated pneumonia including selective oropharyngeal decontamination. Intensive Care Med. 2018;44(11):1777–86
60 Büchler AC, Jackson H, Landelle C., et al. Sustained effect of a multifaceted VAP prevention program over more than seven years including the COVID-19 pandemic. Antimicrob Resist Infect Control. 2025 Nov 14;14(1):139. doi: 10.1186/s13756-025-01646-y. PMID: 41239530; PMCID: PMC12619505.
61 De Vlam B, Khan S, Hans G. A systematic review of health economic studies on endotracheal tubes in preventing ventilator-associated pneumonia. Medicine (Baltimore). 2025 Aug 8;104(32):e43877. doi: 10.1097/MD.0000000000043877. PMID: 40797412; PMCID: PMC12338191.
62 Treggiari M, Sharp ES, Ohnuma T, et al. Hospital and long-term outcomes for subglottic suction and polyurethane cuff versus standard endotracheal tubes in emergency intubation (PreVent 2): a randomised controlled phase 2 trial. Lancet Respir Med 2025; published online Nov 27. https://doi.org/10.1016/S2213-2600(25)00294-2.
63 Klompas M, Branson R. Time to pull the plug on subglottic secretion drainage? Lancet Respir Med. 2025 Nov 27:S2213-2600(25)00410-2. doi: 10.1016/S2213-2600(25)00410-2. Epub ahead of print. PMID: 41319664.
64 Smulders K, van der Hoeven H, Weers-Pothoff I, Vandenbroucke-Grauls C. A randomized clinical trial of intermittent subglottic secretion drainage in patients receiving mechanical ventilation. Chest 2002; 121: 858–62.
65 Lorente L, Lecuona M, Jimenez A, Mora ML, Sierra A. Influence of an endotracheal tube with polyurethane cuff and subglottic secretion drainage on pneumonia. Am J Respir Crit Care Med 2007;176: 1079–83.
66 Deem S, Yanez D, Sissons-Ross L, Broeckel JA, Daniel S, Treggiari M. Randomized pilot trial of two modified endotracheal tubes to prevent ventilator-associated pneumonia. Ann Am Thorac Soc 2016; 13: 72–80.
67 Berra L, De Marchi L, Panigada M, Yu ZX, Baccarelli A, Kolobow T. Evaluation of continuous aspiration of subglottic secretion in an in vivo study. Crit Care Med 2004; 32: 2071–78.
68 Girou E, Buu-Hoi A, Stephan F, et al. Airway colonisation in long-term mechanically ventilated patients. Effect of semi-recumbent position and continuous subglottic suctioning. Intensive Care Med 2004; 30: 225–33.

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

Fabian Heinold, Omoerer Moerer, Lars Olav 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.

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.

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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.

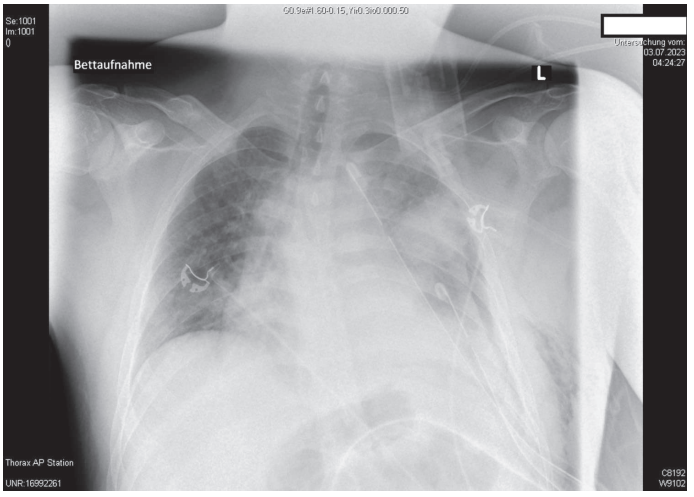

Figure 1. Chest radiography upon ICU admission, with two indwelling left sided chest drains in place, in the presence of persistent left sided pneumo- and hemothorax.

Three days after admission, the patient developed severe pneumonia and had to be intubated and ventilated. The tremaining 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 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 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).

