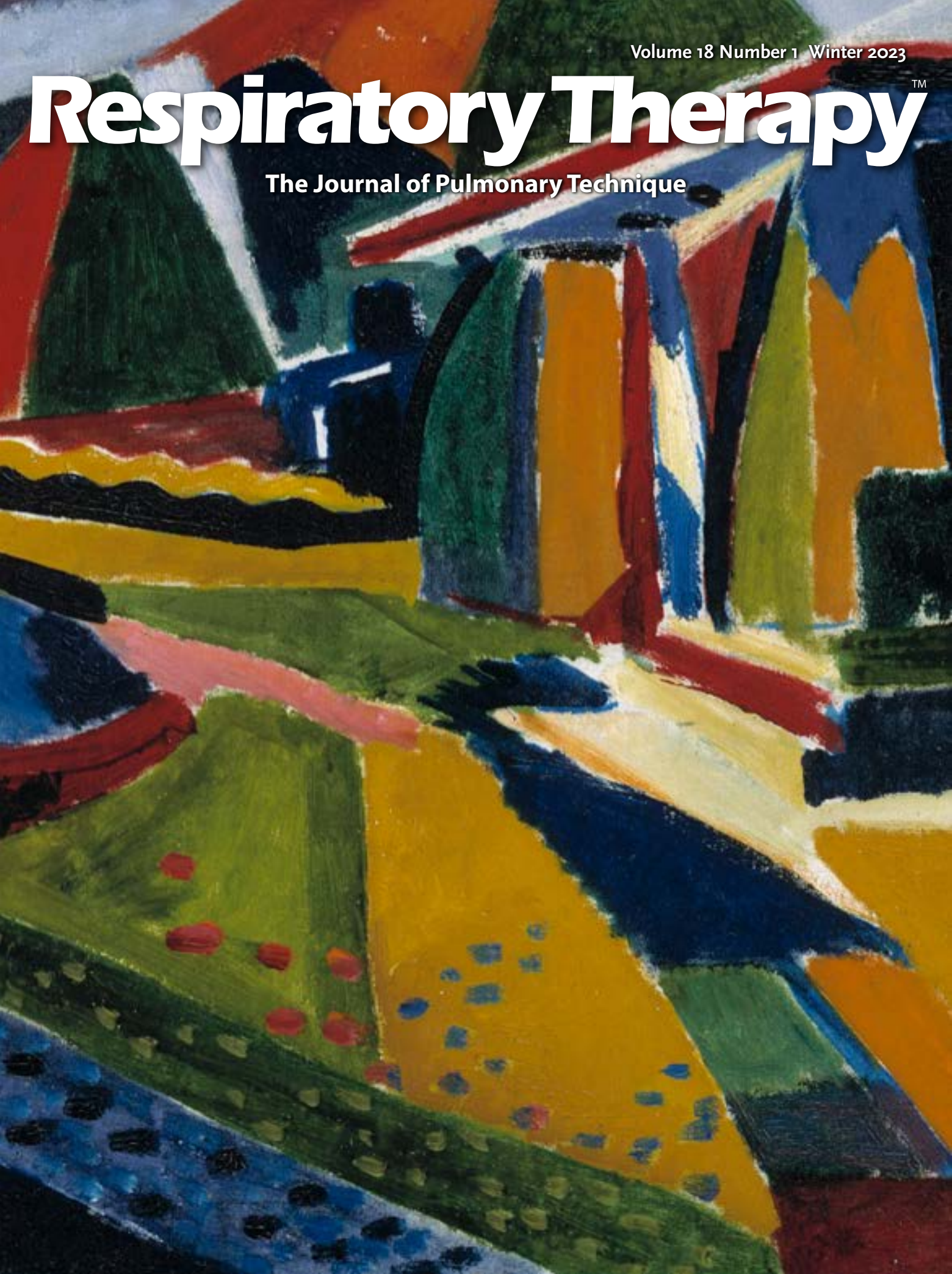
Volume 18 Number 1 Winter 2023

Respiratory Therapy™

The Journal of Pulmonary Technique



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[1]Hasani A et al. *Chron Respir Dis*. 2008;5(2):81-86. [2] Roca O et al. *Respir Care*. 2010;55(4):408-413.

* The softFlow is FDA cleared for flow rates up to 50 L/min and in hospital and long-term care facilities. The 60 L/min version and the home use version are being made available in the US under the FDA Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the COVID-19 Public Health Emergency.

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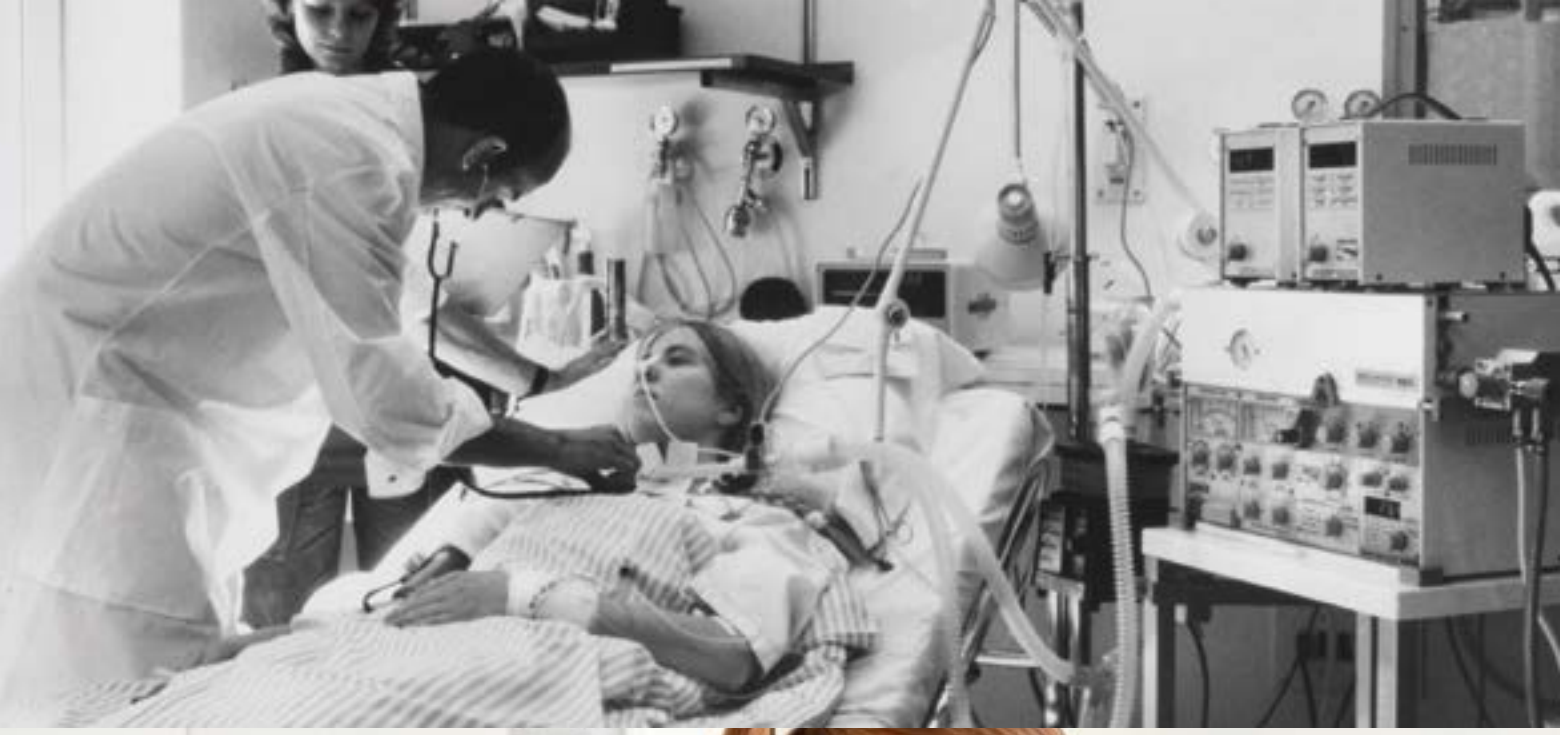

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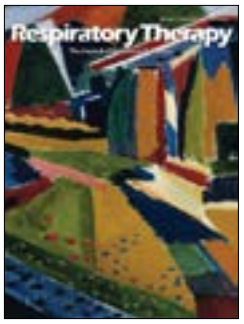
GETINGE



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■ Winter 2023

New Lung Treatment for Neonates

Beyond Air, Inc., a clinical-stage medical device and biopharmaceutical company focused on developing inhaled nitric oxide (NO) for the treatment of patients with respiratory conditions, including serious lung infections and pulmonary hypertension, and, through its affiliate Beyond Cancer, ultra-high concentration nitric oxide (UNO) for the treatment of solid tumors, announced that the US Food and Drug Administration (FDA) has approved LungFit PH to treat term and near-term neonates with hypoxic respiratory failure (often referred to as persistent pulmonary hypertension of the newborn or PPHN) (prescription use only). LungFit PH is the initial device from the LungFit therapeutic platform of nitric oxide generators that use our patented Ionizer technology and is the first FDA-approved product for Beyond Air. Steve Lisi, Chairman and CEO of Beyond Air, commented, "The FDA approval of LungFit PH enables a new era of nitric oxide therapy and marks a pivotal event for Beyond Air as we officially enter the U.S. market. As the first and only approved nitric oxide generator and delivery system, LungFit PH empowers healthcare providers to maximize the efficiency of a hospital when treating PPHN by moving beyond their reliance on traditional, inefficient delivery systems and the associated burdensome logistics and safety requirements." Lisi added, "I am immensely proud of the Beyond Air team for navigating a multitude of obstacles over the past five years, especially the last 27 months during the global pandemic, to bring this revolutionary device to market. The approval of LungFit PH validates our patented Ionizer technology and lays out a premarket approval model for our other LungFit platform devices, including LungFit PRO and LungFit GO. We believe that LungFit PH is just the first in a series of our medical devices that, if approved, will become available for treating a wide variety of respiratory diseases as we remain dedicated to our mission of harnessing the power of nitric oxide for all who can benefit from this transformational therapy." LungFit PH uses patented Ionizer technology to generate unlimited on-demand nitric oxide 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 uses power equivalent to a 60-watt lightbulb to ionize the nitrogen and oxygen molecules, forming nitric oxide with low levels of nitrogen dioxide (NO2) created as a byproduct. The gas is then passed through a Smart Filter, which removes the toxic NO2 from the internal circuit. For the treatment of PPHN, the novel LungFit PH system is designed to deliver 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 takes just a few seconds. NO gas is a vasodilator approved in dozens of countries to improve oxygenation and reduce the need for extracorporeal membrane oxygenation (ECMO) in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilator support and other appropriate agents. Low concentration inhaled NO therapy has been the standard-of-care for PPHN for over 20 years in the United States. PPHN is a lethal condition and secondary to failure of normal circulatory transition at birth. It is a syndrome characterized by elevated pulmonary vascular resistance (PVR) that causes labile hypoxemia due to decreased pulmonary blood flow and right-to-left shunting of blood. Its incidence has been reported as 1.9 per 1,000 live births (0.4-6.8/1,000 live births) with a mortality rate ranging between 4-33%. This syndrome complicates the course of about 10% of infants with respiratory failure and remains a source of considerable morbidity and mortality. The Beyond Air commercial team will be actively working with select hospitals beginning this month to make LungFit PH

Acute Care Diagnostics

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available to them with a broader US hospital launch expected in the first half of 2023.

Company Launches Full Market Release of Watch

Masimo announced the full market release of Hydration Index (Hi) for the Masimo W1 watch. The Masimo W1, an advanced health tracking wearable, is the first watch to offer accurate, continuous pulse oximetry measurements and insightful health data, from the leader in hospital pulse oximetry. Hydration Index, first announced earlier this year in a limited market release, provides an index that tracks an individual's hydration levels and integrates seamlessly with other continuous Masimo W1 health data, such as oxygen saturation (SpO2), pulse rate, respiration, and more. Hydration level has been one of the most sought out parameters by athletes, vocalists, and others seeking to optimize their performance. Since creating PVi—which allows clinicians to assess fluid responsiveness of mechanically ventilated patients—nearly 15 years ago, Masimo has been working to invent a way to help people gain insight into hydration. Proper hydration is widely recognized as an important aspect of health and performance, and lack of proper hydration affects many physiological parameters, as the body works to restore homeostasis. Masimo W1 is designed to help you identify your hydration baseline, helping you understand your hydration level, which not only affects athletic performance, but can also support healthier lifestyle decisions. Whether you're an elite athlete, a vocalist, a health-focused individual, or just keen to gain more insight into your body's physiological status, Masimo W1 with Hydration Index represents a breakthrough solution to better understand and manage hydration health. Tommy Haas, Olympic silver medalist and professional tennis player, said, "I have wanted to know the level of my hydration since I began competing, but always had to guess about it. Masimo W1 with Hydration Index finally makes this possible." Nick Mayhugh, World Record holder and three-time Paralympic champion, added, "As a professional athlete who trains six days a week and ten hours a day, I need to know my hydration levels at all times. Masimo's Hydration Index technology will provide athletes of all levels the opportunity to maximize their training and recovery programs, leading to optimal performance." Known for its exceptional accuracy and reliability during challenging conditions, such as motion and low perfusion, Masimo, with the Masimo W1, brings its expertise in signal processing, photonics, and bio-sensing to consumers looking to take control of their personal health, make better health decisions, and monitor their overall physiological status. Masimo W1 pairs via secure Bluetooth to the Masimo Health smartphone app to unlock meaningful, actionable insights. The integrated Personal SafetyNet subscription service gives users access to sophisticated reporting tools to help them review their physiological status over time and facilitates sharing data with family members, fitness trainers, wellness coaches, and where allowed, healthcare providers. Benefiting from Masimo's expertise in hospital connectivity and hospital automation, a medical version of Masimo W1 will be available outside the US for use in telehealth and telemonitoring applications via Masimo SafetyNet and Personal SafetyNet for healthcare providers and payers, as well as individual use. Masimo W1 is a convenient, reliable remote monitoring and telehealth solution enabling hospitals and clinicians to proactively keep track of their patients' physiological status from afar, even as patients go about everyday tasks at home. A natural complement to the Masimo SafetyNet remote patient monitoring platform, Masimo W1 enables wireless transmission of patient data to the Masimo SafetyNet app and Masimo's secure data cloud, where it can be reviewed in near-real time by remote monitoring teams in centralized locations for signs of physiological decline or sudden changes, such as falls or spikes in heart rate. Dr Amin, Professor, Endowed Chair of Medicine and Executive Director of Hospital Medicine at the University of California, Irvine, said, "Evaluating intravascular volume status is a common problem in clinical care, particularly for post-op patients and those with complicated chronic conditions such as congestive heart failure (CHF). These patients often seek care in the emergency department (ED) for monitoring and treatment. Masimo W1 helps individuals understand their hydration level by tracking their Hydration index (Hi), and provides a common additional monitoring endpoint beyond daily weights for evaluation of hydration. Having continuous, noninvasive monitoring of Hi available in a wearable device means people are now able to access important, real-time information at home. This has the potential to be a game changer for all involved in the management of chronic conditions like CHF, and also for those managing post-op patients." Joe Kiani, Founder and CEO of Masimo, said, "Masimo W1 represents numerous firsts: the first wrist-worn wearable device to offer consumers accurate, continuous pulse oximetry. The first—but not the last—such device from Masimo. And, with Hydration Index, the first watch to give users actionable, insightful hydration data, helping everyone to make healthier decisions so that they can live their best lives." Masimo W1 and Hi have not been cleared by the FDA and are not available for use in medical applications in the US.

MediPines Expands Distribution of Technology to Canada

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leader in the development of gas exchange measurements, has announced that its MediPines AGM100, the world's first FDA-cleared, non-invasive pulmonary gas exchange analyzer, is now available throughout Canada, thanks to an agreement with LevoMed Canada Inc., a company focused on providing the Canadian health care market with high quality innovative products. This Canadian national distribution launch kicked off at the 50th meeting of the Respiratory Therapy Society of Ontario to help meet the growing demand for non-invasive assessments in the face of surging respiratory care. The MediPines AGM100 is the world's only medical device which delivers a measure of a patient's Oxygen Deficit (a non-invasive respiratory impairment severity measurement). The technology provides reliable, discriminative readings that enable real-time decision support for healthcare providers during times of surging respiratory patients and medical staff shortages. "As the exclusive Canadian distribution partner of MediPines, we are excited to bring the benefits of the AGM100 to the Canadian healthcare system," said Madhu Venkat, LevoMed Canada's CEO. "We're enthusiastic about the partnership and are keen to support the growing need for effective, quick, and accurate gas exchange monitoring for the Canadian population with the help of the unique AGM100. It is an innovative cardiopulmonary diagnostic support technology, which we see as an important scientific innovation for detecting respiratory impairment non-invasively." "It's great to have a group of MedTech veterans such as Madhu, John, Mark, Perry, and William of the LevoMed team spearheading our technology adoption in leading hospitals throughout Canada, especially during this time of increased need," said MediPines CEO, Steve Lee. Last year, the World Health Organization (WHO) designated the MediPines AGM100 as one of notable innovative health technologies for the treatment of COVID-19 and other global priority diseases in its WHO Compendium of Innovative Health Technologies.

Medical Masks, N95s May Offer Similar Prevention vs COVID: Study

Regular medical masks might provide protection similar to that of N95 respirators in preventing SARS-CoV-2 infection among healthcare workers, according to the first randomized trial that tested the two types of masks head to head in the COVID-19 era. Owing to limitations in the study, however, the authors were only formally able to conclude that healthcare workers who wore medical masks while treating COVID-19 patients were not twice as likely to contract the virus as workers wearing N95 respirators. "Nonetheless, this trial provides the best evidence to date on comparative effectiveness of mask types in preventing SARS-CoV-2 infection in health care workers providing routine patient care," writes Roger Chou, MD, in an editorial published with the study. In summarizing, Chou said that "the results indicate that medical masks may be similar to N95 respirators in Omicron-era settings with high COVID-19" rates, but the researchers set a low bar for establishing whether one is more effective than the other. "Therefore, the results are not definitive," Chou writes. In the study, published in *Annals of Internal Medicine*, the authors evaluated 1009 healthcare workers in Canada, Israel, Pakistan, and Egypt who had not been vaccinated against SARS-CoV-2 and had not previously been infected by the virus. Participants were randomly assigned to wear either a medical mask or an N95 respirator for 10 consecutive weeks. The study period was from May 2020 to March 2022. Reverse transcriptase polymerase chain reaction tests confirmed that COVID occurred in 52 of 497 (10.46%) participants in the medical mask group, vs 47 of 507 (9.27%) in the N95 respirator group (hazard ratio [HR], 1.14; 95% CI, 0.77–1.69). The World Health Organization recommends medical masks (sometimes called surgical masks) for routine care, while the Centers for Disease Control and Prevention recommends that N95s be used while caring for COVID-19 patients. Prior to the pandemic, research showed that N95s and medical masks carried similar risks while caring for patients with influenzalike illnesses.

Persistent Asthma Linked to Higher Carotid Plaque Burden

Persistent asthma is associated with increased carotid plaque burden and higher levels of inflammation, putting these patients at risk for atherosclerotic cardiovascular disease (ASCVD) events, new research suggests. Using data from the MESA study, investigators analyzed more than 5000 individuals, comparing carotid plaque and inflammatory markers in those with and without asthma.

