Volume 20 Number 2 Spring 2025

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Publisher/Editor in Chief
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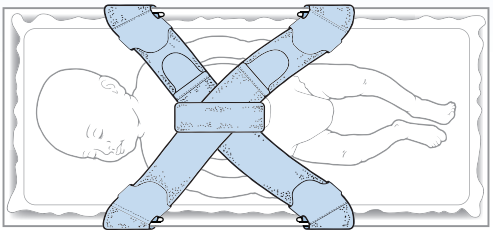

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News

■ Spring 2025

Company Earns Mark in Europe

Beyond Air, Inc., a commercial stage medical device and biopharmaceutical company focused on harnessing the power of nitric oxide (NO) to improve the lives of patients, announced European CE mark approval of the LungFit PH system. This CE mark approval allows Beyond Air to market LungFit PH in the European Union and all other countries that recognize this certification. LungFit PH, the first device in the LungFit therapeutic platform of nitric oxide generators, leverages the company's patented Ionizer technology and has already received FDA approval in the United States.

"We are thrilled to announce CE mark for LungFit PH, paving the way for commercial sales in Europe and other global regions. In anticipation of this approval, we partnered with Business Asia Consultants to leverage their extensive international distribution network," stated Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. "I am incredibly proud of the team that made this happen over the past 30 months and look forward to initiating shipments to our Asia-Pacific partner, Getz Healthcare, and other international partners in 2025." Under the terms of Beyond Air's existing commercialization agreement with Getz Healthcare for LungFit PH, Getz will make a $1 million milestone payment to Beyond Air upon CE mark certification. In addition, Beyond Air will receive ongoing royalty payments based on LungFit PH net sales. The partnership provides access to hospitals in Australia, New Zealand, Thailand, Philippines, Taiwan, Hong Kong, Malaysia, Pakistan, Singapore and Vietnam. The specific indications for LungFit PH under CE Mark certification include: the treatment of infants > 34 weeks gestation with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, in order to improve oxygenation and to reduce the need for extracorporeal membrane oxygenation; the treatment of peri- and post-operative pulmonary hypertension in adults and newborn infants, infants and toddlers, children and adolescents, ages 0-17 years in conjunction to heart surgery, in order to selectively decrease pulmonary arterial pressure and improve right ventricular function. LungFit PH uses Ionizer technology to generate unlimited on-demand NO from ambient air and deliver it to a ventilator circuit, regardless of dose or flow. The device uses a compressor to drive room air through a plasma chamber where pulses of electrical discharge are created between two electrodes. The LungFit PH system ionizes the nitrogen and oxygen molecules, forming NO with low levels of nitrogen dioxide (NO2) created as a byproduct. The gas is then passed through a Smart Filter, which removes toxic NO2 from the internal circuit. LungFit PH represents a significant step forward in sustainable healthcare solutions. Since the device generates NO conveniently and cleanly from ambient air, without the need for tanks or chemicals, it is highly energy-efficient, using only the power equivalent to a 60-watt light bulb. By eliminating the emissions associated with truck transport and cylinder refills, LungFit PH supports hospital sustainability initiatives, helping facilities reduce their carbon footprint while delivering critical care to patients. For the approved indications, the novel LungFit PH system is designed to deliver a dosage of NO to the lungs that is consistent with the current standard of care for delivery of 20 ppm NO, with a range of 0.5 ppm-80 ppm (low concentration NO) for ventilated patients. Each Smart Filter will last 12 hours regardless of ventilator demands, and replacing a filter only takes seconds. Potential customers can visit the LungFit PH website, www.lungfitph.com, for additional information, including the product label, and to sign up for updates.

Beyond Air Provides LungFit PH System to Hospital

Beyond Air, Inc., a commercial stage medical device and biopharmaceutical company focused on harnessing the power of nitric oxide (NO) to improve the lives of patients, is proud to announce the deployment of its groundbreaking LungFit PH system to the US Naval Hospital Guam. This partnership, made possible through collaboration with TrillaMed, marks a significant advancement in the neonatal critical care unit, offering enhanced care for newborns in need of respiratory support. The LungFit PH system is an innovative device designed to generate Nitric Oxide (NO) from room air and deliver NO for the treatment of persistent

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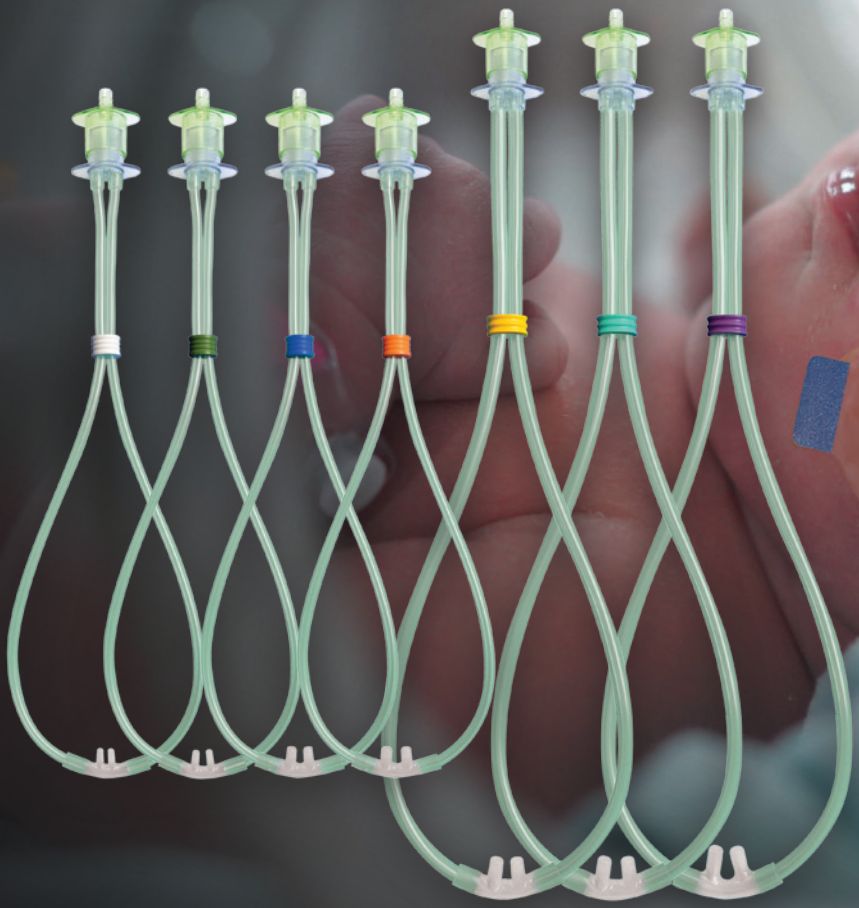

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pulmonary hypertension in neonates (PPHN), a condition that affects the lungs and heart of newborns. The system provides a safe, efficient, and user-friendly solution to address critical respiratory conditions, ensuring that the hospital's youngest and most vulnerable patients receive the highest standard of care. Key Features of the LungFit PH System: Portable and compact design, making it ideal for intensive care settings; advanced nitric oxide generating technology with no need for high-pressure cylinders; rapid response for improved oxygenation in neonates with PPHN; easy integration into existing hospital infrastructure. "We are honored to support the US Naval Hospital Guam in their mission to provide top-tier neonatal care," said Steve Lisi, CEO of Beyond Air. "Through our partnership with TrillaMed, we are able to extend the reach of our LungFit PH, delivering critical solutions to the healthcare community. This collaboration is a testament to our commitment to advancing neonatal care and improving patient outcomes." The US Naval Hospital Guam serves as a critical care provider for the military community in the region. More than 17,000 active-duty military personnel and family members currently are stationed on Guam, which is expected to increase by 2,500 in the next two years. The US Naval Hospital Guam delivers an average of 315 babies per year, with that number expected to rise to 487 births by 2033. The introduction of the LungFit PH system underscores the hospital's dedication to utilizing state-of-the-art technologies in neonatal care, ensuring military families have access to the latest in respiratory treatment options.

Company Announces US FDA Filing

Linde Gas & Equipment Inc. announced the submission of a 510(k) premarket notification application with the US Food and Drug Administration (FDA) for NOXBOX I PLUS, a nitric oxide delivery and monitoring system for NOXIVENT (nitric oxide) gas, for inhalation. "This FDA submission builds on the success of our innovative NOxBOX i delivery system," said Jason Aexel, Director of Clinical Healthcare, Linde Gas & Equipment providing healthcare professionals with an enhanced system that offers an economical and reliable way to deliver inhaled nitric oxide therapy." Linde has made targeted enhancements to the delivery system's functionality including a streamlined setup process, ergonomic refinements, precise controls, and further compatibility with various ventilators allowing for an enhanced user experience "We look forward to NOXBOX I PLUS' 510(k) clearance, and we remain steadfast in our commitment to nitric oxide therapy and continuous improvement in our technology," said Jason Aexel, Director of Clinical Healthcare, Linde Gas & Equipment Inc. Linde's NOXIVENT (nitric oxide) gas, for inhalation is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents. The NOxBOX i delivery system has been in commercial use in 40+ countries since 2013 and in the US since October 2018. Currently, in the US, the NOxBOX i delivery system is being used in hundreds of locations. Contraindication: NOXIVENT is contraindicated in neonates dependent on right-to-left shunting of blood. Rebound: Abrupt discontinuation of NOXIVENT may lead to worsening oxygenation and increasing pulmonary artery pressure The NOxBOX i delivery system and NOXIVENT (nitric oxide) gas, for inhalation must only be used in accordance with the indications, contraindications, warnings, precautions, and other information and conditions of use described in the nitric oxide drug prescribing information and labeling (currently neonates). Refer to this material before use. Important safety information and full prescribing information can be found at www.noxiventus.com.

Nicotinamide Riboside Relieves Airway Inflammation in COPD

Nicotinamide riboside (NR) supplementation may reduce airway inflammation and, thereby, lower the risk for exacerbation in patients with noneosinophilic chronic obstructive pulmonary disease (COPD) who smoked previously. The anti-inflammatory effect of NR has been previously documented, and the current study investigated whether its supplementation could reduce airway inflammation in patients with noneosinophilic COPD who smoked previously. The researchers conducted a randomized controlled trial involving patients with COPD (n = 40; mean age, 71.9 years) who had an eosinophilic count $< 0.3 \times 10^9$ cells/L and a history of smoking greater than 10 pack-years, as well as control individuals with no history of smoking or lung disease (n = 18; mean age, 70.9 years). In each group, patients were randomly assigned to receive either NR (2 g/d) or placebo for 6 weeks, with assessments conducted at pretreatment, posttreatment, and 12-week follow-up visits posttreatment. The primary outcome was the effect of NR supplementation on airway inflammation as assessed by changes in the levels of sputum interleukin (IL) 8, which is an essential aggravator of cellular senescence and associated with disease severity in COPD. The secondary outcome was the effect of NR supplementation on levels of anti-inflammatory markers, including whole blood nicotinamide adenine dinucleotide (NAD+) and plasma IL-6. Six weeks of NR supplementation

vs placebo resulted in a significant reduction in sputum IL-8 levels (estimated treatment difference, –52.6%; $P = .030$), which persisted until 12 weeks after the end of treatment (estimated treatment difference, –63.7%; $P = .034$). NR supplementation increased NAD+ levels in whole blood by 71.1 µM in patients with COPD and by 49.4 µM in healthy control individuals, with no changes observed with any of the placebo arms. NR treatment had no effect on plasma IL-6 levels. Overall, 29 adverse events were reported by 26 participants; however, no differences in adverse events were noted between NR supplementation and placebo in both patients with COPD and control individuals. The exploratory analyses showed indications of upregulated gene pathways related to lowered epigenetic aging; however, further studies are needed to confirm these results. "Our findings suggest that NR could possibly be a viable treatment option for patients with COPD," the authors wrote. "We acknowledge that our results need to be confirmed and replicated in longer-term trials with larger sample sizes, applying multiple methods to assess cellular senescence," they further added. The study was led by Kristoffer L. Norheim, Department of Cellular and Molecular Medicine, Center for Healthy Aging, University of Copenhagen, Copenhagen, Denmark. It was published online on November 15, 2024, in *Nature Aging*.

New Tracheostomy Filter Now Available

Passy-Muir, Inc., Irvine, California, announces the release of a new filter designed for tracheostomy patients. Responding to the need for an effective, lightweight filter for patients with tracheostomy, the new Passy Muir Tracheostomy Viral and Bacterial Airway Protection Filter (PM-APF15) attaches easily to the 15mm hub of a tracheostomy tube and safely and effectively filters out viral, bacterial, and other particulate matter. The new lightweight, non-sterile filter is designed for single-patient use for non-mechanically ventilated pediatric and adult tracheostomy patients, and provides bacterial and viral filtration efficiency of 99.9%, while effectively filtering out 99% of all airborne particulates. For use in clinical settings, including hospitals, sub-acute, rehabilitation, outpatient, skilled nursing, and long-term care, as well as in the home setting. For adults with Tidal Volumes 300 ml and pediatrics with Tidal Volumes >80 ml. Not for use on neonate or infant patients. The PM-APF15 filter comes with detailed instructions for use, and is manufactured in the United States. For more information, or to order, visit www.passymuir.com, or call 1-800-634-5397.

At-home Device Unveiled

Durable and home medical equipment providers in the United States will now have another solution to meet their respiratory patients' at-home oxygen therapy needs. CAIRE announced the addition of the new IntenOxy 5 stationary oxygen concentrator to its portfolio at its global manufacturing headquarters north of Atlanta. According to an article published in the National Library of Medicine database, the Centers for Medicare and Medicaid Services estimate that more than 1 million Medicare recipients receive long-term oxygen therapy (LTOT) at home. The IntenOxy 5 offers effective oxygen delivery with up to 95.5 percent concentration and flow settings from 0.5 to 5 liters per minute (LPM), meeting a broad range of prescription needs. Patients will appreciate its simple user interface with easy-to-understand alerts. Weighing only 34.2 lbs., this concentrator is sleek and compact, blending into the surroundings and boasting a low power consumption of 350W at the 5 LPM setting. When combined with CAIRE's award-winning FreeStyle Comfort portable oxygen concentrator, the IntenOxy 5 provides yet another solution to help DME and HME customers stock their fleets with what the industry calls non-delivery solutions—equipment that requires minimal maintenance and reduces overall operating expenses. "The IntenOxy 5 Stationary Oxygen Concentrator has been an excellent addition to our oxygen therapy portfolio. The unit is a key component to how our DME and HME customers serve their respiratory patients, providing them with an at-home device that delivers the oxygen they need as they navigate activities of daily living," said Ken Hosako, CAIRE President and Chief Executive Officer. The unit has a three-year warranty and will soon be available in Canada. For more information, visit https://www.caireinc.com/product/intenoxy-5-provider/ or email customerservice.usa@caireinc.com.

New Heat Moisture Exchanger

Passy-Muir, Inc., Irvine, California, announces the release of a new Heat Moisture Exchanger (HME) for patients with a tracheostomy. Not to be confused with a speaking valve, the PM-HME Heat Moisture Exchanger is a non-sterile, lightweight, single patient use, device designed to be positioned on a tracheostomy tube to warm and humidify air breathed by a patient. The PM-HME is intended for use in clinical settings including hospitals, sub-acute, rehabilitation, outpatient, pre-hospital, skilled nursing, long-term care, and the home setting. Made in USA and Latex free. For more information, or to order, visit www.passymuir.com, or call 1-800-634-5397.

PM1 Pollution Drives Respiratory Hospitalizations

Air quality has a huge impact on health, with exposure to

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Mary Washington Hospital Advances OLE Therapy To Help Treat COPD Exacerbations With the Volara System

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease that affects 12.5 million Americans.[1] It accounts for millions of emergency department visits and creates a significant healthcare burden, including hospitalizations and economic costs.[2] A hospital in Fredericksburg, Virginia, is in the heart of tobacco country, and sees a significant number of COPD patients, some of whom were returning to the hospital. They decided to do something about it.

Overview

Mary Washington Hospital had been using the MetaNeb System for many years. As these devices were nearing end of service, they looked to replace them. Their Baxter representative introduced them to the Volara System and brought it in to educate the staff on how it could help them deliver Oscillation & Lung Expansion (OLE) therapy for respiratory patients throughout the hospital.

At the same time, one of the hospital's big initiatives for 2023 was to see a reduction in 30-day readmissions in COPD and pneumonia. "The timing of the Volara System being brought in by our Baxter representative was perfect," says Carrie Ludwig, Director of Respiratory Therapy at the hospital. "We were above the acceptable benchmark for seeing COPD patients come back to the hospital. There was a big drive to address it."

Setting Up An Evaluation

In addition to bringing in the Volara System, their Baxter representative introduced Carrie to a University of Oklahoma study which used the Volara System to treat patients coming into the emergency department with COPD exacerbation. "They showed a very significant reduction in those admissions," Carrie says.[3] "I started thinking how we could leverage it to help reduce that patient population here at Mary Washington Hospital." Carrie and her team put together a 60-day evaluation, adjusting the study protocol to work for their facility. One of the challenges in the emergency department was that different providers had their own "recipe" for treating different disease processes. The team set out to streamline those approaches based on literature and evidence, creating a protocol for patients coming to the emergency department exhibiting COPD-like symptoms.

Provided by Baxter.

HIGHLIGHTS

Facility
Mary Washington Hospital Fredericksburg, VA

Profile
- 471-bed acute care facility
- Level 2 trauma center
- Level 3 NICU
- Cardiovascular Surgery
- Certified Primary Stroke Center

Partner
Carrie Ludwig, Director of Respiratory Therapy, Sleep and Wake Disorders Center and Neurodiagnostics

Reported Impact
- Reduced COPD readmissions
- Improved patient tolerance
- Expansion of COPD program to freestanding emergency departments
- Device adoption throughout the Mary Washington Healthcare system
- Improved time efficiency by allowing Respiratory Therapists to focus on the patient

The results were impressive. "We saw 83 patients and we looked back at 50 patients. There was an overall reduction of COPD admissions by 28 percent," she says. "We also had a significant group that went to an observation unit instead of admission. Thirty-one percent of admitted patients were discharged within — or less — than their expected length of stay."

According to Carrie, the success of the evaluation allowed them to make their case for the Volara System. "We not only replaced the ten MetaNeb System units that we had," she noted, "but we actually purchased 25 Volara System units based on the results of the evaluation that we were able to take to our executives."

Putting the System To Use

Once the Volara Systems were in place, the respiratory team quickly discovered how they would be able to help provide the

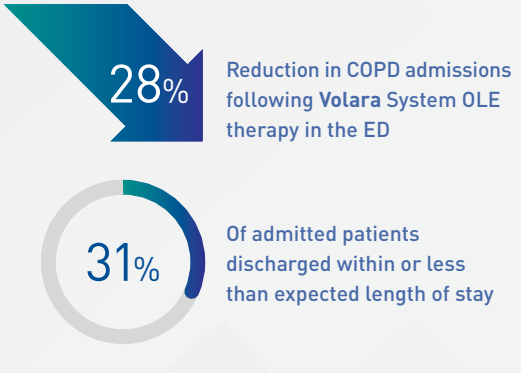
We started to see immediate improvement in patients, seeing them go home from the emergency department, or seeing them go to the observation unit and go home the next day.
– Carrie Ludwig
Director of Respiratory Therapy

care their patients needed. "It's very user-friendly, very easy to set up, basically plug-and-play," Carrie says.[4] "We're not having to manipulate dials back and forth like we did on the MetaNeb System." The Volara System is being used throughout the hospital, in the emergency department, the adult ICUs, and all of the general care floors. "It allows for better deposition of medications so the treatment gets deeper into the lungs. We use it for secretion clearance as well as lung inflation or recruiting alveoli to treat atelectasis."

Another feature that stood out was the Volara System's electromechanical drive as opposed to the MetaNeb System's pneumatic system.[4] "Given the complexity of everything going on with a patient, one of the issues with the MetaNeb System was we had to plug it into an oxygen outlet, which is a hot commodity in patient rooms, especially if you have several devices requiring an oxygen source," she says. "We had many instances with a patient on high-flow nasal cannula that would have to be disconnected, then the caregiver would need to plug in the MetaNeb System, deliver the treatment, then unplug the MetaNeb System and remember to plug the high-flow back in, moving things around an IV pole. There was a lot of room for confusion and error. With the Volara System, it's not an issue."