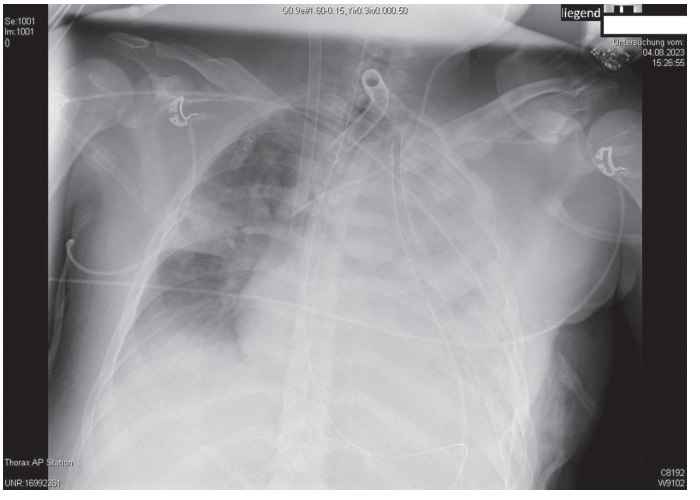

Figure 2. Chest radiography following ECMO and Tracheostomy tube placement in ARDS.

	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.

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.

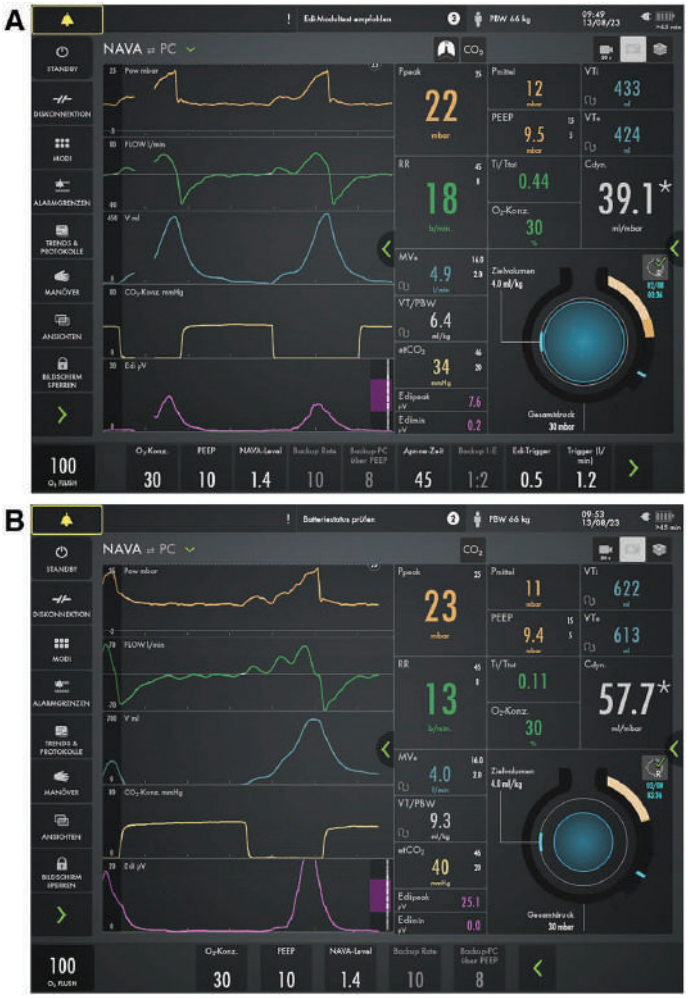

Figure 3. a] before gas flow break. b] after gas flow break.

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.

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.

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.

Response to: ECMO-Weaning Facilitated by Neurally Adjusted Ventilatory Assist (NAVA): A Case for Principal Clarification. Fabian Heinold, Omoerer Moerer, Lars Olav Harnisch

Henry Szymanski, RRT
Marketing/Product Manager – Critical Care
Getinge

Article Discussion/Comment: This case report highlights a novel application of Neurally Adjusted Ventilatory Assist (NAVA) and the Edi signal to support the weaning process from ECMO in adult patients. Weaning from ECMO remains a complex challenge, often associated with increased morbidity and extended hospital stays. Lung-protective strategies during ECMO are essential to minimize ventilator-induced lung injury (VILI), facilitate earlier weaning, and promote better recovery outcomes.