They found that carotid plaque was present in half of participants without asthma and half of those with intermittent asthma, but in close to 70% of participants with persistent asthma. Moreover, those with persistent asthma had higher interleukin-6 (IL-6) levels, compared with those without asthma or those with intermittent asthma. "The take-home message is that the current study, paired with prior studies, highlights that individuals with more significant forms of asthma may be at higher cardiovascular risk, and make it imperative to address modifiable risk factors among patients with asthma," *Continued on page 22…*

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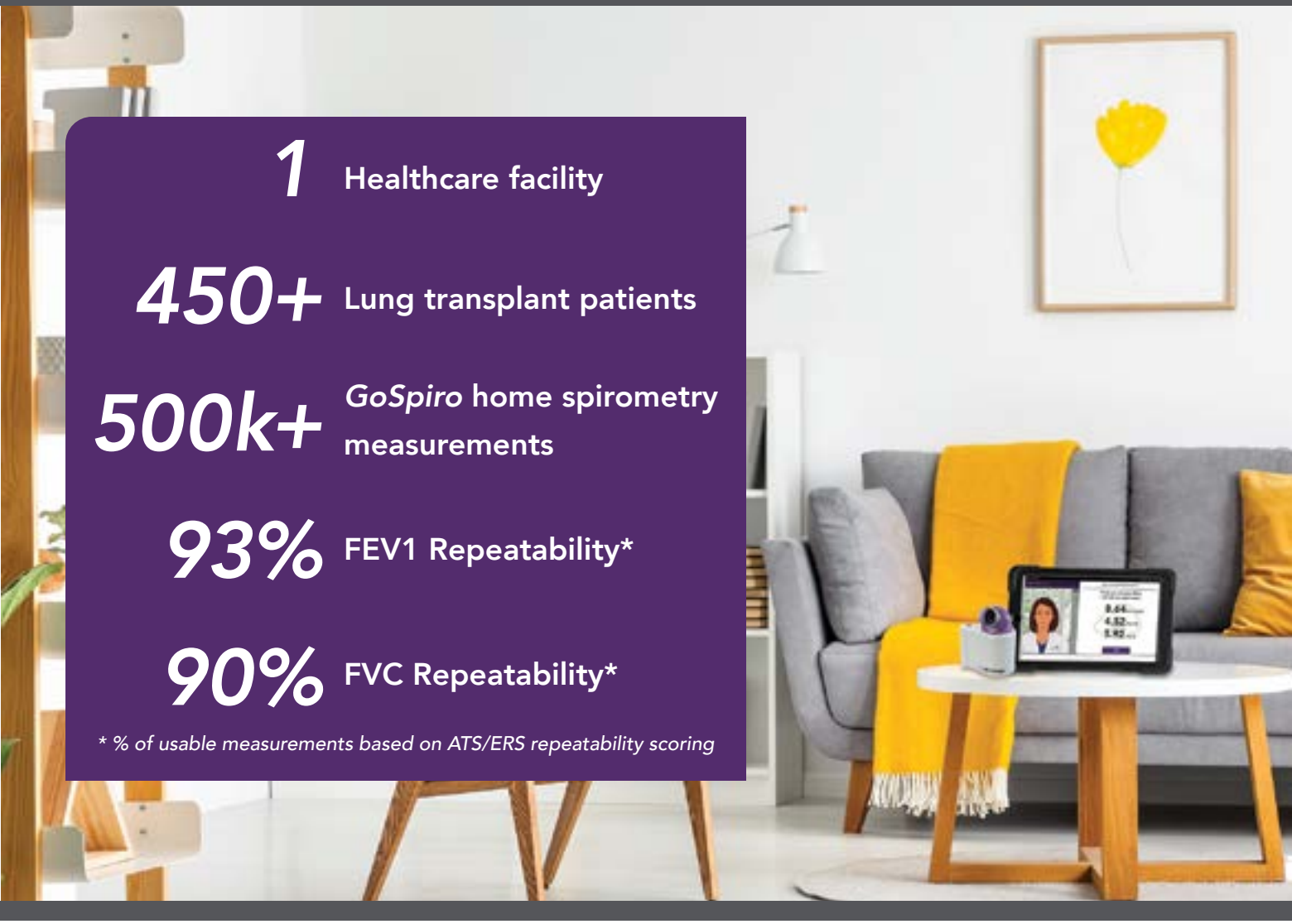

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GoSpiro Spirometer

Monitored Therapeutics Inc. (MTI) is the leader in respiratory technology for remote healthcare and clinical trial applications. The maker of the GoSpiro spirometer, MTI offers solutions that capture lab quality spirometry anywhere; helping providers and care teams better manage and monitor patients with COPD, Cystic Fibrosis, Asthma, IPF, Lung and Stem Cell Transplant as well as neurological diseases.

The GoSpiro has specific FDA clearance for home self-testing and complies with the most recent 2019 ATS/ERS requirements. Avatar-assisted technology within the application coaches patients to consistently perform quality ATS/ERS measurements, then instantly uploads the data into the GoCarePortal for clinician review.

The versatile GoSpiro platform supports both in-clinic diagnostics and ongoing remote patient monitoring with integrated tracking and trending of a patient's spirometry, weight, pulse oximetry, blood pressure, or temperature (or many other physiologic parameters). Automated alarms and alerts inform care teams of significant changes in a patient's lung function, leading to earlier interventions and better outcomes. Disease specific CarePlans help make care coordination more efficient by enhancing clinical decision making, boosting patient engagement and automating data review. GoSpiro monitoring also helps reduce healthcare costs by reducing unnecessary appointments, ED visits and hospital admissions, while creating efficiencies for the clinical staff.

PulmOne's MiniBox+

PulmOne's MiniBox+ is the first portable, cabinless pulmonary function test (PFT) device with gasless LVM plethysmography, as well as spirometry and diffusion testing. It complies with all COVID-19 safety recommendations.

The MiniBox+ provides spirometry, fully automatic lung volumes and single breath diffusing capacity (DLCO) testing in as little as 15-20 minutes. Measurements are simple to perform for the clinician and comfortable for the patient.

In a recent multi-center study published in CHEST, MiniBox+ lung volumes were shown to be equivalent to body plethysmography ("body box").

Easy: Fully Automatic Lung Volume Measurements and DLCO. Testing can be performed by anyone on the medical office staff. All results are automatically generated.

- Accurate: Clinically validated in 700+ patients at 11 medical centers, results are highly accurate and repeatable.
- Fast: Lung volumes are performed with as little as 60 seconds of tidal breathing. Spirometry, lung volumes and DLCO are performed in as little as 15-20 minutes.
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- Reimbursable: All tests are eligible for reimbursement in the USA. (subject to specific health plan policy). Visit us: www.pulm-one.com

SPOTLIGHT ON VENTILATION

Breas

Responses provided by Mark Kolnsberg, Senior Director of Marketing and Product Management at Breas Medical, Inc.

Tell us about Breas product offers and features.

Breas Medical offers travel sleep along with post-acute and home patient ventilation solutions. Founded in 1991 in Gothenburg, Sweden, Breas Medical has become one of the global leaders in Home Mechanical Ventilation, Airway Clearance, and Sleep Therapy. Our vision is to provide *Innovation for better*

We could send **23,000+** patients to your office to tell you how well the Philips InCourage system works.

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61% **Yearly rate of hospitalization decreased**

RespirTech patients reported after 12 months of Philips InCourage vest therapy.[1,2]

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Methodology: Phone surveys at regular intervals with bronchiectasis patients using the InCourage system. Data collection began 10/01/2013. As of 05/31/2021, the total cohort was 23,213 patients; 21,049 patients completed the baseline survey; 13,303 patients in 1-month cohort; 9,569 in 6-month cohort; 7,720 in 12-month cohort

breathing and *quality of life* to respiratory patients and to help patients transition *from Hospital to Home*. Breas is headquartered in Sweden and has a subsidiary in USA.

Breas Medical's Travel Sleep solutions includes the **Z2 Auto CPAP** and the **Nitelog® app.** The Z2 Auto features a quiet motor and an Auto Start/Stop Feature and the Qlite to muffle the noise at the mask. At just 6.48" × 3.30" × 2.02" and 10.5 oz, it fits easily into your bag and won't weigh you down. It's perfect for taking your sleep apnea therapy with you when you travel. The **Free Nitelog® app** lets one download sleep data to any iOS or Android mobile phone or tablet to track sleep data or share it with a healthcare provider.

For post-acute and home ventilations solutions, Breas Medical offer includes the **Vivo 45 LS** and **EveryWare.** The Vivo 45 LS, one of the smallest full featured Life Support ventilators on the market, provides invasive and non-invasive continuous or intermittent ventilatory support in home, post-acute, hospital and portable applications for pediatric through adult patients weighing more than 5 kg (11 lbs.). Designed to maximize patient independence and mobility with an ultra-small footprint, it also provides the comfortable eSync trigger technology along with ultra-quiet operation. It also provides etCO2, SpO2, FiO2 and PtCO2 monitoring and connection to EveryWare by Breas, a securely hosted cloud-based application, which can help deliver an insightful approach to home care of respiratory patients.

New for 2022 is the **Xpac** external battery that enhances ventilator dependent patient mobility with boost of battery life of the Breas Vivo 50 and Vivo 65 by 12 hours and the Vivo 45 LS by 18 hours. With Xpac, the ultra-compact and lightweight Vivo 45 LS can now run 25.5 hours off the grid.

About Breas Training and Support.
Breas Medical offers full in-service clinical and service center training s as well as on demand telephone support for our customers.

Breas looking to the future.
Breas Medical expects the trend to move more patient care from acute and post-acute into the home care environment, empowered by mobility and remote connectivity patient ventilation solutions.

Bunnell

What ventilation products does your company offer?
For 34 years, Bunnell, Inc. has manufactured and supported the LifePulse High Frequency "Jet" Ventilator for the treatment of critically ill babies complicated by respiratory failure. In 2017 Bunnell introduced the new model 204 LifePulse HFJV. The "Jet" ventilator is unique to the NICU and PICU populations and is used primarily to treat air leaks and help provide lung-protective ventilation. Utilizing lower MAP than other forms of HFV, the Jet delivers very fast inspirations via transitional flow with relatively slower, passive exhalation along with variable expiratory times. Jet breaths delivered via the LifePort Adapter produce approximate tidal volumes of around 1 mL/kg at very short inspiratory times to ventilate effectively and efficiently. Tiny breaths with attenuated pressures, combined with the transitional flow pattern, avoid the injured areas of the lungs with higher airway resistance and allow those areas to heal.

What are the new features?
The LifePulse HFJV model 204 incorporates new features requested by clinicians. The new Jet is about half the size and weight as the old model, and it has a custom stand for improved mobility and a smaller footprint at the bedside. Upgrades also include a comprehensive visual alarm system, a back-up battery power supply, and an oxygen monitoring port.

Bunnell's LifePulse HFJV has become the standard of gentle ventilation as more clinicians than ever understand how certain patients will benefit from High Frequency Jet Ventilation. The Jet is used in hundreds of level III and level IV NICU's across the US and Canada, and in Australia and Malaysia. We encourage anyone interested in adding the Jet to their toolbox to contact Bunnell for a free trail of the LifePulse HFJV.

Tell us about your company's current or recent R&D efforts.
Bunnell, Inc. remains committed to developing future products in the pursuit of excellence in healthcare with the valuable input from clinicians everywhere. Bunnell welcomes your suggestions. Let us know what we can do better.

Discuss the training and support services you offer.
Bunnell, Inc. goes above and beyond with free education, training and support for all clinicians utilizing HFJV and we offer a 24-hour clinical and technical hotline. We strive to provide superior clinical education and operational training for all those involved in the care of the most fragile patients. We provide initial training and continuing education for the life of the ventilators, including the Jet fundamentals, understanding alarms and troubleshooting, and advanced patient management strategies.

Where are your products used? (ie, hospital, home, etc.)
The Bunnell LifePulse HFJV models 203 and 204 ventilators are level III life-support devices utilized only in neonatal and pediatric intensive care units by trained health care professionals.

Bunnell offers Jet rentals that can typically be delivered anywhere in the country within 2-4 hours for emergent care.

What developments do you foresee for ventilation products and applications?
Like everything else, HFV is evolving. In the last 50 years, both ventilator modes and capabilities along with the age of viability for premature-infants have drastically changed. Continuous advances in technology will allow greater success in caring for patients in the next 50 years. Bunnell will be there setting the standard for gentle ventilation and advancing effective strategies to improve patient outcomes.

Getinge

Responses provided by Henry Szymanski, US Product Manager for Critical Care at Getinge.

Tell us about Getinge's ventilation technologies and modalities currently available.
The Servo ventilator platform has been a mainstay of innovation in critical care ventilation for over 50 years. We're very proud of our legacy of leadership in bringing new

ventilation modalities to the bedside and providing tools to clinicians that support patient care.

What excites us most are the tools that we have been able to incorporate in our ventilators that allow the clinician to really see how breaths are being delivered to the patient and better evaluate the impact of the support on the patient. Many of these technologies such as NAVA, Servo Compass, Open Lung Tool, and Transpulmonary Pressure monitoring simply could not have been incorporated into a critical ventilator without the advances in processing capabilities now standard in all critical care ventilators.

The Servo Compass provides a continuous display of important volume and pressure targets including driving pressures and tidal volume per predicted body weight.

The Open Lung Tool provides a breath-by-breath presentation of measured ventilator values, lung mechanics and gas exchange. It also provides two unique automated workflows to facilitate lung recruitment maneuvers, the Auto RM and Auto SRM.

Our Transpulmonary Pressure monitoring feature, though not unique itself, is very easy to use removing the complexity often associated with other devices. Our display eases the assessment of balloon placement and interpretation of the measurements.

We place a high value on ease of use with these advanced modalities to promote fast and safe adoption by clinicians to benefit more patients.

What drives the innovation and development process at Getinge?

Through strong and collaborative relationships with clinicians around the world we have been able to stay ahead of the curve in identifying technologies early that will enhance ventilatory support by making it safer and more effective. A very good example of this is our NAVA (neurally adjusted ventilatory assist) technology.

How is NAVA different than other ventilator modalities?

Most mechanical ventilators available today use pneumatic control systems for the triggering and ending of a breath. These methods, while very good, are inherently less efficient due to poor signal detection, delays in signal transmission, and response times of the ventilators. NAVA is not just a tool for triggering or cycling the breath. Using a physiologic approach, NAVA uses the electrical activity of the diaphragm (Edi) to trigger, cycle, and adjust the level of support in proportion to the patient's respiratory drive. The electrical diaphragmatic activity is detected using a specially designed nasogastric tube which puts the patient in control of the level of support delivered. The patient and ventilator become fully synchronized.

Edi monitoring is available on Servo ventilators in all invasive and non-invasive ventilation modes and can be used from day zero to discharge from the intensive care unit as a respiratory vital sign. It is a tool that can be used to optimize all levels of respiratory support. NAVA is a unique technology that is only available on Servo ventilators.

What impact does NAVA have on the effectiveness of mechanical ventilation?

Asynchrony is common problem in patients on mechanical ventilation. It occurs across modes of ventilation and it can be difficult for clinicians to detect. This asynchrony impacts effectiveness of breath delivery, increases the use of sedation, and may contribute ventilator induced lung injury.[1,2]

With the Edi catheter in place, the Edi tracing is displayed on the Servo screen along with standard waveforms such as pressure, flow, and volumes. This provides a very clear picture diaphragmatic activity, patient effort, synchrony with the ventilator, and effectiveness of the overall level of support.

Through improved patient-ventilator synchrony, NAVA may reduce extubation failure, may reduce the need for sedation, allow earlier and more successful weaning, and may decrease the time of mechanical ventilation.[3,4,5]

What patient populations has NAVA been used in?

NAVA may be used in neonates through adult patients. We have a line of catheters from 6Fr-16Fr at varying lengths to accommodate a wide range of patients. Additionally, the Edi catheters are functional nasogastric tubes and we recently introduced a new catheter design with the ENfit catheter.

We have seen wide adoption of NAVA in the NICU patient population with numerous publications reporting on its use and impact on these patients. Adoption of NAVA in the adult population has been a little slower but here also there have been a number of recent publications reporting on its use and impact on ventilator management.

We believe that NAVA, transpulmonary pressure monitoring, the Open Lung Tool, and the Servo Compass are complimentary technologies that arm the clinician with tools to easily assess the patient and truly personalize the level of ventilatory support.

Additional information is available on our website, www.getinge.com.

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SPOTLIGHT ON BLOOD GAS

Werfen GEM Premier 5000

The GEM® Premier™ 5000 blood gas testing system from Werfen is the Intelligent Analyzer for point-of-care and centralized laboratory testing. Results for Arterial Blood Gas (ABG), Electrolytes, Glu, Lac, Hct, tHb, O_2Hb, COHb, HHb, MetHb, sO_2, tBili can be obtained from a single sample. Integrated Intelligent Quality Management 2 (iQM®2)—an active quality process control program designed to provide continuous monitoring of the analytical process, before, during, and after each sample measurement—assures real-time, automatic error detection, automatic correction and automatic documentation of all corrective actions. Maintenance-free, multi-use, self-contained GEM PAK™ cartridges incorporate all components needed for testing. The GEM Premier 5000 with iQM2 is a complete solution for enhanced efficiency and patient care.

Siemens Healthineers Blood Analysis Solutions

During the COVID-19 pandemic the terms "silent hypoxia" and "O2 levels" became common topics of household conversation. Clinicians have long understood that Arterial blood gas (ABG) testing is the gold standard in evaluating oxygenation, acid-base balance, and ventilation in critically ill patients (J Appl Physiol, 2004). Today, the diagnosis of critically ill patients is further enhanced with the expansion of blood analysis to include not only blood gas but also a broad menu of electrolytes and metabolites, offering a snapshot into patient health.

The RAPIDPoint® 500e Blood Gas System and epoc® Blood Analysis System are important critical care analyzers supporting rapid diagnosis and enabling treatment decisions across many clinical indications. The analyzers integrate seamlessly into hospital networks with the Point of Care Ecosystem®, which offers remote management of operators and devices.

The epoc® Blood Analysis System is a handheld, bedside solution that provides lab-accurate blood gas, electrolyte, and metabolite (BGEM) results at the patient's side in less than 1 minute. The epoc system consists of three components: the NXS Host mobile computer, the Reader, and the BGEM Test Card. The Test Card has 13 analytes on a single-use card that requires no refrigeration. The epoc system helps improve workflow and the clinical experience, with benefits to your blood-gas testing program that were previously unavailable in a point-of-care system.

The RAPIDPoint® 500e system elevates Siemens Healthineers blood gas offering to a new level, allowing you to spend more time focused on patient care. Implement a proven end-to-end blood gas solution that reduces the daily burden of device management and enables you to give your full care and attention where it matters most. With an improved user experience, the analyzer transforms care delivery, setting an elevated standard in simplicity, quality assurance, and data security for healthcare organizations. www.siemens-healthineers.us/bloodgas

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What if you had the ability to monitor patient safety from anywhere in the hospital—and never miss a beat? Now you can,

with the RespArray™ patient monitor. Designed for procedural sedation and medical-surgical units, now every patient can be continuously monitored. It includes world-class Nellcor™ pulse oximetry and Microstream™ capnography technologies to help detect respiratory compromise early. Also monitor noninvasive blood pressure (NIBP), ECG (3- or 5-lead), and temperature. The monitor includes an HL7 interface, is WiFi-enabled, wirelessly connects to your EMR and remote surveillance platforms, and easily integrates into your workflow to save time. You'll have continuous support from a dedicated team who is always there for you, from training to set up and beyond. Learn more at www.Medtronic.com/RespArray.

Nonin Medical Blood Gas Products

For more than 35 years, Nonin Medical has designed and manufactured noninvasive patient monitoring devices that deliver actionable measurements across a diverse range of patients and conditions, even in cases of movement, low perfusion, and diverse skin pigmentation.[1,2]

Nonin's exclusive technologies perform across a broad range of patients and conditions. Nonin's PureSAT® signal processing reads the entire waveform, filters out interference, and uses smart averaging to provide fast and actionable readings.[1] Additionally, Nonin's PureLight® sensor technology produces a high-intensity pure light spectrum to eliminate variations in readings at critical SpO_2 levels.[1]

Nonin's oximetry products range from fingertips to tabletops, and wrist-worn oximeters to OEM oximetry solutions. Nonin also offers a wide range of reusable and disposable sensors designed for different patient sizes, including neonates. Measurement parameters include SpO2, COHb, MetHb, and pulse rate.

The COVID-19 pandemic has underscored the importance of pulse oximeters, especially ones that read accurately on all patients.[3,4,5] Nonin's noninvasive monitoring solutions work wherever and whenever you need them — even in challenging conditions — so you can concentrate on delivering the highest quality patient care.

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Blood Gas Products at Masimo

At Masimo, we deliver pulse oximetry solutions that are versatile, customizable, and transportable. Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry empowers clinicians with accurate, real-time patient oxygenation data even during periods of motion and low perfusion. Whether it's continuous pulse oximetry monitoring in critical care areas or spot-check patient monitoring during vital signs checking, Masimo SET® technology can be used anywhere pulse oximetry is needed — in pre-hospital, acute, and post-acute care settings.

Designed for a variety of clinical scenarios, we offer RD SET® sensors for all patient populations as well as specialty sensors, which are designed specifically to meet the needs of trauma, neonatal, infant, and pediatric patients.

Alongside SET® pulse oximetry, advanced Masimo rainbow® measurements enable clinicians to gain an array of additional insights into patient status in real time, including pleth variability index (PVi®), total hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), methemoglobin (SpMet®), oxygen content (SpOC™), and acoustic respiration rate (RRa®). With more information at their fingertips, clinicians can make better informed care decisions.

We help clinicians manage this important patient data with the Root® Patient Monitoring and Connectivity Platform. Root's advanced connectivity capabilities aggregate and display data from other Masimo and even third-party devices. With the assistance of Masimo Iris Gateway® or Patient SafetyNet™, that data can be automatically transferred into hospital electronic medical records (EMRs) and displayed at central view stations and on UniView®, which intelligently visualizes data and alarms to help reduce cognitive overload and streamline care team workflows. Root is compatible with both third-party devices and our expanded portfolio of noninvasive monitoring technologies and devices, which includes brain monitoring (Next Generation SedLine® and O3® Regional Oximetry) and ventilation monitoring solutions (NomoLine® Capnography and rainbow Acoustic Monitoring®).