Performance under pressure

The ability to precisely deliver the pressure needed by each patient is helping the team optimize therapy. "The Volara System allows us to set driving pressure based on patient need and comfort level, making sure we're delivering enough pressure to recruit the alveoli without too much pressure," says Carrie. "Being able to deliver higher pressure means you're going to reach those smaller airways and that's going to help secretion clearance. As long as the patient can tolerate it, the higher pressure is definitely more beneficial. For more complex patients, we're able to manually set those pressures. But for the average COPD patients, the presets are really effective."



Seeing is believing

Given that her team includes traveling respiratory therapists, Carrie saw how quickly they adopted the Volara System. "Anything new is going to be met with some hesitation. But once they got to use it and see it in action, the ease of use was just tremendous," she says.

They weren't having to work so hard to give the therapy. They were able to monitor their patient versus focusing on setting up the device and having to move things around."

Patients were saying, "Where is that machine I had in the emergency department? I want this at home. It was a life saver."
– Carrie Ludwig Director of Respiratory Therapy

Invest In Success

For Carrie and Mary Washington Hospital, their adoption of the Volara System as an important component of their OLE therapy delivery has definitely been worth the investment. "There are savings to be had within the healthcare system," she says. "I would encourage any manager or director to leverage the data out there. Make sure you're connecting it to your organizational goals. Tie it to showing improved outcomes from other facilities and say, 'This is what the Volara System could do here.' For us, it was all about COPD readmission. I was able to tie this project into that initiative and get it through."

For more information, contact your Baxter Sales Representative, call us at 1-800-426-4224 or email us at cfs_customer_service@baxter.com.

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particles with an aerodynamic diameter of < 1 µm (PM1) significantly increasing the number of hospital admissions related to respiratory diseases. A study published in the journal *Respirology* examined 408,658 patients from Guangdong Province, China, who were hospitalized for respiratory conditions between January 2016 and December 2019, highlighting the link between PM1 exposure and respiratory health risks. "Numerous epidemiological studies have shown that exposure to fine particulate matter (PM2.5) is closely associated with several diseases such as chronic obstructive pulmonary disease (COPD), pneumonia, and asthma," explained the study's authors, led by Chenghui Zhong, from Guangzhou Medical University in Guangzhou, China. The research team noted that smaller particulate matter, such as PM1, is considered more toxic than PM2.5, due to its ability to carry toxic carcinogens and settle deeper in the respiratory system. "The acute effects of pollution from chest dust (PM10) or fine dust (PM2.5) pollutants regulated by European directives and described by the World Health Organization (WHO) guidelines on hospital admissions for respiratory diseases have been well documented in the scientific literature for decades," Giovanni Viegi, MD, PhD, past president of the European Respiratory Society (ERS), said. Viegi, a senior research associate at the National Research Council's Institute of Clinical Physiology and Institute of Information Technology, was awarded the ERS Life Achievement in Epidemiology and Environment in 2024. He is also active in national pneumology and allergology societies, including the Italian Society of Pneumology. with a 1.39%, 1.97%, and 1.69% increase in odds of hospitalizations for total respiratory diseases, COPD, and pneumonia, respectively, with older patients (over 75

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Environmental Benefits of Bedside Ionic Nitric Oxide Generation

David Webster and Mark Rimkus RRT, PEng

Abstract

Nitric oxide (NO) has been recognized for its therapeutic potential, particularly in respiratory care for conditions such as pulmonary hypertension and neonatal asphyxia. Traditionally, NO is generated industrially, stored in high-pressure cylinders, and transported to healthcare settings. This process, while effective, poses environmental challenges related to production, transportation, and storage hazards. Recent advancements in technology have enabled the bedside generation of inhaled NO using ionic chambers, which extract nitrogen from room air. This paper explores the environmental benefits associated with bedside generation of inhaled nitric oxide over traditional methods.

Introduction

Nitric oxide plays a critical role in various physiological processes, and its inhalation has emerged as a crucial therapeutic intervention in clinical settings. However, the methods of NO generation and delivery can significantly influence environmental sustainability. This paper aims to highlight the environmental impact of traditional high-pressure storage systems compared to bedside generation technologies utilizing ionic chambers.

Traditional Nitric Oxide Generation

Industrial Generation

Nitrous oxide is produced commercially by heating ammonium nitrate to a temperature of 245-270°C. This process creates several compounds, including nitric oxide, ammonia nitrogen, nitrogen and nitric acid which contribute to the Earth's greenhouse gas burden. Additionally, the transport of high-pressure cylinders requires extensive energy, resulting in a carbon footprint associated with logistics and transportation. Finally, the disposal of high-pressure tanks can have significant environmental impacts, including gas emissions, safety hazards, material waste, and chemical contamination.

High-Pressure Cylinder Storage

Storing NO in high-pressure cylinders presents environmental risks such as potential leaks or explosions, which can lead to air pollution and other hazardous situations. The disposal of these cylinders also poses challenges, where improper handling can introduce toxic materials into the environment.

David Webster is the Chief Commercial Officer at Beyond Air Inc.
900 Stewart Ave, Suite 301, Garden City, NY 11530.
Email: DWebster@beyondair.net
Mark Rimkus RRT, PEng is the VP Clinical Affairs at Beyond Air Inc.
Email: MRimkus@beyondair.net

Bedside Generation of Nitric Oxide With Ionic Chambers

Process Overview

Ionic chambers generate NO by extracting nitrogen from ambient air and utilizing electrochemical processes. This innovative technology not only produces nitric oxide on-demand at the bedside but also eliminates the need for bulky storage tanks.

Environmental Advantages

- **Reduction in Carbon Footprint:** By generating nitric oxide from ambient air, bedside systems significantly reduce the reliance on fossil fuels for both production and transportation purposes, thereby lowering CO2 emissions associated with traditional methods.
- **Elimination of High-Pressure Tank Manufacturing:** The environmental impact of manufacturing high-pressure cylinders, typically used for storing gases like oxygen and nitrogen, involves various stages, from raw material extraction to production processes, and end-of-life disposal. While high-pressure cylinder manufacturing is essential for various industries, its environmental impact can be substantial, efforts towards eliminating tanks where possible are crucial for mitigating its effects.
- **Minimized Transportation Needs:** The implementation of bedside ionic generation alleviates the need for frequent transportation of high-pressure cylinders, reducing logistics emissions and fostering a more efficient use of healthcare resources.
- **Lower Risk of Environmental Hazard:** The elimination of high-pressure storage reduces risks associated with leaks and bursts, minimizing potential contamination of hospital environments and surrounding areas. In cases of fire, high pressure cylinders become very dangerous to hospital staff and firefighters, irrespective of cylinder contents.
- **Sustainability:** Utilizing room air for NO generation aligns with sustainability principles, as it leverages readily available resources, leading to a reduction in resource depletion associated with traditional manufacturing processes.

Conclusion

The shift from traditional industrial generation of nitric oxide to bedside generation using ionic chambers offer significant environmental benefits. The reduction in fossil fuel dependence, lower transportation emissions, decreased risk of hazards, and enhanced sustainability underscore the potential of this technology to promote a greener healthcare paradigm. As the medical community continues to prioritize environmentally friendly practices, the adoption of bedside nitric oxide generation could play a pivotal role in advancing public health while respecting ecological health.

Early Tracheostomy for the Prevention of VAP Evidence and Management

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. The webinar adapted below was presented by Lexie Caraway and Gail Drescher of Clay County Hospital in Flora, Illinois.

Tracy Cook: Hello, everyone, and welcome to our webinar. My name is Tracy Cook with Saxe Healthcare Communications, and I'd like to show our audience how you can send in your questions throughout the webinar. A speaker will try and answer as many as possible at the end of the presentation. Please type your questions into the questions box.

You can also download today's handout from the handout section of the GoToWebinar control panel. I would like to introduce our moderator, Lexie Caraway. Lexie is currently the cardiopulmonary manager at Clay County Hospital in Flora, Illinois, and a senior patient trainer for Baxter.

Lexie is a member of the Illinois Society for Respiratory Care Board of Directors, currently serving as delegate and as Illinois PACT co-chair. Lexie has published several abstracts for the AARC Open Forum, including a study titled Telemedicine: Improving Quality Metrics in a Rural Community Hospital. She has presented at several state and national respiratory care conferences. Lexie, welcome.

Lexie Caraway: Thank you, Tracy, for that kind introduction. The title of our webinar today is Early Tracheostomy for the Prevention of VAP: Evidence and Management. Speaking on this very timely topic, is my colleague and one of the experts on the topic, Gail Drescher. Gail is currently a science writer at International Consulting Firm, and the technical editor for the American Association of Respiratory Care Journal.

Additionally, Gail is a clinical specialist at Washington Hospital Center, Washington, DC, where she is involved with research, program development, and process improvement. She has published extensively in several peer-reviewed journals, and has lectured frequently at regional and national conferences.

Recently, Gail has been awarded the Excellence in Respiratory Care Award from the Maryland/DC Society for Respiratory Care, and the Charles W. Serby COPD Research Fellowship Award from the American Respiratory Care Foundation. The speaker has disclosed no financial relationships associated with this presentation.

This activity has been approved for one contact hour of continuing education for nurses and respiratory therapists.

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

At the end of this webinar, you can obtain those continuing education credits. The URL will be provided at the conclusion of the webinar. Accreditation statements are below.

This activity is supported by an education grant from Dale Medical Products, Inc. And now I will turn this presentation over to my friend and colleague, Gail Drescher.

Gail Drescher: Thank you very much, Lexie, I appreciate your introduction. And yes, my name is Gail Drescher. I'm going to be talking to you today about early tracheostomy for the prevention of ventilator-associated pneumonia or VAP. Today our learning objectives are to define and describe ventilator-associated events and pneumonia.

To describe the evidence from the new updated 2022 guidelines for the prevention of VAP, including the additional approach of early tracheostomy. Discuss factors influencing the placement of an early tracheostomy. And then describe bedside management of the trach such as trach care, fixation, health care-associated pressure injuries or HAPIs. And then handling dislodgement and obstruction of the tracheostomy.

So before we get started on those topics, it might be helpful to actually define what ventilator-associated events and ventilator-associated pneumonia is. The CDC created a surveillance and diagnostic criteria. They updated this in 2013, because there were issues with the accuracy and consistency of diagnosing ventilator-associated pneumonia.

And they created this hierarchy of ventilator-associated events, ventilator-associated complications, infection-related, ventilator-associated complications, and possible ventilator-associated pneumonia or VAP. And there are a variety of diagnostic and clinical criteria that go along with this. Typically, pneumonia is defined by clinical, radiographic and microbiological criteria.

Hopefully, there is microbiologic criteria because that can really guide antibiotic management, as well as isolation precautions, but these are often not sensitive or specific. And for a test or set of criteria to be sensitive, you want it to diagnose people that actually have it, so you want to rule those people in.

But you also want to be able to rule out people that don't have a specific disease, in this case pneumonia, and that is known as specificity. So typically, the diagnosis of VAP has been subjective

and so the diagnosis variable. So again, the CDC developed these very specific criteria for ventilator-associated events.

The panel to your left, infection-related, ventilator-associated conditions, and ventilator-associated pneumonia. If we go to the far left, ventilator-associated conditions. That's typically going to be diagnosed by an increase in the need for PEEP or FiO2, meaning that oxygenation has worsened after the patient has been on the ventilator for at least two days.

So day one being intubation, and then the first eligible day to diagnosis would be day three. And then an infection-related, ventilator-associated complication, the patient has signs of inflammation. They either have temperature irregularities or irregularities in their white blood cells that you can see here, and they have been on an antibiotic for equal to or greater than four days.

When they meet concurrent criteria for a possible infection, only one criterion is necessary. So they've done a sputum culture, they did a BAL. They had a tracheal aspirate that showed some type of organism. If the patient has purulent secretions and an organism was found, then they can proceed with the diagnosis of ventilator-associated pneumonia, again, from some type of microbiologic confirmation of VAP.

And typically, the CDC is going to look at these ventilator-associated events in VAP, they're going to look at it and measure it based on total vent days. So whatever the event is over total vent days, and that's often how it's reported. There are quite a few adverse events that are associated with ventilator-associated events, including prolonged ventilation, prolonged ICU and hospital length of stay.

More use of antimicrobials and also the potential for development of resistance, and then increased mortality with some studies showing up to an increase in mortality of 50%. So the scope of the problem is quite large. In a variety of literature, ventilator-associated events and ventilator-associated pneumonia were reported to be between 5% to 10%.

But keep in mind that these studies are quite old, anywhere between 2012 to 2017. Usually, we like more recent data like within the last five years, but that's going to be a little bit difficult simply because of the pandemic. And that pandemic could have influenced the development and the rates of these relative to what was going on with patients prior to the pandemic.

So not surprisingly, we saw a decrease between 2021 and 2022 in the rates of ventilator-associated events both in ICU patients and non-ICU patients. Just keeping in mind that ventilator-associated events are not necessarily ventilator-associated pneumonia, but other literature has shown that ventilator-associated pneumonia can be upwards of 40%.

I know in my institution, it varies widely by month, and this is percent of patients. This isn't by ventilator days. This is a percent of patients developing it. And when we looked at that recently using ICD-10 codes, one month we found patients a rate of up to 65% of our patients, but it varied greatly from, say, 25% to 35%, all the way up to 65% of our patients.

But interestingly enough, our hospital is not tracking it, nor are any of the hospitals within the MedStar Health System. In terms of mortality, VAP is a major cause of mortality within the hospital and mortality secondary to a nosocomial infection. I think the one diagnosis that might beat it is CLABSI, so a central line bloodstream infection might top a ventilator-associated pneumonia.

Ventilated patients are going to be three to 10 times more likely to develop a healthcare-acquired pneumonia compared to our non-vented patients. And again, with pretty high mortality rates, and really the significant clinical outcomes are what we're looking at. And not surprisingly, it increases ICU length of stay and increases costs.

And it can increase cost between $35,000 to $40,000 for a patient, which is very significant to a hospital's bottom line. There are a variety of risk factors for developing VAP that have been identified in the literature, sedatives. Sedatives often increase the length of stay on the ventilator, as do opioids. Fluid balance. A positive fluid balance can create a favorable environment for these bugs to grow, but also it can inhibit weaning.

Blood transfusions also can relate to the functioning of the immune system, development of an inflammatory response, as well as fluid overload in some cases. For oral care, which allows the proliferation of potentially pathogenic microorganisms. Stress ulcer prophylaxis, which reduces gastric pH, which again, may allow the proliferation of microorganisms.

Patient transport, which can jiggle that ET tube, dislodge that ET tube, create that opportunity for aspiration and leak. Reintubation, which is associated with much higher VAP rates, and then neuromuscular blocking agents, which can impair mucociliary clearance. There are some bundled therapies that have been shown to be protective for VAP.

Not surprisingly, minimizing sedation, having those spontaneous awakenings and spontaneous breathing trials. Early mobility for patient strength, and then a conservative fluid management, either they're euvolemic or net negative. We're going to talk quickly about the strategies to prevent ventilator-associated pneumonia in acute care, those updated 2022 guidelines updated from 2014. This document was sponsored by the Society for Healthcare Epidemiology.

But it was a collaborative effort with the Infectious Diseases Society of America, the American Hospital Association, and the Association for Professionals in Infection Control and Epidemiology. So again, it was updated from 2014, with practical recommendations for acute-care hospitals to prioritize or implement to prevent VAP, as well as ventilator-associated events and non-ventilator healthcare-acquired pneumonia.

So in figuring out, well, what should be the recommendations that they were going to put into this document? They looked at not only did these strategies reduce VAP, but they reduced VAP and were also associated with clinically significant outcomes to our patients, such as duration of ventilation, length of stay, mortality, ventilator-associated events and antibiotic use.

And the recommendations were categorized as essential practices or additional approaches. So essential practices, they want hospitals or a healthcare organization to implement. Additional approaches were defined as, I guess, what's the word that I want? They're defined as tasks that you can do within the

hospital, if the essential practices are insufficient to prevent these healthcare-associated infections.

Some of the essential practices per the guidelines, were the use of high-flow nasal cannula or non-invasive ventilation. So we know these modes can prevent intubation, but they can also prevent reintubation as well. This is the quality of evidence as being high. And I will tell you, almost every major medical society is promoting the use of post-extubation high-flow nasal cannula or non-invasive ventilation for their patients, even in relatively low-risk patients.

The European Society of Intensive Medicine, the American College of Physicians, the European Respiratory Society, and the American Association of Respiratory Care, all advocate the use of high-flow nasal cannula or non-invasive ventilation post-extubation. Not surprisingly sedation, to minimize, use multimodal, which basically would reduce the dose of some of these sedatives that have been associated with failed extubation, as well as sedation protocols.

Vent liberation or wean protocols, again, also not surprising, because they can facilitate the patient getting off the ventilator quickly. Early mobilization for strength, elevating the head of the bed. So even though the quality of that evidence is low, it has been associated with significant, important outcomes for the patient by reducing aspiration of those oropharyngeal secretions. Oral care to reduce bacteria within the mouth.

Enteral nutrition to make sure that our GI tract is functioning as optimally as possible. And maintaining the ventilator circuits, meaning we don't break the circuit if at all possible, and we don't routinely change that ventilator circuit. There are some additional approaches per the guidelines. So again, if these essential practices are not working, then these additional approaches should be used.

So selective decontamination of the oropharynx and GI tract, and they might use some antibiotics to get rid of some potential pathogenic organisms. ET tubes with subglottic secretion drainage, that was recently reclassified into an additional approach out of essential approaches. Post-pyloric feeding tube placement in patients with gastric feeding. So the pyloric valve is at the bottom of the stomach, and so that tube would go right into the duodenum or the jejunum.

And then last but not least, consideration of early tracheostomy. So one of the reasons that that was not put in as an essential practice, was because although it reduced VAP rate, the data was insufficient regarding duration of ventilation and they found no difference in mortality. So remember, we don't just want to reduce VAP rates, but we want that reduction in VAP rates to be associated with something that's really meaningful to our patients.

Now, let's look at tracheostomy for VAP prevention and examine the evidence that came from those guidelines. Now, early versus late tracheostomy, typically tracheostomy is not really considered related to VAP prevention. Usually, providers are trying to think, "Well, did the patient fail a wean trial? Did they require reintubation?"

Is there some upper airway, anatomical abnormality that would say, "Oh, we're not going to be able to safely extubate this patient, we're going to have to trach this patient"? Also, the definitions of early and late tracheostomy frequently vary, and it can vary by region, by institution, by the type of provider or patient population.

And then even when you're trying to evaluate the studies to see if it's applicable to your patient population or facility, there may be differences in how early versus late tracheostomy is defined. Is early tracheostomy six to eight days? Less than seven days? Less than 10 days? So there's just a variety of definitions that are used, that make interpreting the literature difficult in terms of what our best practice should be.

Now, early on in 2010, there was a randomized controlled trial in 12 ICUs, and we know randomized controlled trials are kind of the gold standard of our data and its multicenter. They looked at early tracheostomy and they defined it as six to eight days, versus late tracheostomy, which was defined as 13 to 15 days. And they found no significant difference in the development of that.

And if we come over here to our right, we have something called a Kaplan-Meier curve. And basically, a Kaplan-Meier curve looks at an outcome over time. And in these 419 patients, so about 209 in one group and 210 in another. Early tracheostomy was not associated with a reduction in the rates of ventilator-associated pneumonia, even though it did reduce the duration of invasive mechanical ventilation.

But recently in 2021, published in JAMA, there was a meta-analysis of 17 randomized controlled trials with over 3,100 patients. The comparator was early tracheostomy equal to or less than seven days versus late tracheostomy. And that was defined as either no trach, so it just remained intubated, or that tracheostomy was later after seven day., and their primary outcomes were duration of ventilation, as well as VAP.

And just a quick refresher on what a meta-analysis is. It's just a statistical method of combining a lot of studies that have similar outcomes and similar methods, to increase the sample size to increase our power in determining effect size. So how much of an effect would an early tracheostomy have on reducing our VAP rates? That's what that means.

And these are the results. And what you're seeing here, over to your left, this graph, this is known as a forest plot. So over on your left side favors early tracheostomy, over on your right side favors late tracheostomy. Each one of these lines, these horizontal lines represents a study, and that box represents the sample size. Usually, the larger the box, the greater the sample size in the study and vice versa.