NAVA technology offers an objective assessment of the patient's work of breathing (WOB) through the Edi signal, providing valuable insight into diaphragmatic function and readiness for separation from ECMO. As described in the report, NAVA enabled a more integrated approach to ECMO weaning by aligning ventilator settings with real-time respiratory mechanics and lung function.

This patient-centered, data-driven method lays the groundwork for developing standardized ECMO weaning protocols. Moreover, the use of NAVA may help prevent further lung injury and enhance patient recovery.

References

1 Assouline B, Combes A, Schmidt M. Setting and monitoring of mechanical ventilation during venovenous ECMO. Crit Care. 2023;27:95. https://doi.org/10.1186/s13054-023-04372-2.

2 Barwing J, Pedroni C, Olgemöller U, et al. Electrical activity of the diaphragm (EAdi) as a monitoring parameter in difficult weaning from respirator: a pilot study. Crit Care. 2013;17:R182. https:// doi.org/10.1186/cc12865.

3 Brander L, Leong-Poi H, Beck J, et al. Titration and implementation of neurally adjusted ventilatory assist in critically Ill patients. Chest. 2009;135:695–703. https://doi.org/10.1378/chest.08-1747.

4 Broman LM, Malfertheiner MV, Montisci A, Pappalardo F (2018) Weaning from veno-venous extracorporeal membrane oxygenation: how I do it. J Thorac Dis. 10: S692–S697. https://doi.org/10. 21037/jtd.2017.09.95

5 Combes A, Hajage D, Capellier G, et al. Extracorporeal membrane oxygenation for severe acute respiratory distress syndrome. N Engl J Med. 2018;378:1965–75. https://doi.org/10.1056/NEJMo a1800385.

6 Doorduin J, Van Hees HWH, Van Der Hoeven JG, Heunks LMA. Monitoring of the respiratory muscles in the critically Ill. Am J Respir Crit Care Med. 2013;187:20–7. https://doi.org/10.1164/ rccm.201206-1117CP.

7 Dres M, Demoule A. Diaphragm dysfunction during weaning from mechanical ventilation: an underestimated phenomenon with clinical implications. Crit Care. 2018;22:73. https://doi.org/ 10.1186/s13054-018-1992-2.

8 Ehrlich H, Bisbee C, Ali A, et al. Extracorporeal membrane oxygenation utilization in blunt and penetrating traumatic injuries: a systematic review. Am Surg. 2022;88:2670–7. https://doi.org/10. 1177/00031348211011112.

9 Engelhardt LJ, Olbricht C, Niemann M, et al. Outcome comparison of acute respiratory distress syndrome (ARDS) in patients with trauma-associated and non-trauma-associated ARDS: a retrospective 11-year period analysis. JCM. 2022;11:5734. https:// doi.org/10.3390/jcm11195734.

10 Gurumahan V, Thavalingam S, Schindler T et al (2022) Reference values for diaphragm electrical activity (Edi) in newborn infants. https://doi.org/10.21203/rs.3.rs-1387574/v1

11 Harnisch L-O, Moerer O. Contraindications to the initiation of Veno-Venous ECMO for severe acute respiratory failure in adults: a systematic review and practical approach based on the current literature. Membranes. 2021;11:584. https://doi.org/10.3390/ membranes11080584.

12 Heunks LM, Van Der Hoeven JG. Clinical review: the ABC of weaning failure—a structured approach. Crit Care. 2010;14:245. https://doi.org/10.1186/cc9296.

13 Jung B, Moury PH, Mahul M, et al. Diaphragmatic dysfunction in patients with ICU-acquired weakness and its impact on extubation failure. Intensive Care Med. 2016;42:853–61. https://doi.org/10. 1007/s00134-015-4125-2.

14 Karagiannidis C, Strassmann S, Schwarz S, et al. Control of respiratory drive by extracorporeal CO2 removal in acute exacerbation of COPD breathing on non-invasive NAVA. Crit Care. 2019;23:135. https://doi.org/10.1186/s13054-019-2404-y.