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Check the Technique Fixing: 40 Years of Inhaler Failure

In this interview, we feature a Respiratory Therapist who shares COVID applications, inhaler techniques and specific products and therapies for COPD patients. Participating in the interview is Michael W. Hess, MPH, RRT, RPFT.

Mark Russell: Welcome to another edition of Exhale, brought to you by Vitalograph, a podcast series where we discuss topical information about spirometry and respiratory care. I'm your host, Mark Russell, marketing communications manager for Vitalograph US, a global leader in respiratory diagnostics.

I am continuing our podcast series with more current pandemic information. Today's topics are COVID-19 pandemic effects at Western Michigan University, telehealth, and cross contamination for bacterial viral filters. Today's guest is Michael Hess, a respiratory therapist, and he is currently the chronic lung disease coordinator at Western Michigan University. He has focused on treating chronic obstructive pulmonary disease such as COPD for the last several years.

Okay, Michael. Hey, welcome, and thanks for joining us on this podcast. And why don't you tell our audience a little bit about yourself and a little bit of your background and where you are right now?

Michael Hess: Great. Thanks, Mark. I really appreciate the opportunity to come in and chat with you today. My name is Michael Hess. I've been a respiratory therapist for just about 15 years now and a registered pulmonary function technologist for about four years. Currently, I work at WMed Health in Kalamazoo, Michigan, part of our medical school here in town. My official title is chronic lung disease coordinator. I focus a lot on improving care for COPD and asthma folks, primarily COPD, but including diagnostics and disease management plans and inhaler technique and all that stuff.

Mark Russell: Wonderful. And so here we are three, four months in with COVID-19. I was wondering, what do you feel like at this stage, especially in your area, where are you at as compared to the rest of the country?

Michael Hess: Well, as with many things with this whole pandemic, it depends on who you ask. We have been celebrated in the news in the last couple of days because we have largely flattened a lot of the curve as the buzzword is. We have successfully managed a lot of our cases and we've had a good bit of downswing with that. Unfortunately, it does seem like we're starting to see a little bit of an uptick again as we have started reopening most of the state as far as restaurants and bars and social activities. We are in the tail end of the two weeks after that started happening. So the next few days will really be revelatory.

Here in Southwestern, Michigan, we have not had it as rough as many places. We locked down fairly early. We had a lot of positive response with masking and social distancing and all of that sort of thing. Anecdotally, I have seen that wane a little bit in the last week or so. I am concerned that folks are still getting a little bit complacent and they think we're out of the woods because we all want to be, and I'm not sure if the virus is quite done with us yet. So we'll see.

Mark Russell: Understandable. And it seems like that's happening quite a bit around the country. We're the same way here in Kansas, and we're starting to reopen, and we've seen a spike here just recently of increased cases. It's a tough battle. It's something of economics and also health and wellbeing, and you don't know how to balance that out, so to speak.

So why don't you tell our audience about your clinic and what type of patients you see and maybe give a brief description what it was like before COVID-19 and what now you're going to be preparing while you start to see more patients as you continue to reopen your clinic?

Michael Hess: Well, sure thing. I always describe myself as one of the oddball RTs that actually works outside the hospital and even outside a pulmonology clinic. I work in primary care. I work in our primary care clinic that's part, as I said, of our medical school. I pitched this job a few years back to one of our associate deans at the time because as many people likely know, we don't do the best job at managing COPD and other chronic respiratory stuff in general for a variety of factors. There's a time crunch in primary care. Are we disseminating the information properly? Are our clinicians equipped to handle these conditions? So my goal was to demonstrate the value of a respiratory therapist in this clinic, doing a lot of the teaching and things like that that would normally come from another provider but they simply don't have time to do. So like I said, we're talking spirometry, we're talking tobacco cessation, inhaler technique, inhaler

Michael is a respiratory therapist and previously the Chronic Lung Disease Coordinator at Western Michigan University Homer Stryker M.D. School of Medicine. He has focused on treating chronic obstructive pulmonary disease (COPD) for the last several years, and is the project coordinator for WMed's NHLBI COPD Learn More, Breath Better subcontract in Kalamazoo. Michael is now Senior Director of Public Outreach and Education for the COPD Foundation. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

training, care management, coordination for other specialties, all that sort of thing.

I would like to think that it was going pretty well. It was very well received by our residents and our attendings. All I usually have to do is wave the picture of the infamous inhaler poster around at them and show them all the different kinds of devices and all that stuff. And they were very appreciative of having somebody who could be knowledgeable in all that stuff and take some of their burden off. The patient seemed to really enjoy it too. We had some early success with improving quality of life scores. We actually presented at a COPD conference a few years back, and it was really a win-win for a lot of folks.

Mark Russell: Great. And what was your volume that you were doing before this pandemic came up? How much did the primary care doctors and attending doctors utilized you per day, do to speak?

Michael Hess: As much as possible, I do have a hybrid role where I do some teaching and some research and things like that, and I had a clinic two days a week, scheduled clinic two days a week, and they kept me very busy on those days, plus there was always the odd consult here and there. I wouldn't say we were the busiest clinic in the place, but we serviced our population quite well.

Mark Russell: Good. And so when the pandemic opened up, did you guys shut down? Did you continue operations? What was it like when pandemic was full stream and was affecting every healthcare provider in the country?

Michael Hess: Well, the clinic as a whole virtually shut down. It was very difficult, very challenging, I should say, to get everybody converted to virtual visits, telephone visits. We wanted to make sure that everybody was as safe as possible because as much as we still don't know about this thing now, we knew even less a few months ago. So we wanted to, of course, minimize anybody's exposure, minimize anybody's risks, plus we had a lot of logistical issues. Our public transportation system shut down, again, to reduce risk, and we have a lot of folks who are dependent on that to get to appointments. Ride shares were shut down pretty much. It was difficult for a lot of our folks to get to the clinic even if they wanted to. So we tried to accommodate that again with the addition of a lot of video and telephone visits. My clinic almost completely shut down. As you might expect, folks with COPD in particular are at a relatively higher risk in a respiratory pandemic.

Mark Russell: Sure.

Michael Hess: So we really didn't want to expose those folks to the waiting room or anything like that.

Mark Russell: Right. And then when you guys started and opening up, what kind of preparation did you do to prepare for seeing patients as compared to what it was before this pandemic?

Michael Hess: We've established screeners at the entrances to check temperatures, to evaluate for symptoms. We've taken a lot of steps to protect our registration staff. We've installed the now almost ubiquitous plexiglass barriers you might see in a grocery store or what have you. We're demanding social distancing in our waiting areas and requiring mask use, all that sort of thing. It is an evolving process. I will say that. We're still looking at how to deliver some procedures and some appointments carefully. We're doing a lot more deep cleaning and all that, but we're still in the process of seeing what's going to work best with everybody's workflow and keep everybody safe.

Mark Russell: So you mentioned virtual visits and such. Is there a percentage of that, about 50/50? Tell me a little bit about that, what some of the process and is it for training, is it for just checking in on patients on progress? What does that all involve?

Michael Hess: It really depends on the individual patient. There are a lot of things that you can gain from simply by looking at someone or speaking to them, watching how they breathe, that sort of thing that you don't necessarily have to be in the same room for. I am a big proponent of telehealth. And I was reading an article the other day where a physician said, "80% of what I need to know, I can get just by looking at somebody on a screen even." There's never going to be a substitute for a human touch, but if you have a rash, you can hold that up to the camera. If you are wheezing and huffing and puffing because you're having an asthma flare or a COPD flare, that's usually pretty noticeable on camera and oftentimes even on a telephone. So you can have those discussions, again, without putting people at risk and without violating any social distancing or anything like that.

Mark Russell: What about monitors or any type of spirometry? Have you done any of that via telehealth?

Michael Hess: We have not yet. As you might guess, it is difficult to do that thing remotely, unless you have a device like some of the monitors that Vitalograph puts out there that have Bluetooth connectivity, that can potentially then forward that information on to clinical staff. Those types of devices, if we can get them deployed in a broader area or wider numbers, it would certainly be a boon for a lot of these things because that will allow us to even expand out even more what we can do remotely while keeping people not only safe, but it's an interesting idea that we're doing these things to keep people safe, but these are also things that probably should have been brewing for a while. It is difficult for a lot of our COPD people to get out into public.

Mark Russell: Sure.

Michael Hess: They're generally at high risk anyway or they have oxygen tanks or they're concerned about coughing or any of those sorts of things. And a lot of them are simply more comfortable doing these visits in their home.

Mark Russell: Right.

Michael Hess: So hopefully, as I mentioned, we can get more of those connected devices out there. We can start doing some of these things more remotely while still offering coaching and get the high quality data that we need for good clinical decision-making.

Mark Russell: Absolutely. To me, we're right in the middle of probably a high peak allergy season, and basically some of these COPD and asthma patients are just struggling, and it would be more comfortable, like you said, just do this in their own home

and be able to send out data via the internet or through their phones type situation. Absolutely.

Mark Russell: So also, I understand you mentioned about the inhaler training. How has that been received in your clinic? I know you love the AIM that Vitalograph has produced and it's a great tool to educate people, especially first time they've ever used an inhaler.

Michael Hess: Oh, I do. The Aerosol Inhalation Monitor was a game changer when I came across that. It is really eyeopening for patients and clinicians alike to see just how complex using a metered dose inhaler is and how often people get it wrong. I tell people probably better than 90% of the people who come into my clinic for the first time use their MDI incorrectly, and the AIM allows me to evaluate exactly where the error point is or error points. It's an excellent teaching tool as well. It's evaluation and it's teaching because then we can go through the process a little bit better. I can demonstrate to them what a good inhale looks like, and then they can perform that maneuver as well and get excellent audio and video feedback, visual feedback on their technique.

Mark Russell: Yeah. I'd tell you. When I first came on to Vitalograph, we went through a product training course of all our products, and the AIM was an eyeopener. It was amazing how I've never used an inhaler before and how many times it took to for me to get it right. It really is a good guide for somebody that has no idea how to use an inhaler.

Michael Hess: It absolutely is. And I think there's a lot of follow on benefits from that too because we have a lot of what I call inadvertent non-adherence. You have somebody who maybe thinks they're taking their medication just exactly as they should as prescribed and everything, and it's "not working." Without the AIM, we would have no idea whether it's them, whether it's the molecule, whatever it is, but with the AIM, we can actually see what adjustments need to be made and to ensure that our patients are getting the improved quality of life from actually getting what they're supposed to get out of the inhaler.

Mark Russell: Sure. And also, not only that, it helps them with the economics, the cost. If they're not using it correctly, then they're using that inhaler quite a bit and it's not doing them any good and that means they need to get more inhalers. And sometimes, this prescribed medication is not cheap.

Michael Hess: Oh, not at all, particularly when it comes to inhaled medicines where we still have relatively few generic options. We have relatively few formulary options in some cases. It's an excellent point about the financial repercussions too because you're exactly right, when somebody is taking their albuterol four or five, six times a day because they're not getting a full dose each time when we can cut that in half or by two-thirds, that's a really big difference for a lot of folks.

Mark Russell: Big savings, for sure. So you touched upon, getting back to your clinic, on scheduling visits, taking temperatures of patients, looking at telehealth to help you with some of the visits and such. And you just briefly touched upon cleanliness, and why don't you tell us about some of the procedures that you're doing now when you do see a patient and making sure that you don't contaminate not only other patients but your staff?

Michael Hess: Well, that has been a big issue of ours. Traditionally, I have seen patients in my own office, which is not really practical anymore. We can't really keep a good six feet social distancing in there, plus the air turnover is questionable, so we've switched over to a lot of exam rooms, trying to consolidate visits and that sort of thing. One of the biggest issues that we have seen right now is actually in pulmonary function testing. We have spirometers and a pulmonary function device where we are still concerned about contamination. These are devices that have an open channel through them. There's been some debate, what pulmonary function tests are aerosol generating? In my view, they all have the potential to be because if anybody has ever done even basic spirometry, you know how frequently people will cough because it is a maximal inhale. And even somebody with perfectly healthy lungs tends to get dry toward the end and start coughing a little bit.

We don't really have, with our current installations, we don't really have a good filtration system for that. So we're really looking to see what can we do as far as facilities? Do we need to repurpose a negative pressure room? Do we need to build a new negative pressure room? Is a moveable plexiglass sheet, is that enough? What kind of PPE do we need? Do we have enough PPE? All of these questions are still up in the air, and that has been a barrier to restarting some of our testing.

Mark Russell: Well, I know Vitalograph has done some testing of their own products, their filters, and we found out that not only from our own testing but also outside agencies that they filter out 99.99% of any type of contamination or viruses that could be passed through. So we're excited about that. We're trying to get the word out to people that these filters, and they're disposable filters so that you don't have to go back in and clean a lot of the devices. Is that something that you've been looking at also? Because I know some of the other products that are out there, the spirometers, you have spirettes and don't have any type of filtrations.

Michael Hess: Well, and that's something we may end up having to look at. It hasn't necessarily been on the table because in a fine bit of irony, we upgraded to our current system not terribly long ago so before anybody had ever heard of this novel coronavirus, so that's just bad luck on our part perhaps. But I would highly recommend that any clinic who is looking at capital purchases for any kind of lung function testing equipment now, seriously consider the importance of filtration and the importance of keeping things clean as much as possible, and that starts with reducing the exposure. It's great to be able to wipe everything down and everything else, but if you can filter that out at the point of testing, that's going to make it a lot easier for everybody else down the road.

Mark Russell: Absolutely. And I think this COVID virus, I know it's a terrible thing. It's affected a lot of people's lives, but hopefully positive things will come out of it with more cleanliness, not only in our clinics but in hotels and airports and other public transit systems, any areas that we have a lot of people in and out that maybe going forth is going to be more sanitary opportunities for us. And who knows, the next COVID 20 may come out and we'll be prepared for it?

Michael Hess: I'd like to think so. I always try to find the silver lining, as you said. And I think much like with the telehealth

aspects of things, these are probably things that we should have been doing all along, but we didn't necessarily have the impetus to do it. We didn't have the rush or the drive, and now we do. And now, it's one of those things where we get back to doing the things that we should be doing rather than the things that, well, we can do it for now, but we can wait to make improvements. Nobody really likes to rush to improvements because they're expensive and change is hard and everything else. But I do think that we're going to come out on the other side of this stronger in a variety of aspects.

Mark Russell: I agree with you. I, myself, before all this, my insurance company really stressed upon virtual visits and they basically were encouraging us now by dropping copays to utilize it. We had this all in place probably five to 10 years ago, but people were just not accepting of this new process. And now that we have this new reality, it'll be better off for us. I think it saves you time. I think it saves you wear and tear for a lot of people that are susceptible to disease. And I think in the long run, I think life is going to change. That's for sure.

Michael Hess: I agree. I'm seeing some positive rumblings coming out of Washington where a lot of the payment models are going to be reformed a little bit as far as promoting telehealth in that regard too, which was another barrier to acceptance, maybe more on the clinician or administrative side. But I think this is also a chance to drive a lot of innovation. We touched on a little bit some of the Vitalograph Bluetooth monitors. Again, I would love to see more widespread utilization of those. And I think this is a whole new era of hopefully driving relatively low cost, maybe not disposable but cheap enough so that they can go into the patient home, remote monitoring devices. I think this could be a golden era for medical technology.

Mark Russell: I agree. We've got the equipment to do it. We have these smartphones with all the apps functions, doing various things, and why not embrace more of the healthcare industry and what it could provide? I hope our government will ease on some of the restrictions, the HIPAA laws and such that we can accommodate this. That's for sure. So do you have anything else to add to our podcast?

Michael Hess: Well, just as I said, great to see that there are companies out there who are well positioned to take advantage of some of these opportunities. I do believe wholeheartedly that telehealth and remote monitoring are going to be huge parts of our healthcare system going forward, and I'm really excited to see a lot of the innovation that's coming out of companies like Vitalograph to help keep people safe, to help keep people comfortable and to help keep people breathing their best.

Mark Russell: Great. Mike, hey, I appreciate you taking the time and doing our podcast, and I hope this information has been informative to our audience.

Michael Hess: Great. Thanks again, Mark. I really appreciate the chance.

Mark Russell: You've been listening to Exhale with Vitalograph. I hope you enjoyed what you've heard today. Please leave us a review and subscribe for new episodes. Thank you for listening and look forward to you joining me again on Exhale with Vitalograph.

News…continued from page 10
lead author Matthew Tattersall, DO, MS, assistant professor of cardiovascular medicine, University of Wisconsin School of Medicine and Public Health, Madison, said.

Acquisition Being Finalized

CAIRE Inc., a subsidiary of NGK SPARK PLUG CO., LTD., will acquire St. Paul, Minnesota-based MGC Diagnostics Holdings, Inc. (MGC). MGC designs, develops, manufactures, and markets non-invasive cardiorespiratory diagnostic systems, accessories, and consumables for the detection, classification, and management of cardiorespiratory disease. The acquisition will close by the end of the year. Established in 1977, MGC is the number two player globally in the cardiorespiratory diagnostics sector. In addition to its St. Paul headquarters, MGC has facilities in Belgium, Germany, France, and Australia with more than two hundred employees. The company has a broad portfolio of products anchored by its pulmonary function testing systems, cardiopulmonary exercise systems, spirometers, flow sensors, gas analyzers, and associated consumables. An aging population contributes to continued growth in prevalent populations for conditions requiring cardiorespiratory diagnostic testing. More than 65 million patients suffer from COPD, the third leading cause of death worldwide, and more than 300 million patients suffer from asthma globally. Both these populations continue to grow annually and are responsible for more than $100 billion annually in healthcare spending. The acquisition is a significant step in advancing CAIRE's mission to connect with patients throughout the progression of pulmonary disease — including awareness, diagnosis, therapy, and monitoring. Following the acquisition of Spirosure (now CAIRE Diagnostics), a developer and manufacturer of a proprietary asthma diagnostic technology in 2020, the company will now have a global distribution channel directly into hospitals and clinics. "CAIRE is firmly committed to driving future growth by expanding our offerings in the clinical setting to better serve those individuals affected by cardiorespiratory diseases. MGC has a state-of-the-art portfolio that is widely adopted to diagnose respiratory disease and to ensure that the information obtained benefits disease management. These tools are an excellent complement to CAIRE's complete range of oxygen therapy solutions," said Earl Lawson, CAIRE President and CEO. "Furthermore, we are very excited to work with the talented MGC senior management team and global team of professionals who were responsible for the strategic planning and execution driving MGC's strong growth. This will be key to a seamless integration of the business and the ongoing expansion in the marketplace." "The MGC team is excited to become a part of the CAIRE organization. After outperforming the market consistently, we look forward to leveraging the resources of CAIRE and NGK SPARK PLUG to drive continued growth in our existing markets and to launch new products and technologies through our best-in-class distribution channels, "said Todd Austin, MGC CEO. The acquisition also supports the continued expansion of the Japan-based NGK SPARK PLUG portfolio of solutions to serve the greater medical and healthcare markets, as part of the overall diversification of its portfolio outside of its core internal combustion engine business.

New Study on Pulse Oximetry Accuracy

Masimo announced the publication of a peer-reviewed study regarding Masimo SET pulse oximetry performance in varying skin pigmentation in the *Journal of Clinical Monitoring and* *Continued on page 24…*

The Benefits of Protective Control in Ventilators

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Mark Rogers, Global Marketing and Product Manager with Nihon Kohden OrangeMed.

Since when does Nihon Kohden make ventilators?
Nihon Kohden has been developing medical devices for 70 years, with expertise that spans many disciplines. In fact, Nihon Kohden's Takuo Aoyagi invented pulse oximetry in 1974.

Nihon Kohden is probably best noted for our bedside monitors, neurodiagnostic systems and AED's. Respiratory Care departments may know us from our polysomnography devices for their sleep labs and home sleep apnea testing programs. Nihon Kohden is probably best noted for our bedside monitors, neurodiagnostic systems and AED's.

Nihon Kohden OrangeMed is Nihon Kohden's ventilation R&D and manufacturing company in Santa Ana, California. Although we are one of the newer ventilator manufacturers, our development team has worked in ventilator design and development for many years! Our medical advisory board members are globally recognized leaders in mechanical ventilation and have been involved in the design concepts of our products since the beginning.

What ventilation products do you offer?
We currently have two ventilation platforms in the global market.

The **NKV-550 Series Ventilator System** is our flagship ventilator for neonatal through adult patients. The NKV-550 ventilator being "app-based" allows users to hide less frequently used apps and keep the frequently used ones on the main screen. This approach helps reduce screen clutter yet maintains full functionality. The App-based design also gives some hospitals flexibility based on their clinical and budgetary needs.