A small box typically relates to a smaller study population. And as each of these lines crosses one, the line of null effect, it means that there is no difference between early versus late in the prevention of VAP. In this case, in looking at all the data and combining all of these studies, they found that it reduced VAP by 40%. And what you see here, CI, is confidence intervals, 95% confidence intervals.

And basically, what that means is we're 95% sure that the true value of how much it reduced ventilator-associated pneumonia, was anywhere between 65% and 1%. However, there was no difference in the duration of mechanical ventilation. And if you

come over to our forest plot on the right-hand side, you can see that big diamond at the very bottom. That big diamond crosses zero or that line of null effect, and there was no difference.

However, there was a difference in ventilator-free days. So what's the difference between ventilator-free days and the duration of invasive mechanical ventilation? Well, the difference is ventilator-free days takes into account mortality in that calculation. And at the bottom, you see an OR of 1.74. So it was the mean difference of 1.74 days of ventilator-free days with the actual rate, our 95% confidence intervals, being 0.48 days to actually three days.

So we can see from some of this data, that the benefits of tracheostomy are that it can reduce VAP and can increase the amount of ventilator-free days, but it does other things and it improves patient comfort and mobilization. It can reduce sedation needs, improve oral hygiene. It reduces airflow resistance because we no longer have all that dead space associated with that ET tube.

It can reduce work of breathing because now we have a removable inner cannula, so that biofilm that may build up, we can change that inner cannula daily. So again, all of these things lead to reduction in VAP. But how do these important clinical outcomes with a trach influence the development of VAP? Let's talk just a little bit more about that.

Obviously, by increasing ventilator-free days, the longer a patient is ventilated, the more they're going to be at risk of developing VAP because they're in the ICU longer. So they're exposed to all the potential germs that are in the ICU, despite our best efforts with universal and precise isolation precaution. The length of time they're intubated with that ET tube with biofilm formation and aspiration.

Typically, when you have an ET tube, your patient is going to require to be sedated. There may be multiple ventilation episodes and the patient has to be reintubated. Maintenance of the ventilator circuit for a prolonged period of time becomes difficult, and the humidification method. We switch from HME to active humidity to make sure we're keeping those secretions moving.

The other thing to keep in mind is about one-third of patients are going to be trached following a failed extubation. And I hear over and over again from providers, "We're just going to try to extubate that patient. We're just going to give it a shot." So let's look at what happens when a patient is trached following reintubation. So this was a prospective, multicenter observational study of about 180 patients.

The primary outcome was length of stay in the ICU, as well as the mortality. So trached patients tended to be in the ICU longer, but there is no difference in mortality and you can see that at the very bottom of this table. But what they found, interestingly enough, is they found that there were lower rates of ventilator-associated pneumonia in patients after they were reintubated, if they were trached versus they were not trached.

And you can see that was a significant P-value, although they did not give an effect size to determine just how significant that difference was. In terms of extubation, again, oftentimes doctors will attempt a trial. They just want to give it a shot and we'll just reintubate right away if the patient doesn't tolerate it, but that can be risky and this meta-analysis proves it.

41 studies, close to 30,000 patients and the risk of VAP with reintubation. The odds' ratio, so they were over 7.5 times more likely to develop VAP if they were reintubated, with the true value lying somewhere, 95% sure, between 3.6 and 15.8 times more likely to develop VAP. And you can see over here our forest plot to our right, we have general population at the top, and then the cardiac surgery population pulled out at the bottom.

And patients who were never reintubated, regardless of length of time on the ventilator, had much lower rates of developing ventilator-associated pneumonia. And maybe that's because it was an emergent reintubation where sterile technique wasn't necessarily used, or maybe the patient aspirated. Or there's a variety of reasons why reintubation is risky, but just the act of it itself for a second time, can lay the patient open to infection.

Sedation and ventilator-associated pneumonia. So we know that maintenance of sedation without sedation vacations, can increase the rate of ventilator-associated pneumonia, and this study showed that. And what they did was they had daily sedation vacations versus routine sedation vacations, which didn't necessarily coincide with waking the patient up on a daily basis.

And what you're seeing over here, is information from the study group where there was daily sedation vacation versus the control group. And they used the modified Clinical Pulmonary Infection Score to diagnose pneumonia. And on each of these days, you can see that that score was lower in patients that had daily sedation vacations versus more routine sedation vacations.

Actually, by day three, I believe the pneumonia rates were zero in the study group, 15% in the control group. And then it was 50% more by day five in the control group versus the study group in terms of the development of VAP. So continuous sedation, what many of our patients are on, are associated with longer duration of ventilation.

They may also be associated with development of delirium, particularly certain types of sedation including benzodiazepines. And again, when a patient is sedated, that can influence their airway protection. So reducing that sedation can reduce the duration in mechanical ventilation as well as VAP. Now, when a patient is trached, it typically reduces their sedation needs.

And oftentimes, the patient's on no sedation in my hospital, because that airway is now no longer going through the oropharynx. So it improves patient comfort, it can improve their autonomy and their mental status, again, because we aren't using that sedation, that continuous analgesia and sedation. Propofol is probably the most common one.

If we can't manage them on propofol, more frequently, we're adding DEX to it, which doesn't carry the same risks as the benzodiazepines such as midazolam or the addition of an opiate. So all of these drugs, propofol, midazolam and fentanyl, they're all lipophilic. And particularly in our obese patients, they're going to hide out in that fatty tissue.

And then even though you stop the continuous infusion, that drug is going to be continuously released to the patient. Now,

if we come over here and we look at these graphs, what you're seeing on the Y-axis here are morphine milligram equivalents. So that's just the potency of an opiate relative to morphine. And if you come down to the Y-axis, you see pre-tracheostomy and then you see post.

And looking at the graph on the left-hand side, you can see a precipitous drop after the tracheostomy in MMEs. And then over to the right, they've actually broken this down by unit, medical intensive care unit, cardiovascular intensive care unit, surgical intensive care unit. In all units, morphine milligram equivalents dropped after tracheostomy.

It was most pronounced however, in MICU patients. And perhaps that's because they tended to be on higher doses to begin with, but regardless, there was a significant reduction in morphine milligram equivalents. The other issue with the endotracheal tube is microaspiration around the cuff. So these pathogenic microorganisms rapidly colonize the oropharyngeal area that are mucosal surfaces, the sinuses, the stomachs within 24 hours.

And we also know that that ET tube disrupts normal anatomy and normal airway defense mechanisms. There may be an accumulation of oropharyngeal secretions above the cuff. We do our best to suction out that oral airway. We try to get that Yankauer back there as far as possible without completely gagging our patient, but still the patient may aspirate around the cuff.

So we know that the cuff always has to be inflated during invasive ventilation on an ICU ventilator, it's going to start to auto-trigger if there is a significant amount of leak. But even if we've used minimal occlusive volume or we think we have a good seal, we've auscultated that return volumes are looking good, there may still be microaspiration around the folds in the cuff. This can also occur with a trach though.

And if you look at this picture over to our right and you're looking at the cuff here. You can see that the esophagus and trachea are anatomically back to back, if that cuff is inflated and it can impinge on the anterior portion of the esophagus and lead to a swallow disorder. But tracheostomies in general can desensitize the larynx, they can impede the movement of the larynx, which can alter our normal swallow mechanism.

So if we can reduce the duration of invasive ventilation, maybe then we can deflate the cuff, but also there are some non-ICU ventilators that can be adjusted like it'll tolerate a cuff leak. I'm thinking of the [inaudible 00:31:15], which I think is going away pretty soon. But you can deflate the cuff, increase the tidal volume to compensate for that deflated cuff to allow the patient to speak.

Either we'll do a partial cuff deflation or a full-cuff deflation with use of the Passy Muir Valve, but in theory, that can put the patient at risk for aspiration when you do that. And just the act of deflating the cuff, get ready to suction. You should have that suction catheter down there already when you're deflating that cuff, to catch all those secretions that are going to rain down when you do it.

Typically, we are maintaining that cuff pressure between 20 and 30, so tracheal capillary pressure is between 22 and 32. We try not to go over that and we're striking a balance between tissue ischemia, and then under inflating the cuff, which allows even more frank aspiration with the patient. But even the act of monitoring cuff pressure, once you attach that cuff manometer, it's going to pull a volume of air out.

And if you used minimal occlusive volume, you may no longer be safe in adequately sealing off that trachea as best as you can. So even that carries some risk, but of course, you want to monitor it because you don't want to be too low and you don't want to be too high. And there are even some ventilators that allow continuous cuff monitoring and titration of cuff pressure, which has been shown to reduce VAP.

The other issues with endotracheal tubes is the formation of biofilm, which literally occurs within hours. In this prospective, observational study of 81 subjects, their primary outcome was a microbiological assessment, as well as scanning with electron microscopy, to determine the diameter of the tube as well. So they looked at these endotracheal tubes from these 81 subjects.

Biofilm was present in 95% of these subjects. Microorganisms were found in 56% of those endotracheal tube aspirates, that's what ETA is. And Pseudomonas was the most frequent in both the endotracheal tube aspirates as well as the biofilm. And VAP bacteria was found in the biofilm in about 50% of cases. And it is associated not only with treatment resistance, but it's also associated with a recurrence of that ventilator-associated pneumonia.

And what you're seeing over here, was that electron microscopy and you can see the biofilm and just look at it. If you look at it, you can see it forming a matrix. And that matrix really firms it up and allows it to adhere to the endotracheal tube, which is quite significant. So biofilm, as well as micro-aspiration, those are two of the big ones in terms of causative factors related to VAP.

But biofilm doesn't just cause VAP and lead to that, it can also reduce the diameter of our endotracheal tube, which is a problem particularly related to weaning. And this was 24 critically ill, mechanically ventilated subjects. They looked at the diameter of the ET tube in this graph that you're seeing up here on the Y-axis, is the area of the ET tube, 7.5 ET tube that they used.

And the Y-axis is the distance from the opening of the endotracheal tube or the adapter. The black line is a clean tube, and the other green, red and blue lines are measurements at different points in time after the patient was intubated. And you can see over time, that the diameter of that endotracheal tube became less and less.

And in some cases, it can become significantly less, which can influence work of breathing and resistance for our patient. But one of the things that this study emphasized, that this biofilm was present almost immediately within hours and there were many pathogenic organisms, and that's what you're seeing in the table below, both gram-positive and gram-negative.

And some of the big ones that we don't like to see, like staph aureus, like Pseudomonas, Klebsiella, Enterobacter, some of the more common ones that we might see in a patient's chart, if they have been diagnosed with possible ventilator-associated pneumonia. Biofilm has been associated with antibiotic resistance, as we talked about earlier.

So our endotracheal tubes are going to reduce mucociliary clearance, disrupt our normal cough mechanism, because no longer can the patient close off their airway and perform a Valsalva maneuver. That can promote the accumulation of secretions, which is the perfect environment. And if you look at this picture over here, the bacteria adhere to the ET tube's surface and they colonize it.

They multiply it and they form that matrix that we saw in that previous picture, but after they form, they can be released down into that lower airway. And if you think about we're suctioning that patient, we're instilling them maybe with normal saline. There are a variety of things that can break off that biofilm, and send it right down into the lower airway and then the cycle begins all over again.

Now, even though we say, "Well, there's a lot of bad things associated with the endotracheal tube. So when it becomes clear maybe that the patient isn't going to come off the ventilator anytime soon, why don't we just go ahead and trach?" Well, typically the doctor is trying to balance the risks of a major surgery like that, with what's going on with the patient like the duration of their mechanical ventilation.

How long are they predicted to stay in the ICU and potential mortality? A lot of times the patient isn't stable right away in order to undergo a trach, even if you're quite sure that the patient is going to remain on this ventilator for quite some time. There's also diverse patient populations where it might be considered more doable or the right thing, particularly in patients that are encephalopathic.

There is a Stroke-Related Early Tracheostomy score. And generally the scores greater than 10 predict, "Well, yeah, this patient probably should undergo early tracheostomy. And then we can reduce some meaningful outcomes for the patient, including duration of ventilation, duration in the ICU, and then hospital length of stay as well." But oftentimes, there's an uncertain patient trajectory.

Maybe the patient appears to be improving, so do we really want to trach that patient? And then other times there's family preferences. There have been times where the family has said no, they don't want that patient to be trached. Or the provider may think this prognosis doesn't look good, and they're talking to the family maybe about do they want to withdraw care on this patient or not escalate care on this patient?

And the patient declines. And then last but not least, transfer of the patient, transfer of the patient within the hospital from the ICU to general care, that's a whole different nursing responsibility. As well as long-term care placement can be more difficult for a trached patient or a vent patient requiring much greater skilled nursing.

We're going to move on now to bedside tracheostomy management. How we manage the trach, in some cases depends on, well, what type of trach is it? Now there's some standard things that we're always going to do, but there are differences in trachs, differences in sizes, whether that trach is cuffed. Typically, in acute care we're using high-volume, low-pressure cuffs.

But people come in, patients come into our hospital with tight-to-shaft, which is a whole different thing. That tight-to-shaft is water-filled, you can't measure cuff pressure. If you are going to continuously inflate the cuff, which it's not supposed to be done, you can have really high-tracheal wall pressures upward of 80 to 100 centimeters of water, when remember, we're shooting for a cuff pressure of 20 to 30.

There may be a tapered cuff because that has been associated with lower cuff pressures against the tracheal wall. A foam cuff that automatically inflates when the pilot balloon is opened to the atmosphere. Cuffless, no cuff versus, again, cuffed. Jackson Silver is a typical example. The outer cannula, unfenestrated versus fenestrated, and use of an inner cannula, disposable or nondisposable.

The Shiley and the Portex is the most common one. This is an example of a fenestrated tube that you're seeing right here. I don't see these coming in very much. I used to work with these quite a lot. And what I found over time in many of these patients, was that granuloma tissue would grow right into that fenestration.

Now that fenestration is there because if you remove the inner cannula and there's no cuff or you deflate the cuff, it's supposed to facilitate airflow up through the upper airway, which improves the patient being able to speak. What you see below here is the foam cuff, there's the tight-to-shaft cuff here, and then the Shiley metal as well. So tracheostomy care, new versus established.

A lot of times what we're doing is very similar. Whether the patient is fresh post-op or whether they have an established trach, on both, you're going to do a stoma site assessment and you're going to clean it. There may be maintenance of STAY sutures, so what are STAY sutures? They're placed around the tracheal rings or between the skin in a lower trachea.

And they can be used to literally pull the trachea up to make that opening wider. Now our surgeons use them. Our ENT does not use them. We will clean the stoma site, change the gauze. You might need more frequent gauze changing in a fresh trach. Tracheal fixation, some doctors, and it's more rare that I see that the flange is actually sutured to the stoma site, but that has not been shown to reduce early, post-op dislodgement.

Changing the inner cannula quite frequently in order to prevent, whatever your hospital policy, in order to prevent plugging or inspissation of secretions. Whether the cuff should be inflated or deflated, that should be up to the provider. And based on whether the patient is at risk for aspiration and has passed a swallow test and been evaluated by speech-language pathology. Suctioning should always be PRN.

I often hear the question, "Do we put saline down the trach or the artificial airway in general?" And there's nearly no good literature that says that we should be consistently doing it, or that it works at all or that we even get all of the saline back. Now I can tell you anecdotally, after 35 years of experience, that I can have a patient with very thick secretions and I put a little saline down and it just all tends to start bubbling up.

So that's anecdotal, but I don't know that there are studies really out there to support it. And then I will also say that the acquisition and maintenance of equipment is very important to have like a trach the same size or a size lower, in case the trach

does come out. And to have that equipment very visible where everybody can see it.

Because in an emergency, it's going to be a hot mess and you need to be able to rapidly access it and everybody needs to know where that is. But we want to provide trach care because it does prevent irritation, reduces that infection risk. The buildup of dried secretions, which can block the trach and skin irritation, which of course, may lead to a pressure ulcer.

Now one of the issues you'll find, is it's more difficult to manage a trach in obese patients. The operative technique tends to be more difficult in these patients, and then making sure that these patients have the correct size tube. Sometimes they need an extra length tube to go through all of that adipose tissue. There can be difficulty accessing and assessing the airway or even assessing the stoma.

And oftentimes, these patients are at greater risk of skin breakdown because of that tissue that falls around the tracheostomy, just makes it very difficult to keep the area dry. And we know moisture is associated with more friction, it's also associated with microorganisms as well. So what I just pulled up here is a picture of an extended length tracheostomy tube, of which there are different brands that have that.

Now, do we use an inline suction kit? If we possibly can, on ventilator patients, we can, versus just an open suction kit. Now the AARC recommends reducing the number of times the ventilator circuit is broken. Typically, that's related to circuit changes and not just disconnecting the ventilator, and the maintenance of oxygenation and ventilation or PEEP.

The literature has been mixed about whether closed systems actually reduce the incidence of VAP, which some people may find surprising. But you can see in this meta-analysis here done in 2015, using a closed system did reduce the incidence of VAP. But ET tube cleaning devices like the endOclear, like the CAM Rescue cath, surprisingly have not been associated with a reduction of VAP.

And maybe when you're cleaning it out, you're just releasing that matrix, so to speak, but it hasn't been associated with increase in VAP, I will say that much. To inflate or not to deflate? Obviously, in a spontaneously breathing patient that's not an aspiration risk, cleared by speech-language pathology, you probably want to do it because it improves swallow.

And again, sometimes we will deflate the cuff and increase the tidal volume to allow a patient to speak. Cuff inflation will protect against some aspiration, but again, as we discussed before, it can also increase the aspiration risk by impinging on that anterior portion of the esophagus. There are different tracheostomy fixation methods post-operatively.

There may be suturing, STAY sutures or lateral flange sutures. Cloth ties are often used initially, as well as trach tube holders. Cloth ties, if they can be changed quickly, it's probably better, because there's not a really good distribution of that pressure to the patient. And then post-tract maturation, of course, we recommend trach tube holders.

Interestingly enough, suturing, whether it's STAY sutures or flange sutures, have not been associated with reduction in early, post-operative dislodgement. And second from the bottom, you can see that shown here. But in some cases, it's been associated with an adverse event including broken tracheal rings when those STAY sutures are used. There are some risk factors for dislodgement, loosened straps.

You should usually have two fingers under it tight or one. Excuse me, one finger tight, two loose. Neck edema, the torque or traction on the trach. Excessive coughing, agitation or delirium frequently will put restraints on these patients, but I know they don't like to because we can't bring them to LTAC when they have restraints on them.

So typically, there needs to be a good reason for it and this would be one, or an inappropriately sized trach for morbid obesity or just patient anatomy in general. And what you're seeing here are a variety of extended length tracheostomies. Now, if a patient does become decannulated or the trach becomes dislodged, there's information that you need to gather immediately.

You need to assess does this airway need to be resecured immediately because this patient is in distress? Or they're desaturated, do they have a functional upper airway? So how am I going to oxygenate this patient, through the upper airway, or do I need to do it through the stoma? The type of tracheostomy, STAY sutures should not be cut, flange sutures should.

If it's a percutaneous tracheostomy, it will have a smaller stoma in tract, and it may take longer for that tract to mature. Typically, we say an immature tract is less than seven days and this is an emergency, we don't recommend a blind reinsertion of that trach because it may create a false passage for that patient. We have these signs that we put above the patient bed.

Because again, if you're having to gather information, you want to be able to know that quickly when something happens. So you want a sign that has a lot of white space that only gives necessary information, so that you can make rapid decisions at the bedside in terms of what to do for your patient. So whether it's an unstable or stable patient, you are going to call a Code Critical Airway and apply an oxygen source.

If the patient has their trach dislodged and they can't breathe around the tube after you've deflated the cuff, then you're going to have to remove that tracheostomy. Cut flange sutures, maintain STAY sutures, because remember, the STAY sutures can be pulled up to open up that tracheostomy stoma. If there's no resistance, 10 to 14 days, you can push that trach back in.

And then the other possibility is resecuring the airway through the oral route. And then in the meantime, if they have a functional upper airway, you can oxygenate through the upper airway in whatever fashion is necessary. Keeping in mind, if there's no functional upper airway, like the patient is a laryngectomy. Those are actually supposed to be some of the more safer airways, even if they're new, fresh laryngectomies.

Because they directly sew that trachea to the skin, so that it's very difficult to create a false tract. In a stable patient with no respiratory distress and a mature tract, you can attempt to push that tracheostomy back in. Or oxygenate the patient through the upper airway, if there is resistance and you find you can't push it in until a provider gets there.