15 Lourenço RV, Cherniack NS, Malm JR, Fishman AP. Nervous output from the respiratory center during obstructed breathing. J Appl Physiol. 1966;21:527–33. https://doi.org/10.1152/jappl. 1966.21.2.527.

16 Mauri T, Bellani G, Confalonieri A, et al. Neurally adjusted ventilatory assist reduces asynchrony and patient effort in severe acute respiratory distress syndrome patients undergoing extracorporeal membrane oxygenation. Crit Care. 2011;15:P191. https://doi.org/ 10.1186/cc9611.

17 Moerer O, Barwing J, Quintel M. „Neurally adjusted ventilatory assist (NAVA): Ein neuartiges assistiertes Beatmungsverfahren. Anaesthesist. 2008;57:998–1005. https://doi.org/10.1007/ s00101-008-1412-0.

18 Mohamed MSA, Moerer O, Harnisch L. Recording of a left ventricle assist device electrical current with a neurally adjusted ventilation assist (NAVA) catheter: a small case series. J Clin Monit Comput. 2023. https://doi.org/10.1007/s10877-023-01055-9.

19 Pham T, Heunks L, Bellani G, et al. Weaning from mechanical ventilation in intensive care units across 50 countries (WEAN SAFE): a multicentre, prospective, observational cohort study. Lancet Respir Med. 2023;11:465–76. https://doi.org/10.1016/ S2213-2600(22)00449-0.

20 Ramanathan K, Shekar K, Ling RR, et al. Extracorporeal membrane oxygenation for COVID-19: a systematic review and meta-analysis. Crit Care. 2021;25:211. https://doi.org/10.1186/ s13054-021-03634-1.

21 Sauer CM, Yuh DD, Bonde P. Extracorporeal membrane oxygenation use has increased by 433% in adults in the United States from 2006 to 2011. ASAIO J. 2015;61:31–6. https://doi.org/10.1097/ MAT.0000000000000160.

22 Schefold JC, Bierbrauer J, Weber-Carstens S. Intensive care unit—acquired weakness (ICUAW) and muscle wasting in critically ill patients with severe sepsis and septic shock. J cachexia sarcopenia muscle. 2010;1:147–57. https://doi.org/10.1007/ s13539-010-0010-6.

23 Shah SD, Anjum F (2023) Neurally adjusted ventilatory assist (NAVA). StatPearls

24 Sinderby C, Navalesi P, Beck J, et al. Neural control of mechanical ventilation in respiratory failure. Nat Med. 1999;5:1433–6. https:// doi.org/10.1038/71012.

25 Tsiouris A, Protos AN, Saikus CE, Jeyakumar AKC. Fundamentals of weaning veno-arterial and veno-venous extracorporeal membrane oxygenation. Indian J Thorac Cardiovasc Surg. 2023;39:123–33. https://doi.org/10.1007/s12055-023-01474-y.

26 Weber-Carstens S, Goldmann A, Quintel M, et al. Extracorporeal lung support in H1N1 provoked acute respiratory failure. Dtsch Arztebl Int. 2013. https://doi.org/10.3238/arztebl.2013.0543.

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Budesonide Plus Pulmonary Surfactant Shows Promise in Preventing Bronchopulmonary Dysplasia in Premature Infants

Budesonide combined with pulmonary surfactant was linked to a nearly one third reduction in the incidence of bronchopulmonary dysplasia (BPD) compared with pulmonary surfactant alone in premature infants, a recent meta-analysis showed. Researchers conducted a meta-analysis of 12 randomized controlled trials involving 2428 premature infants, comparing intratracheal budesonide plus pulmonary surfactant with pulmonary surfactant alone. Data were extracted from databases such as EMBASE, MEDLINE, Web of Science, and Cochrane Central. The primary outcome was the incidence of BPD in infants receiving combined therapy vs those receiving pulmonary surfactant alone. Secondary outcomes were in-hospital mortality, need for repeated surfactant use, duration of hospital stay, and pulmonary hemorrhage incidence. Combined budesonide-surfactant therapy significantly reduced the risk for BPD (relative risk [RR], 0.66; $P < .01$). Treatment with combined therapy reduced in-hospital mortality (RR, 0.80), pulmonary hemorrhage incidence (RR, 0.61), and the need for repeated pulmonary surfactant administration (RR, 0.52; $P \leq .02$ for all). "Compared with the use of PS [pulmonary surfactant] alone, the combination of budesonide and PS may reduce the incidence of BPD, pulmonary hemorrhage, and in-hospital mortality in premature infants," the authors of the study wrote.