Rogers has been a Respiratory Care Practitioner since 1986. He worked at Loma Linda University Medical Center, primarily in the Pediatric and Neonatal Intensive Care Units. His interests turned to research, and he became the research coordinator for the Departments of Respiratory Care, Pediatric Critical Care, and Critical Care Medicine at LLUMC. In 1996, Rogers became (and remains) a faculty instructor at Loma Linda University School of Allied Health's Department of Cardiopulmonary Sciences. Rogers went to the "dark side" in 2004, taking the role of product manager and later group manager for upstream marketing. After working briefly as a clinical educator at Children's Hospital of Orange County, Rogers transitioned back into the medical device industry to assume his current role as global marketing and product manager, overseeing activities for the NKV-330 and NKV-550 ventilators. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

The **NKV-330 Ventilator System.** The NKV-330 is a turbine-driven pediatric through adult non-invasive ventilator that has been sold globally since 2019 and just received FDA 510(k) in July of this year. The NKV-330 ventilator provides ventilation across all care environments from ED, transport, and ICU through rehab and recovery.

What is Protective Control®?
Protective Control® is a fully functional, second user interface for the NKV-550 that can be positioned outside the patient's room, allowing clinicians to immediately make ventilator changes to a deteriorating patient before safely and thoughtfully donning PPE.

We have learned from recent pandemics and outbreaks (e.g., SARS-CoV-2 and Ebola). When patients are in an isolation room due to contagious diseases or for their protection, the clinician may not always be in the room. When the patient's condition suddenly deteriorates, requiring immediate action, such as urgently changing ventilator settings, it may take several minutes to put on personal protection equipment (PPE) before the clinician can enter the room. While this process of donning and doffing PPE provides the best protection against coming in contact with and possibly spreading biohazard, it delays the response to provide urgent care. Too frequently, clinicians rush to don PPE (or worse, go in without).

It is important to note that the second GUI feature does not simply remove the GUI from the ventilator and move it outside the room. The GUI on the ventilator remains in place, while the second GUI is outside the room. Simply removing the GUI and placing it outside the room may be problematic as no ventilator changes can be made at the bedside and frequently requires a second clinician to make changes.

How do the applications on the NKV-550 work?
The concept of an application-based platform means that only those applications important to the hospital or patient can be placed on the main screen to reduce clutter.

The NKV-550 features the Gentle Lung® suite of apps. These three apps help the clinician with the lung recruitment process. The Recruitablility Assessment will help the clinician determine if a lung recruitment maneuver could benefit the patient. The Recruitment Maneuver app helps standardize the recruitment maneuver. And finally, the PEEP titration app assists the clinician in choosing the PEEP associated with the best

compliance. These apps help standardize the process and ensure consistency between clinicians.

Other notable apps include Open and Closed suction, Transpulmonary and Auxiliary Pressure Monitoring and Volumetric Capnography. These apps help fulfill our goal of providing clinically relevant tools at the right time.

What are the unique features of the NKV-330?

There are many features that set the NKV-330 apart from the other NIV platforms on the market. The NKV-330 Ventilator is turbine-based providing wall independence from compressed air and it features dual HEPA-filtration. This level of filtration employs a HEPA filter at the gas inlet of the turbine and a HEPA filter at the gas outlet protecting both ventilator and patient.

There is also built-in SPO_2 and $ETCO_2$ monitoring. Our cap-ONE NIV mask can be connected to our integrated mainstream capnography sensor proving continuous CO_2 monitoring during NIV.

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Computing. The retrospective trial, "Racial effects on Masimo pulse oximetry: a laboratory study," by Drs Steven J. Barker and Wilson C. Wilson, found that there was no clinically significant difference in the accuracy or bias between Black and White subjects studied with Masimo SET pulse oximetry and Masimo RD SET sensors. For this newly published study Dr Barker (Chief Science Officer, Masimo) and Dr Wilson (Chief Medical Officer, Masimo) performed a retrospective analysis of Masimo laboratory data obtained from self-identified Black and White volunteer subjects, to evaluate differences in Masimo pulse oximeter accuracy and bias on the basis of skin tone. The investigators reviewed data collected between October 2015 and July 2021, which included 7,183 paired samples (3,201 Black and 3,982 White) collected from 75 subjects (39 Black and 36 White), who were screened with the same criteria to remove potential bias based on health conditions. All subjects were exposed to the same hypoxia protocol, which varied the arterial saturation of hemoglobin (SaO_2) between 70% and 100%. Noninvasive oxygen saturation (SpO_2) values were obtained from Masimo SET pulse oximeters with RD SET sensors and time-matched with simultaneously taken arterial blood gas (ABG) samples analyzed using an ABL-835 blood gas analyzer. The data were analyzed to determine the bias (mean difference in paired SpO_2 and SaO_2 samples), precision (standard deviation of the difference), and accuracy (root mean squared error, A_{RMS}) for both groups. A negative bias of 0.20% was found for Black subjects, compared to 0.05% for White subjects. This difference of 0.15% ($p < 0.001$) is not clinically significant and the values are numerically indistinguishable because the SpO_2 display resolution is 1% on commercially available pulse oximeters (both from Masimo and other manufacturers). The investigators also found a precision of 1.40% for Black subjects and 1.35% for White subjects. Accuracy (A_{RMS}) was 1.42% for Black subjects and 1.35% for White subjects. These results are consistent with the accuracy specifications of RD SET sensors (1.5% accuracy A_{RMS}), which are twice as good as the current FDA clearance thresholds for medical-grade pulse oximeters (3.0% accuracy A_{RMS}). In discussing their findings, Drs. Barker and Wilson describe how Masimo SET accounts for skin pigmentation when measuring SpO_2. "The absence of racial bias, and highly accurate overall performance exhibited by Masimo SET pulse oximetry can be logically explained by Masimo's engineering design and testing paradigm. … Conventional pulse oximetry uses the standard red over infrared algorithm to provide SpO_2, while Masimo SET uses that conventional algorithm along with four additional signal processing engines that all run in parallel. These signal processing systems allow the distinction between arterial and venous signal during motion and low perfusion by identifying and isolating the non-arterial and venous noise SpO_2 from the true arterial SpO_2 components in the signal. These multiple signal processing engines work together to overcome limitations of each independent method. This advanced technique allows for a more accurate picture of the pulsatile (arterial) signal and significantly reduces the impact of static absorbers such as skin pigment, bone density, and tissue thickness (e.g., finger, toe, or earlobe). Finally, the Masimo SET SpO_2 algorithm is calibrated and then validated using nearly equal numbers of dark and light-skinned subjects." Drs Barker and Wilson summarized, "In conclusion, this retrospective study of healthy human volunteers monitored with Masimo RD SET pulse oximeter sensors showed an absence of clinically significant differences in accuracy between Black and White subjects." The authors suggested that additional prospective

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Developing Best Practice Guidelines for Management of Mouthpiece Ventilation in Neuromuscular Disorders

Highlights from the 252nd European Neuromuscular Centre (ENMC) International Workshop (closed session convened in Amsterdam, Netherlands): Developing Best Practice Guidelines for Management of Mouthpiece Ventilation in Neuromuscular Disorders 2020. Large panel of experts on behalf of the ENMC Respiratory Therapy Consortium included: Michelle Chatwin (London UK), Miguel Gonçalves (Porto, Portugal), Jesus Gonzalez-Bermejo (Paris, France), Michel Toussaint (Vlezenbeek, Belgium).

One of the most devastating consequences of neuromuscular disease (NMD) progression is the progressive weakening of muscles of the respiratory system resulting in hypoventilation. This increases the risk of pneumonia and serious comorbidities and ultimately leads to death.[1] In patients with advanced NMDs, ventilatory support is of critical importance both during the day and at night in enabling patient functioning, limiting comorbidities and extending survival. During early stages non-invasive ventilation (NIV) via a mask is sufficient. However, as the disease progresses, bulbar insufficiency worsens and ventilator dependence increases making invasive ventilation methods such as tracheostomy increasingly necessary. These different ventilation methods have notable drawbacks. Quality of life and survival can be improved by NIV[2] but the masks can cause issues such as pressure sores and swallowing difficulties. Tracheostomy on the other hand, can cause pulmonary haemorrhage and loss of speech.[3] A practical alternative is NIV with mouthpiece (open-circuit ventilation [MPV]). This allows daytime support which can be disconnected to allow eating and speaking. The technique is not new and dates back to the polio epidemics in 1953 (Dr John Affeldt)[4] but only became more widely used much later.[5]

MPV has been increasingly used over the past 30 years to increase NIV tolerance and delay or even avoid the need for tracheostomy. It reduces dyspnoea and fatigue and improves patients' speech.

MPV has been increasingly used over the past 30 years as a method to increase NIV tolerance and delay or even avoid the need for tracheostomy.[6] The technique is proven to reduce dyspnoea and fatigue and has also improved speaking capabilities and aids communication.[4] A serious issue in MPV, however, is maintaining the position of the mouthpiece/interface in patients with severe motor impairment. The ENMC Group therefore recommends that patients should undergo a trial of MPV prior to consideration of tracheostomy. They also assert that opting for long-term tracheostomy is a choice only for the patient to make.[7,8] See Table 1 for an overview of ENMC recommendations on MPV use in NMDs.

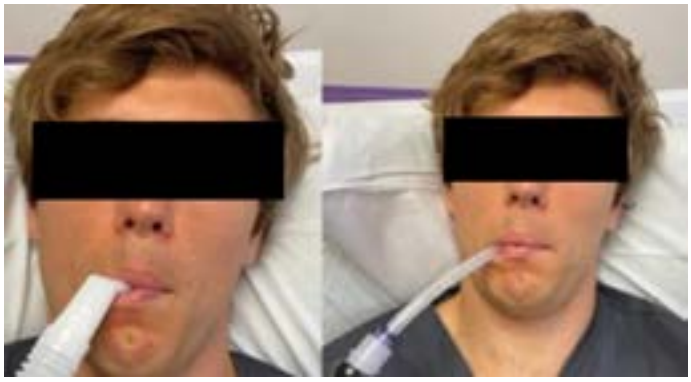

Figure 1. Differing interfaces for mouthpiece ventilation. 1. Patient using mouthpiece ventilation with a mouthpiece and 2. a straw (Phillips Respironics, Murrysville, PA, US). Source: Chatwin et al. 2020[7]

In NMD patients, day and night time ventilatory support requirements are very different. At night, patients are mostly still, silent and tend to cough and swallow less, so there is decreased need for ventilator autonomy. By day, however, patients are awake, moving, eating and coughing. MPV technology needs to accommodate this with an interface that allows and facilitates these different activities.

MPV is a more convenient alternative to an interface at the patient's face but there have been no randomised studies showing superior survival for this technique over tracheostomy. A recent survey found wide variation in the provision of MPV both within countries and internationally.[7] MPV is usually delivered via a volume-cycled mode of ventilation[9] that delivers a tidal volume of >700ml and ≤1500ml[10,11] without positive expiratory pressure (PEEP), via a mouthpiece or straw supported by a flexible arm/support.[11,12] It is not currently clear which of pressure or volume modes of MPV is superior and whether PEEP has any benefit.[9,10,13,14]

The ENMC Group preference is to start with volume-cycled mode but pressure mode is more applicable in young children. The different interfaces used for MPV are shown in Figure 1.

Submitted by Breas Medical.

An example MPV system and mouthpiece components are illustrated in Figure 2.

Day and night time ventilatory support requirements are very different. At night, there is decreased need for ventilator autonomy whereas by day, patients are awake, moving, eating and coughing. MPV needs to accommodate this and facilitate these activities.

In MPV, there are multiple different mouthpieces with no consensus on which is optimal or factors leading to choosing a specific type.[15] Treatment centres use either custom-made or commercially produced arm supports; these must be able to move with the patient and maintain their position. Patients should be allowed to try different mouthpieces or a straw and determine what suits them and should also receive anxiety and psychological support from psychology services and advocacy groups.

MPV is a challenge for home ventilators due to irregular breathing, changing load and intermittent disconnection.[12,16,17] More recent home ventilators have a pneumatic system and use an algorithm to adjust pressure based on previous cycles. This creates a long feedback loop and the ventilator reacts slowly to changing load and tidal volume overshoot during disconnection.[14] This effect is greater during pressure-cycled MPV than with volumetric MPV. It also varies between different ventilator types which need 2-6 cycles to stabilise volume.[13] The choice of ventilator unit should be based on the type of ventilation planned and the advantages/limitations of each one.

Figure 2. Example of commercially available open-circuit ventilation MPV system (Vivo 45LS – Breas Medical). Source: Breas Medical

MPV is considered the treatment of choice for daytime ventilation and is suitable when ventilatory support is needed >12 hours/day (with or without hypercapnia). MPV is suitable for those with dyspnoea and tachypnoea, however, it can only be used in patients who can maintain a lip seal.[4,18-20]

Timing is also an important issue in MPV implementation. The ENMC Group considered that the optimal timing for MPV initiation should be when:

- Use of mask ventilation is ≥12 hours/day.
- There is daytime hypercapnia with nocturnal normocapnia.
- Dyspnoea is relieved by ventilatory support.
- Voice volume needs increasing.
- Cough strength outside the home needed increasing.

MPV at home and in long-term use requires accurate monitoring. A small study of patients using home polygraphy (n=8) found MPV to be effective but most patients could under-ventilate and that effective alarms were vital to alert the patient to the issue.[17] Notable barriers to the provision of MPV at some treatment centres are lack of knowledge and training.[10,11] There is also a lack of protocols for MPV and individualised patient care is required which may not be possible at many treatment centres particularly those unfamiliar with this treatment.[21,22] Patient training is an important aspect of MPV usage; it should include teaching patients to assist cough by a single deep breath in pressure mode or 'breath-stacking' in volume mode.[22,23]

MPV mobility presents technical challenges when used with wheelchairs. The wheelchair must be able to accommodate the equipment and have batteries sufficient to provide life-support for extended periods. Mouthpieces have recently been developed that remain in place when used with patients in a wheel chairs allowing improved mobile ventilation.[24]

MPV has been reported to provide benefits for patients with various different NMDs. These include Duchenne muscular dystrophy for which recent interface developments have enabled more secure ventilation in patients who often cannot hold a mouthpiece.[20] Some patients with amyotrophic lateral sclerosis (ALS) also benefit from MPV in terms of quality of life and reduced hospitalisations.[19] In one study, MPV prolonged tracheostomy-free survival in ALS by 9.5 months but only 19.5% of patients successfully used MPV. MPV has also provided effective ventilation patients with spinal muscular atrophy (SMA) type II. In children with SMA, MPV mouthpieces provide increased ability to speak and participate in school activities and help prevent mid-facial hypoplasia and pectus excavatum.[25] MPV has also shown benefits in patients with congenital myopathies and cervical spine injury.

MPV has shown benefits in patients with Duchenne muscular dystrophy, amyotrophic lateral sclerosis, spinal muscular atrophy, Becker muscular dystrophy, metabolic myopathy, post poliomyelitis and multiple other neuromuscular diseases.

Some small studies report limited MPV use in various other NMDs including: maltase deficiency, myotonic dystrophy limb girdle muscular dystrophy, fascioscapular muscular dystrophy, congenital myopathy, Becker muscular dystrophy, metabolic myopathy, post poliomyelitis, primary adhalinopathy, congenital dystrophies, Pompe's disease and some other neuromuscular diseases.[9,17,24,26] The ENMC Group concluded that all NMD patients should be considered for MPV regardless of a lack of study evidence for use in specific diseases.[7]

In NMDs, swallowing capability can be can be lost or impaired but this function can be improved during NIV and reduces swallowing fragmentation and dyspnoea.[27] This was highlighted by a study of 10 patients with NMDs showing that MPV improved swallowing compared with spontaneous breathing.[28] Patients receiving MPV should be trained in how to swallow and MPV settings should be adjusted differently to allow eating vs normal breathing. The ENMC Group also recommends that MPV should not be taken away during critical care in patients who use it long-term.

In patients receiving MPV, exercise such as walking can be challenging due the need for a portable respirator. This issue

has been partly addressed by some MPV systems allowing physical activity and some have been shown to increase exercise tolerance in those with diaphragm paralysis.[29]

For MPV to be successful, the ENMC Group identified the following conditions/abilities:

- Retention of the mouthpiece.
- Reach the maximal insufflation capacity (>vital capacity).
- Understand the advantages and disadvantages of MPV and tracheostomy.

The ENMC Group also noted that in future, manufacturers need to involve clinicians and patients in ventilator/mask development. They should also provide better arm supports and mouth interfaces and should bench test all new systems to ensure they function adequately. They also stressed that additional work is needed to evaluate MPV effects on speech, swallowing and QoL and that a registry of patients receiving MPV should be established. Improved patient education, MPV passports and social networks could also improve the MPV experience and patient support. Finally, at present MPV usage appears to be mainly based on local experience at particular treatment centres. Greater awareness of and familiarity with the technique among healthcare providers would help improve outcomes for many patients with DMDs who need ventilatory support.

MPV usage appears to be based on local experience. Greater awareness and use of the technique would help improve outcomes for many patients with DMDs who need ventilatory support.

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clinical studies should be conducted to validate their results in critically ill patients utilizing Masimo SET pulse oximeters and those from other manufacturers.

Sentec Acquires Percussionaire

Focused on advancing respiratory care, Sentec has acquired Percussionaire. Percussionaire was founded nearly 40 years ago by the late Dr Forrest Bird who was a pioneer in respiratory care. "For us, this acquisition is a unique opportunity to build on the legacy of Dr Bird and continue to invest in products that make a positive impact to patient care," said Chairman of Sentec, AG, Dominik Ellenrieder, "In this new era, with COVID reminding us of the importance of respiratory monitoring and therapies, we believe the Percussionaire products have an important part to play to improve patient care by enabling the least invasive interventions." With this acquisition, Sentec will diversify its product lines focused on respiratory monitoring to now include the Percussionaire range of products built on TRUE-IPV technology, increasing its ability to service and support respiratory care customers. Both Sentec and Percussionaire product lines play vital roles in the management of critical care patients; Bringing these products together provides the unique ability to simultaneously monitor and treat patients with varying levels of compromised respiratory function. Percussionaire is a specialty ventilation company that develops, manufactures, and markets products that are used in respiratory care. The company was formed nearly 40 years ago in Sandpoint, ID, still the home of its manufacturing and research and development facility, where Percussionaire continues to build on the legacy of its founder, Dr Forrest Bird. His breakthrough of Flow Ventilation and True-IPV technology is at the heart of Percussionaire, the only company offering these solutions across all patient types and clinical settings. Sentec is a market leader of non-invasive monitoring solutions who develops, manufactures, and markets patient-centric, cost-effective technologies and products that provide clinicians with greater insight to quickly to identify trends, rapidly and more accurately assess patient status, and make well-informed, timely care decisions that can improve patient care. Sentec is driven by the belief that noninvasive monitoring should enable the delivery of less invasive care. Sentec Headquarters is in Basel Switzerland.

Repeat COVID Infection Doubles the Risk of Death

Getting COVID-19 a second time doubles a person's chance of dying and triples the likelihood of being hospitalized, a new study found. Vaccination and booster status did not improve survival or hospitalization rates among people who were infected more than once. "Reinfection with COVID-19 increases the risk of both acute outcomes and long COVID," study author Ziyad Al-Aly, MD, told Reuters. "This was evident in unvaccinated, vaccinated and boosted people." Researchers analyzed U.S. Department of Veterans Affairs data :

- 443,588 people with a first infection of SARS-CoV-2
- 40,947 people who were infected two or more times
- 5.3 million people who had not been infected with coronavirus, whose data served as the control group

"During the past few months, there's been an air of invincibility among people who have had COVID-19 or their vaccinations and boosters, and especially among people who have had an infection and also received vaccines; some people started to [refer] to these individuals as having a sort of superimmunity
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Measurements to Individualize Mechanical Ventilation

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview are Professor Francesco Mojoli and Dr Tommaso Mauri.

Caroline Brown: Good afternoon to everyone joining us today for our second webinar on esophageal pressure measurement. My name is Caroline Brown from Hamilton Medical, and I'm very pleased to welcome back Professor Francesco Mojoli from Pavia in Italy, and our very regular guest Dr Tommaso Mauri from Milan in Italy. Following last week's webinar where they talked about how they manage the catheter and measurements, today they're going to talk about how they use those measurements to individualize mechanical ventilation. If you are joining our Experts on Air for the first time, please note your cameras and microphones are switched off, but you can ask as many questions as you like using the Q&A function. The session is being recorded and a link to the recording will be sent you in an email a few days after the event. The webinar should take around 45 minutes with questions and answers throughout, so we hope you'll stay with us for the whole event. And now it's over to Tommaso Mauri in the interviewer seat. Thanks, Tommaso.

Dr Tommaso Mauri: Thank you. Thank you for the introduction. Thank you to Hamilton. So last time, I forgot to present who is Francesco Mojoli because he is too much an expert and renowned in this field, but he is professor of anesthesia and critical care at University of Pavia in Italy. And he spoke to many different congress around the world, and he is especially interested in research in esophageal pressure, which he studies now I think since 20 years time, it could be. His focus of research has been mostly on how to properly use esophageal pressure and interpret results, which is key. It's not so difficult maybe we can say now after 20 year, but it's key to understand how to use it. Indeed, today, we will switch from how to measure to how to interpreter and integrate in the physiology of the patient and the clinical practice the numbers.