For an obstructed tracheostomy, these are the things you want to do in very rapid succession. Remove or replace that inner cannula. Try to pass that suction catheter and deflate that cuff. So if you still can't bag valve mask, again, you're going to have to remove that tube, cut those flange sutures, and leave those STAY sutures. And then how it's done will depend on upper airway anatomy.

Sometimes if you can do a little bit of ventilation for the patient, they'll try to unblock the tube using a bougie. But again, in an immature tract, you just don't want to try blind reinsertion because it may create that false tract. In terms of bedside tracheostomy management, bundle care is recommended. And the American Association of Respiratory Care put out recent clinical practice guidelines for the management of adult patients with tracheostomy and acute care.

And they're saying that the bundle care does have the evidence to support improved, meaningful clinical outcomes. Meaning that you're increasing the rate of decannulation, reducing the rates of complications. So what would be included in a bundle? Like maybe a checklist where you round on patients to determine cuff status, to determine to look at the stoma site. You have a protocol for decannulation and so forth.

And just saying it's an interdisciplinary trach team. And in fact, speech-language pathology contacted me to say, "Let's start rounding on these trachs, because things were happening to these trached patients. We were having events with these trached patients of plugging or bleeding, or leaks around the cuff, and these were causing significant events for our patient."

So the goal was to prevent these significant events from happening with our patients. And then healthcare-associated pressure injuries and tracheostomy management, they are relatively rare in the study that you're seeing to your left. The only thing that was really associated with it, it wasn't service, it wasn't diagnosis. The only thing associated with it was length of stay. There are things that can be done to reduce the incidence of these.

The hydrophilic or hydrocolloid dressings, a use of a foam fixation device, neutral head position so that you minimize torque on that tracheostomy, and keeping that site clean and dry, particularly if it is a mature tract. Whereas you might want a little bit of moisture in a new post-surgical tracheostomy, you want to control the exudate by frequently changing that gauze when a patient is a fresh post-op.

After that, you want to keep that area clean and dry. So in summary, the guidelines, Strategies to Prevent Ventilator-Associated Pneumonia, updated in 2022, they recommend an early tracheostomy as an additional measure to prevent VAP. Early trach may reduce VAP by increasing ventilator-free days, reducing sedation and biofilm that forms on the ET tube, and improve oral hygiene.

Trach care should be performed daily, including cleaning and assessment of the stoma, and changing that inner cannula to reduce infection risk. Tracheostomy obstruction or dislodgement are an emergency situation. The response is going to depend on how old the trach is. And then tracheostomy-related HAPI events are rare, but they can occur. I think we had one in three years in our hospital, only one.

Fixation methods can address that, however, as can the use of skin barriers, including solid skin barriers such as pectin-based creams. So now I'm going to return everyone to our moderator, Lexie. It has been a pleasure to talk with everyone today. She has a little bit more information to provide and then I'm going to answer questions.

Lexie Caraway: Thank you, Gail, for a most informative session, I would like to inform our viewers how to obtain their CEs for this session. This activity has been approved for one contact hour. You can obtain those continuing education credits by logging on to www.saxetesting.com/p. You will need to register on the site and complete the evaluation form.

Upon successful submission, you will be able to print your certificate of completion. This activity is supported by an education grant from Dale Medical Products, Inc. An archive/on-demand version will be available on www.perspectivesinnursing.org. The on-demand version will be accredited for CEs. Okay. I have a couple questions for you, Gail, from the audience.

Our first question here today is from Anne. She asked, "When do you begin tracheostomy discussions with the families? And then this seems to be a barrier in many cases, and then also, who initiates that conversation?"

Gail Drescher: Typically, in my hospital, the providers. We're a teaching hospital, so it's usually going to be one of the residents who treats these patients. And typically, when the patient is stable enough to undergo the procedure, but it really varies by patient population, as well as by unit. They may not initiate it until the patient has failed extubation, or we've tried over and over again to wean this patient and we just can't.

So in order to facilitate weaning, they will tell the family, "Well, we think a tracheostomy might be able to achieve that." In other cases, the provider has had the conversation with the family and the family is declining it. Or the provider thinks, "Oh, this patient is going downhill. They're very elderly, their encephalopathic, their prognosis is poor," so we don't want to try to trach this patient.

We want to withdraw care, and the family's like, "No, no, no, no. We want you to do everything and everything is going to include that tracheostomy."

Lexie Caraway: Thank you. And along those same lines, what is your timeline for traching patients after a failed extubation trial?

Gail Drescher: So typically, they will start writing in the progress notes almost immediately that they want to try to trach this patient, if they think that that reintubation and the cause of that reintubation wasn't something that's going to lead to another prolonged bout of invasive mechanical ventilation. If they've done it because they just were just trying to wean that, "Let's just see if we can extubate this patient."

But it's an encephalopathic patient or there's something long-term that shows that this patient probably isn't going to be easily weaned, they'll start the conversation soon. But in terms of when they start documenting and when they start saying they're going to do the trach to when they actually trach the patient. Following reintubation, almost exclusively depends on patient stability.

Now sometimes I've seen them do it percutaneously at the bedside, because they just don't feel like the patient can be moved. But a lot of people don't like those percutaneous trachs because they are smaller, they have a smaller stoma. As I said before, it takes longer for that stoma to mature and so forth.

Lexie Caraway: This is a big question, but I feel it's really important, so I want to go ahead and see if we can squeeze it in here.

So this question is how do we know if it's a VAP versus another infection source? And how do we exactly test for that, is it the sputum? And then how do we know it's actually from the ventilator?

Gail Drescher: Well, the CDC criteria were developed to be very specific, just because of all those unknowns. Now, I can't say for sure that our providers are looking at that temperature at less than 36, greater than 38. White blood cells, less than 4,000 or greater than 12,000, along with antibiotic use and whether they've actually gotten that microbiologic culture.

Now, typically when they suspect VAP, they immediately get an ID consult, they get an infection control consult on these patients, so we do protected specimen brushes. Other hospitals do BALs with these patients or they take tracheal aspirates. But again, we're typically diagnosing our VAP through protected specimen brushing.

That's just what we do at our hospital. Other times if there's a bronch, they'll get a sample, or if they've done thoracotomy, they might get a sample of pleural fluid. So it's clinical signs, like I said, white blood cells, temperature. It's radiographic evidence that this patient has an infiltrate.

And then they try very hard to get these microbiologic specimens that are not contaminated that can show, "Aha, this is the organism." And if it's a bacteria, we're going to treat it. Oftentimes, they'll do broad and then they'll narrow it down once they figure out the offending organism.

Lexie Caraway: Thank you. And then we have time for one more question here. We've had a lot of really great questions from our audience.

So how long do you normally see physicians waiting to remove the sutures at your facilities, and who is removing those sutures?

Gail Drescher: Very good questions. This leads to a broader topic. Whoever places the trach, owns the trach, which is a problem. So typically, trachs are placed in our hospital either by ENT or by surgery. So surgery, they're the only people that use STAY sutures and very rarely do I see flange sutures. Once they feel that that stoma is mature, that tract is mature, they remove either the flange and/or the STAY sutures.

Now, just in terms of trach ownership, and I'm going to comment on that on this because I think it's so important. When we have patients that come in particularly with a trach and they haven't been an in-house trach, nobody wants to own them. ENT doesn't want to own them, surgery doesn't want to own them.

Let's say they've come in with a tight-to-shaft and I'm like, "But now they're on continuous mechanical ventilation. Somebody has to do something about this trach." Well, no one wants to own it, and the hospitalist punts it to pulmonary, pulmonary punts it to ENT. ENT says, "No, I didn't place this trach. I'm not going to do anything about it." It becomes a real issue.

But after gold surgery signs off, even if it's in an in-house trach, then what ENT says, "I didn't place that trach." So it becomes a real issue in terms of trach ownership and remediating issues when there is a trach. Now when we're calling a Code Critical Airway, ENT is going to come. Sometimes trauma surgery comes as well, and they have to do something then, but then it's too late.

We said all along, "The patient is having issues with their trach." It shouldn't have come to the point where we had to call a Code Critical Airway. And I've actually been-

Lexie Caraway: That's very common.

Gail Drescher: You know what I'm saying?

Lexie Caraway: I feel like that's a very common, across the United States, that's a very, very common problem.

Gail Drescher: And honestly, I was blasted when I never called the Code Critical Airway because technically, we still had the airway and they thought that I called it. I said, "Well, I didn't." And then the doctor that really called it hid, but suffice to say, we had been having trouble with this trach for days and no one would do anything about it.

And then I kept telling the doctor because I had manipulated the circuit and the trach just so to keep this patient ventilating because there was discussion of whether they were going to withdraw care, but they hadn't. So if they haven't withdrawn care, I'm legally obligated to continue to ventilate this patient. And the doctor came in, I said, "Don't touch that circuit."

Well, guess what he did? He touched that circuit and we could no longer ventilate the patient. He got scared, he called the Code Critical Airway and it became a whole thing. But that's just an example of what happens when there isn't ownership of this trach within the hospital.

Lexie Caraway: Thank you. Okay. Well, thank you everyone for attending this webinar. And I'm now going to turn the presentation over to Tracy for some concluding remarks.

Tracy Cook: Thank you, Lexie. And again, thank you, Gail, for such a great presentation. I'd like to thank everyone for attending this webinar. Immediately upon the conclusion of this webinar, you will be presented with an online survey. Please keep your web browser open and we appreciate your feedback.

In one hour following the conclusion of this webinar, you will receive an email with instructions in this link to obtain your CE credits. That's www.saxetesting.com/p. And again, we'd like to thank everyone for attending today's webinar, and we hope you have a great rest of your day. Thank you.

Gail Drescher: Thanks, everyone.

Here is a link to the webinar
https://www.perspectivesinnursing.org/early-trach

Clinical Effectiveness of High Frequency Chest Wall Oscillation (HFCWO) in a Bronchiectasis Population – A Case Series

George M Solomon, Julie Philley, Colin Swenson, Kathryn Vickers

Introduction

Bronchiectasis is a chronic progressive pulmonary condition, characterized by abnormally widened and thickened bronchi. The condition can affect one area of the lung or many sections of both lungs. Usually, bronchiectasis is caused by a repeated cycle of infection and inflammation resulting in ineffective mucociliary clearance. An impaired mucociliary escalator leads to mucostasis and bacterial colonization, resulting in recurrent exacerbations, further perpetuating the vicious cycle.[1] This can ultimately lead to an increase in pulmonary exacerbations and permanent loss of lung function over time.[2]

In healthy individuals, clearance of excess mucus from the respiratory tract is efficiently accomplished by normal mucociliary action and cough; however, congenital and/or environmental impairment of the normal mucociliary transport system, or hypersecretion of mucus in the respiratory epithelium, can result in the accumulation of mucus in the lungs which can cause severe comorbidities such as hypoxemia, chronic bronchitis and pneumonia.[3] Retained pulmonary mucus can harbour pathogenic microorganisms often leading to recurrent lung infections. Complications can significantly decrease the patient's quality of life, and comorbidities can lead to permanent pulmonary structural injury or even death in the most severe cases.[4]

Manual chest physiotherapy (CPT) has had a long history of clinical benefit through improved airway clearance by manually cupping, clapping, and/or physically striking the external chest wall of patients.[5] CPT is normally delivered by trained health care professionals; however, due to cost concerns and a lack of available trained professionals, patient caregivers often deliver CPT in the home as well. Despite clear clinical benefits, CPT may not be the most effective therapy for all patients.[6] Multiple challenges and limitations may compromise CPT therapeutic benefits including, for example, inadequate or in consistent CPT technique, insufficient physical strength of the CPT practitioner, time constraints and/or limited access to health care professionals who perform CPT. These limitations may significantly contribute to erratic or ineffective treatment.

The need for a dependable, automated, more consistent form of therapy led to the development of alternative percussive techniques including high frequency chest wall oscillation (HFCWO). HFCWO uses an inflatable vest attached to a generator to mechanically perform chest physiotherapy by rapid oscillation and compression. The oscillations create a shearing force within the airways which loosen and thin mucus promoting airway clearance and improving bronchial drainage. This case series was conducted to evaluate the clinical effectiveness of HFCWO in a bronchiectasis population.

Methods

This single-arm, nonrandomized, open label, observational trial evaluated HFCWO effects on patient quality of life (QoL) by comparing QoL at baseline (before treatment) to QoL after 2, 6, and 12 months of HFCWO treatment (i.e., each subject served as their own control). This study was reviewed and approved by the appropriate IRB and written informed consent was obtained from each patient before study activities began.

Patients were included if they were 18 years of age or older, had a previous bronchiectasis diagnosis confirmed by high resolution computed tomography within last 6 months, at least 6 months of medical records related to bronchiectasis, stable standard of care for bronchiectasis (e.g., hypertonic saline and/or positive expiratory pressure), at least one exacerbation within the last 12 months, and a previous and existing productive cough. Exclusion criteria were a known diagnosis of cystic fibrosis, primary ciliary dyskinesia (PCD), chronic obstructive pulmonary disease (COPD) without bronchiectasis, ventilation through an artificial airway, presence of severe bronchospasm based on exam or history, and any comorbidities or contraindications that would normally complicate HFCWO treatment tolerance.

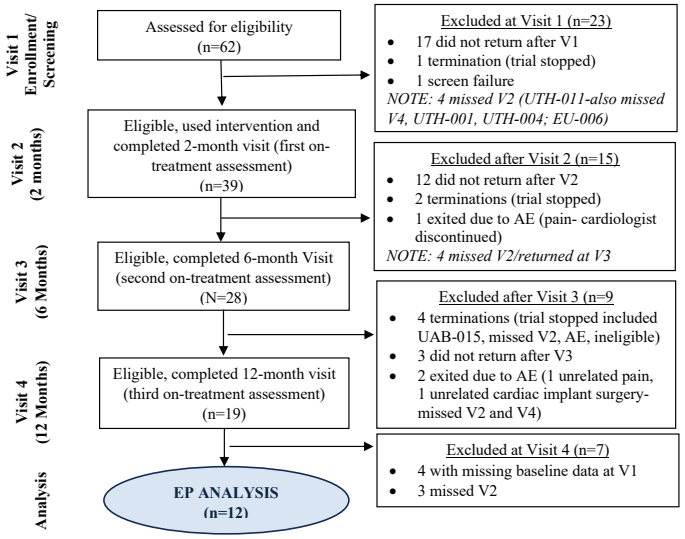
Study subjects who met all inclusion and no exclusion criteria were prescribed a SmartVest Airway Clearance System, Model SQL (Electromed, Inc., New Prague, MN). The primary endpoint compared responses to the Quality of Life-Bronchiectasis questionnaire (QoL-B) at baseline with standard of care (SOC) alone to HFCWO (SmartVest) use as indicated for 2, 6 and 12 months in addition to SOC treatment. Secondary endpoints compared historical bronchiectasis-related exacerbations and validated breathlessness, cough and sputum scale (BCSS) questionnaire scores at baseline to those same measures after 2, 6 and 12 months of HFCWO use. Absolute change values were calculated as: Post Baseline Value – Baseline Value and were analyzed using descriptive statistics. Adverse events were assessed at each visit.

George M Solomon and Kathryn Vickers are with the University of Alabama at Birmingham, Birmingham, Alabama. Julie Philley is with the University of Texas Health Science Center at Tyler, Tyler, Texas. Colin Swenson is with the Emory University School of Medicine, Atlanta, Georgia.

Results

The study was conducted between February 2020 and November 2023, but hampered by the COVID-19 pandemic and was therefore stopped early, after only 62 of the planned 100 subjects were enrolled. Only 12 subjects completed all four visits (baseline, 2, 6, and 12 months) (Figure 1).

Figure 1. Flow Diagram (number of subjects completing each visit)



Flow chart modified from STROBE: Strengthening The Reporting of Observational studies in Epidemiology available at https://www.strobe-statement.org/ and https://journals.lww.com/epidem/fulltext/2007/11000/strengthening_the_reporting_of_observational.28.aspx

The 12 subjects evaluated in this case series were older (median 69.5 years) and predominantly female (67%). This small sample was limited to a slightly overweight (mean BMI 26.3), entirely white race and non-Hispanic ethnicity population (Table 1).

Table 1. Study Subject Demographics

Description	Result
Age (years)	
Median [Min, Max]	69.5 [50, 80]
Age Group [n (%)]	
<40	0 (0.0%)
40-64	4 (33.3%)
65+	8 (66.7%)
Biological Sex [n (%)]	
Male	4 (33.3%)
Female	8 (66.7%)
Body Mass Index (pounds/square inch)	
Mean Weight (pounds, SD)	160.6±44.5
Mean BMI (calc: lb/in2*703, SD)	26.3±6.4

Clinical improvements in QoL-B scores greater than 8 units were identified in Social Functioning and Respiratory Symptoms QoL-B domains as early as two months on SmartVest treatment and the physical functioning, role functioning, social functioning, health perceptions and respiratory symptoms QoL-B domains all showed improvements greater than 8 units consistently after 6 and 12 months of SmartVest treatment compared to baseline while vitality, emotional functioning, treatment burden were not as robust. The absolute changes in QoL-B domains over time on SmartVest therapy indicated clinical improvements in the majority (62.5%, 5/8) of assessed QoL-B domains (Table 2).

Similar to the QoL-B data, the BCSS data showed improvements (i.e., reductions greater than 1 unit) after 6 and 12 months of HFCWO use (Table 3).

The apparent exacerbation rate after 12 months of HFCWO treatment remained relatively unchanged compared to the historical rate during the 12 months before HFCWO treatment (22 pre versus 21 post). Four of the subjects were frequent exacerbators with 3 or more exacerbations per year, pre and post HFCWO treatment.

Across all patients and all visits, 12 adverse events were reported in 9 patients, with an individual event frequency of no more than 16.7%. Two AEs (16.7%) were serious because pneumonia led to hospitalization in one patient. One other hospitalization was reported, however additional details were not available to determine severity or relation to the study procedure. Three AEs (25%) were not expected and were not related to the SmartVest device (fractured elbow with numbness in hand, hernia surgery, and ear infection). Aches and pains (16.7%) were reported as were unrelated events like a fractured rib (8.3%) or a fractured elbow (8.3%) during this trial (Table 4).

No safety concerns (either alone or in aggregate with all the other AEs) were considered overwhelming and none suggested the SmartVest device risks outweighed the benefits to the patient when used as indicated

Discussion

The goals of bronchiectasis treatments are to minimize exacerbations and improve a patient's quality of life. By mobilizing airway secretions, improving ventilation, and reducing exacerbations, HFCWO is a powerful tool in the bronchiectasis treatment armamentarium. Prior studies showed a statistically significant reduction in bronchiectasis-related healthcare utilization and antibiotic and steroid use with the use of SmartVest[7] and a significant reduction in bronchiectasis-related excerabations.[8] The present clinical trial was designed to evaluate if SmartVest treatment for one year in addition to the SOC improved QoL-B for bronchiectasis patients.

Both the validated QoL-B and BCSS instruments showed clinical improvement in the twelve subjects documented here. One author[9] reported a minimal clinically important difference (MCID) range for QoL-B was from 6.8 to 10 points. In this study, the QoL-B showed improvements in Social Functioning and Respiratory Symptoms QoL-B domains as early as two months on SmartVest treatment and the Physical Functioning, Role Functioning, Social Functioning, Health Perceptions and Respiratory Symptoms QoL-B domains all showed improvements exceeding the MCID consistently after 6 and 12 months of SmartVest treatment.

One author[10] suggested BCSS changes were clinically meaningful when the values decreased by -1.1 to -1.9 points. The BCSS changes documented here showed improvements (i.e., decreased more than -1.1) after 6 and 12 months of SmartVest treatment compared to baseline and suggested these BCSS improvements may be clinically meaningful. These findings also suggested the observed BCSS improvements (like the QoL-B changes) may be durable over time from 6 to 12 months on SmartVest treatment.