New Strategies Help Respiratory Patients Overcome Exercise Barriers

For patients with severe respiratory impairment, the simple act of breathing can be a struggle, making exercise seem like an insurmountable challenge. However, with the right strategies, even the most severely affected patients can participate in and greatly benefit from rehabilitation, said experts at the European Respiratory Society (ERS) International Congress 2025. "The most important [thing] is to be aware that even in the severely impaired patients, it's possible to implement exercise training," José Miguel dos Santos Castro Padilha, MD, PhD, an assistant professor and rehabilitation specialist at the Nursing School of the University of Porto, Portugal, said. Physical activity, however, must be "implemented by a very well-educated, interprofessional team with the clinical experience to adapt the intervention to the features of the patient," he said. Dyspnea, or the uncomfortable feeling of shortness of breath, is a barrier to exercise for this demographic, and helping patients overcome it requires an understanding of its underlying causes, said J. Alberto Neder, MD, a respirologist and clinical physiologist at Queen's University in Kingston, Ontario, Canada. Dyspnea is a mismatch between high ventilatory demand and low ventilatory capacity, which can be caused by excessive breathing, such as hyperventilation, or constrained breathing, such as mechanical restraints on breathing. Anxiety, panic attacks, or dysfunctional breathing patterns can cause excessive breathing. It can also arise from chemical drivers, including hypoxemia, a high CO_2 flow from the periphery to the lungs, and early-onset lactic acidosis during exercise. Strategies to manage excessive breathing focus on reducing ventilatory demand. "This involves a combination of clinical treatment and rehabilitation," Neder explained. Techniques include desensitization to the feeling of dyspnea, anxiety control, and diaphragmatic breathing exercises to improve efficiency. Constrained breathing, on the other hand, results from mechanical limitations. Expiratory flow limitation is a major issue, leading to progressive dynamic hyperinflation as the patient is unable to exhale fully during exertion. This "breath stacking" increases the work of breathing and exacerbates dyspnea. Interventions to improve respiratory capacity, such as bronchodilators, supplemental oxygen, and noninvasive ventilation (NIV), can be beneficial in alleviating these constraints and making dynamic exercise possible.

Oxygen and Mandibular Device Combo Boosts Treatment Efficacy in Moderate-to-Severe Sleep Apnea

Combining supplemental oxygen with mandibular advancement device (MAD) therapy significantly reduced obstructive sleep apnea (OSA) severity compared with sham treatment and offered a 14% greater improvement than MAD alone in patients with moderate-to-severe OSA. Researchers conducted a multicenter randomized crossover trial with 41 participants with moderate-to-severe OSA (median age, 54 years; women-to-men ratio, 14:27; 80% treatment-naive) to evaluate whether supplemental oxygen combined with MAD reduces OSA severity compared with MAD alone. Patients received four interventions in random order—supplemental oxygen (4 L/min via nasal cannula), MAD, combination therapy (MAD plus oxygen), and sham (room air at 4 L/min)—with each treatment scheduled 1 week apart and separated by a 6-night washout period. The primary outcome was the apnea-hypopnea index (AHI), including hypopneas without desaturation or arousals, and secondary outcomes were the arousal index, patient-reported sleep quality (assessed via the visual analog scale), and changes in blood pressure. The combination of MAD and supplemental oxygen provided a greater reduction in AHI than MAD alone (difference in change from baseline, -14%; $P = .009$). Compared with sham, the combination decreased arousal index scores and increased visual analog scale scores for sleep quality; however, compared with MAD alone, the combination did not offer a significant improvement. All interventions reduced physiologic burdens compared with sham; however, only hypoxic and heart rate burdens showed greater reductions with combination therapy than with MAD alone. "Combined upper airway and ventilatory control therapies could also provide an alternative treatment approach beyond the combined upper airway plus upper airway modalities currently being explored with considerable early success," the authors wrote.