Dr Tommaso Mauri: So we will start as usual with the poll to understand where we are with our audience and let attend this connect. So I launch the poll, Francesco. Okay.

Francesco Mojoli: Perfect.

Dr Tommaso Mauri: So the poll is what you already do, or if you don't use yet esophageal pressure, what you would like to use it for? So you think there is a place in your unit in your patient to set the PEEP level more adequately, physiological PEEP level or to understand the safety of mechanical ventilation. So the plateau, the limit for tidal volume, the limit for driving pressure. And then when the patient is switched to assisted ventilation, you want to know the effort because of the diaphragm protection and to improve the interaction to limit [inaudible 00:03:32]. These are also the topics we will speak about today, and we want to see where is especially your interest, your focus in the clinical practice in using esophageal pressure measurement. So we leave sometimes more than after the attendees answered, we leave 20 seconds more. So it's more the control ventilation or more the assisted part that you're interested in. Okay. I think we can end the poll and share the results. So Francesco, you want to comment PEEP level and driving pressure one but third this patient effort.

Francesco Mojoli: Yeah, so we have a double work today to explain how to use in the completely passive patient as well how to profit from esophageal pressure when the patient starts to have a spontaneous efforts. Yeah, it's not surprising to me that the first point is the PEEP setting.

Dr Tommaso Mauri: Okay. So I stop sharing this. If you want to start sharing your slides, Francesco, we can start with the presentation. Please attendees, keep in mind that you can post your questions in the question and answer tool. So I will interrupt Francesco if there are question related to the slides shown. So don't wait to the end to pose your question but post them. Please, Francesco, you can start.

Francesco Mojoli: Yeah. So thank you, Tommaso, for your introduction and good afternoon and welcome to everybody to this second part of this webinar dedicated to esophageal pressure. The topics for this afternoon are this. So we start with some definition and the main rational for the use of esophageal pressure. So you know that we measure esophageal pressure in order to have a surrogate for the pleural pressure. So the pressure in the thorax surrounding the lungs because this can be used to compute the transpulmonary pressure. That is the real pressure distending the lung tissue. So the stress applied to the lungs of our patient. The computation is very simple. So it's alveolar pressure. So static pressure minus the pleural or esophageal pressure. And of course this way, it's possible to distinguish two very different condition for our patients. So sometimes, we set a high pressure on our ventilator because the lung is too small or stiff. And in this case, the one on the left of the screen, the risk is to apply too much stress to the lung, eventually injurious.

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

Whereas on the right, you see that sometimes there is also a chest wall component. So the chest wall is not normal, not normally soft but somehow stiff. In this case, the pressure is applied to move the lung but also to move the chest wall. And this can be associated with an abnormal increase of intrathoracic pressure, eventually decreasing the venous return and following venous congestion for instance in the intra-abdominal compartment. And it's also important to remember that every time the pressure, the intrathoracic pressure is high, the reason is the chest wall, but this may have very different origins. On the left, you see a patient with a large blood collection in the abdomen, generating intra-abdominal hypertension and making very stiff this chest wall. So in this patient, the chest wall compliance is abnormally low, and we have to set a very high driving pressure to inflate these respiratory systems.

On the other side on the right, you see a completely different patient. This is a morbidly obese patient with pneumonia. In this case, the compliance of the chest wall is completely normal. The problem is the weight of the chest wall. So we have to set a high peak level in this patient to try to keep open the lung. So here, the interesting point is that we need not only the respiratory changes of intrathoracic pressure but also the absolute value. Otherwise, we completely miss the problem on the right. So the problem of the patient with a very heavy chest wall.

So we can move now to the first clinical application that seems is one of the most interesting for you. So the PEEP setting guided by esophageal pressure. The theory is very simple. In this case, we want to set the PEEP according to the value of intrathoracic pressure in order to keep and maintain a positive value of the expiratory transpulmonary pressure with the aim to limit the expiratory derecruitment of the lung and the opening and closing. So the so-called atelectrauma. Of course, this is not a good idea if the lung is completely consolidated because this lung is not recruitable or derecruitable. So it doesn't make sense to set PEEP according to esophageal pressure in this case.

And this is very, very, very important to remind that we have to set PEEP according to esophageal pressure in order to obtain a positive transpulmonary pressure during aspiration only in recruitable patient, in patient with a high potential for lung recruitment and derecruitment. Whereas in patient with very low potential for lung recruitment, we have to set low moderate PEEP level irrespective of the value of intrathoracic pressure. And this is very important for our patient because if we set low PEEP in a patient with high recruitability or high PEEP in patient with low recruitability, this is associated with a very, very poor outcome.

So the first point when we want to set PEEP according to esophageal pressure is to check the potential for lung recruitment. This is only for recruitable patient, very important. You know that to assess lung recruitability, the goal standard is quantitative CT scan that is not bedside, at the bedside. You can profit from lung ultrasound to distinguish the focal versus non-focal lung morphology. Focal patient are those patient that are not PEEP-responder, or we can profit from an advanced assessment of respiratory mechanics, for instance computing the recruitment inflation ratio or performing a pressure-volume curve.

Dr Tommaso Mauri: Okay, Francesco. Sorry to interrupt but there are already two very interesting question to what you explain up to now. So the first one is, do you have any criteria to select patients that you would like to have esophageal pressure in? Do you put in all patient with suspect of intra-abdominal hypertension, in all obese patient in your unit? What is the criteria that you used to start?

Francesco Mojoli: Well, I think that one good criteria is to use and think esophageal pressure monitoring in patient that are difficult to ventilate where the difficult to ventilate can be defined as when you have to set high pressure. So high pressure means that your mechanical ventilation is becoming potentially injurious. And probably at this time, you have to increase your capability of monitoring.

Dr Tommaso Mauri: Okay. So rather than the patient condition, look at the... Because you can have a lot of risk factor, but in the end, the patient is quite easy to be ventilated and you would skip. This is your message even if you had a suspect. And the other question is, are you interested in introduce the concept of recruitability assessment, let's say before setting very high people with, for example, deposit transformer pressure method? So the question from... I'm sorry but it's an anonymous attendee, so I don't know the name. He or she is asking, "Do you think that esophageal pressure is not useful non-recruitable patient?"

Francesco Mojoli: Yeah, this is an interesting question. It's not to be used to set PEEP but is still useful. And we'll see. So to check whether your tidal ventilation is safe, is very useful even in no recruitable patient. But it's true that you have not to set PEEP according to esophageal pressure if your patient is not recruitable. So you have to assess recruitability and decide whether to use or not the esophageal pressure to set PEEP.

Dr Tommaso Mauri: Do you agree... Can we say that if you have a patient who is not recruitable but with the high end-expiratory esophageal pressure, this can be seen as a very difficult and severe patient?

Francesco Mojoli: Sorry. With the high?

Dr Tommaso Mauri: And expiratory esophageal pressure. So you put esophageal pressure. You have high end-expiratory esophageal pressure, but the patient is not recruitable.

Francesco Mojoli: Yeah. In this case, probably the one option that you have to consider is to decrease PEEP because it's not effective in keeping the lung open because your patient is not recruitable. And maybe this could be effective in improving hemodynamics, for instance...

Dr Tommaso Mauri: Okay.

Francesco Mojoli: ... because the intrathoracic pressure of your patient is going to be done.

Dr Tommaso Mauri: Yes. So then Mario is asking, "How do you assess recruitability?" But this is a little off-topic. Maybe you can answer later online. Francesco, we can go on with the presentation I think.

Francesco Mojoli: Okay. Yeah. My favorite technique to assess recruitability is lung ultrasound right after the intubation and then I move to pressure-volume curve. Once you assess the recruitability, you can think about making it simpler, let's

say. So for instance, an approach could be to set PEEP level proportional to the level of recruitability, to the potential of lung recruitment.

But actually, this is not a good idea because it was very well-demonstrated that the lung recruitability, so the size of the recruitable lung and the level of PEEP that you need to keep it open are almost independent. That means that we really need the two information. So we need to assess lung recruitability. So to answer the question if and how much the lung tissue is recruitable, in other words, if the door of the [inaudible 00:19:40] is locked or not. And the intrathoracic pressure or the pleural pressure, in order to know how much PEP is needed to keep open the lung or for the [inaudible 00:19:55], how much is heavy the door? How much pressure I have to apply to open the door? And of course before setting your PEEP level in the specific patient, you have also to consider the gas exchange and the hemodynamics.

In other words, it depends on the cards you have in your hands. If the recruitability of your patient is high and the PEEP requirements is low, that means that you need a low level of PEEP to keep this lung tissue open. The pressure in your patient is okay, but the gas exchange is very poor. The clinical decision is very easy in this case. Okay. In this case, we use esophageal pressure to guide the PEEP setting. A completely different combination could be a patient with a lower recruitability but with high PEEP requirements. So in theory, you had to apply very high level of PEEP to keep open a very small lung portion. The patient is hemodynamic or unstable, but the gas change are not that bad. So in this case, of course, is again very easy, our clinical decision. We have to set a low moderate PEEP irrespective of esophageal pressure.

Of course in between these two extreme conditions, there are several other combination, sometimes more difficult. But my message here is that whatever the combination, whatever the cards you have in your hands, you have to remember to check always these four points before setting PEEP in your patient. And the second point, we already mentioned in the first part of the webinar on esophageal pressure is that if you want to set PEEP according to esophageal pressure, you have to obtain a reliable absolute value of intrathoracic pressure.

The problem here is that with esophageal pressure catheter, we tend to overestimate the real pleural pressure. If you do not calibrate your measurement, this is potentially harmful for your patient because you tend to overestimate the best PEEP and underestimate the lung stress, the stress that you are applying to the lung of your patient. So you need a sort of automatic standard calibration, or you have to perform a manual simplified procedure as already mentioned. So at this point, you are ready to apply these calibrated esophageal pressure approach to set PEEP in order to keep a positive, usually two to five centimeter of water transpulmonary pressure during expiration.

Dr Tommaso Mauri: So, Francesco, attendees started a lot, and Natalia is asking, "Do you also use the elastance derived approach once you set PEEP in this way or is either one or the other?

Francesco Mojoli: Yeah, the elastance approach is another approach. That has a pro and con. The advantage of this approach is that you have to rely only on respiratory changes of esophageal pressure. This is good, but this also means that you can use the elastance derived approach to limit the inspiratory pressure, the inspiratory stress apply to your patient for a simple reasons that when you use the elastance derived approach, you are assuming that the expiratory transpulmonary pressure is zero. And of course, this is not the case independent part of the lung where you have to know apply positive pressure that is PEEP to keep it open. So it's a good approach for limiting tidal volume and driving pressure.

Dr Tommaso Mauri: Okay. Can we say they can integrate? You can set PEEP with the absolute value and check the plateau level with the other method?

Francesco Mojoli: Exactly.

Dr Tommaso Mauri: They are compatible. And so after putting transpulmonary pressure and expiratory around zero. So yeah, there is a question on driving pressure at tidal volume, but this is exactly your next topic.

Francesco Mojoli: Yeah.

Dr Tommaso Mauri: Please keep in mind that we have only 20 minutes to end the webinar. You decided the topics you want to speak in this 20 minutes.

Francesco Mojoli: Okay, perfect. So we moved to how to make the ventilation safe, limiting the tidal volume and the driving pressure. So, if we can measure the inspiratory transpulmonary pressure, we can set tidal volume and driving pressure to avoid lung overdistention, especially in the ventral anterior part of the lung. Here, the point is what is the threshold? So what is the safe limit for the inspiratory transpulmonary pressure? And one line of reasoning could be that in the end, this value of inspiratory transpulmonary pressure is the expiratory one. So we said two to five centimeter of water plus the inspiratory increase of transpulmonary pressure. That is the lung driving pressure.

The driving pressure that is mainly known is the respiratory system driving pressure is computed as plateau pressure minus PEEP. And the safe threshold, the safe limit for these respiratory system driving pressure is below 15 centimeter of water. But of course, the lung driving pressure is only one of the two components of the respiratory system driving pressure. So this limit should be probably lower. And this is actually the case. This is a secondary analysis of the first expiratory pressure, esophageal pressure guided mechanical ventilation trial from Daniel Talmor. And in this paper, they suggested that the safe limit could be 10 centimeter of water of lung driving pressure. And very recently, a very similar value was suggested that is below 12 centimeter of water in these observational, multicenter clinical study. So, to answer our question, the limit for inspiratory pressure could be computed as two to five centimeter of water of expiratory transpulmonary pressure plus 10 to 12. That means that probably a reasonable limit could be below 15. So again, very simple number to remember. Of course, these...

Dr Tommaso Mauri: And, Francesco, if you can... There are three questions, maybe rapid answers. So if you go back to the tracing that you just showed, Tibur, if the pronunciation is correct says, "Once you have this transpulmonary pressure screenshot, waveforms, where do I see these numbers you're speaking

about?" I don't know if you can start your point or feature. "And show us which parameters I should consider on this tracing."

Francesco Mojoli: Yeah, first of all, you have to perform an occlusion maneuver, attend expiration for PEEP setting and attend inspiration for limiting the inspiratory stress. So this one is the end-inspiratory occlusion maneuver. During the maneuver, you stop the floor. So the pressure is the static pressure, the pressure in the alveoli, the white signal, whereas the yellow signal is the calibrated esophageal pressure. So the difference between the plateau pressure and the calibrated esophageal pressure during the maneuver is the end-inspiratory transpulmonary pressure.

Dr Tommaso Mauri: And then the expiratory, Where do you see it?

Francesco Mojoli: This is the end-exploratory maneuver. Maybe we can go back to...

Dr Tommaso Mauri: If the white is higher than the yellow, then it's positive.

Francesco Mojoli: Yeah.

Dr Tommaso Mauri: Okay.

Francesco Mojoli: So, again, here we set a PEEP to keep a positive value of expiratory transpulmonary pressure. Because the white, that is the total PEEP. So the alveoli pressure during expiration is higher than the intrathoracic pressure that is measure as a calibrated esophageal pressure in yellow.

Dr Tommaso Mauri: Okay. Then two quick questions. Do you use different targets in lobar or diffuse ARDS?

Francesco Mojoli: Yes. We check as right after intubation the morphology in our patient. Patient with a lobar disease, that means a focal loss of aeration are usually PEEP non-responder. That means that they have usually a low potential of recruitability. So in this patient, if you check recruitability is low. So you have to select a low or moderate level of PEEP irrespective of the level of intrathoracic pressure...

Dr Tommaso Mauri: Okay. And [inaudible 00:32:53]...

Francesco Mojoli: ... improve gas exchange and ventilation...

Dr Tommaso Mauri: ... higher tidal volume.

Francesco Mojoli: ... in this patient. Sorry. Yeah.

Dr Tommaso Mauri: You use higher tidal volume and drive pressure in focal? That's a question from the audience.

Francesco Mojoli: No, I think it's not... You have also always to measure. So you have to set tidal volume according to the inspiratory stress that you are measuring.

Dr Tommaso Mauri: Okay.

Francesco Mojoli: If the plateau pressure is safe, if you have esophageal pressure monitoring, of course, if the end-inspiratory transpulmonary pressure is safe, okay, your tidal volume is okay.

Dr Tommaso Mauri: Okay. And what is low PEEP for you when the patient is not recruiter? How do you select?

Francesco Mojoli: Yeah, low PEEP in the early ARDS is difficult in my clinical experience to set a level of PEEP below eight centimeter of water. Maybe later in the disease, sometimes we set even lower level in a way. Moderate to low level of PEEP to me means at least eight centimeter of water.

Dr Tommaso Mauri: Okay. And then another is asking, there is a gradient in pleural pressure. So esophageal pressure is just regional. Do you ever consider this when you move the patient? Do you perform other measurement?

Francesco Mojoli: Yeah, taking into account pressure gradient in the chest wall is sometimes important but for PEEP setting and for assessing the inspiratory stress. So for PEEP setting, you have to consider that the less aerated is the lung, the more heavy is as well. So if the aeration is very low, you have to move to four, to five centimeter of water of positive and expiratory transpulmonary pressure. And the same for the limit of inspiratory stress. You have to consider that the lung tissue that is more at risk for barotrauma is the most non-dependent one. So the ventral part of the lung. And you are actually measuring the intrathoracic pressure at mid level.

Dr Tommaso Mauri: Okay.

Francesco Mojoli: So this means that when you measure in end-inspiratory transpulmonary pressure of 15 in at mid level, this is somehow an underestimation of what is applied in the most non-dependent part of the lung.

Dr Tommaso Mauri: Okay. I think we can finish your presentation and keep the last question for the end.

Francesco Mojoli: Yeah, this was just to say that of course, these threshold are based on expert opinion and on observational findings and need clinical trials to be fully validated. And it's also important to remember that if you use this safe threshold for mechanical ventilation, not only the lung but also the right heart will be happy in your patient. So now we can move to the active patient. So the patient that is intubated with spontaneous activity. Here, the scenario is even more complex because the pressure and the stress that is applied to the lung of our patient is not under our full control because it's due to the positive pressure applied by the ventilator, and the negative pressure generated by the respiratory muscle of the patient.

We can make emerge the patient effort by performing an end-inspiratory occlusion maneuver. And as long as we obtain a stable pressure, we can check and measure plateau pressure and driving pressure of the respiratory system also in active patient as you see in the screen. And of course, if you have the esophageal pressure monitoring ongoing, you will get as well the inspiratory transpulmonary pressure and the lung driving pressure.

This is a patient where we decrease the pressure support from 10 centimeter of water on the left down to five centimeter of water. And what is interesting here is that you see the tidal volume is exactly the same as well as the plateau pressure and the transpulmonary pressure. So, this is interesting for two main points. The first one is that, okay, we know it's not... This

is a condition where the stress applied to the lung is not under our full control. The other interesting point is that we can monitor the problem with a very simple parameter. That is tidal volume. And the last part of my presentation is dedicated to the monitoring of the spontaneous activity of the patient.

Dr Tommaso Mauri: Two, three minutes.

Francesco Mojoli: Yes.

Dr Tommaso Mauri: We have a final question.

Francesco Mojoli: This is just two minutes. In other words, we can profit from esophageal pressure to set the process support with the aim of maintaining a physiologic respiratory activity in our patient. If we hear you, you see several waveforms. Just focus on airway pressure in gray, esophageal pressure in green and muscle operation in red. You see during the occlusion maneuver in gray, you can measure the pressure generated by the inspiratory muscles as the drop in esophageal pressure but exactly the same value you can get from airway pressure. So you don't need for these esophageal pressure. And the other interesting thing is that if you look at the esophageal pressure's wing during in the assisted breath, these are underestimating the real muscle pressure. So the pressure generated by the inspiratory muscle. The main reasons is that during an assisted effort, the pressure, the negative pressure generated by the inspiratory muscle is partially compensated by the elastic recoil pressure of the chest wall that increases during inspiration because the volume of the respiratory system is increasing. And of course, this is not the case for the occluded effort.

The second reason is that an isometric contraction is a little bit stronger in physiology. So this is the reason why we have to consider different threshold if we look at the esophageal pressure's wings or at Pmask obtain during an end-expiratory occlusion maneuver.

So to summarize my suggestion for the active patient, we can use and monitor continuously tidal volume and delta pes or respiratory swing of esophageal pressure. And then perform periodic end-inspiratory occlusions to precisely assess lung stress and periodic and expiratory occlusions to precisely assess muscle activity. And this was my last slide.

Dr Tommaso Mauri: Thank you, Francesco.

Francesco Mojoli: Thank you for your attention, and I'm ready for the last question.

Dr Tommaso Mauri: Fantastic.

Francesco Mojoli: And I'm ready for the last question.

Dr Tommaso Mauri: Yeah, we are like two minutes. So one question is, how do you select the patient on assisted ventilation that may need esophageal pressure? One is the answer is if you have it in the controlled period, use it again. But if you didn't, do you sometimes add specifically in spontaneously breathing patient?

Francesco Mojoli: Yeah, of course. The patient with the very high respiratory drive is the right one because it's very difficult to keep it on pressure support ventilation on assist mode. So you need a more advanced monitoring in this case.

Dr Tommaso Mauri: Okay. So there is still a little confusion on the gray, how to set PEEP with the... Do you use zero transpulmonary pressure than expiration? And another question is, do you still continue to use it in spontaneously breathing in patient in pressure support?

Francesco Mojoli: Yeah. So for the first question, my numbers are, yeah, the expiratory transpulmonary pressure should be positive for sure. I keep it between two to five centimeter of water because you have to consider that you are measuring at mid level. So if you want to keep open also the most dependent part of the line, you have to set slightly higher in expiratory pressure. And the other question... Oh, if I use... Yeah. Usually when you shift to pressure support to assist mode in patient recovering from ARDS is not that much an issue anymore the PEEP setting. But if this is the case and probably you are running to pressure support, yes, why not?

Dr Tommaso Mauri: Okay, so there are also a few couple question left on control ventilation that you may answer maybe on the website. And then there are for Caroline, and then we can conclude the topics for the next webinar because an attendees asking they're using non-intubated patient during IV and CPAP, and this is another chapter. And another chapter is [inaudible 00:46:00] interaction. So how to improve our understanding of hemodynamics with esophageal pressure. I think another very interesting topic, but we are done for today, I guess.