This case series showed improvements in the Social Functioning and Respiratory Symptoms QoL-B domains after as little as

Table 2. QoL-B Domain Scores

QoL-B Domain	V1	V2	Change V2-V1	V3	Change V3-V1	V4	Change V4-V1
Physical Functioning Domain	43.3±24.5	52.7±30.6 (N=11)	7.3±23.8	59.4±31.3	16.1±30.5	63.6±30.9 (N=11)	21.8±16.1
Role Functioning Domain	53.9±21.4	58.3±22.9	4.4±12.8	65.0±25.3	11.1±15.7	66.1±26.1	12.2±15.0
Vitality Domain	38.0±20.9	45.5±30.0 (N=11)	7.1±17.4	46.3±22.6	6.5±17.4	44.4±20.5 (N=11)	8.1±14.1
Emotional Functioning Domain	79.9±22.3	85.6±13.5 (N=11)	4.5±20.5	83.3±16.7	3.5±16.1	86.4±15.0 (N=11)	8.3±17.1
Social Functioning Domain	39.6±23.6	48.1±20.0	8.6±23.0	51.4±25.8	11.8±21.2	53.5±24.0	13.9±22.1
Treatment Burden Domain	52.5±22.3 (N=11)	56.6±18.9 (N=11)	6.7±20.4	50.9±24.4	-3.0±10.1	60.6±20.7 (N=11)	5.6±22.4
Health Perceptions Domain	41.0±19.8	48.4±19.9	7.4±14.0	49.3±22.5	8.3±19.1	50.7±23.4	10.2±22.1
Respiratory Symptoms Domain	52.5±23.1	63.3±22.3 (N=11)	8.4±22.7	68.8±16.7	16.3±16.7	63.6±23.8 (N=11)	11.4±14.0

* All values shown are mean ± SD

Table 3. BCSS Results

Data Group	V1	V2	Change V2-V1	V3	Change V3-V1	V4	Change V4-V1
BCSS Score	5.8±1.9	5.0±2.4	-0.8±2.5	3.98±2.43	-1.9±2.2	4.6±3.2	-1.3±2.7

* All values shown are mean ± SD, bolded differences are above the MCID for results from the QoL-B questionnaire in bronchiectasis patients.

Table 4. Adverse Events

Characteristic, n (%)	V2	V3	V4	Total
AE count (N, % subjects)	4 (3, 25.0%)	4 (2, 16.7%)	4 (4, 33.3%)	12 (9, 75%)
Pain	1 (8.3%)	1 (8.3%)		
Pneumonia/hospitalization		2 (16.7%)		
AE/hospitalization, NOS	1 (8.3%)	1 (8.3%)	2 (16.7%)	
Surgery, hernia	1 (8.3%)			
Infection, right ear	1 (8.3%)			
Syncope (passed out; low BP)			1 (8.3%)	
Fracture, rib				
Fracture, elbow/numbness in hand			1 (8.3%)	

two months on SmartVest therapy and these improvements in QoL-B were sustained as a durable measure at 6 months and one year on SmartVest treatment. The difference of only one exacerbation between the year prior to HFCWO use and the full year of SmartVest use among 12 study subjects suggests no obvious change in exacerbations; however, the number of study subjects is small, and four patients had the frequent exacerbator phenotype. This may suggest a role for earlier initiation of HFCWO therapy among frequent exacerbators, but further research is needed regarding the impact of SmartVest HFCWO therapy on exacerbation rates. Additional study limitations included slow enrollment, early termination due to futility during the COVID 19 pandemic, lack of a comparator arm, blinding or randomization and several originally planned endpoint measurements were not available for analysis.

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Finding the Best Respiratory Support Strategies for Premature Babies

Chris Campbell

Anyone who has ever seen a premature baby has likely had their heart broken.

That's because these tiny, fragile humans face such a long, uphill battle that requires volumes of strategic planning by a team of medical professionals every step of the way.

One of the biggest issues faced by neonates who are born preterm is poor lung development, plus the risk of lung injury caused by the thing that's trying to help them breathe — respiratory support.

As the neonate struggles to grow, their breathing mechanics will continue to change and any ventilator strategy must be adjusted along with those changes and be designed to be as non-invasive as possible. This ranges from the early days after birth all the way to even school age, meaning strategies are needed amid the transition to home. This transition includes reducing the strain on caregivers feeling the burden of home care amid the risks of preventable mortality.

A 2023 review argues that more study is "desperately needed" into finding better ventilator strategies for children with severe bronchopulmonary dysplasia (BPD), especially in the area of "timing of transition to chronic respiratory support and the optimal chronic ventilatory strategies.

This is according to the review by Erik B. Hysinger and Shawn K. Ahlfeld out of the University of Cincinnati College of Medicine, Cincinnati Children's Hospital, who advocated for more prospective trials into the issue.

The authors detailed in their review the long road faced by many neonates who are born preterm, and how "gentle" strategies are needed for respiratory support.

"Early in the disease course respiratory support should focus on limiting additional lung injury by utilizing non-invasive ventilation or 'gentle' invasive mechanical ventilation with a low tidal volume, short inspiratory time, and high respiratory rate strategy," the authors write. "However, for those infants who go on to need chronic respiratory support, worsening obstructive lung disease requires a transition to longer inspiratory times, lower rates, and a higher tidal volume strategy to optimize ventilation."

Chris Campbell is the Senior Editor of Respiratory Therapy.

The authors said other reviews have looked into surrounding issues[1-21] and provided "excellent" information on the "safety and efficacy of non-invasive modes of respiratory support."

The review also delves into issues when the neonate gets older and how these issues have been studied.

"While the majority of infants require a period of invasive mechanical ventilation, by 36 weeks' corrected gestational age, more than 90% will have been extubated and supported non-invasively,"[16,21] the authors write. "…comparing the efficacy of various modes of non-invasive support is emerging, but presently nCPAP comprises the bulk of available data. Since 2008, 5 large multicenter RCTs (COIN,[9] SUPPORT,[17] CURPAP,[19] Vermont Oxford,[18] and now OPTIMIST-A[20]) have enrolled over 3,000 infants born at 24-29 weeks' gestation and cared for with nCPAP and, therefore, provide a wealth of safety and efficacy data. However, despite wide-spread acceptance and use of non-invasive ventilation in both the United States (10) and United Kindom,[22] nearly 50% of surviving infants continue to develop BPD.[16,21] Preclinical and clinical evidence implies that outcomes may be improved by prolonging the duration of constant distending pressure. A strategy employing prolonged, prophylactic support on nCPAP until respiratory stability is achieved and infants can be weaned directly to room air is associated with the lowest rates of BPD.[23]

"Supporting evidence derived from preclinical animal models demonstrates that constant distending pressure minimizes lung injury and augments lung growth. In both murine and rabbit models of hyperoxic neonatal lung injury, compared to no support, use of CPAP reduced inflammation, preserved alveolar-capillary development, and durably improved lung function.[24,25] Exposure of juvenile ferrets to 2 weeks of constant distending pressure significantly increased lung weight and DNA content and increased total lung capacity by 40% while preserving elastic recoil, thus implying CPAP induced not merely lung distension but lung growth.[26] In infants with severe congenital diaphragmatic hernia, tracheal occlusion (resulting in lung fluid retention and constant distension of the developing lungs) improved survival and reduced the need for ECMO, strongly-implying improved lung function.[27] Recent clinical evidence indicates that extremely preterm infants with evolving BPD may similarly benefit from prolonged constant distending pressure."

The Long Term

The review also detailed the sad situation faced by some premature infants who aren't able to wean from positive pressure ventilation, meaning they will need chronic ventilation support.

But there is also a lack of information on different strategies, the authors write.

"There is no clear timing when providers should transition to chronic ventilator strategies, and there is wide variation based on center,"[28] say the authors. "However, once it has been determined that an infant with BPD will be treated with chronic mechanical ventilation, the ventilation strategy should shift. While there should be continued efforts to minimize lung injury as much as possible, the primary focus transitions to providing optimal respiratory support for patient comfort, growth and development, and gas exchange, which appears to improve in neonates with BPD following placement of a tracheostomy tube and chronic mechanical ventilation.[29] Currently, there is an extreme paucity of data comparing different chronic ventilator strategies in established severe BPD; consequently, a physiologic approach to mechanical ventilation must be considered."

The review details the use by care providers of a series of time and flow triggers for chronic mechanical ventilation, but add that some patients may have delayed or failed triggers.

"In one report, a majority patients with severe BPD treated with chronic mechanical ventilation experienced failed triggers, with nearly 15% of breaths resulting in a wasted effort," said the authors. "The inability to trigger, results in patient ventilator dysnchronization and patient discomfort. This may manifest with agitation, hypoxemic episodes, poor ventilation, and increased need for sedation."[30]

The report also looks as gas exchange, PEEP, tidal volumes and mandated respiratory rates.

The review also circles back to the difficulties with the transition to home due to the lack of data on the subject.

"In general, most providers will attempt to transition to the home ventilator on settings consistent with the hospital ventilator. In some situations, it may not be possible to achieve identical settings. Trigger sensitivity is less for home ventilators, which can lead delayed or failed triggers during the transition. Further, hospital ventilators may allow a longer inspiratory time than is feasible on a home ventilator, particularly with smaller tidal volumes, which can be problematic in children who need long inspiratory times to ensure recruitment of regions with long time constants."[31]

Caregivers at home face anxiety and even depression if they don't have access to home nursing support.[32-34]

"Fatigue is of particular importance as in-home mortality in this population exceeds 15%, and many of the events resulting in the patient's demise are preventable or treatable e.g., mucus plugs or accidental decannulation rather than progression of the underlying lung disease,"[35-38] the authors write. "Because of the risks, most programs provide extensive training for caregivers of technology-dependent children that center on management of the tracheostomy, ventilator, and all other equipment that will be necessary to meet the child's needs at home. Caregivers should also be trained in cardiopulmonary resuscitation and patient transfers."

The review also said study is needed on weaning chronic mechanical ventilation, as well as weaning non-invasive support.

"As with weaning of mechanical ventilation, there is precious little data for the optimal strategies to wean non-invasive support following hospital discharge," the authors write.

Conclusion

In the end, the authors strongly urge more study.

"Ventilator strategies for children born premature evolve as the disease process progresses," they say. "While there is currently a wealth of information highlighting the use of lung protective strategies with non-invasive positive pressure ventilation or invasive ventilation with small tidal volumes and high mandatory rates during the earliest phase of disease, there is a dearth of data about the timing of transition to chronic respiratory support and the optimal chronic ventilatory strategies. Ultimately, children will gradually wean from support, typically by school-age. Prospective trials that establish optimal ventilator strategies for children with severe established BPD are desperately needed, and the need for such studies continues to grow as the limit of viability is decreased and more children will need chronic mechanical ventilation."

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Engaging Clinicians To Reduce Carbon-Intensive, Unnecessary Tests and Procedures

Wendy Levinson, MD and William K Silverstein, MD

Up to 30% of ordered tests and treatments do not add value and can even harm patients.[1-3] It stands to reason that eliminating the use of these unnecessary tests and treatments can reduce a component of health-care's greenhouse gas emissions, as every test and treatment has a carbon footprint.[4] Generally speaking, physicians and other health-care professionals (hereafter referred to as clinicians) do not know how to change their daily practice to mitigate progression of the climate crisis.[5,6] In this Comment, we describe a campaign led by national professional societies to develop specific and actionable recommendations that clinicians can implement in their daily practice to decrease their carbon footprint through elimination of carbon-intensive, unnecessary tests and treatments.

Choosing Wisely Canada (CWC) is a campaign that aims to decrease the use of unnecessary tests, treatments, and procedures. Since its inception 10 years ago, CWC has engaged over 80 national societies (including nursing, medicine, pharmacy, and dentistry societies) to identify approximately 600 commonly used tests and treatments that are not supported by evidence and could expose patients to harm. This approach has galvanised awareness and contributed to a reduction in the provision of unnecessary care.[1,7,8] Given its previous successes and the pressing need for action to combat the climate crisis, CWC has leveraged its network of national professional societies to develop recommendations that promote climate-conscious practice.

Twenty-one national societies, representing a diversity of specialities, developed recommendations to reduce clinical care that is common, potentially exposes patients to harm, is avoidable, and negatively impacts the environment. Thus, high-quality patient care is the priority of the recommendations, with an associated co-benefit of decreasing environmental harm. Societies were asked to develop recommendations that were practical for clinicians to implement and within the speciality's scope.

For each recommendation, societies created a statement (eg, "Do not use gloves when hand hygiene is sufficient") accompanied by a succinct rationale and provided scientific references. Typically, societies developed recommendations through working groups of members with expertise in quality improvement and planetary health, followed by engagement of the broad membership for feedback. As part of this process, many frontline clinicians considered how clinical practice could be modified to decrease environmental harm.

The first call for recommendations took place in December, 2023. In the first 4 months, 21 societies submitted between one and ten recommendations each. These were vetted by a panel of planetary health experts and patients to ensure that they were scientifically sound and patient-centred, and 41 recommendations were accepted.

The recommendations are grouped into five categories of planetary harm: medications, energy use, waste reduction, travel, and purchasing (examples are shown in the table). These categories are divided into subthemes; for example, medication recommendations focus on avoiding, where possible, the use of specific drugs with high greenhouse emissions (such as anaesthetic gases and metered dose inhalers), minimising the use of carbon-intensive intravenous routes of administration, and optimising medication disposal. Recommendations related to energy use include decreasing the use of surgical instruments and autoclaving, and promoting appropriate waste disposal. Waste reduction recommendations focus on reducing single-use items. Many recommendations can be instituted by individual clinicians, but some suggest structural changes for which health-care professionals and their respective professional society could advocate, such that an institution would make a climate-friendly change in the local clinical setting or in the broader health system. For example, for family medicine, one recommendation is to avoid conducting in-person visits where a virtual assessment would provide equivalent clinical value. This recommendation could be supported by equivalent reimbursement of virtual visits by payers. Clinicians could also advocate that their health systems purchase environmentally friendly medical supplies.

The number of societies who participated in this first call for recommendations reflects strong clinician interest in attenuating the impact of the climate crisis. The provision of guidelines and policy statements from professional associations highlighting that individual clinicians can act to mitigate the negative effect that health care has on planetary health is a crucial awareness-building activity that is necessary for meaningful behaviour change.[5,9] However, the provision

Dr Wendy Levinson is Chair of Choosing Wisely Canada and Choosing Wisely international. She is an internist and Professor of Medicine at the University of Toronto. She is an Officer in the Order of Canada (OC). William K Silverstein, MD, is an Assistant Professor of Medicine at University of Toronto.

Table 1. Recommendation themes, subthemes, and examples

Medications	Recommendation	Society
Anaesthetic gases	Do not use desflurane when other anaesthetic drugs and techniques are equally effective and less harmful to the environment	Canadian Anesthesiologists' Society
Metered-dose inhaler	Do not prescribe greenhouse gas-intensive metered-dose inhalers for asthma or chronic obstructive pulmonary disease where an alternative inhaler with a lower carbon footprint (eg, dry powder inhaler, soft-mist inhaler, or metered-dose inhaler with a low greenhouse gas potential propellant) containing medications with comparable efficacy is available and for which the patient has demonstrated adequate technique and patient preference has been considered	Canadian Thoracic Society
Intravenous medications	Do not prescribe intravenous antibiotics for patients who can safely be treated with an oral option, given that intravenous antibiotics have a higher carbon footprint than oral antibiotics	Canadian Society of Internal Medicine
Medication optimisation	Do not continue medications upon hospital transitions (admissions, transfers, and discharges) unless there is a clinical indication.	Canadian Society of Hospital Pharmacists
Medication disposal	Do not discard medications that are appropriate for redispensing	Canadian Society of Hospital Pharmacists
Energy use		
Instrument reduction and autoclaving	Do not include unnecessary or rarely used surgical instruments and supplies on surgical trays for routine otolaryngology procedures	Canadian Society of Otolaryngology-Head and Neck Surgery
Incineration	Do not dispose of non-contaminated wrapping materials in contaminated waste bins	Canadian Orthopaedic Association
Imaging	Do not perform serological, imaging, or genetic tests without checking for and considering past available results	Canadian Rheumatology Association
Waste reduction		
Single-use items	Do not use single-use vials of anaesthetic agents such as xylocaine to prepare injections for patients	Canadian Academy of Sport and Exercise Medicine
Gloves	Do not use gloves when hand hygiene is sufficient	Canadian Critical Care Society
Paper	Do not excessively print or use paper unnecessarily, and encourage the use of digital information and resource sharing when possible	Canadian Pharmacists Association and Canadian Society of Hospital Pharmacists
Purchasing	Do not purchase laboratory equipment or supplies without considering sustainability and environmental impact while maintaining diagnostic proficiency	Canadian Society of Clinical Chemists
Travel		
Virtual care	Do not conduct in-person visits for gastrointestinal care when a virtual visit can be conducted, is clinically appropriate (eg, routine follow-up visit and post-endoscopy review of normal biopsy results), and is preferred by the patient	Canadian Association of Gastroenterology
Travel (consolidating appointments)	Do not book multiday patient visits for radiation treatments when these can be coordinated into a single trip	Canadian Association of Radiation Oncology

of such guidelines is just the first step; implementation of recommendations, a challenging task, is essential to decrease emissions and ultimately protect the health of the planet and patients. For example, the widespread adoption of virtual care during the COVID-19 pandemic in Ontario, Canada, avoided 545-658 million kg of CO_2 emissions, which represents 0.2% of Ontario's total annual CO_2 emissions.[10]

This national campaign is a broad-scale Canadian effort led by clinicians and their national societies to make specific recommendations aimed at empowering clinicians to modify their practice to decrease health-care's impact on climate change. This model can be adopted by clinicians in other countries interested in reducing their carbon footprint.

The authors both receive a stipend from Choosing Wisely Canada. Department of Medicine, University of Toronto, Toronto, ON M5S 3H2, Canada (WL, WKS); Department of Medicine, St Michael's Hospital, Toronto, ON, Canada (WL); Division of General Internal Medicine, Sunnybrook Health Sciences Centre, Toronto, ON, Canada (WKS).

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News…continued from page 12
years) experiencing a greater negative effect. These data showed the acute effects of PM1 exposure. Viegi emphasized that "acute effects," such as hospitalizations occur either on the same day or within a short delay of up to 7 days following the measured concentration of air pollutants.

Tongue Cleaner Unveiled

Dale Medical Products, Inc., a recognized leader in disposable medical products, is announced its latest innovation, the patent pending Scrape-n-Suction Tongue Cleaner, invented by a clinician to enhance patient care. This revolutionary Tongue Cleaner sets a new standard in oral care. Scrape-n-Suction is the culmination of in-depth marketing research and engineering design. It represents Dale Medical's commitment to delivering innovative patient solutions designed to meet the evolving needs of patients and clinicians. The Dale Medical Scrape-n-Suction Tongue Cleaner is the only product on the market that offers a unique combination of effective scraping and suction to thoroughly clear tongue biofilm. This innovative design helps remove bacteria and toxins, potentially reducing the risk of ventilator-associated pneumonia (VAP) and other respiratory infections. "We are excited that our new device enables clinicians to significantly improve the oral care of acutely ill patients, ultimately supporting their overall health and recovery," said Bob Simpson, Dale Medical President & CEO. The Scrape-n-Suction Tongue Cleaner (product Ref. #220) will become available in early February 2025 through our distributors worldwide. For more information about the Scrape-n-Suction Tongue Cleaner, 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 are committed to strengthening our position as a financially successful market leader through innovation and continuous improvement.

Early-Onset Asthma May Slow Memory Development

Children with asthma scored significantly lower than those without asthma on measures of episodic memory, based on longitudinal data from nearly 500 individuals. Animal models have shown associations between asthma and memory problems, but data for children are lacking, wrote Nicholas J. Christopher-Hayes, MA, of the University of California, Davis, and colleagues. "Asthma is very frequent among children, and there is mounting evidence from rodent models that asthma may result in neural injury in the hippocampus, which in turn may cause memory loss," Christopher-Hayes said in an interview. "Although there is also a good amount of research with older adults, very little research has been done with children, the period that is most frequently linked to asthma onset," he said. Therefore, the researchers leveraged a large national study on child development to examine development of memory as a function of asthma exposure. In this study published in *JAMA Network Open*, the researchers conducted both a longitudinal and cross-sectional analysis of data from the Adolescent Brain Cognitive Development Study, which began in 2015. Children were enrolled at ages 9-10 years with a follow-up assessment 1-2 years later. The participants were categorized as early childhood-onset asthma (asthma at baseline and follow-up), later childhood-onset asthma (asthma at follow-up only), or no asthma history. The primary outcome of the longitudinal analysis was episodic memory. Approximately half of the participants
Continued on page 41…

Cannula Design: Does it Matter?