New Score Flags Kids at Risk for Poor Lung Growth in Asthma

Previous research indicates that approximately 25% of children with asthma exhibit impaired lung growth, with better initial function identified as a potential risk factor. A conditional change score for FEV_1, accounting for time intervals between measurements and independent of baseline values, has been proposed. Researchers analyzed data of 295 children with confirmed asthma to determine whether the conditional change score can identify a subgroup with impaired lung growth and to identify risk factors for impaired lung growth. Asthma was confirmed by either a significant bronchodilator response or a diagnosis of an asthma exacerbation; children had undergone at least 10 spirometry tests beginning at nearly 8 years of age. For each child, the annualized change in prebronchodilator FEV_1 percent predicted was estimated, and conditional change scores were calculated; scores between -1.96 and +1.96 indicated normal growth, scores below -1.96 indicated impaired growth,

and scores above +1.96 indicated enhanced growth. Median follow-up durations for children with enhanced, normal, or impaired growth were 5.9, 6.5, and 6.6 years, respectively. Overall, 16% of the children exhibited impaired lung growth during the follow-up period. These participants also experienced a greater decline in lung function over time and had lower FEV1 at the final visit than those in other groups.

Thermal Management Solution Released

Respiralogics, a Global Respiratory Solutions, Inc. company, announced the release of the Preemie Beenie Poly-Lined Knit Hat, an innovative thermal management solution designed to reduce cranial heat loss in extremely low birth weight (ELBW) and full-term infants. Newborns, particularly those born prematurely, are highly vulnerable to heat loss, especially through the head. The Preemie Beenie addresses this critical challenge with a specially engineered polyurethane liner placed between two layers of soft, stretchable cotton knit, offering a snug, skin-friendly fit that helps maintain optimal body temperature during the earliest, most vulnerable stages of life. Key Features and Benefits: Poly-lined design reduces evaporative and conductive heat loss. Soft, stretchable cotton knit ensures easy application and a secure fit. Latex-free, DEHP-free materials for gentle skin contact. Color-coded sizing system for fast identification. Available in three sizes to fit infants from ≤25 weeks to full term. Single-patient use to support infection control protocols. The Preemie Beenie Poly-Lined Knit Hat joins Respiralogics' growing portfolio of neonatal and pediatric respiratory care products, all designed to meet the highest standards of clinical effectiveness and patient comfort.

Next Generation Device Launched

React Health has announced the launch of the Phoenix 5L, a next- generation stationary oxygen concentrator designed to deliver powerful performance in a reliable, easy to use package. Built with patients and providers in mind, the Phoenix 5L offers quiet operation, low power consumption, and robust safety features, making it an ideal solution for home respiratory therapy. "The Phoenix 5L was engineered to balance quality, simplicity, and value," said Bill Shoop, CEO of React Health. "This concentrator is designed to support patient therapy while reducing operational strain on healthcare providers." Key highlights of the PhoenixTM 5L include: Reliable Performance: Patented air separation control system and low running temperatures extend the lifespan of internal components. Ease of Maintenance: Intuitive access to internal parts with only 5 screws—making service fast and simple. Smart Safety Features: Includes an integrated internal fire break valve and alarms for low purity, high/low pressure, power loss, and more. Compact, Lightweight Design: Weighing just 35 lbs and measuring 20 x 13.7 x 11 inches, the Phoenix 5L is easy to fit into any living space. With flow rates from 0.5–5.0 LPM and oxygen concentration of 93% ±3%, the Phoenix 5L meets a wide range of therapy needs. Designed with intelligent airflow to prevent gas recirculation, it ensures consistent delivery of high-quality oxygen therapy day after day. React Health will begin shipping the Phoenix 5L immediately to select providers.