Caroline Brown: So that brings us... Oh sorry. So that brings us to the end of today's webinar everybody. Thanks to all of you for joining. And as always, of course, a very big thanks to our two experts. The link to the recording will be in your inbox early next week. And for those of you with unanswered questions, we'll send out a link to those in a follow-up email a few days after that. If you haven't signed up for our events newsletter, you can do so now using the QR code that will be shown on the screen. And also there was a link placed in the chat to stay informed about future Experts on Air webinars. We hope you've enjoyed them so far, and we look forward to seeing you again after the summer break. Thanks everybody and bye for now.

Dr Tommaso Mauri: Bye. Thanks.

Francesco Mojoli: Bye-bye.

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Understanding Pulse Oximetry Technology for Better Patient Outcomes

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This webinar was hosted by Nonin Medical.

This educational webinar seeks to provide viewers with a comprehensive understanding of pulse oximetry technology. Viewers will learn how accuracy can be measured and validated with clinical evidence, as well as compare the performance of leading manufacturers' oximetry technology in challenging conditions. Additionally, this webinar will touch on key aspects of Nonin technology that have demonstrated accuracy in low perfusion and across diverse skin pigmentation.

Hello to everyone, and welcome to Nonin an SpO_2 Education. The objective of this training is for you to develop a comprehensive understanding of pulse oximetry technology, along with the advantages of choosing Nonin pulse oximetry to provide the best possible care for your patients. For you to develop that understanding, we'll dive into the following topics. I will start by providing an overview of pulse oximetry, I'll review the physiology and science of pulse oximetry, I will describe how we conduct our pulse oximetry accuracy studies, I will then showcase how Nonin has demonstrated accuracy and clinical results that support our accuracy. Lastly, we will lay out the key differences in Nonin technology.

What can you expect to take away from this today? You will learn what the true gold standard is for determining accuracy in pulse oximetry, and how leading companies like Nonin compare to that standard in challenging conditions, which is when you need reliable pulse oximetry the most. You'll also learn why pulse oximetry has historically been monitored from the finger, along with key aspects of Nonin technology that have demonstrated accuracy in low perfusion and skin pigmentation. Let's get started.

You can see right away where the Nonin name comes from, as it's short for non-invasive. Pulse oximetry is what some people refer to as the fifth vital sign. It is a non-invasive method for measuring a patient's oxygen level or SpO_2, and heart rate. It's a simple, painless way to determine how effectively oxygen is being transferred to different parts of the body and how often the heart is beating. There are however, some challenges that may impact the accuracy of your pulse oximetry device, low perfusion, skin pigmentation, patient size, patient motion, such as tremors and shivering, and nail polish can all impact the overall accuracy of a reading. Therefore, it is very important to select a pulse oximetry technology that has demonstrated accuracy under all these circumstances. Now, let's get into a bit of the physiology and science of pulse oximetry.

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Oxygen is vital to the functioning of cells, thus oxygen delivery to cells is an important indicator of patients health. A pulse oximeter uses two frequencies of light, red and infrared, to determine the percentage of hemoglobin in the blood that is saturated with oxygen, and heart rate. This oxygen saturation is an indicator of oxygen transport in the body and indicates if sufficient oxygen is being supplied to the body, especially to the lungs. Oxygen binds to hemoglobin and red blood cells and is transported throughout the body as arterial blood. Oxygen makes the blood red and that's why arterial blood is red and venous blood is blue. In simple terms, pulse oximetry reads how red your blood is. Perfusion is the circulation of blood through tissues. The image on the right side indicates normal perfusion of the hand, and areas of greatest perfusion are darker or more red in color. And therefore, we commonly take a pulse ox reading on fingers or toes, as they're usually well perfused areas of the body.

The science of pulse oximetry starts with two different light sources, red and infrared lights. These two different light sources control to be on at different times, are passed through the blood, as indicated in the image shown. The amount of light that passes through is then picked up by a photo detector, where an algorithm within a signal processor then calculates the SpO_2 measurement. The result of this is a number that provides useful information on the patient's medical condition. Impure light sources can shift the calibration and effect accuracy, most

To view the webinar, please visit: Nonin.com/resource/unlocking-oximetry-technology/. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

notably when the saturation is below 95% and/or with dark skin pigmentation. And therefore, high-quality LEDs make a difference in your measurements. Nonin's oximetry technology and accuracy all begins with a quality sensor, or sometimes referred to as a probe. And Nonin has 30 plus years of experience in light sensing technologies. Nonin's PureLight® sensor technologies provides only the purest red and infrared LEDs to provide a high intensity pure light spectrum which eliminates variations in readings for consistent measurements, especially at critical SpO_2 levels, such as below 80%. High quality sensors also ensure that accuracy is not degraded due to skin pigmentation.

Now, let's get into how Nonin conducts accuracy testing studies you understand how Nonin ensures we are delivering measurements that you can trust. A pulse oximeter is intended to read the saturation of arterial blood, and referenced is an image of an external OEM pulse oximeter, as well as a fingertip pulse oximeter. Now, Nonin conducts accuracy clinical studies to ensure the pulse oximeter's stated accuracy. Now, let's discuss the process for accuracy studies. The true gold standard for saturation is measured on a co-oximeter, and this is a picture of a co-oximeter and a blood gas analyzer. Pulse oximeters are calibrated against an invasive blood gas machine or co-oximeter, to determine accuracy to standards and regulatory claims. And a co-oximeter does require a blood draw. And in order to get a blood draw, we place an arterial line in a subject, along with connecting the subject to a pulse oximeter. We then take some readings with our device and compare them to the co-oximeter readings. For the average healthy adult, normal saturation can range from between 95 and a hundred percent.

However, for patients experiencing compromised respiratory function, their saturation can be much lower, and it is critical that pulse oximeters be able to read accurately in these situations. We connect a subject to an anesthesia machine and do what we call induced hypoxia. We slowly take away oxygen to lower the subject's oxygen levels, which allows us to evaluate Nonin's accuracy at lower saturations. And we repeat the simultaneous measurement on the pulse oximeter and sensor across a range of saturations. And we then repeat this for a statistically significant group of subjects. What does that data look like? I have two figures here that will illustrate this study. On the left is a time plot, the lower access shows time. We plot SpO_2 over time. And whenever a blood draw is done, we plot that too, indicated by red dots, at the same time.

And on the right is a scatter plot, which shows the SpO_2, also indicated by red dots at the co-oximeter reading. And over time, we see the SpO_2 reading. And at 46 minutes into the hour, we do a blood draw, indicated by the red dot here. The pulse oximeter read in the upper 90s and so did the co-oximeter, so we continue this process as we desaturate the subject. And now we see the SpO_2 dropping, and the only way to confirm the subject's blood oxygen saturation is indeed dropping, is to do another blood draw. This pattern of pulse oximeter readings and blood draws will continue as we desaturate the subject in accordance with the approved protocols. Then we give the subject some oxygen to build their reserve back up, which you'll see here. Now, I hope this provides you with a deeper understanding of how Nonin demonstrates accuracy, even in challenging conditions. Now, let's take a look at how leading companies compare to this standard in challenging conditions.

Before we get into too much of the data, I wanted to highlight an important call out within this article. The authors state, "Clinically important bias should be considered when monitoring patients with saturation below 80%, especially those with darkly pigmented skin."[1]

This ensures you can trust your measurements on all patients, even in the most challenging conditions. All co-oximeters read slightly differently. The only way to get a true apples to apples comparison on pulse oximetry technology, is to compare devices against the same subjects and co-oximeter. And based on a peer reviewed published study of three major oximetry technologies, Masimo, Nellcor and Nonin, with varying subject demographics as you can see listed here, the following illustration represents how each technology compared to the actual blood gas or co-oximeter measurements at different reference values. Now, bias is the mean of the differences between oximeter reading and the functional SpO_2 values, as measured by a co-oximeter from an arterial sample. Positive bias means the test oximeter overestimates saturation, and negative bias means the oximeter underestimates the saturation. The Nonin PureSAT® oximeter with clip sensor was compared with the Masimo radical with clip sensor and the Nellcor OxiMax N 595 with clip sensor. And all three of these products meet regulatory accuracy requirements but they all differ in their bias at different SpO_2 levels.

And based on the results, the Nonin PureSAT oximeter with clip sensor had the lowest bias compared to the gold standard blood gas or co-oximetry throughout the oxygen saturation levels and for all skin pigmentations. And in this most challenging environment of low saturation where the SaO_2 is from 70 to 80% and dark skin pigmentation, the bias for the Nonin PureSAT oxymetry with clip sensor was minimal at negative 0.6%. This is in contrast to the competitor's clip sensor results, with a mean bias of 2.61% and 2.59% in the same subgroup. And in this study, Nonin readings biased slightly below the blood gas reference, which may ensure greater patient safety, as higher readings may run the risk of failing to identify a patient status that could represent a clinical concern.

As we mentioned earlier, bias is the mean difference between oximeter reading and co-oximeter. Precision is the standard deviation of differences from co-oximeter measurements. And accuracy, or A_{RMS}, is a standard method for reporting pulse oximeter accuracy which combines both bias and precision into a simple term. And as we mentioned previously, all three products meet regulatory accuracy A_{RMS} requirements, but they all differ in their bias, precision and accuracy at different SpO_2 levels. A_{RMS} error for SaO_2 of 70 to a hundred percent is what is used for the Food and Drug Administration device approval. An above 3.0 A_{RMS} is not acceptable, yet this study demonstrated that there were several instances of oximeter probe combinations with values over 3.0 A_{RMS}. The Nonin PureSAT oximeter with clip sensor was more accurate compared to the gold standard blood gas or oximetry throughout the oxygen saturation levels and for all skin pigmentations, than the competitors with clip sensors. Nonin was the only clip-on fingertip oximeter that provided accurate readings in the tested individuals at all saturations, regardless of skin pigmentation, below or within the FDA acceptable limit.[1]

And this study also concluded that the Nonin technology with clip-on probe tested did not show an effect in patients with all the tested skin pigmentations. And this study indicated that the tested Masimo clip-on and Nellcor adhesive sensors read nearly 10 points differently in dark skin subjects at lower saturation

levels. You may ask, "Why is accuracy so important or why does it matter what oximetry or oximeter I select?"

Well, for one, your technology or system helps in the diagnosis or treatment of patients with potentially severe medical conditions. Patients' lives may be at risk, and they deserve the best possible treatment, which is why you need a pulse oximetry technology that has demonstrated accuracy and is FDA cleared. Your system is intended to work on patients of all skin pigmentations, so you need a pulse oximetry technology that is not degraded due to a patient's skin pigmentation. And not all patients are healthy, and the patients most at risk are counting on your system to provide the treatment or care that they need. And oxygen saturation is an important indicator in a patient's health, so don't you want an accurate representation, even in the presence of motion and low perfusion? A patient's status may rapidly be changing, which is why you need pulse oximetry technology with a fast response time, to ensure treatment is provided on time. And inaccurate or higher readings may run the risk of failing to identify patient status that could represent a clinical concern.

And additionally, there are high costs associated with patients being readmitted, which is another reason for selecting accurate pulse oximetry. Now, let me ask you, if it were your family member needing care or treatment, wouldn't you want them to be monitored with the most accurate pulse oximetry technology? This is certainly the way that I think about it, and why it is so important to select a pulse oximetry technology that has demonstrated accuracy time and again in challenging conditions and on all skin pigmentations. Accuracy does matter. From the release of the world's first fingertip oximeter, Nonin has been creating durable and accurate solutions for patients, regardless of skin pigmentation. And there are four key things I want you to understand about why Nonin is different. Quality sensors, low perfusion filter, true pulse detection and smart averaging.

Now, we previously discussed that Nonin's accuracy starts with the quality sensor. All pulse oximeters use red and infrared light to measure SpO_2 levels, but Nonin's PureLight sensor technology uses only the purest red and infrared LEDs to produce a high intensity pure light spectrum, which eliminates variations in readings for consistent measurements. Nonin's PureSAT technology offers a low perfusion filter that provides a true reliable reading that is FDA cleared for plus or minus 3% SpO_2 accuracy in low perfusion. And this filter automatically removes noise from weak or low perfusion signals, to obtain a reading with challenging patients.

And Nonin's PureSAT technology also features true pulse detection, which reduces false readings by locating the true pulse in low perfusion and motion. And this eliminates false readings due to patient motion, reducing the time required to obtain a reliable measurement. And what we mean by reliable, is a measurement that is consistent, trustworthy and in good quality. It is also FDA cleared for plus or minus 3% SpO_2 accuracy in motion.

And Nonin's PureSAT technology is equipped with pulse by pulse smart averaging that automatically adjusts for three second averaging or faster. And this saves you time as there are no modes to set, and the intelligent automatic averaging adjusts for challenging conditions. And the combination of the Nonin PureSAT signal processing technology and PureLight sensor technology provides a highly responsive and precise system for accurate and reliable readings, even under the most challenging patient conditions. And these are the key aspects that really help create the Nonin difference.

Thank you for your time today. You now have a clearer understanding of the true gold standard for determining accuracy in pulse oximetry, and how leading companies like Nonin compare to that standard in challenging conditions, which is when you need reliable pulse oximetry the most. And you also now understand why pulse oximetry has historically been monitored from the finger, along with key aspects of Nonin technology that have demonstrated accuracy in low perfusion, motion and skin pigmentation. Thank you. Now, this concludes the primary content that we wanted to share with you. And if you would like to learn a bit more about Nonin's fast averaging and how accuracy of leading companies compare at common intervention points, we will now share some additional content with you.

Nonin Medical's PureSAT pulse oximetry technology utilizes an intelligent pulse by pulse averaging algorithm that is able to adjust with the patient's condition for precision accuracy. And the PureSAT averaging algorithm automatically adjust to provide fast response of three seconds or faster, with no modes to set or adjust. And in the example shown, Nonin's PureSAT SpO_2 average value was plotted along with the unaveraged SpO_2 value taken on each pulse. The PureSAT SpO_2 averaging equals one second, and Nonin's intelligent PureSAT technology provides quick averaging and identifies the true pulse for patient assessment. And this saves you time, as there are no modes to set and the intelligent automatic averaging adjusts for challenging conditions. Now, Nonin took the data from the UCSF lab research a step further. Nonin evaluated the study data at saturation points commonly used and defined by medical professionals, to help assess the need for intervention.

And this first slide looks at 88% saturation point, which is described in various standards and guidelines for intervention. With Nonin technology, more patients were correctly identified for oxygen delivery at the intervention point of 88%. For all patients tested, Nonin identified 91% of patients at the SaO_2 intervention point of 88%, Where Nellcor and Masimo identified only 25 and 32%. And for dark skin patients tested, Nonin identified 97% of patients at the SaO_2 intervention point of 88%, where Nellcor and Masimo identified only 13% and 22%.[1]

Now, let's look at the 92% saturation point. And this slide looks at 92% saturation point, which is described in other various standards and guidelines for intervention. And for all the patients tested, Nonin identified 82% of patients at the SaO_2 intervention point of 92%, where Nellcor and Masimo each identified only 42%. And for dark skin patients tested, Nonin identified 85% of patients at the SaO_2 intervention point of 92%, where Nellcor and Masimo identified only 29% and 30%. With Nonin's fast pulse by pulse averaging, we can detect saturations quicker. As this data indicates, we are more likely to show desaturations and identify interventions at clinically significant levels. This concludes the backup portion of this presentation, thank you.

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When to Leverage High-Frequency Chest Wall Oscillation: A Rountable Discussion with Pulmonologists

Heather Gorby, PhD (ALKU) and Martha Camacho Urribarri, RN (Baxter)

Introduction

Non-cystic fibrosis bronchiectasis (hereafter referred to as BE) is a chronic progressive respiratory disease characterized by an irreversible and abnormal dilation of the bronchial lumen.[1] BE can develop in both children and adults and can be caused by immunological disorders, systemic factors or other respiratory conditions.[2] Patients typically develop BE as a result of a vicious cycle of inflammation, recurrent infection, and bronchial wall damage caused by infections, genetics, inflammation, environmental factors, and/or allergies.[3,4] Symptoms can significantly overlap with other respiratory conditions, such as chronic obstructive pulmonary disorder (COPD) and asthma.[5,6] The pathophysiology of BE is commonly a chronic cough with purulent sputum production, dyspnea, and fatigue.[2,7]

Given the lack of current treatment guidelines[6] regarding best practices for treating BE, in 2021 a select group of 15 US based pulmonologists participated in a series of webinar panel discussions to discuss treating patients with BE. The practitioners shared perspectives on potential solutions that may improve treatment strategies for BE patients and promote better outcomes.[8] Notable insights are shared here.

BE Disease Challenges in the US

According to US government and private payor health care claims, BE is a disease with a growing prevalence.[5,9,10] This could be explained by increased use of high-resolution CT scans better able to detect it.[5] Estimates based on U.S. data from 2009 to 2013 suggest an annual incidence at 29 cases per 100,000 persons.[5] The findings also suggest between 340,000 and 522,000 adults were receiving treatment for BE, with 70,000 adults newly diagnosed in 2013.[5] More women than men were diagnosed with BE (67% versus 33%), and 76% of patients were 65 years of age or older.[5] There also appears to be an 8% increase in new cases per year since 2001.[5] Considering symptoms can be similar to other respiratory conditions, diagnosing BE can be challenging, leading to delayed diagnosis and underdiagnosis.[5]

> "We're just not trained well in BE – throughout pulmonary training. The vast majority of pulmonologists undertreat BE, treat incorrectly, and don't follow these patients closely enough.[8]"

Untreated, BE may lead to repeated and serious lung infections that result in increased hospitalizations and health care utilization.[11] Impairment of mucociliary clearance may contribute to chronic inflammation and exacerbations because of the persistent presence of micro-organisms in the bronchial tree.[7] Chronic inflammation may further disrupt mucociliary function, resulting in tissue damage and remodeling, and a cycle of infection and inflammation that contributes to frequent exacerbations.[7] Sputum retention may also cause mucus plugs that reduce airway diameter and contribute to airflow obstruction. Exacerbations of BE lead to increased daily symptoms, health care utilization and related costs,[7,13] lower quality of life, declining lung function, and mortality.[14-17]

Current disease management can be complex, including treatment of concurrent etiologic conditions, promotion of airway clearance, reduction in bronchial inflammation, and suppression or prevention of chronic bronchial infection.[7,12] The goal of treatment is to interrupt the vicious cycle of infections.[7] Patients with BE often require frequent medical treatment over extended periods.[2,9] However, there is limited research on the effectiveness of available treatments over the long term for BE.[12]

Pulmonologists Discuss BE Diagnosis

Pulmonologists were asked to discuss some of the commonly occurring issues and barriers to diagnosis of BE. To some, high-resolution CT images provide a straightforward diagnosis. Many mentioned the potential delay for this group of patients to be referred to a specialist who can diagnose BE, at times taking years. Patients may have been treated for several years for respiratory exacerbations by primary care physicians, and this can lead to the initial BE diagnosis occurring at an advanced disease stage and in older patients. When gone undiagnosed and untreated, patients may have extensive lung damage, as well as significantly decreased lung function and poor quality of life. Some pulmonologists felt that training on how to diagnose and treat BE was lacking, even for specialists.

Heather Gorby, PhD, an award-winning medical writer has helped to author dozens of journal articles and white papers in a variety of therapeutic areas. Dr. Gorby received her PhD from Stony Brook University and did a postdoctoral fellowship at the National Institutes of Health, National Institute of Mental Health (NIH/NIMH). Martha Camacho Urribarri is a Medical Affairs Manager for Respiratory Health at Baxter. Martha specializes on the research of therapies for patients with bronchiectasis. Prior to her current role, she worked as a registered nurse in critical care units. In her career she strives to positively impact the lives of others in the quest of problem solving and personal growth. In her free time, Martha is an avid reader and experiments with recipes in her kitchen.

> "I think I made the pitfall of not just jumping to the more aggressive things for those people… clearly, they've just got structural lung damage, and this can be a long-term issue. You know, I think that makes a lot more sense…upfront.[8]"

Considering BE is usually diagnosed via chest CT, the pulmonologists worried radiologists who focus more on detecting lung nodules may underrecognize BE. If more radiologists were able to detect and report BE, it could help speed diagnosis. Additionally, many primary care physicians do not refer patients for chest CT, which also may delay diagnosis.