Jessica Whittle, MD, PhD, Jeanne Pettinichi, MSN, RN, CPN and Matthew S Pavlichko, MS, RRT-NPS, FAARC

High velocity therapy is an advanced form of high flow oxygen therapy that provides optimally conditioned breathing gases through specialized small-bore nasal cannulas. Small-bore cannulas produce a higher gas velocity at the same flow rate compared to large-bore cannulas because the smaller diameter forces the gas through a narrower space, increasing its kinetic energy.[1-3] Clinicians often ask, "does cannula design actually impact therapy?"

The Science Behind the Cannula

Through small bore cannulas, therapeutic effects of gas flow levels during high velocity therapy are maximized by generating faster "gas speeds" through higher kinetic energy.

More Kinetic Energy = More Dead Space "Flush"

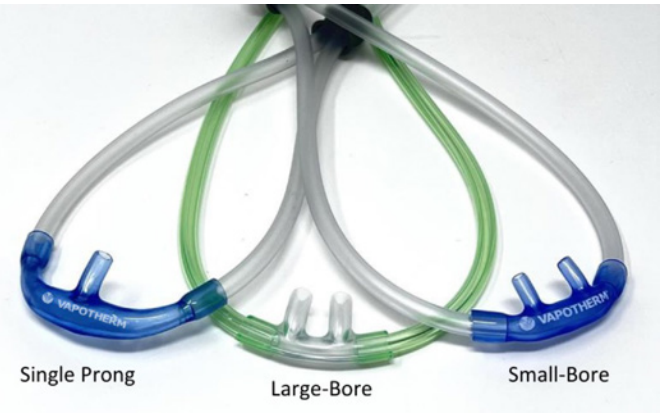
More kinetic energy means more turbulence, more mixing, and deeper penetration in the upper airway resulting in more rapid dead space "flush". This is why greater flush can be measured at lower flow rates from velocity-based systems compared to other high flow systems.[2,5] This concept was originally highlighted by Frizzola et al, in an animal model showing that the small-bore cannula design optimizes the potential to "flush" extrathoracic dead space by eliminating CO_2 in a flow dependent manner. The small-bore cannula produced better physiologic ventilation and lower tracheal pressure compared to a large bore design.[4]

One of the reasons it is important to only use cannulas designed and tested for any specific system is that the bore size impacts the back pressure. Most traditional high flow systems are not designed to handle pressure generated by a small-bore cannula.

Jessica Whittle is the Chief Medical Officer and VP of Clinical Research at Vapotherm. She is a Professor and Vice Chair of Research for the Department of Emergency Medicine at the University of Tennessee – Chattanooga/Erlanger Health System.

Jeanne Pettinichi has 34 years' experience as a nurse including 20 years working in Pediatric Emergency Nursing. Jeanne currently serves as the Clinical Nurse Educator for Vapotherm.

Matthew S Pavlichko is the Director of Professional Development and Education, Respiratory Therapy at Vapotherm. He has been in the respiratory therapy field for over 25 years, practicing in South Central Pennsylvania and North Carolina as a respiratory therapist, educator, manager, and director, managing all aspects of respiratory care.



Additionally, when using a system intended for a small-bore cannula, changing to a larger bore cannula or occluding the nares more than 50% potentially generates unquantified airway pressures and the clinical implications of this are not fully studied. So, back to the question—does cannula design impact patients?

Demonstration 1: Healthy Volunteers[6]

We recruited 4 healthy adult volunteers without any respiratory symptoms.

1. **First Five Minutes:** The volunteers were asked to breathe comfortably at rest for 5 minutes to establish a baseline respiratory rate.
2. **Ten Minutes with the Established Respiratory Rate on Therapy:** Using a metronome, the volunteers were then prompted to maintain their resting respiratory rate while therapy was being delivered. An observer measured their transcutaneous CO_2 levels for 10 minutes.
3. **Repeat at Different Flow Rates and with Different Cannulas:** Each volunteer repeated the experiment using a small-bore cannula, large-bore cannula, or a single prong cannula, each at 3 different flow rates (15 L/min, 25 L/min, and 45 L/min). (Figure: 1)

What does this demonstration tell us?

Normally, our body works very hard to maintain homeostasis. If there is a change in the acid-base balance in the blood, exhaled CO_2 quantities will change, and the body will reflexively adjust the respiration rate and/or tidal volume to return the blood to neutral pH.

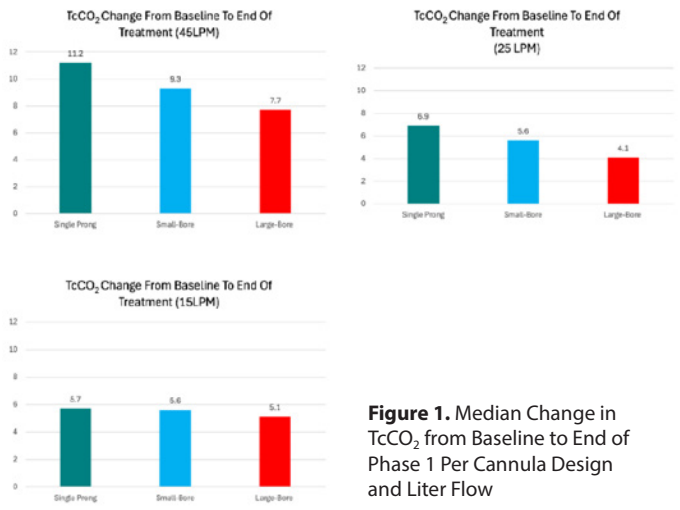


Figure 1. Median Change in $TcCO_2$ from Baseline to End of Phase 1 Per Cannula Design and Liter Flow

In this demonstration, we flushed the upper airways but asked the volunteer to keep their respiration rate the same (unfortunately, we could not control tidal volume). Since the body's natural reflex was blunted, the flush of CO_2 could be observed. Notice the impact of the different cannulas (Figure 1).

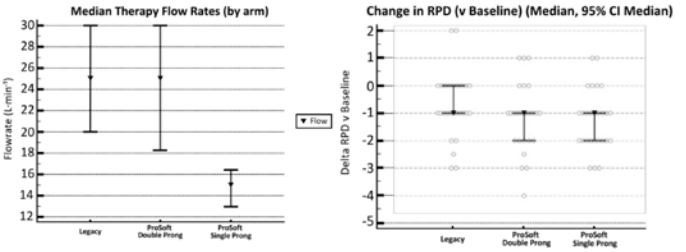
On average at the same flow rates, the small-bore cannula has a greater impact on CO_2 than the large bore cannula, and the single prong cannula flushes even more. (As with all therapies, there is some individual-to-individual variability). If the primary goal of therapy for a patient is to optimize CO_2 clearance, a small-bore cannula or a single prong cannula might be the optimal choice.

Demonstration 2: Hypercapnic Patients (a clinical trial)[7]

In this clinical trial, patients with mild to moderate hypercapnic COPD complaining of dyspnea and sought treatment at the Pulmonologists' office or were in the hospital, were asked to evaluate 3 different nasal cannulas on high velocity therapy.

The purpose of the study was to 1) test a new double prong cannula that was made from a softer material and 2) test the impact of a cannula designed from the same material but with only a single prong.

Patients were first treated with Vapotherm's usual double prong small-bore cannula made from a traditional material (called legacy cannula). The flowrate was titrated until the patient reported optimal relief of dyspnea. Once the patient was feeling better, they were asked to stop therapy long enough for their dyspnea to return (about 5 min). At this time, patients were provided therapy using either the new material dual prong small-bore cannula made from the ProSoft material (ProSoft), or the single prong cannula also made from the ProSoft material and re-titrated for optimal flowrate.



Rated Perceived Dyspnea (RPD) scores were collected under each cannula therapy and researchers documented the new flow rate that provided comfortable therapy with relief of dyspnea.

Note that both the double prong and single prong ProSoft cannulas led to continued relief of dyspnea, but the single prong did it at approximately half the flow rates. What does this tell us about the relative importance of flow and velocity when thinking about flush and gas exchange?

Conclusion

These data support the claim that small-bore cannulas generate higher velocity gas and more efficient flush. Higher velocity with unobstructed outflow created by a single prong cannula design maximizes gas exchange and CO_2 flush of the upper airway. For patients with severe hypercarbia or situations where limited flow is preferred, the single prong cannula provides another option for patients. In addition, these data demonstrate why it is so important to use the correct cannula when delivering high velocity therapy.

Right device + right cannula = intended therapy

Therefore, to ensure patient safety use the cannula specifically designed for the corresponding device.

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Disclaimer

Vapotherm does not practice medicine or provide medical services or advice. Any clinical recommendations provided herein are solely those of the authors as clinicians. Vapotherm high velocity therapy is not intended to provide total ventilatory requirements of the patient and is for spontaneously breathing patients only. Caution: US Federal law restricts this device to sale by or on the order of a physician.

The Evolution of Inhaled Therapies: Advancements in Respiratory Disease Management

Seth Hall, Vani Ravichandran, Savan Patel, Gareth Gwyn

The management of respiratory diseases has been revolutionized by inhaled therapies as they offer targeted drug delivery to the lungs. From early nebulizer innovations to newer dry powder inhalers (DPIs), these advancements have transformed care for millions of patients. This article explores the history, benefits, and future potential of inhaled therapies, with a special focus on emerging technologies.

A Brief History of Inhaled Therapies

Inhaled therapies date back nearly 4,000 years. Early medicinal practices such as Ayurveda emerged in India around 2000 BCE, where herbal compounds like *Datura* were inhaled for their bronchodilatory properties (Patwardhan et al., 2005). By 1500 BCE, Egyptians inhaled vapors of black henbane (*Hyoscyamus*), a plant containing hyoscyamine, for respiratory relief (Nunn, 2002). Ancient Greeks, under Hippocrates, developed one of the earliest inhalation devices: a simple pot with a reed for inhaling medicinal vapors (Nutton, 2004). These early practices, also seen in the use of pipes in Central and South America, formed the foundation for modern inhalation therapies (Anderson, 2005; Parameswaran et al., 2018). The evolution of inhaled therapies reflects ongoing innovation in medication delivery. Some common inhalation mechanisms are delineated below.

Nebulizers: The first modern inhalation devices, nebulizers emerged in the 19th century, delivering medication via aerosolized liquid droplets (Anderson, 2005). While effective, traditional nebulizers can be cumbersome due to size and required assembly, along with being time-consuming, and often impractical for daily use.

Metered-Dose Inhalers (MDIs): Introduced in the 1950s, MDIs offered a portable alternative to nebulizers (Dolovich et al., 2005). However, they require precise coordination between actuation and inhalation, presenting challenges for some patients.

Dry Powder Inhalers (DPIs): With the emergence of DPIs in the 1990s, many limitations of earlier devices were addressed. DPIs simplify drug delivery by relying on the patient's inhalation effort to disperse the medication (breath-actuation), enhancing usability and adherence (Lavorini et al., 2008).

Seth Hall, Vani Ravichandran, Savan Patel, and Gareth Gwyn are with Global Medical Affairs at Liquidia Technologies, Inc. in Morrisville, NC.

The Benefits of Direct Lung Delivery

Direct lung delivery has proven to be a cornerstone of effective treatment for respiratory diseases. By administering medication to the lungs, therapeutic agents reach their intended site of action directly, avoiding untoward side effects that result from systemic delivery methods such as oral or IV administration. This localized drug delivery can enable lower therapeutic dosing thereby minimizing toxicity, while providing rapid, targeted relief for symptoms like bronchoconstriction, vasoconstriction, inflammation, and airway obstruction (Parameswaran et al., 2018).

The Advantages and Limitations of Dry Powder Inhalers

Dry powder inhalers (DPIs) have become a preferred choice for many respiratory diseases due to their portability, ease of use, and patient adherence. Unlike MDIs, DPIs do not require precise timing, propellants, or spacers, and their compact design makes them ideal for on-the-go use (Usmani et al., 2021). From a functional perspective, DPIs are breath-actuated and utilize the energy of inhalation to overcome the cohesive forces within the powder, breaking up the particles in a process known as deagglomeration. The resistance within the inhalation device provides mechanical assistance with deagglomeration and distribution of drug particles to the lungs (Newman and Busse, 2020). Despite these technological advancements, inhaled drug delivery efficiency remains poor (Kleinstreuer et al., 2008). For instance, in the case of DPI's, patients with restrictive lung diseases may have limited ability to use higher resistance inhalers, inhibiting complete particle deagglomeration. Inadequate deagglomeration of dry powder increases variability in particle sizes, causing larger particle aggregates to deposit in the oropharynx and upper airways, leading to cough (Grob et al., 2022). Apart from increasing potential upper airway irritation, the resulting insufficient delivery of medication to the lower airways may result in increased systemic absorption, creating additional tolerability challenges for patients. A critical advancement in the inhalation delivery space would be in the development of particles with physical and chemical flow properties that resist aggregation, as this would directly improve the mixture's aerosol distribution (Telko and Hickey, 2005). Such an advancement would enable the use of lower resistance inhalers that require less inspiratory effort for a patient, reducing treatment burden and improving drug delivery efficiency.

A Novel Formulation Approach: PRINT® Technology by Liquidia

PRINT® (Particle Replication in Non-Wetting Templates) technology has the potential to significantly advance the manufacturing of dry powder inhaled DPI formulations (Liquidia, 2025). This next-generation technology offers the unique ability to control inhaled particle sizes and shapes, giving users a higher degree of confidence that the drug reaches the targeted lung region. The geometric precision or shape of these particles can significantly enhance aerosolization, potentially allowing PRINT® engineered formulations to be compatible with a diverse array of DPI devices—ranging from low to high resistance and tailored to the specific pathophysiology of various respiratory conditions. Furthermore, PRINT® technology is designed to ensure homogeneity in particle concentration, a critical factor in maintaining consistent dosing and therapeutic efficacy. This uniformity (Figure 1) potentially mitigates variability in drug delivery, which could result in better patient outcomes (Garcia et al, 2012).

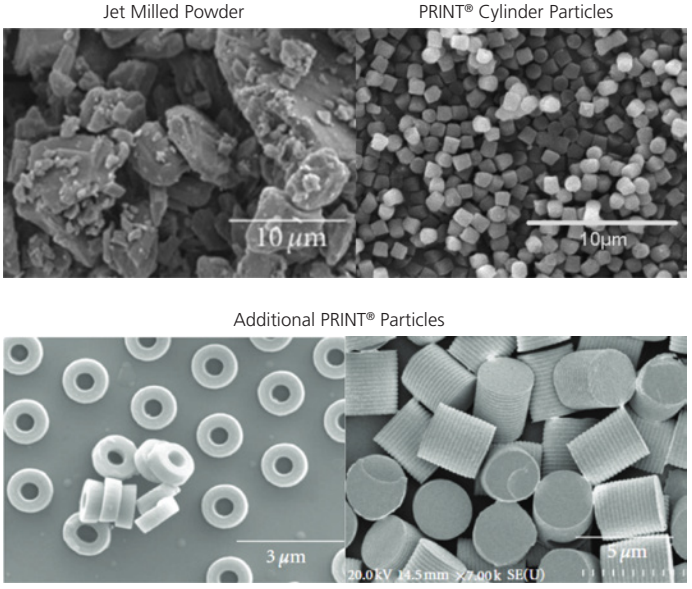

Figure 1. PRINT® particle size and shape uniformity.

Note: Many inhalation powders are made by micronization (jet milling) or spray drying resulting in large particle size distributions. PRINT® technology provides control over particle size and shape for uniformity.

PRINT® particles, which can be as small as 1 micron, also exhibit uniform aerodynamic properties, and are engineered to minimize inter-particle cohesion and provide uniform drug delivery as seen in Figure 2 (Garcia et al, 2012). Consequently, the administration process does not necessitate higher resistance (high patient effort) devices for deagglomeration, enabling the use of user-friendly, low-effort inhalation DPI devices. This novel approach facilitates the production of highly specialized inhaled particles, potentially enhancing therapeutic delivery.

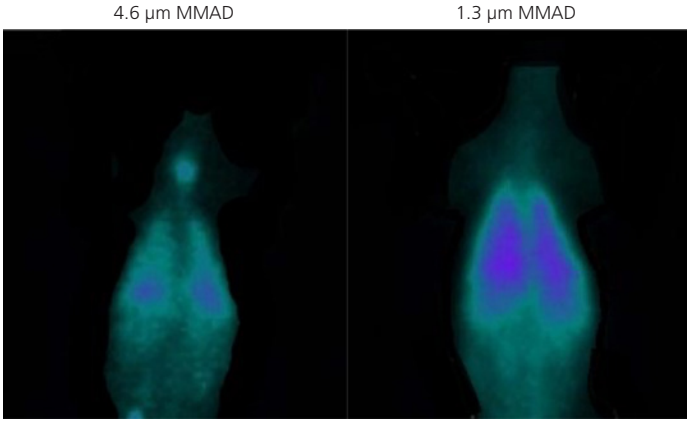

Figure 2. PRINT® torus-shaped particles.

Note: Particle size provides preferential delivery to alveolar region and less upper airway deposition as seen in a canine model using Tc99 scintigraphy with PRINT® particles.

The Future of Inhaled Therapies

The evolution of device technology in concert with advancements in drug formulations holds great promise in improving pulmonary drug delivery. Emerging liposomal formulations may mark a significant milestone in this ongoing effort. Liposomes are nanoscale lipid vesicles that can encapsulate drugs to extend their release profiles, enhance stability, and reduce dosing frequency (Sercombe et al., 2015). These innovations could potentially provide sustained therapeutic benefits for a variety of respiratory illnesses, reducing the burden of frequent dosing, and possibly improving patient adherence.

Conclusion

The development of inhaled therapies demonstrates the relentless pursuit of more tolerable, patient-friendly respiratory treatment options. Innovations such as PRINT® technology and liposomal formulations underscore the commitment to optimizing drug delivery for challenging lung conditions. As research continues, the future of inhaled therapies holds immense potential to address unmet needs and improve quality of life for patients worldwide.

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were boys, and slightly more than half were White. Among 474 children reviewed in the longitudinal analysis, 135 had early-onset asthma, 102 had later-onset asthma, and 237 had no asthma and served as control individuals. Overall, those with early-onset asthma showed significantly lower rates of longitudinal memory improvements at follow-up compared with the comparison group ($P < .01$). Developmental memory improvement in children with later-onset asthma was not significantly different from the control individuals.

Product Maintains Mobility

React Health has announced the availability of the Platinum 10L, a product backed by a long-standing reputation for quality and performance. The Platinum 10L offers a range of key features designed to meet the needs of both patients and healthcare providers: Unmatched Reliability, built to deliver consistent performance, ensuring peace of mind for both clinicians and patients. HomeFill Compatibility, enables patients with prescriptions greater than 3 LPM to maintain mobility with ambulatory oxygen, allowing them to stay active even as their condition progresses—without the need to transition to a different device. User-Friendly Design, features an intuitive control panel for easy operation, a built-in humidifier bottle holder, and simple filter access for convenient maintenance. Efficient Performance, operates with lower heat generation and reduced power consumption compared to other high-flow concentrators, offering enhanced comfort and energy savings. As the newest addition to our comprehensive product portfolio, the Platinum 10L enhances our existing oxygen solutions, joining the React Health HomeFill Oxygen System—which promotes greater patient ambulation—and the Stratus 5L Concentrator. React Health is committed to delivering products that prioritize patient comfort and enhance experience. We welcome the opportunity to discuss how the React Health line of respiratory care products can meet your specific business needs and improve your overall satisfaction with our solutions.

Product Approved for Australia

Beyond Air, Inc., a commercial stage medical device and biopharmaceutical company focused on harnessing the power of nitric oxide (NO) to improve the lives of patients, announced that the LungFit PH has received market authorization from the Australian Therapeutic Goods Administration (TGA) for sale as a Class IIb medical device to deliver nitric oxide, a vasodilator, generated by the device into the inspiratory limb of the patient breathing circuit of a ventilator in a way that provides a constant concentration of nitric oxide, as set by the user, to the patient throughout the inspired breath. “We are excited to have the opportunity to introduce our revolutionary LungFit PH system to hospitals in Australia following this market authorization by the TGA. We expect to initiate shipments to Australia in a few months through Getz Healthcare, which is our partner in the Asian Pacific region,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. “The global LungFit PH story begins now, as we begin to ramp up our commercial activities outside the U.S. so that patients and medical staff in countries around the world will benefit from nitric oxide generated from room air. CE Mark in the European Union was granted just two months ago and now approval in Australia has come. We expect additional market approvals to be granted throughout 2025 and to add to our global partner network.” LungFit PH, the first device in the LungFit therapeutic platform
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Using an Active or Passive Circuit With a Passy-Muir Valve: What Is the Difference?