Oxygen Concentrator Now Available in the US

CAIRE's award-winning FreeStyle Comfort portable oxygen concentrator with proprietary autoSAT technology is now available in the US. This patented, clinically proven feature is most well-known for being a key innovative oxygen delivery feature on the Eclipse 5 transportable oxygen concentrator, used by clinicians and healthcare providers as part of hospital discharge programs for newly prescribed oxygen patients. The autoSAT technology adjusts oxygen delivery to deliver a consistent volume of oxygen with the patient's breath rate during activity or at rest. "Today's announcement is a major step forward in serving today's oxygen therapy users with the technology they need to support a more active lifestyle and better quality of life. Instead of the respiratory patient having to adapt to their portable oxygen device, this device adapts to them through our patented technology," said Ken Hosako, President and CEO of CAIRE Inc. Portable oxygen concentrators, operational via battery or electrical power, take ambient air, filter it, and then deliver up to 95 percent purified oxygen to the user. The convenience of being able to plug in and recharge anywhere has contributed to the increasing popularity of portable oxygen concentrators among individuals prescribed long-term supplemental oxygen therapy to treat severe respiratory conditions, including Chronic Obstructive Pulmonary Disease (COPD). Last month, the FreeStyle Comfort with autoSAT was prominently featured in a study by Georgia State University published in the Pulmonary Therapy journal. The bench study compared FiO_2 delivery from portable oxygen concentrators, wall oxygen, and a standalone concentrator (CAIRE Companion 5) using a respiratory failure-specific lung simulator replicating an adult with chronic respiratory disease at 15-40 breaths/min. Among the portable oxygen concentrators tested, the FreeStyle Comfort, with or without autoSAT, consistently achieved the highest or equivalent FiO 2 at elevated breathing rates (30-40 bpm). However, at lower rates (15-20 bpm), results varied by device. The FreeStyle Comfort with autoSAT at 40 breaths per minute on setting 2 and sensitivity 5 delivered a statistically significant higher FiO_2 (0.25 vs 0.24, p < 0.01) than wall oxygen. Also, of note, fixed-bolus technology like autoSAT helped sustain FiO_2 during exertion, reducing the need for patients to manually adjust settings—potentially supporting therapy adherence. The study was funded by CAIRE, but independently conducted and analyzed at Georgia State University. No clinical outcomes in patients were measured. "As a respiratory therapist, I've seen how discouraging it can be when portable oxygen doesn't seem to meet a patient's needs. The FreeStyle Comfort with autoSAT technology adapts to each breath, helping restore confidence in therapy and giving patients back the freedom they may have thought was lost," said Cara Collins, RRT, RRT-NPS, and CAIRE Product Manager. The FreeStyle Comfort is manufactured at CAIRE's global manufacturing headquarters, located north of Atlanta. The 5-pound FreeStyle Comfort is designed with an innovative ergonomic, curved shell and delivery features to ensure oxygen is provided with each breath. In addition to the autoSAT technology, this device offers other smart oxygen delivery features, such as CAIRE's UltraSense technology, which ensures that oxygen is delivered in conjunction with the patient's breath rate, and autoDOSE, which ensures delivery of oxygen even if no breath is detected. The new device introduces enhanced functionality through an expanded control menu, giving users the ability to personalize their oxygen therapy with features such as autoSAT technology, adjustable breath sensitivity, and convenient airplane mode for travel. Designed with ease of use in mind, the device also meets FAA guidelines for in-flight use on commercial airlines.