Another contributing factor to the underdiagnosis of BE is the disease symptoms often overlapping with COPD and other respiratory diseases.[5] Some of these symptoms include chronic cough, recurrent respiratory infection, a productive cough that gets better throughout the day, and multiple courses of antibiotics with relatively normal X-rays. The resulting underdiagnosis leads to delays in patients receiving appropriate treatment for BE.[18] An analysis of US Medicare enrollees from 2006 to 2014 with prescription drug plans showed that prior to diagnosis, BE patients experienced higher inpatient and outpatient visit utilization during the year before diagnosis than that of other Medicare enrollees.[9] Of these patients, 23.4% were hospitalized at least once.[9] Additionally, about half (51.2%) also had a diagnosis of COPD/emphysema and 28.3% had asthma.[9]

Pulmonologists suggested a few steps to improve overall diagnosis of BE and perhaps diagnose it earlier. Some noted that referral for chest CT along with radiologist recognition of BE would speed diagnosis. Another suggestion encouraged pulmonologists to specifically note the suspicion of BE on the chest CT order to ensure the radiologist is looking for it and that the scan is high resolution. It may help to educate primary care physicians to emphasize the need to order a high-resolution CT to rule out BE for a patient with chronic cough. Educating primary care physicians on what to look for and when to refer to a pulmonologist may also aid earlier diagnoses.

BE Treatment Choices and Airway Clearance

Chronic cough and sputum production may increase the risk of progressive decline in clinical and functional status of patients with BE.[2] Airway clearance therapies (ACTs) are non-pharmacological interventions often recommended to help patients expectorate sputum from the lungs.[12,19]

A variety of ACTs are used in clinical practice, including positioning, gravity-assisted drainage, chest physiotherapy (CPT), breathing strategies, directed coughing, positive expiratory pressure (PEP) devices, and high frequency chest wall oscillation (HFCWO) devices.[19,20]

A Cochrane review of the effectiveness of ACTs with BE patients concluded their efficacy clearing mucus from the lungs, potential improvement of lung function, and improvement in quality of life.[20] Current guidelines for BE do suggest the use of prescription ACTs:[7,12,21]

- The American College of Chest Physician guidelines (2018) recommends that children and adults with productive cough due to BE should be taught ACT by professionals with advanced training in ACT.[12] Frequency should be determined by disease severity and amount of secretions and should be individualized to the patient.[12]
- The European Respiratory Society guidelines (2017) recommend patients with chronic productive cough or difficulty to expectorate sputum should be taught an ACT by a trained respiratory physiotherapist.[7]

However, only 56% of US patients diagnosed with BE are prescribed a non-pharmacologic ACT intervention to improve bronchial hygiene, likely due to limited clinical evidence or large, randomized, controlled trials.[4,12]

Pulmonologists Discuss Treatment Choices and Introducing Airway Clearance Therapies

The discussion around ACTs was centered on PEP and HFCWO therapies. The modalities selected for first-line therapy may depend on patient characteristics. For mild symptomatic patients, many pulmonologists described a combination of a PEP device with hypertonic saline and a nebulizer as first-line therapies. They noted many of these were easy to prescribe; specifically easy to order from a pharmacy and easy to use for a patient.

Effectiveness of PEP is mixed.[22] Pulmonologists state it requires careful training, coaching, and follow up. Some noted PEP does not change the course of illness and patients can remain symptomatic. Some claimed PEP works for milder cases of BE and symptoms may stabilize without aggressive ACT.

Pulmonologists typically monitor for one year. If the patient has exacerbations or hospitalization and is producing excess secretions, additional treatments are considered. Some mentioned chronic infection, signs of colonization, or disease worsening on chest CT indicate a given treatment is not working and it is time to move towards a more aggressive form of ACT.

HFCWO is administered with a vest-like garment capable of generating airflow oscillations that produce cough-like forces that may shear secretions from the walls of the airways and decrease secretion viscosity.[23] HFCWO has become a beneficial part of therapy for patients with cystic fibrosis, with many studies reporting benefits in combination with other therapies.[19] It was noted that physicians in the US often wait to prescribe HFCWO for BE patients who have more severe disease, frequent exacerbations, symptoms, and secretions. Some noted older patients were more likely to be prescribed HFCWO.

Some pulmonologists prescribe HFCWO earlier in the course of the disease instead of waiting for declining lung function and increased exacerbations and mentioned that it is effective and relatively harmless. They noted earlier treatment with HFCWO and keeping airways clear is one of the only ways to stabilize BE.

Should HFCWO Be Leveraged More?

Although there is limited data on the use of HFCWO to treat BE, there are studies comparing its clinical outcomes with other ACTs, alone and in combination with other therapies. One study compared traditional PEP/CPT techniques, HFCWO, and medication only (control group). This study found that HFCWO showed significant improvement in quality of life measures, markers of inflammation and some lung function parameters compared to the control group and PEP/CPT.[24]

Another group of patients with BE, symptoms and more than two exacerbations in the previous year, were assigned to an observational study adding HFCWO to a standard treatment regimen for BE (nebulized bronchodilator, nebulized mucolytic, and assessment for macrolide therapy).[25] Patients were observed every two to three months for a period of one year. The treatment algorithm, including use of HFCWO, significantly decreased severe exacerbations as well as the number of courses of antibiotics and lung function remained stable.[25] Additionally, a case review reported reductions in BE-related health care utilization, like antibiotic and steroid use after one year of HFCWO therapy.[26] Newly analyzed claims data suggests HFCWO may lead to decreases in hospitalization, office visits, and antibiotic use, sustained out to three years.[27-30]

Pulmonologists Discuss If HFCWO Should Be Leveraged More

Pulmonologists thought HFCWO device usage reduces the frequency of exacerbations and patients tend to do very well with the therapy. However, some pulmonologists mentioned HFCWO devices may only be tried when a patient has been hospitalized. If HFCWO was useful at the hospital, it may then be prescribed for home use. They noted physicians, particularly non-pulmonologists, may not be aware of the benefits of using HFCWO and broader awareness of treatment options for BE is needed. Some mentioned that when a patient's lungs are infected with organisms such as non-tuberculosis mycobacterium (NTM), treatment tends to be more aggressive.

Most pulmonologists recommended individualized treatment versus applying any standard algorithm or guideline. Evidence of BE condition worsening supported by imaging and spirometry data are indications for HFCWO. Pulmonologists mentioned multiple exacerbations and/or hospitalizations with difficulty bringing up secretions or hypersecretion indicate the need for additional treatments. Some pulmonologists noted patients with structural lung damage may start on more aggressive treatment.

Pulmonologists Discuss HFCWO Therapy Compliance and Keys to Success

Patient selection along with expectation setting is key-the motivated patient is a suitable candidate for treatment with HFCWO. Therapy adherence issues were mentioned as an example of a barrier to patient compliance to HFCWO therapy, explained to be resulting from a variety of factors including understanding of therapy benefits, commitment to doing the therapy, and some chest pain. Patients with back or chest pain, compression fractures etc., may not do well with HFCWO and may prefer another airway clearance device like oscillation and lung expansion (OLE) therapy. Patients with pacemakers or other subcutaneous devices may not be able to use HFCWO and report discomfort.

Physicians also need to be committed to their patients and working through any issues that may arise to effectively treat BE. There was a suggestion to investigate why a patient may not be using HFCWO as prescribed and tease out the source of the issue to see if it can be worked through. There may be instances where frequency and duration of HFCWO use can be reduced when a patient feels better. Pulmonologists reiterated tracking patients with BE was important and adjusting their treatments or providing additional patient education was vital to success. Patients who find benefit with HFCWO are likely to keep using it.

Summarizing Perspectives and Keys for Therapy Adoption

Patient education, device introduction, and training are key. Patients need to understand how to operate their device correctly and to access easy customer support. Pulmonologists stressed patient education in the office by a respiratory therapist to help them understand the importance of ACT upfront.

Address treatment "learning curve." Patients may benefit from added guidance using their device at home appropriately. It was noted that patients who are smaller in body size, and may be somewhat frail, can benefit from HFCWO but may not like it (at first) because it overwhelms their physical size.

Set patients' expectations to optimize outcomes. It can be helpful to inform patients the benefit is cumulative and may take several weeks to start feeling better. Proper technique for the treatments that may be prescribed is also important and a valuable tool for patients to understand.

Patient motivation. A patient's willingness to use medical devices is fundamental. Some will not be motivated to use HFCWO, which may include time commitment, knowledge of proper technique, and comfort level of the device itself in addition to other factors.

Pulmonologists Discuss HFCWO Device Cost and Insurance Reimbursement

Perceptions of device reimbursement and initial cost can be a barrier for both patients and physicians. A few pulmonologists mentioned a minority of their patients were resistant to HFCWO because of costs, but for most, it is not a concern. Some noted cost was a bigger concern a few years ago but it has lessened since due to increased insurance reimbursement. Among the group, there was varied experience with insurance coverage for HFCWO. Some pulmonologists will monitor exacerbations for at least a year before considering adding HFCWO. Some noted that a patient had to experience three or more exacerbations in a year and have documented failure with standard treatments for mobilizing retained secretions prior to receiving Medicare reimbursement for HFCWO.

Preliminary data suggests health care costs are reduced after the first year of HFCWO use, sustained to three years, driven by decreases in hospitalization, office visits, and antibiotic use.[27-30]

Pulmonologist Insights Towards Moving the Field Forward

Additional education for physicians on BE could help further understanding of the disease and enable more informed decisions regarding diagnosis, treatment options and optimal use. Additionally, it is important to follow up with patients more frequently regarding their therapy progress. This will help identify the need to improve adherence of current therapies and better understand when to transition to a more aggressive therapy. Pulmonologists mentioned some patients could benefit from additional training and education in the outpatient setting. Non-branded materials on BE, such as lung diagrams, educational videos, etc. could be useful tools.

Additional clinical research and studies to help understand BE and treat it more effectively are also needed. Specifically, studying the effectiveness of HFCWO could help drive earlier adoption of this therapy. Much of the current evidence on ACTs and HFCWO is based on short-term studies.[6,20] More research carried out for a longer duration could help to establish efficacy.[6,20] Research on the optimal timing for HFCWO was also requested by pulmonologists.More evidence on outcomes related to exacerbation rates, hospitalization, and antibiotic prescription in patients treated with HFCWO could be helpful to establish its place in the treatment algorithm for BE.[20]

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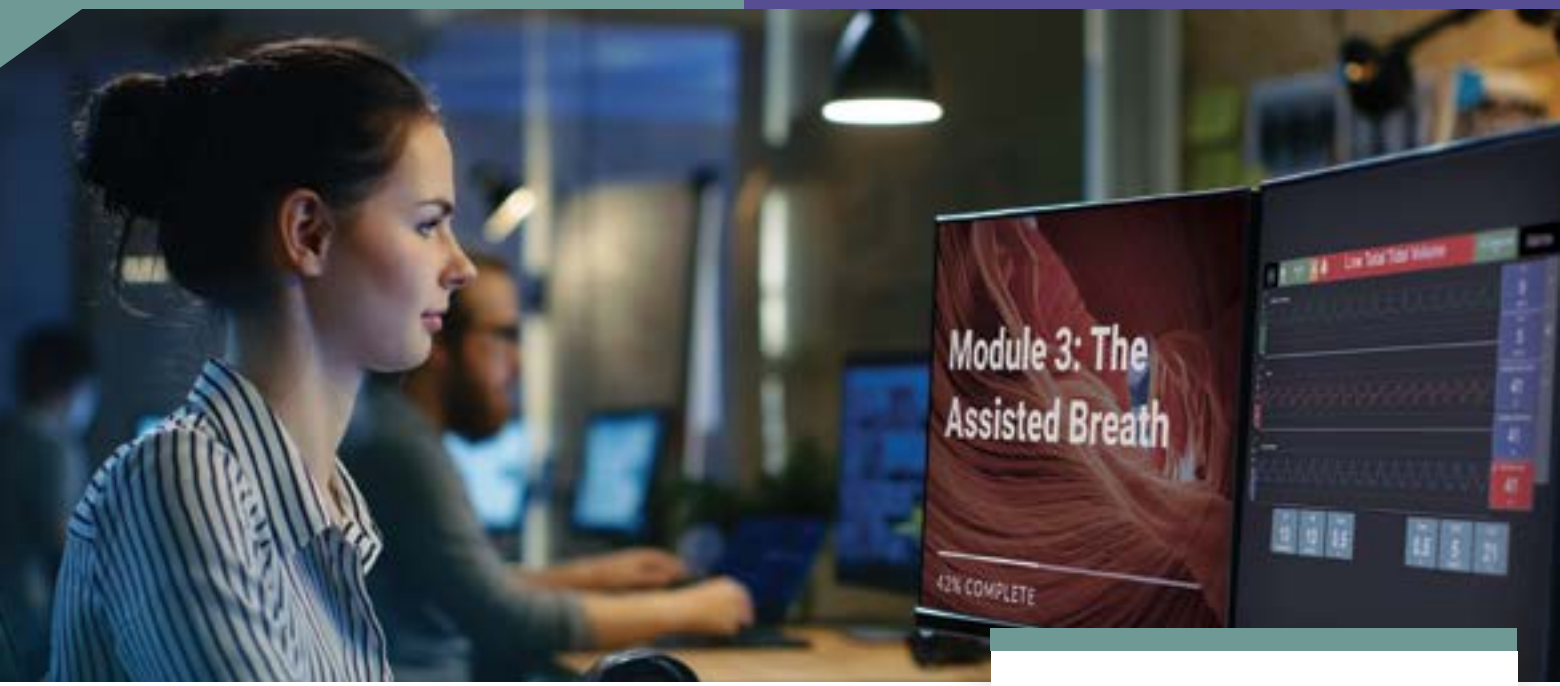

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A Paradigm Shift in Respiratory Training

Respiratory Therapy regularly conducts interviews with experts in their field about the latest trends in equipment and education. Here we talk with Brian Linn, president of IngMar Medical, about the company's role in the education and training of RT professionals.

How do you believe the paradigm is shifting in respiratory training considering the trend toward more hybrid and remote learning?
Throughout the pandemic, educators and learners have been forced to adapt by leveraging a mix of educational modalities including hybrid and virtual learning. As long as simulation products and services continue to adapt to meet the evolving needs of educators, we believe this trend can have a positive impact on educators and learners alike. However, our users seem to share our opinion that, due to the fact that all mechanical ventilators have their own nuances, modes, and settings that make them unique, there is no true substitute for hands-on training with real ventilators.

What role does IngMar Medical plan to serve in helping respiratory educators succeed in the future with these trends in mind?
We will focus on being a comprehensive provider of solutions that satisfy all types of training in all environments. In this sense, we believe we can actually help set educators up for success better than ever before. While we believe there will always be a need for hands-on, in-person training, our newly introduced virtual training platform, RespiSim® eLearning, can bridge the gap between classroom instruction and hands-on simulations. This platform provides users with the ability to practice making changes to a virtual ventilator in a software-based environment in addition to a library of e-learning courses covering key concepts in ventilation. By utilizing these tools, learners can build a solid foundation that will help to make the valuable time they spend in the simulation lab, with real ventilators, that much more effective.

How are IngMar Medical products evolving to more broadly meet the needs of educators using simulation?
Going forward, we plan to focus on delivering exceptional value to our customers. For many users, this may require products that are at the highest level of realism and versatility. However, we understand that not all users are created equal, so we plan to expand our offerings to include more solutions that are geared toward the delivery of basic, foundational education. By doing this, we expect to be able to provide solutions that are tailored better to the needs of all educators.

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

What makes IngMar Medical products unique?
Our simulators are predominantly known for their ability to model highly realistic respiratory patients. The ASL 5000® Breathing Simulator is used to model mechanically ventilated patients of all sizes and conditions, prompting interactions on real ventilators and respiratory devices that are indistinguishable from a real patient. We will always pride ourselves on creating the most immersive and realistic environment for teaching mechanical ventilation; however, in recent years, we have focused heavily on *ease of use* and *practicality*. We will be continuously updating our software platform so that our users can build simulations and facilitate them with ease—allowing them more time to focus on observing the learners and teaching.

What do your customers value most about your products and services?
The value we provide to our customers extends far beyond the products themselves. We focus on providing the best overall customer experience. We understand that users are at times frustrated with the technological challenges inherent to simulation as well as the time it takes to build and run great scenarios. Therefore, we focus on surrounding our products with excellent support, training, and pre-built simulation exercises so that our customers can truly unlock the full potential of their simulators.

What does success look like for your customers?
Our simulators are used to provide respiratory and ventilation training in many different capacities from undergraduate Respiratory Therapy programs to hospital-based training for fellows, residents, and practicing physicians. In any of these cases, the goal is essentially the same. To raise the level of competency and confidence of clinicians who are responsible for managing a ventilated patient. Success means better trained clinicians, and ultimately, better patient outcomes.

How do you approach post-sale support and education in a way that ensures your customers are set up for success?
At IngMar Medical, we believe we are only as successful as we're able to make our customers. We understand that simulation technology can be difficult to manage at times, and building simulations can be a complex and time consuming process. Therefore, we have built a Customer Experience team to ensure we are prepared to set our customers up for success throughout their entire journey with our products. We

have a robust support team including in-house Respiratory Therapists who provide support, consultation, and product training to our customers regularly. We also believe in the value of talking to a real person as quickly as possible when an issue arises.

Do you have any new and exciting updates to share with your customers?

We have just officially launched a new subscription-based service, RespiSim® eLearning! Subscribers get access to our new Virtual Ventilator, a software-based platform that allows users to run simulations in a fully virtual environment while tapping into the power of the ASL 5000 lung modeling technology. Additionally, subscribers get access to self-guided, e-learning content including the acclaimed Standardized Education for Ventilatory Assistance (SEVA™) Curriculum, developed by the Cleveland Clinic. These services bring affordable, fundamental ventilation training to educators of all kinds, in any environment.

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to the virus," Al-Aly said in a press release from the Washington University School of Medicine in St. Louis. "Without ambiguity, our research showed that getting an infection a second, third or fourth time contributes to additional health risks in the acute phase, meaning the first 30 days after infection, and in the months beyond, meaning the long COVID phase." Being infected with COVID-19 more than once also dramatically increased the risk of developing lung problems, heart conditions or brain conditions. The heightened risks persisted for six months.

RSV Causes 1 in 50 Deaths in Children Under Age 5: Study

The respiratory illness RSV causes 1 in 50 deaths in children under age 5, mostly in low-income and middle-income countries, a new study says. But RSV — formally known as respiratory syncytial virus — is also a problem in high-income nations. In those countries, 1 in 56 otherwise healthy babies are hospitalized with RSV during their first year of life, said the study, which was published in *The Lancet Respiratory Medicine.* Researchers looked at the health records of 9,154 infants born between July 1, 2017, and July 31, 2020, who were treated at health centers across Europe. Previous studies have concentrated on babies with pre-existing conditions, but this one looked at otherwise healthy children, researchers said. "This is the lowest-risk baby who is being hospitalized for this, so really, numbers are really much higher than I think some people would have guessed," said study co-author Louis Bont, MD, a professor of pediatric infectious diseases at Wilhelmina Children's Hospital at University Medical Center Utrecht in the Netherlands. He is also chairman of the ReSViNET foundation, which aims to reduce RSV infection globally. The study said more than 97% of deaths from RSV occur in low-income and middle-income countries. The study concluded that "maternal vaccination and passive [immunization] could have a profound impact on the RSV burden." In developed nations, children who get RSV usually survive because they have access to ventilators and other health care equipment. Still, just being treated for RSV can have long-range negative effects on a child's health, Kristina Deeter, MD, chair of pediatrics at the University of Nevada, Reno, School of Medicine said. "Whether that is just traumatic psychosocial, emotional issues after hospitalization or even having more vulnerable lungs — you can develop asthma later on, for instance, if you've had a really severe infection at a young age — it can damage your lungs permanently," she said of the study. "It's still an important virus in our world and something that we really focus on." *The Lancet* study was published days after the CDC warned public health officials that respiratory viruses, including RSV, are surging among children across the country.

Beyond Air Announces Positive Data for Inhaled Nitric Oxide (NO) to Treat COVID-19

Beyond Air, Inc., a medical device and biopharmaceutical company focused on developing inhaled nitric oxide (NO) for the treatment of patients with respiratory conditions, including serious lung infections and pulmonary hypertension, and, through its affiliate Beyond Cancer, Ltd., ultra-high concentration nitric oxide (UNO) for the treatment of solid tumors, today announced positive data from the LungFit PRO pilot study of high-concentration inhaled NO in Viral Community-Acquired Pneumonia (VCAP), including COVID-19. Incremental data from the completed pilot study was provided in a poster presentation at IDWeek 2022, held in Washington, D.C. Initial topline data

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The Benefits of Respiratory Products in NICUs

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Craig McCrary, President Neotech Products LLC on Specialty Respiratory Products for the NICU. Neotech Products LLC is a medical device manufacturer based in Valencia, California.

How long has Neotech Products LLC been in business?
We are celebrating 35 years in business. In 1987, the name Neotech was chosen as "Neo" for new and "tech" for technology. The founders wanted to create new technology, but it was not meant to be specific to the NICU. But the name transitioned well when we began developing and manufacturing products for the neonatal market.

In 1997, we attended our first-ever NANN Conference (National Association of Neonatal Nurses) and introduced three benchmark products—the NeoShades® Phototherapy Eye Shields, the NeoBridge® Umbilical Catheter Holder, and the NeoBar® ET Tube Holder. All three of these products featured skin friendly hydrocolloid adhesive.