Gabriela Ortiz, BS, RCP

The use of speaking valves for patients on mechanical ventilation has primarily been centered around patient tolerance and the knowledge level of clinicians.[1] Speaking valves, such as the Passy-Muir Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV), allow patients with tracheostomies to communicate verbally. The benefits of the PMV extend beyond speech, with research finding improved swallowing, reduced aspiration risk, and aid in weaning from the ventilator.[2]

Originally, the Passy-Muir Valve was designed to be used in-line with mechanical ventilation, allowing patients who were dependent on mechanical ventilation to speak.[3] While the initial development was for in-line use, some healthcare professionals have posed questions associated with its use in clinical practice. These questions typically relate to concerns with airway pressure, secretion management, air trapping, and hyperinflation. Proper staff training, valve placement, and patient monitoring are crucial to ensure safe and efficacious use of the Valve.

Clinician knowledge and training are essential for appropriate and effective use of speaking valves. This knowledge includes understanding indications, contraindications, proper fitting techniques, and the ability to monitor for signs of patient distress. Comprehensive education helps clinicians build confidence and competence in using speaking valves and ultimately enhancing patient care.

The PMV is compatible with traditional modes of ventilation whether volume or pressure ventilating in a control or spontaneous mode. Screen features, setting options, and circuits will vary from ventilator to ventilator; therefore, the clinician running the ventilator must be knowledgeable about how the ventilator reacts to changes in flow and pressures. Whether in acute care or transitioning to the homecare setting, the type of ventilator may impact some of the considerations for Valve use. If the ventilator accommodates two pre-set settings and has the option to choose a circuit with "active" or "passive" exhalation valves, this affects in how the ventilator measures and controls parameters.

Active Circuit includes an exhalation valve that actively manages the flow of air during inspiration and expiration. This active exhalation valve can manage a single or dual limb circuit, allowing for precise control over the timing and volume of breaths delivered to the patient. The exhalation side of the circuit plays a crucial role in maintaining positive end-expiratory pressure (PEEP) by preventing complete exhalation, which helps improve oxygenation and prevents lung collapse.[4]

Passive Circuit is single-limb, for both inhalation and exhalation, with an intentional leak to direct exhaled air out of the circuit.[5] The intentional leak is created by the passive ("whisper swivel") exhalation valve. This configuration can be used for invasive and non-invasive ventilation. The passive circuit is often preferred in certain settings for its simplicity and reduced complexity, providing a low-resistance pathway for the delivery of oxygen and air to the patient's airway.

Active or Passive—when should one be used over the other?

Though a ventilator circuit may seem straightforward, it involves complexities that require careful attention. A ventilator circuit is essential for delivering the correct flow and pressure of air or oxygen to the patient. It consists of tubing and connectors that link the ventilator to the patient's tracheostomy tube or endotracheal tube, ensuring that air reaches the lungs effectively.

An active circuit is normally chosen for a critically ill patient who requires close monitoring since it allows precise control over the timing and volume of breaths delivered to the patient.[5] This configuration is often common for pediatric care. A passive circuit is usually the choice for patients in a stable state who are transitioning to a step-down level of care or to home. The circuit is simple, easy to manage, and less costly. But passive circuits usually cause the most issues when placing a Valve in-line, being that it has a greater leak.

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.

Patient using a PMV 007 (Aqua colorTM) Valve in-line with an active ventilatory circuit.

The best way for a ventilator to calculate and measure patient parameters is when there are no leaks within the circuit, as even minor leaks can significantly impact the performance of the ventilator and the patient's ability to use a PMV safely. When there is a leak, the ventilator is unable to deliver the prescribed volume or pressure of air to the patient, which could lead to hypoventilation, inadequate oxygenation, or even respiratory distress if not properly managed. Understanding this leak, its cause, and how to compensate for it when needed are essential when using a Valve in-line with mechanical ventilation.

Proper humidification, secretion management, and awareness of potential obstructions are additional factors clinicians must manage when working with a patient on or off mechanical ventilation. One of the key roles of humidification is to prevent the drying out of the airway, which can lead to discomfort, mucosal damage, and impaired secretion clearance. In mechanical ventilation, especially in long-term use, it becomes crucial to ensure that the airway remains adequately humidified to keep secretions thin and easier to manage. This is especially important when using invasive ventilation, as the air delivered through the ventilator can be dry and lead to mucosal drying if humidification is not provided.

Considerations When Placing a Valve

A Passy Muir Valve is designed for patients who are stable medically, can tolerate cuff deflation, and have manageable secretions and a patent airway. The patient's ventilator parameters may also serve as support for Valve use and medical stability. The typical guidelines are that $FiO_2 \leq 50\%$, PEEP ≤ 10 cmH_2O, and PIP ≤ 40 cmH_2O. If the patient's measurements fall within these suggested parameters, the assessment usually progresses to cuff deflation and potentially Valve placement.

The assessment becomes complex when adjustments need to be made to meet specific patient needs. Integrating a speaking valve into the circuit requires proper ventilation settings and management. Maintaining positive-end expiratory pressure and monitoring the patient for signs of respiratory distress or inadequate airflow are essential during the assessment process. To address proper ventilator management, one must first understand how the Valve works.

Understanding how the Valve works. Knowing how the Valve works and how it affects flow are crucial for its effective and safe use. The Passy-Muir Valve is designed for patients with tracheostomy tubes. It allows airflow to go in through the tracheostomy tube but closes at the end of inhalation. is closed throughout exhalation, and re-directs airflow up to the vocal cords, out through the nose and mouth. This redirection of flow enables speech.[3] This redirection also restores more normal subglottic pressure, which improves swallowing safety and reduces aspiration risk.[6] Other benefits include easier ability to cough which helps clear secretions.

When used with mechanical ventilation, settings may need to be adjusted to accommodate the use of the Valve. A PMV will interrupt the flow of air being delivered to the patient; therefore, interrupting the air returning to the ventilator. This may involve changes to the mode of ventilation or the level of support to ensure the patient is comfortable and can still exhale adequately. Adjustment may also be dependent on the type of circuit being used. For example, if using a passive circuit, the ventilator may rely more heavily on the patient's breathing effort. The Valve's involvement in respiration may lead to challenges in maintaining the prescribed tidal volume or pressure support. Therefore, adjustments to the ventilator may include reducing support levels to allow the patient to breathe more freely, time or flow limiting a breath, or switching to a mode that is more flexible in responding to the patient's own respiratory efforts.

Some modes of ventilation, such as adaptive modes (i.e., Assured Volume Adjusted Pressure Support (AVAPS)), may compensate well with the Valve in-line but may not be ideal due to the inability of the ventilator to measure and calculate, thus making it difficult for the clinician to adjust for adequate ventilation. In AVAPS, the ventilator adjusts the pressure support to ensure that the patient receives a consistent tidal volume, compensating for changes in the patient's compliance or resistance. However, with the PMV in place**,** this dynamic becomes more complicated because the PMV redirects exhalation out through the upper airway and alters the airway pressures during the respiratory cycle. As a result, the ventilator may not be able to accurately assess and adjust based on the patient's true respiratory status. The machine may either overestimate or underestimate the amount of support needed. This could lead to under- or over-ventilation, putting the patient at risk for complications like hypoventilation or discomfort.

Because of these issues, it may sometimes be better to use conventional ventilator modes. Pressure Support Ventilation (PSV) or Assist-Control Ventilation (ACV) may be more adaptable in these situations, but they require careful monitoring and adjustment to ensure that the patient is not over-burdened with the effort of breathing or under-supported.

Active Circuit. With initial consideration of Valve placement, the active circuit may be the better choice compared to the passive circuit. The active circuit setting allows more freedom to adjust alarms; they should be set at levels that allow for safe alarm practices, prevent false positives, and reduce alarm fatigue.

Alarms that monitor low exhaled volume, low tidal volume, and low minute volume cannot be monitored when the Valve is in-line as no flow comes back to the ventilator. Low exhaled volume alarms may be managed by dialing them down or turning them off if available. Low minute volume (LMV) and low minute ventilation can be turned off, to help prevent alarm fatigue. It is crucial to have safe alarm practices which would mean a "disconnect" alarm (if the ventilator is unable to detect breathing or flow) and a "high pressure" alarm (to ensure the ventilator does not deliver excessive pressure) for patient safety and best practice.

Positive End-Expiratory Pressure (PEEP). With most ventilators, PEEP is managed by the amount of bias flow that is flowing through the circuit, creating back pressure to prevent the collapse of the alveoli. If the bias flow is interrupted by a leak in the system (cuff deflated or PMV), the ventilator will react with an auto trigger, auto-cycle, or air turbulence in the patient's airway, all of which can be very uncomfortable. Therefore, it is suggested to decrease the level of PEEP, prior to deflating the patient's tracheostomy tube cuff.[7] In the active circuit set up, PEEP can be dialed down to zero.

Triggers. There are two ways a patient can trigger a breath, via pressure or flow trigger. A pressure trigger occurs with minimal inspiratory effort from the patient, the vent senses the drop in pressure and cycles into the delivery of the breath. A flow trigger may be more common but in this instance with the Valve in-line, a decrease in resistance will divert bias flow away from the circuit and could also cause auto-triggering. So, at this point, a pressure trigger may be more comfortable and convenient. Some ventilators offer a flow and pressure trigger, this can help fine tune the response. If there are trigger issues, adjusting the way the ventilator triggers the breath may allow comfortable breathing.

Passive-Circuit. Application of the Valve with a passive circuit may be a little tricky. With a specific home care ventilator, clinicians are limited when adjusting settings and alarms (see above discussion under active circuit for alarm information).

For instance, with **PEEP,** the lowest available level is 4 cmH_2O. While PEEP itself does not directly cause auto-triggering, if the ventilator is set to deliver breaths based on pressure or flow triggers, the PEEP can affect the overall pressure and flow dynamics in the system. The PMV will affect flow which in turn could cause an auto trigger when the cuff is being deflated, as the bias flow diverts away from the circuit. This becomes the challenge of Valve placement with a passive circuit. However, in other instances, depending on the ventilator's software, the vent may not react significantly to the change in pressure. The patient may not feel discomfort, especially if the patient has already been using the Valve with an active circuit set up. The clinician should monitor and ensure adequate ventilation. The key is the clinician must ensure the patient gets the benefits of the PMV while avoiding issues like auto-triggering, especially as their needs or ventilator settings shift.

Conclusion

Placement of the Passy-Muir Valve is patient specific; some patients may tolerate changes in airflow just fine and others may not. Use of a PMV offers many benefits, ability to communicate, reduction in the risk of aspiration, easier ability to eat and drink, and restoration of positive airway pressure. Though a patient must be medically stable and meet certain guidelines of stability, every patient deserves the right to communicate effectively. Of course, technical aspects must be considered, but with proper education and training, clinicians will know how to manipulate ventilator settings to ensure patient comfort and best efficacy, no matter what mode of ventilation or type of circuit being used.

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Cost-Benefit Analysis: Optimizing Sleep Lab Operations for Economics and Sustainability

Ann Hewitt, RN, BSN, MM

Hospitals are not the only healthcare providers who are dealing with ever-increasing pressure to manage costs at the same time they elevate the care they can provide to patients. Providers working directly with patients in outpatient settings know the impact of decreases in funding, fewer experienced staff members and the prevalence of per-diem and travelers on their department's operations, just like their counterparts working in a hospital.

In the evolving healthcare landscape we've seen since COVID-19, operational efficiency and environmental sustainability are critical factors that influence decision-making in areas not typically associated in the patient's mind with the hospital. An example would be free-standing sleep labs, whether affiliated with a hospital or not. The number of people waiting for an in-lab sleep study is surprisingly high. An aging population presents more cases of obstructive sleep apnea every day. Even though there are about 4500 sleep labs in the US, the number of beds in each site limits the volume of patients who can undergo polysomnography testing on a given night.

Figuring out how to manage costs while providing care that supports patient compliance with their CPAP regimen is a balancing act. Sleep physicians recognize that a properly fitted mask is going to deliver the best clinical outcomes for their patients, and patients recognize that a poor fitting mask is disruptive to getting any good sleep at all.

One sleep center chose to put priority on patient outcomes. They theorized that more properly fitted masks would improve compliance in patients, thereby improving clinical results. They decided to create a daytime fit clinic which would provide multiple options for patient comfort. They evaluated the costs of buying single-use masks of all sizes and models to accommodate their patients. The results demonstrated that the costs would be so high they would be unable to afford to provide the variety they believed was necessary. That led them to consider the potential for purchasing reusable masks that could be reprocessed.

Their methodology consisted of taking stock of every device they would want to use and comparing the cost of single-use and reusable models. They were conservative in the number of times each reusable mask would be reprocessed to make the comparison as fair as possible.

As you can see from the Capital Purchase Cost Analysis (Table A), they realized that reprocessing reusable masks and accessories would cost them a total of $48,100 in the first year—including the cost of capital purchase and installation. That compared favorably with the cost of $58,993 to purchase single use masks for the same volume of patients. The real savings began in year two, once the capital cost was eliminated. After the first year, their ongoing costs were $2800 for masks, and $2300 for thermal high-level disinfection supplies (water and cleaning solution).

With a clinical background and over 30 years of infection prevention experience in industry, Ann Hewitt has a comprehensive perspective on medical device reprocessing. She has been an invited speaker at national and international meetings on reprocessing, a member of the AAMI ST91 working group and a SME for numerous publications and education programs. Ann is currently the Vice President of Sales & Marketing for Cenorin, LLC.

Financial Analysis

	Option 1 Capital Purchase + **Reusable** Masks	Option 2 No Capital Purchase + **Disposable** Masks
Equipment	$ 38,000	
Supplies	$ 2,800	$ 58,993
THLD Supplies	$ 2,300	
Add'l install cost	$ 5,000	

Total Year 1	**$48,100**	**$58,993**	**1 Year Cost Savings**	**$10,893**
Total Year 2	**$53,200**	**$117,985**	**2 Year Cost Savings**	**$64,785**
Total Year 7	**$78,700**	**$412,948**	**7 Year Cost Savings**	**$334,248**

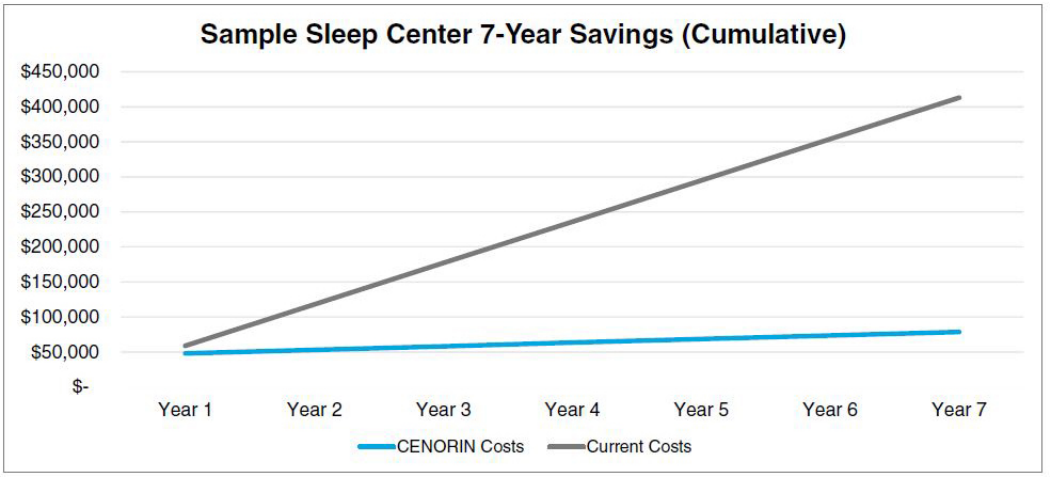

Table A. Yearly and Cumulative Costs Summary.

Those savings were cumulative across the seven year period. (Table B). The total savings of reprocessing reusable masks was $334,248—an astonishing number for a four bed sleep center.

	Option 1 Capital Purchase + **Reusable** Masks	Option 2 No Capital Purchase + **Disposable** Masks
Equipment	$ 38,000	$ -
Supplies	$ 2,800	$ 58,993
THLD Supplies	$ 2,300	$ -
Additonal install cost	$ 5,000	$ -

Inputs

1 Year Costs	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Cumulative Total
Cenorin Costs	$ 48,100	$ 5,100	$ 5,100	$ 5,100	$ 5,100	$ 5,100	$ 5,100	$ 5,100
Current Costs	$ 58,993	$ 58,993	$ 58,993	$ 58,993	$ 58,993	$ 58,993	$ 58,993	$ 58,993
Net Benefit	$ 10,893	$ 53,893	$ 53,893	$ 53,893	$ 53,893	$ 53,893	$ 53,893	$ 53,893

Annual Practice Growth %	0.00%
Annual Cost Increase %	0.00%

Customer Name: Sample Sleep Center

Center 7-Year Savings (Cumulative)

Cumulative Costs	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
CENORIN Costs	$ 48,100	$ 53,200	$ 58,300	$ 63,400	$ 68,500	$ 73,600	$ 78,700
Current Costs	$ 58,993	$ 117,985	$ 176,978	$ 235,970	$ 294,963	$ 353,955	$ 412,948
Net Benefit	$ 10,893	$ 64,785	$ 118,678	$ 172,570	$ 226,463	$ 280,355	$ 334,248

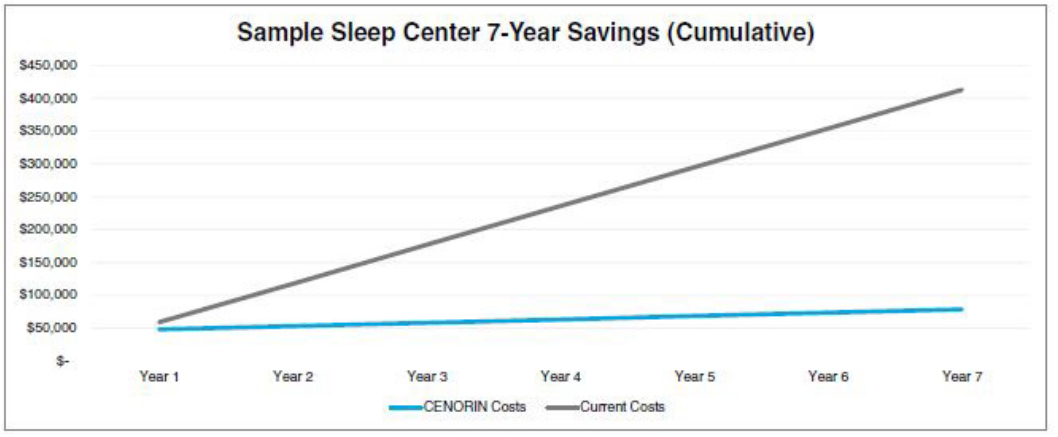

Table B. Capital Purchase Cost Analysis – 1 Year.

A detailed analysis comparing two management options for sleep lab masks, tubing and other respiratory equipment highlights the financial and ecological benefits of adopting reusable solutions.

Financial Insights

- **Initial Investment:** While Option 1 involves a higher upfront cost, the cumulative savings over seven years exceed $330,000.
- **Recurring Costs:** The reliance on disposable masks in Option 2 results in significantly higher annual expenditures, which compound over time.

Environmental Impact

While sustainability and environmental impact were not the primary drivers of their interest in reprocessing reusable devices, the Sleep Lab management team was conscious that healthcare is a big contributor to plastic waste that pollutes the environment. Practice Greenhealth pegs the average plastic waste at 29 pounds per hospital bed. That's per bed, per day. The volume of plastic single-use device waste being discarded by an average sleep lab with 4-6 beds could range from 5000 to 8000 pounds a year. The cost to dispose of this could be as much as $7200 per year, depending on location.[2] These plastics remain in our environment for hundreds of years, degrading incrementally and leaching plastic microparticles into soil and groundwater.

For the sleep professionals in this lab, the insights from Jodi Sherman, MD, an Associate Professor of anesthesiology at Yale School of Medicine and of epidemiology at Yale School of Public Health, really resonated. "Plastic doesn't biodegrade, it just breaks into smaller and smaller pieces that enter the food chain and our water systems," Dr Sherman noted in an interview. "We are continuously exposed to these micro-plastics and nano-plastics, which have been discovered throughout the human body. These plastics are laden with chemical additives that are seeding our bodies with carcinogens, neurotoxins, and endocrine-disrupting chemicals, harming our bodies, our planetary ecosystems, and future generations."[3] As sleep apnea and other neurological disorders continue to grow, the concern that environmental factors could be a contributor to these health challenges made the decision to reprocess even easier.