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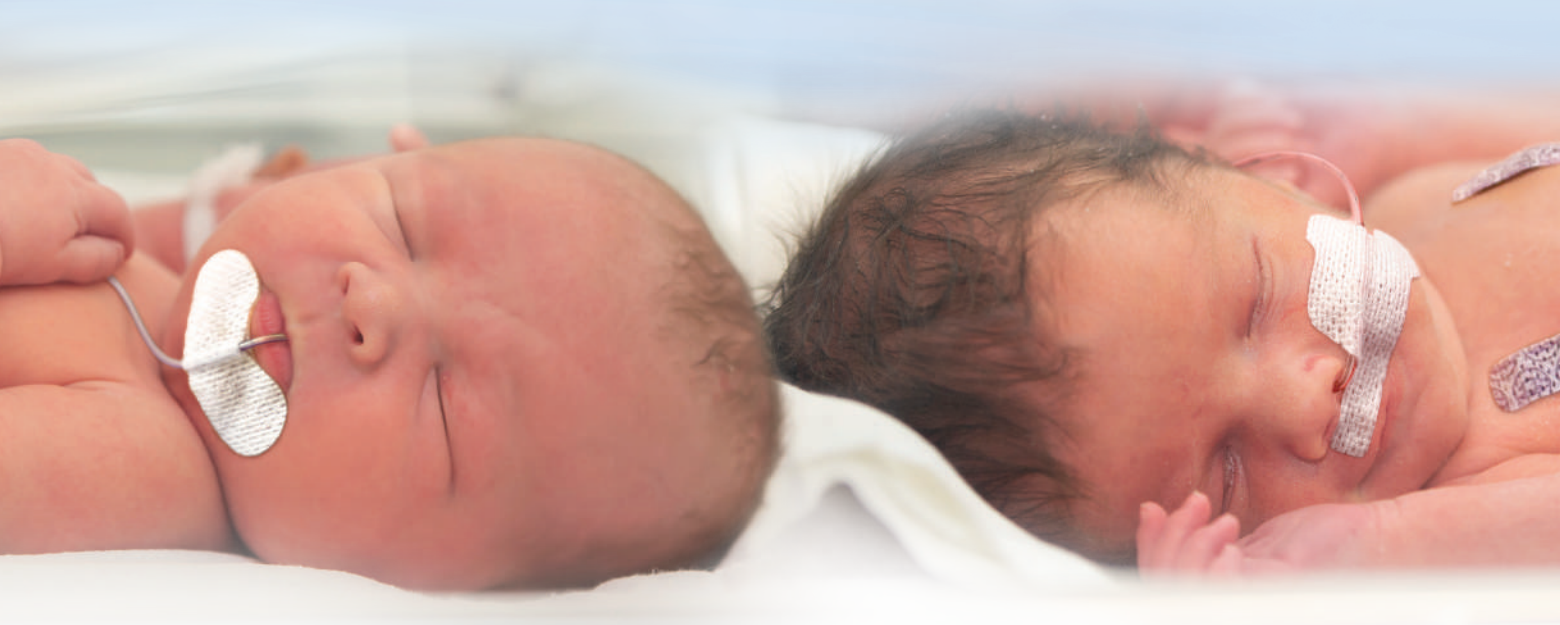

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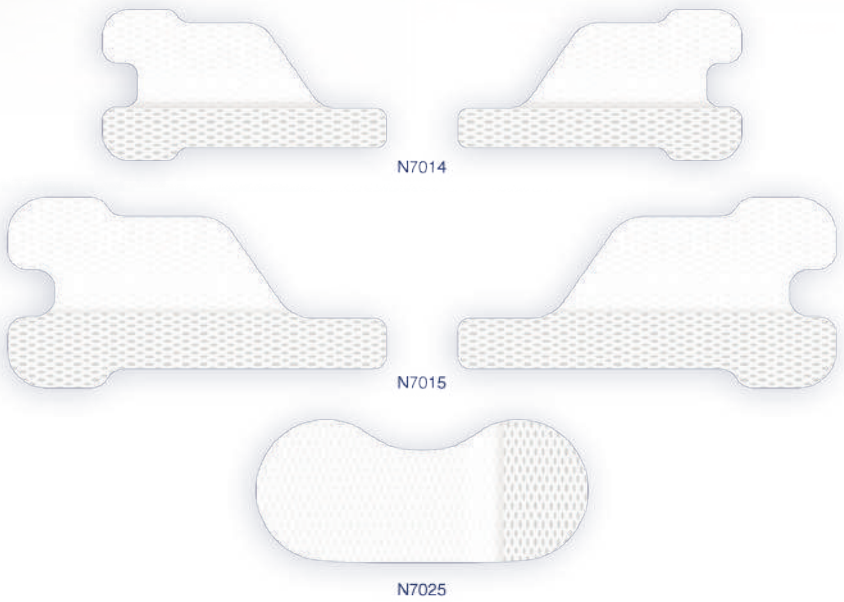

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