As seen in Table C, the sleep lab estimated their cumulative decrease in waste disposal from reprocessing their reusable

devices to be nearly 40,000 pounds over the course of seven years. There were cost savings involved in decreasing waste disposal, which the sleep lab did not evaluate since the financial benefits of reprocessing were so obvious that management didn't require more justification. Once they began reprocessing, however, they also noted that they saved money in shipping costs and recognized that decreasing shipping and extractive technology to manufacture plastic devices further contributed to more eco-conscious operations.

	Option 1 Capital Purchase + **Reusable** Masks	Option 2 No Capital Purchase + **Disposable** Masks		
Total Year 1	**262**	**5,888**	**1 Year Waste Savings (lbs)**	**5,626**
Total Year 2	**524**	**11,776**	**2 Year Waste Savings (lbs)**	**11,252**
Total Year 7	**1,833**	**41,215**	**7 Year Waste Savings (lbs)**	**39,382**

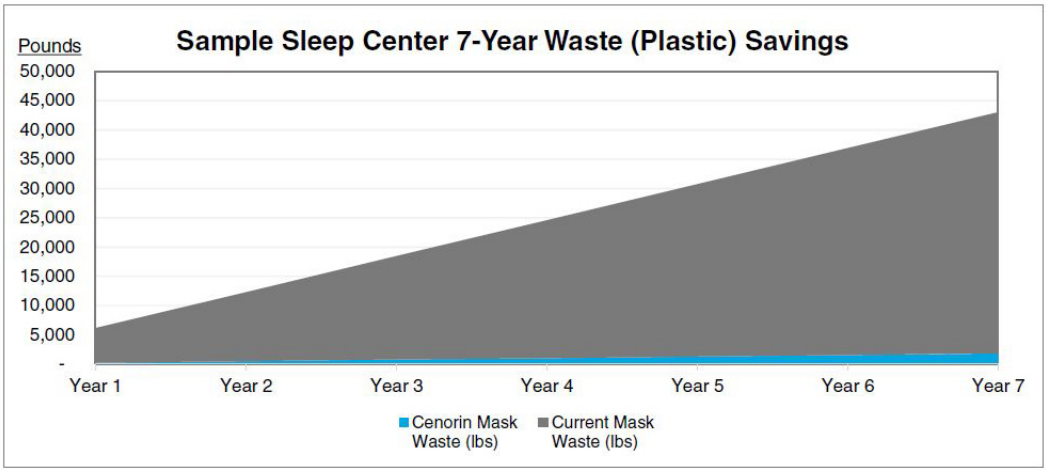

Table C. Environmental Impact – Mask Volume.

Environmental Analysis

In addition to financial advantages, Option 1 dramatically reduces plastic waste, a critical consideration for eco-conscious operations.

Sustainability Insights

- Over seven years, Option 1 reduces plastic waste by nearly 40,000 pounds compared to Option 2, significantly mitigating environmental impact. (See Table D for detailed yearly impact.)
- Adopting reusable masks that are processed using thermal high-level disinfection aligns with global efforts to reduce single-use plastics and support environmental conservation.

Cumulative Counts	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Cenorin Mask Count	270	540	810	1,080	1,350	1,620	1,890
Current Mask Count	6,070	12,140	18,210	24,280	30,350	36,420	42,490
Net Benefit	5,800	11,600	17,400	23,200	29,000	34,800	40,600

Avg Device Weight (lbs)	0.97

Cumulative Weight (lbs)	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Cenorin Mask Waste (lbs)	262	524	786	1,048	1,310	1,571	1,833
Current Mask Waste (lbs)	5,888	11,776	17,664	23,552	29,440	35,327	41,215
Net Benefit	5,626	11,252	16,878	22,504	28,130	33,756	39,382

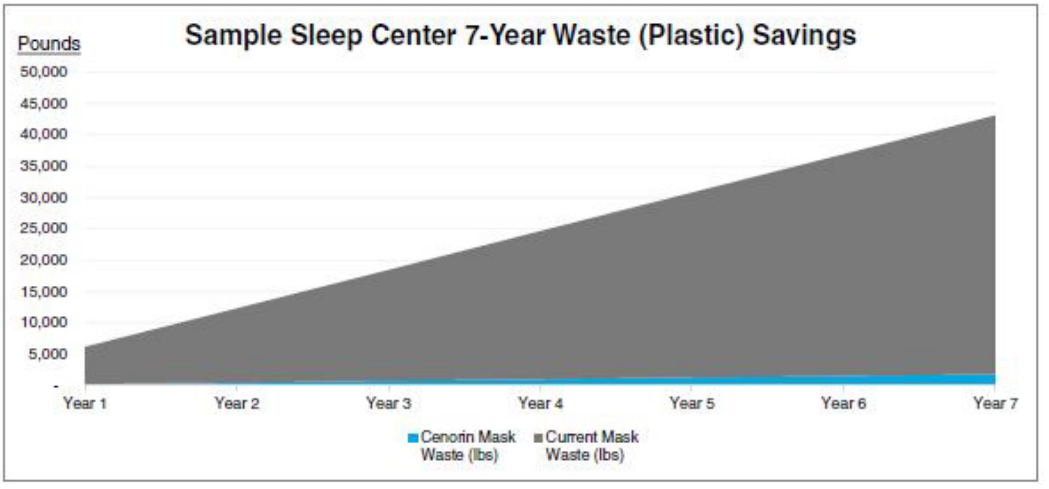

Table D. Plastic Waste Eliminated.

Strategic Insights

While no two sleep labs are alike, most share similarities — a focus on high-quality patient care, an imperative to manage their operations in a cost-effective way, and a mission to "do no harm." Unfortunately, the previously mentioned challenges for labs related to staffing and budget restrictions are coupled with a lack of familiarity about potential solutions.

Based on this analysis, sleep labs should consider implementing thermal high-level disinfection for reusable masks, tubing, humidifiers and other plastic respiratory devices used in their labs and in their fit clinics. The broad outline for a strategy would incorporate:

1. **Prioritizing Long-term Savings:** The upfront investment in Option 1 yields significant cost reductions and supports fiscal responsibility.
2. **Adopting Eco-Friendly Practices:** By minimizing plastic waste, reprocessing reusable masks and accessories contributes to broader sustainability goals and reduces your department's environmental footprint.
3. **Leveraging Economic and Environmental Synergies:** Combining cost-effective operations with sustainable practices enhances the overall value proposition of sleep labs, within the healthcare sphere and for the community at large.

Conclusion

Searching for alternatives to the status quo can yield insights that provide substantial financial and environmental benefits. The comparison in this case study between capital purchase with reusable masks and disposable mask solutions underscores the impact of integrating financial prudence with ecological awareness. Option 1 not only ensures long-term cost savings but also aligns with the healthcare industry's increasing emphasis on sustainability. The numbers don't lie — reprocessing is better for their bottom line and better for their environmental footprint. For sleep labs aiming to optimize operations and budgets while championing environmental stewardship, the choice is clear: invest in reusable solutions for a sustainable future.

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of nitric oxide generators, leverages the company's patented Ionizer® technology and has already received FDA clearance in the United States and European CE Mark approval. LungFit PH uses Ionizer technology to generate unlimited on-demand NO from ambient air and deliver it to a ventilator circuit, regardless of dose or flow. The device uses a compressor to drive room air through a plasma chamber where pulses of electrical discharge are created between two electrodes. The LungFit PH system ionizes the nitrogen and oxygen molecules, forming NO with low levels of nitrogen dioxide (NO2) created as a byproduct. The gas is then passed through a Smart Filter, which removes toxic NO2 from the internal circuit. LungFit PH represents a significant step forward in sustainable healthcare solutions. Since the device generates NO conveniently and cleanly from ambient air, without the need for tanks or chemicals, it is highly energy-efficient, using only the power equivalent to a 60-watt light bulb. By eliminating the emissions associated with truck transport and cylinder refills, LungFit PH supports hospital sustainability initiatives, helping facilities reduce their carbon footprint while delivering critical care to patients. For the approved indications, the novel LungFit PH system is designed to deliver a dosage of NO to the lungs that is consistent with the current standard of care for delivery of 20 ppm NO, with a range of 0.5 ppm – 80 ppm (low concentration NO) for ventilated patients. Each Smart Filter will last 12 hours regardless of ventilator demands, and replacing a filter only takes seconds. Potential customers can visit the LungFit PH website, www.lungfitph.com, for additional information, including the product label, and to sign up for updates.

More Biologics May Be Breaking Through for COPD

New biologic drugs for chronic obstructive pulmonary disease (COPD) are finally here, said Stephen Rennard, MD, in a presentation in a session on new drugs at the 2024 GOLD International COPD Conference. The inflammatory pathways associated with COPD are diverse and offer a range of potential targets for biologics, said Rennard, a professor of pulmonary, critical care, and sleep medicine at the University of Nebraska Medical Center, Omaha, Nebraska. The therapeutic goals of biologics remain the same as with other treatments for COPD, namely restoration of normal inflammatory response and alteration of disease progression, as well as restoration of lost structure and function and improvement of systemic effects, Rennard said in his presentation. Most studies of new and up-and-coming drugs have improvement in acute exacerbation of COPD as the primary outcome, he added. T2 inflammation is "an inflammatory cascade led by IL-4, IL-13, and IL-5," Mona Bafadhel, MD, chair of Respiratory Medicine at King's College London, London, England, said in her presentation during the session. Bafadhel, who served as one of the investigators on the BOREAS and NOTUS studies, explained some of the science behind the development of the new biologics. Eosinophils are powerful regulators of immune response and inflammation by stimulating T-cell production and affecting other immune cell types, she noted. In the context of COPD and drug development, high blood eosinophil counts have been associated with increased COPD-related exacerbations, Bafadhel said. She cited data from a Dutch study of more than 7000 patients with COPD (with and without clinical diagnoses), in which absolute eosinophil counts ≥ 3.3% were associated with increased risk for severe exacerbations of 32% and 84% across all patients with COPD and clinical COPD, respectively.

Continued on page 52…

THERMAL HIGH-LEVEL DISINFECTION

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Several recent studies of up-and-coming biologics have focused on subsets of COPD patients, said Dave Singh, MD, professor of clinical pharmacology and respiratory medicine at The University of Manchester, Manchester, England, in his presentation at the meeting. In September 2024, the US Food and Drug Administration (FDA) approved dupilumab as the first biologic treatment for patients with uncontrolled COPD and type 2 inflammation on the basis of eosinophil counts. Singh cited data from the BOREAS and NOTUS studies in which dupilumab significantly reduced exacerbations and improved lung function in these patients compared with a placebo. Mepolizumab, a biologic approved for asthma, is not currently approved for COPD, but data from a 2017 study showed a trend toward reduced exacerbations compared with placebo in a subset of patients with high blood eosinophil counts, Singh said. In addition, a recent unpublished phase 3 study (MATINEE) showed a reduction in the annualized rate of exacerbations compared with placebo on the basis of up to 2 years' follow-up. Singh also highlighted data from a phase 2a study of astegolimab, a biologic drug that focuses on the IL-33 receptor, in which COPD exacerbation rates were not significantly different between treatment and placebo groups. However, astegolimab has shown safety and efficacy in adults with severe asthma and is under development in phase 3 trials for COPD.

New Product Called a Breakthrough

Precision Medical Inc.'s new Filtered Vacuum Trap is more than just an upgrade; it's a breakthrough in patient safety, infection control, and equipment protection." The 'X' in PMX stands for extra—and that's exactly what the PMX 900 Filtered Vacuum Trap delivers: Extra Protection: Prevents fluids from entering suction regulators and central suction wall systems. "The clear float ball at the bottom of the trap acts as your first line of defense. It rises to seal off the trap if fluids enter, preventing contamination of both the suction regulator and central suction wall systems. This protects vital equipment and avoids costly replacements." Extra Safety: Provides clear and visible positive vacuum flow monitoring for better patient care. "The green float ball ensures reliable positive vacuum flow monitoring. When the vacuum is working correctly, the green ball floats, confirming active flow. If it's not visible, it indicates an occlusion. With as little as 3 liters per minute of flow, you'll know suction is functioning properly." Extra Infection Control: Features a 0.4-micron bacteria filter for enhanced system and patient safety. "The 0.4-micron bacteria filter at the top provides an additional layer of protection, preventing contaminants from entering the vacuum regulator or central suction wall system. This safeguards patients and minimizes the risk of expensive equipment contamination." The PMX 900 is compatible with older Precision Medical vacuum regulators when paired with the PMX 901 adapter, making it an easy and cost-effective upgrade." For more information, visit https://precisionmedical.com/product/pmx900-filtered-vacuum-trap/

Key Topics in 2025 GOLD Report Include CVD Risk, Spirometry

Spirometry information now includes more comprehensive information on lower limit of normal (LLN), z-scores, and reference values, said Claus F. Vogelmeier, MD, of the Philipps-University of Marburg, Marburg, Germany, in a presentation of the report at the 2024 GOLD International COPD Conference. Race-corrected reference values may have important consequences for patients, Vogelmeier noted. He referenced data from a study in *The New England Journal of Medicine* showing that race-neutral or adjusted values may affect clinical outcomes. Although questions remain about the validity of the GLI-Global equations given their lack of consideration of population differences, the new GOLD Report continues to recommend their use as the reference standard to assess lung function impairment, Vogelmeier said. A chart included in the report compares fixed ratio and LLN; although fixed ratio is simple and established, there is a risk for overdiagnosis in older adults, said Vogelmeier. By contrast, LLN relies on reference values. COPD should be considered in any patient with dyspnea, chronic cough or sputum production, and/or a history of exposure, and pre-bronchodilator measures < 0.7 merit further attention, said Vogelmeier. However, forced spirometry showing a post-bronchodilator FEV1/FVC < 0.7 is mandatory for a diagnosis of COPD, he said. The CT section of the report also has been updated to address the use of CT imaging, with new details on its use for detecting emphysema, lung nodules, and COPD-associated morbidities, Vogelmeier said.

New Filter Introduced

Introducing the new Passy Muir Tracheostomy Viral and Bacterial Airway Protection Filter (PM-APF15). This new lightweight, non-sterile filter is designed for single-patient use for non-mechanically ventilated pediatric and adult tracheostomy patients, and provides bacterial and viral filtration efficiency of >99.9%, while effectively filtering out >99% of all airborne particulates.

RSV Vaccines and Treatments Face Global Access Hurdles

Almost 70 years after the discovery of the respiratory syncytial virus (RSV), vaccines and preventive treatments are giving babies a chance to beat the potentially deadly childhood infection. As doctors turn to monoclonal antibody therapies and governments plan vaccination programs, clinical researchers are asking whether these measures will reduce the spread of the virus. Will fewer babies die from RSV, and fewer children develop permanent wheezing? Fabio Midulla, an associate professor of pediatrics at Sapienza University of Rome in Rome, Italy, said that the pharmaceutical industry is poised to push governments to use vaccines and monoclonal antibodies for even more children. "Such a push might work," he said at the European Respiratory Society (ERS) 2024 Congress, "given that several studies have already demonstrated that their use can improve outcomes for children who do become infected and reduce societal costs by reducing hospitalizations." But Mariëlle WH Pijnenburg, a pulmonary specialist at Erasmus University Rotterdam in Rotterdam, the Netherlands, said at the Congress that greater rollout would require governments to force industry to lower prices. If treatments remain beyond the reach of lower-income countries — where the burden of RSV is the greatest — the death toll from this common childhood infection will remain stubbornly high, and the prospect of global elimination will remain forever out of reach, she said. Nirsevimab, a long-acting monoclonal antibody given to newborns to prevent severe infection, was approved by the European Medicines Agency (EMA) in October 2022 and the US Food and Drug Administration (FDA) in July 2023. And Abrysvo, a vaccine given to older adults and pregnant women to stop them from passing the virus to babies from birth through 6 months of age, was approved by the FDA and the EMA in 2023. RSV is responsible for over 33 million lung infections in children younger than 5 years annually, with more than 4 million hospitalizations and
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When paired together, the PMX large gauge vacuum regulator and the filtered vac trap provide an all-in-one solution that enhances patient safety and decreases the chance of contamination.

News…continued from page 52
nearly 200,000 deaths. According to the Centers for Disease Control and Prevention, every year, 2.1 million children younger than 5 years old visit a healthcare provider because of an RSV infection and between 58,000 and 80,000 children younger than 5 years old are hospitalized in the United States. The burden of severe RSV disease is also high among adults, with an estimated 123,000-193,000 hospitalizations, 24,400-34,900 ICU admissions, and 4680-8620 in-hospital deaths occurring annually among US adults. While the virus affects all age groups, it is particularly severe in infants, swelling their airways and causing them to struggle for breath. Infection in infancy can lead to later complications, such as the development of wheezing, a condition that causes breathlessness and a feeling of tightening in the chest, and possibly also asthma. Studies have shown that children and preterm infants infected with RSV who were given monoclonal antibodies experienced less post-infection wheezing, suggesting that RSV prophylaxis could prevent the development of wheezing bronchitis. A study conducted in Galicia, Spain, showed that only 0.3% of infants who received prophylaxis with Nirsevimab were hospitalized for RSV-related lower respiratory tract infections. "This is very promising," Yvonne Maldonado, MD, professor of pediatrics and epidemiology and population health at Stanford University in Stanford, California, said. "But this virus is ubiquitous. It's found everywhere. It comes around every winter season. And immunity is not long-lasting." Older children who are not receiving monoclonal antibodies still experience RSV-related hospitalizations, suggesting the virus continues to circulate at high enough levels in the community. "The vaccine and monoclonal antibodies can reduce the risk of hospitalization and more severe disease in young kids, but they won't eliminate the virus," Maldonado said. "Right now, the goal is to prevent serious infection, not to prevent the spread of the virus completely." Currently, the RSV vaccine and monoclonal antibodies are only given in the United States, Europe, United Kingdom, and Canada to newborns, children at risk for severe disease, and pregnant women. However, Midulla said that pharmaceutical companies are pushing to broaden the rollout to a broader population within these countries. Yet, he said, over 99% of RSV infection–related deaths occur in the Global South. No pharmaceutical company has sought approval in low-income countries such as those in Africa.

Whooping Cough and Newborns: How to Set Boundaries

Whooping cough is making a dangerous comeback across the US, with cases soaring to 4.5 times more this year than last, according to the CDC. For parents of newborns, this highly contagious respiratory illness poses a serious threat — and protecting your baby starts with setting clear boundaries. That might mean asking grandparents, friends, and other loved ones to follow precautions before meeting your little one. If the pandemic taught us anything, asking people to take medical precautions doesn't always go over well. Still, it's necessary. "Babies are very vulnerable in the first 6 months of life," said Rachel C. Orscheln, MD, medical director of ambulatory pediatric infectious diseases at St. Louis Children's Hospital. "So, we try to have multiple layers of protection around them." The stakes are high: *Bordetella pertussis*, the bacteria behind whooping cough, spreads easily through airborne droplets, often hiding behind symptoms that look like a common cold. But with the right strategies, parents and caregivers can work together to keep infants safe. The CDC and American Academy of Pediatrics recommend that parents, relatives (including kids and teens), and caregivers who will be in close contact with a new baby get the pertussis vaccine shots and boosters. Immunity to pertussis develops over about 2 weeks after the shot. "Since pertussis is most serious in those less than 1 year of age, anyone who has close contact with infants should be up to date with their vaccine," said Dean Blumberg, MD, chief of the Division of Pediatric Infectious Diseases at the University of California, Davis, and a spokesperson for the American Academy of Pediatrics. "This protects the infant by decreasing the risk that a contact will potentially infect them. About one third of babies with pertussis need to be hospitalized. And almost all deaths due to pertussis occur in those less than 1 year of age." Asking visitors with cold-like symptoms to postpone their visit is critical. "Pertussis is generally transmitted by close contact, being within 6 feet of an infant," Blumberg said. "Symptom screening — excluding visitors who have symptoms such as fever, cough, sneezing — is always a good strategy to protect infants against pertussis and other respiratory infections." Ultimately, it is up to the parents to decide what measures they would like in place to protect their baby, the experts said. But in general, stricter measures are often better for younger babies, as that's when pertussis is most serious, Blumberg said.

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