The response was so overwhelmingly positive, it defined our path moving forward.

Why is there a need to make respiratory products specifically for preemies and neonates?
Newborns have very fragile skin, especially preemies. We were one of the first companies to use hydrocolloid as the adhesive to protect preemie skin. Many products required the use of medical tape to secure them, but that can be extremely harmful to the skin.

And, of course, the patients are much smaller. It seems obvious, but there aren't a lot of companies that develop tiny products like we do. Whenever we launch a product, specifically designed to be extremely small, we're almost always asked, "can you make it smaller?" Some of these patients are small enough to fit in an adult hand.

It's also a smaller patient population. So, from a business standpoint, it's not as lucrative for some of the big companies. They think the NICU is a small market, so they don't invest as much time and resources to it.

But for Neotech, it's a very important market. It's where we start. We develop products that are better for these tiny patients and help to improve the quality of care for clinicians.

What was Neotech's first respiratory-related product and what made it unique?
The Neotech Meconium Aspirator was our first respiratory product. It was revolutionary because prior to the creation of the device, the standard practice was to mouth suction the meconium from newborns. Which was not only unpleasant, but the potential cross contamination was extremely dangerous to the clinicians.

The Meconium Aspirator changed the standard. A simple device developed specifically to eliminate mouth suctioning.

What are some other respiratory products you offer and what are their benefits?
The NeoBar, mentioned earlier, allows for securement of an ET tube without applying tape to the patient's skin. Skin care is a big deal at Neotech. We use NeoBond® Hydrocolloid on several products that are designed to eliminate tape on the skin.

The EZ-Hold® [tubing and cannula holder] is also made with NeoBond Hydrocolloid.

Our family of Little Sucker® and NeoSucker suction tips are soft and flexible like a bulb syringe. They feature a thumb port that allows the clinician to suction intermittently. We have preemie sizes for the tiniest patients and our NeoSucker XL offers a softer alternative to hard, plastic tips on the markets. It's ideal for patients who are prone to biting.

The Neotech RAM Cannula® has larger bore tubing than a traditional nasal oxygen cannula which makes it ideal for low or high flow humidified oxygen. The curved prongs are extremely soft for patient comfort.

Our EZCare® Trach Ties are so uniquely soft, you have to feel them for yourself. The NeoFoam® material is lightweight and form fitting. And it wicks perspiration to help reduce redness and irritation. We've had adult users tell us about their struggles with skin sensitivity and how much better our trach ties are. And if adults are experiencing irritation with their ties, image a baby's delicate skin.

Neotech Products LLC is a medical device manufacturer based in Valencia, California. They specialize in neonatal and pediatric products, made in America, with an emphasis on respiratory care. Neotech is a Certified B Corporation™ dedicated to their customers, their employees, the community, and the environment. They are also ISO 13485:2016 Certified. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

Our Neotech ChinStrap™ and NeoPulse™ Pulse Oximeter Wrap are made from the same material. When people feel it in person, they're really impressed.

We make a lot of different products, but we emphasize devices that support RTs. All of our products are simple, but effective.

What is the under-the-radar product that clinicians should be aware of?
We're really excited about relaunching our NeoHeart® ECG Pad! It was developed in response to NRP guidelines for delivery room assessment of a newborn.

It has three pre-wire electrodes arranged on one pad. Which allows for quick, one-touch electrode placement on a baby during a high-risk birth. It helps to save critical time when every second matters.

Do you have any new products in the works?
We do have several exciting new products in the works that relate to CPAP, suctioning, tube securement and, more.

We take pride in launching new products. Some of our most revolutionary products are on the horizon.

Tell us about working with product inventors.
For me personally, it's one of the greatest joys I get in business. The absolute best feeling we get is when a new product is launched and the inventor is with us at a trade show or conference exhibit. For the inventor to get firsthand positive feedback is really heartwarming.

They had an idea, they came to Neotech, and now their idea is well received by other healthcare professionals. It's really what Neotech is all about!

At what point in the process does Neotech get involved?
We've seen inventors with a sketch on a napkin to others that have obtained a patent, and even made prototypes. There's no set standard. If we believe in the idea, then we'll jump in at whatever stage they're in and take it from there. All at no cost to the inventor.

Even when we don't take on an inventor's idea, we often try to guide them to other companies in our industry where their idea might be a better fit.

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from the study were included in a presentation at the 32nd European Congress of Clinical Microbiology & Infectious Diseases (ECCMID 2022) on April 25, 2022. "The analysis of the LungFit PRO study in VCAP patients further demonstrates improved efficacy on multiple parameters in the iNO treatment group compared to standard supportive treatment (SST). This is the fourth study in hospitalized subjects suffering from viral respiratory infections completed by Beyond Air with NO concentrations of 150 ppm or more with all studies having data showing a strong safety profile and statistically significant results on key endpoints. We believe high concentration NO delivery with the LungFit PRO generator and delivery system can be a powerful tool against any type of pneumonia, especially COVID-19, and our company is dedicated to bringing this important therapy to market as soon as possible," said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. The multi-center, open-label, randomized clinical trial in Israel enrolled a total of 40 subjects hospitalized for VCAP (COVID-19, n=39; other viruses, n=1). Subjects were randomized in a 1:1 ratio to receive inhalations of 150 ppm NO given intermittently for 40 minutes four times per day for up to seven days in addition to standard supportive treatment (NO + SST) or standard supportive treatment alone (SST, control group). Thirty-five subjects were included in the Intent To Treat (ITT) population, 16 in the inhaled NO + SST group and 19 in the control group. The primary COVID-19 treatments used during the study were Remdesivir (>30%) and Dexamethasone (>65%). Enrolled patients were followed for up to a 180-day period. The study endpoints include safety, and time on oxygen supplementation, among others. Safety data from the study show that inhaled NO treatment was well tolerated overall with no treatment related adverse events as assessed by the investigators. There were two SAEs reported in the group receiving inhaled NO along with SST, which were determined to be related to underlying conditions and unrelated to study device or NO. The efficacy results from the study are summarized below and show a trend of shortening LOS in favor of the inhaled NO treatment group. Also, duration of oxygen support, measured in-hospital and at home, was significantly shorter for inhaled NO treated subjects. Additionally, results from the study show a larger decline in c-reactive protein (CRP) from baseline for subjects treated with NO + SST compared to the control group.

Grifols receives FDA clearance
Grifols, a global leader in plasma-derived medicines and innovative diagnostic solutions, announced that its AlphaID At Home Genetic Health Risk Service, the first-ever free direct-to-consumer program in the U.S. to screen for genetic risk of alpha$_1$-antitrypsin deficiency (alpha-1), has been cleared by the U.S. Food and Drug Administration (FDA). The service, also known as AlphaID At Home, is the company's first FDA clearance for direct-to-consumer use. It will be available beginning in Q2 2023 for U.S. adults to screen for their genetic risk level of developing lung and/or liver disease related to alpha-1 without a medical prescription. Alpha-1 is the most common risk factor for chronic obstructive pulmonary disease (COPD), a group of respiratory diseases that includes emphysema and chronic bronchitis. It's estimated that around 16 million Americans have COPD, with millions more yet to be diagnosed. More than 90% of people with alpha-1 are believed to be undiagnosed. "Many COPD patients don't know their condition could be caused by alpha-1 because its symptoms are similar to those of COPD or
Continued on page 53…

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Communication Related Quality of Life in the Patient with a Tracheostomy

Carmin Bartow, MS, CCC-SLP, BCS-S and Kristin King, PhD, CCC-SLP

Introduction

Healthcare providers have ethical and legal obligations to engage in communication with the patients they treat. There has been a transition in healthcare away from the providers being the primary decision-makers, to a model that actively involves the patient and family in all aspects of care. Practitioners recognize that patients have the right to be informed about the care they receive, make educated decisions about their care, and be heard by their providers. This patient-centered care is becoming the universal model of healthcare. The Institute of Medicine defines patient-centered care as: "providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions."[1] However, ethical responsibilities of the healthcare provider, patient-centered care, and quality of life (QOL) are in jeopardy when patients cannot communicate effectively.

Impaired communication with a tracheostomy

Lack of airflow through the vocal folds due to the presence of a tracheostomy tube can result in the inability to produce audible phonation. Additionally, many patients with a tracheostomy have comorbidities such as critical illness myopathy, neurological disorders, and delirium which may impact their ability to successfully use non-verbal communication methods. Impaired communication in patients with tracheostomy tubes may lead to safety concerns, violation of patient rights, isolation, anxiety, and poor quality of life.[2] Difficulty communicating is one of the most frustrating experiences reported by patients with a tracheostomy and is a major factor impacting QOL.[2,3] While speech-language pathologists play a crucial role in advocating for communication rights and addressing communication needs for patients with tracheostomy; ultimately, it is the responsibility of the medical team to ensure a patient's access to effective communication.

Carmin Bartow, MS, CCC-SLP, BCS-S has over 20 years of clinical experience treating patients in acute care. She has special interest in dysphagia management, head and neck cancer, and tracheostomy and mechanical ventilation. Currently, she is a full-time Clinical Specialist with Passy-Muir, Inc. Kristin King, PhD, CCC-SLP: With 25 years of experience in medical, academic, and industry settings, Dr. King brings a unique perspective of medical speech pathology. Her research, publications, and teachings focus on traumatic brain injury, swallowing disorders, and critical care (tracheostomy and mechanical ventilation) for both pediatric and adult patient populations. She has been an invited speaker both domestically and internationally and has published in peer-reviewed journals. Currently, Dr. King is the Vice President of Clinical Education and Research for Passy-Muir, Inc.

Impact of impaired communication on quality of life

Nakarada-Kordic et al. (2018) conducted a systematic review of the literature investigating the experience and QOL of adults living with a tracheostomy.[4] From the review, they reported the consensus that patients related mostly negative experiences with management of the tracheostomy, communication, well-being, and quality of life. Foster (2010) had earlier reported similar findings and reported that patients described feelings of anger, frustration, and fear related to the presence of a tracheostomy tube.[5]

The inability to communicate has often been reported as the primary instigator of negative emotions and experiences. Loss of control, isolation, powerlessness, and hopelessness have been reported by hospitalized patients who do not have adequate access to communication.[6,7] Magnus and Turkington (2006) found that difficulty communicating led to reduced participation in treatment which could lead to prolonged recovery.[8] Some patients report that the need for communication is even more significant than the risk of tracheostomy-related airway complications.[9]

Freeman-Sanderson et al. (2018) conducted structured interviews six months after tracheostomy decannulation to investigate patient experiences regarding communication and quality of life with a tracheostomy tube.[2] Some of the participants' statements were reported as:

- I was very confused and so the lack of speech makes it worse.
- They gave me one of those cards with pictures of faces and the alphabet, which I couldn't use because I couldn't lift my hands to point at the pictures, so basically, I couldn't communicate at all.
- Sometimes I'd want something, I'd want to ask something, but the nurses couldn't understand properly so I would get frustrated and give up.
- Oh, it was horrendous. To not be able to make a sound is the most awful thing, especially when you can't move either. I just felt complete helplessness and frustration…anger at times.
- I feel like I went a long time without a voice…It affected me quite a lot emotionally, for many months, even now.

This study revealed what patients experience when they are unable to verbally communicate. The authors summarized their findings by stating that the absence of voice restricted the ability of the patient to understand information and to participate in their care. This led to a universal reporting of negative emotions.

Pain Management

Another factor to consider related to quality of life is access to adequate pain management. Patients must be able to describe the location and severity of pain for healthcare providers to prescribe appropriate pain management regimens. Limaye and Katz (2006) found that difficulty communicating with healthcare providers is a significant barrier to accessing pain relief. Poorly managed pain can lead to adverse physical and psychological outcomes.[10] Common psychological responses to pain include anxiety, depression, and stress, and unrelieved pain can prolong the stress response which may adversely affect recovery.[11]

Safety

Patient safety is of utmost importance in the healthcare setting. The Institute of Medicine (IOM) considers patient safety "indistinguishable from the delivery of quality health care." When patients do not have access to effective communication, they are at risk for unsafe health practices.[1] Bartlett et al. (2008) found that "patients with communication problems were three times more likely to experience preventable adverse events than patients without such problems."[12] Even The Joint Commission reported a result from a quality and safety performance analysis that ineffective or inadequate communication between healthcare providers or between care providers and patients and families is a primary cause of sentinel events.[13]

Patient rights

The right to effective communication is supported by the Americans with Disabilities Act (ADA) and The Joint Commission regulations. Both regulate that a patient must have access to the least restrictive means of communication and be able to participate in their medical care. The ADA states that hospitals are obligated to provide access to effective communication, which is critical in healthcare settings as it may impact proper diagnosis medical treatment.[14] The Joint Commission also sets communication standards that address a hospital's responsibility to identify and provide the patient's preferred language and personal devices needed for discussing health care.[15]

The Joint Commission defines effective communication as "the successful joint establishment of meaning wherein patients and health care providers exchange information, enabling patients to participate actively in their care from admission through discharge, and ensuring that the responsibilities of both patients and providers are understood."[16] This report states that hospital staff must address the patient's communication needs before conducting an assessment, providing treatment, obtaining informed consent, discussing end-of-life, or engaging the patient in care discussions.

Improving communication with use of the Passy-Muir® Valve

When considering effective communication, it is defined as that form of communication that is most familiar to an individual and least restrictive. For many patients with tracheostomies, their effective communication would be restoration of voicing. Research has well-established that effective communication is imperative for the patient with a tracheostomy as it impacts care, quality of life, psychological well-being, pain management, and more. Speech language pathologists (SLP) have the knowledge, skills, and responsibility to establish successful communication for this vulnerable patient population.

Since techniques such as lip reading, gesturing, and other non-verbal communication methods may be limiting and ineffective[17], the speech-language pathologist should strive to achieve the most natural means of communication. Restoration of voicing with use of the Passy-Muir Valve (PMV®) is ideal for this complex patient population. The PMV is a no-leak speaking valve that is placed on the hub of a tracheostomy tube or in-line with ventilator circuitry. This one-way valve opens during active inspiration and returns to the resting, closed position at the end of inspiration, thereby, directing airflow around the tracheostomy tube, through the vocal folds, and out the mouth and nose during expiration. This airflow through the vocal folds restores natural voicing and may allow patients with a tracheostomy tube to regain their ability to communicate effectively.

Clinicians should not wait until the patient is weaned from the ventilator to provide communication intervention. There are numerous benefits to early assessment and intervention with the PMV. Research has demonstrated improvements in communication with PMV use but also has shown improvements in secretion management and swallowing[18]; psychological state and decreased ICU delirium[1,19]; and earlier weaning and decannulation.[20]

It has been demonstrated that ventilation and stable respiration may be achieved with placement of a Passy-Muir Valve in-line with the ventilator. Sutt et al. (2016) investigated the use of the PMV for patients with tracheostomy and ventilator dependence. They found that deflating the cuff and using the PMV improved verbal communication and increased end-expiratory lung impedance, thereby improving lung recruitment.[20] Freeman-Sanderson et al. (2016) reported earlier phonation and no increase in patient complications when using the PMV in-line with mechanical ventilation.[19] Restoration of communication also allows the SLP to conduct more thorough swallowing, speech, language, and cognitive evaluations. Early assessment results lead to earlier treatment which may lead to a faster recovery.

Improving communication may lead to improved QOL

Restoring vocal communication allows patients to fully express

themselves and their needs which enhances patient satisfaction and quality of life.[21] Having a voice allows patients to make decisions and to define their goals of care. For many patients, this results in an improved sense of control and well-being. Freeman-Sanderson et al. (2018) reported that relief, satisfaction, and improvements in quality of life were experienced once verbal communication was restored. As one patient reported: Talking helped me recover quicker. I'm no doctor but it made me feel a lot better, when you feel better you recover.

The authors reported that return of voice increased patients' ability to engage with staff and participate in care decisions. Effective communication empowered patients and aided their recovery.[2]

Newman et al. (2022) conducted a systematic review of the literature regarding adult experience with tracheostomy in the ICU. The authors reported their key finding was that patients want to be seen and treated as a whole person, and having a voice makes this easier. The authors recommended that voice restoration should take high priority in tracheostomy management decisions, such as tracheostomy tube size selection, cuff deflation, and use of speaking valves.[22]

Conclusion

Healthcare providers have an ethical responsibility not only to communicate with their patients but to ensure effective communication. When patients with tracheostomies are voiceless, patient-centered care is negatively impacted, patient rights are violated, and poor health related quality of life is reported. Restoration of voice allows patients to express their goals of care, participate in healthcare decisions, and experience improved quality of life. Freeman-Sanderson et al. (2016) reported that restoring voice facilitates effective communication which is beneficial for improved patient care in the ICU and may improve reporting of medical symptoms and assessment, and management of pain, delirium, and emotional distress.[19] Additionally, restoring communication results in compliance with The Joint Commission and ADA regulations. Speech-language pathologists and respiratory therapists are integral members of the healthcare team treating patients with tracheostomy and should work together to make effective communication a standard of care for this patient population.

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News…continued from page 48
asthma," said Scott Santarella, President & CEO of the Alpha-1 Foundation, pointing out that November is awareness month for both alpha-1 and COPD. "We wholeheartedly support initiatives and innovations that contribute to the diagnosis of alpha-1." To use the safe saliva collection kit, individuals simply collect their sample and send it to a certified lab for processing. Within a few weeks and through a secure online portal, they will know if they are at risk of developing alpha-1, a condition due to a lack of alpha$_1$-antitrypsin (AAT). They are encouraged to share the results with their doctor and discuss potential treatment options. A user comprehension study for AlphaID At Home showed that a demographically diverse U.S. population of users (525 participants) could easily comprehend the service reports, with a 90% or greater rate of understanding. AlphaID At Home uses the same accurate test Grifols has made available to physicians globally since 2018 to screen for alpha-1, a focus on diagnosis that has led to more than 1 million patients being screened with Grifols technology over the last 20 years. The test can screen for the 14 most prevalently reported genetic mutations associated with alpha-1 — the most of any test of its kind — including the S, Z, F, I alleles, as well as rare and null alleles. "Grifols is very pleased that the FDA cleared the AlphaID At Home service, reflecting the robustness and accuracy of the testing platform as well as the value it will provide in helping people detect if they are at risk for alpha-1," said Antonio Martínez, President of Grifols Diagnostic. "As leaders in alpha-1 testing and treatment, Grifols is redoubling its commitment to the alpha-1 community." Only a physician or healthcare provider can make a diagnosis of alpha-1. To learn more about alpha-1, please visit the Alpha-1 Foundation at www.alpha1.org.

FDA Clears New Laboratory Blood Glucose Reference Analyzer

The US Food and Drug Administration (FDA) has cleared Nova Primary as a blood glucose reference analyzer. Nova Primary fills the need for a new glucose reference analyzer to replace the discontinued YSI STAT PLUS 2300 Glucose and L-Lactate analyzer. Manufacturers of blood glucose measuring devices and clinical diabetes researchers have relied on the YSI 2300 as a reference and correlation analyzer. However, YSI, Inc. no longer supports the analyzer, and its discontinuation has left a critical industry void. The Nova Primary analyzer fills that need. With today's FDA clearance, Nova Primary is now available in the US and worldwide. According to Matthew McRae, Nova Sales Product Line Manager, "We at Nova Biomedical are pleased to offer the Nova Primary, an accurate, easy-to-use and modernized blood glucose reference analyzer for glucose device manufacturers and clinical diabetes researchers to replace the discontinued YSI Stat Plus glucose analyzer." Like the YSI 2300, Nova Primary uses a single, reusable glucose electrochemical sensor based on glucose oxidase and has a measurement range of 20-900 mg/dL. It uses a small, 25 microliter venous whole blood or plasma sample which is internally diluted as in the YSI. Results are available in approximately 2 minutes. Nova Primary's large color touchscreen display and intuitive, icon-based graphical user interface make it very straightforward to use. A single calibrator pack uses RFID data management to monitor the pack expiration date and number of samples remaining, eliminating the need for separate reagent bottles and daily monitoring of their levels. In clinical laboratory studies using venous whole blood and plasma, the Nova Primary demonstrated excellent correlation to the YSI 2300 and is traceable to NIST
Continued on page 66…

What's New in Pulmonary Function Diagnostics: FOT and FeNO

Forced Oscillation Technique following the latest international ERS Technical standards and its use with FeNO, exhaled Nitric Oxide

Roberto "Roby" Perissin

Forced Oscillation Technique, the history and the advances today

FOT (Forced Oscillation technique or nowadays commonly called "Oscillometry") is a well, established, validated method originally appearing in the literature since the 1950's.

It is becoming, in the last few years, a standardized method that may be employed in the daily clinical routine use, for evaluation of pulmonary obstructions, thanks to the publication, acceptance and use of the latest international ERS Oscillometry technical standards *(G. King et al— European Respiratory Journal, 2020; 55: 1900753— Technical standards for respiratory oscillometry)*.

The basic principle of FOT is to superimpose an oscillating pressure waveform, generated by a loudspeaker, during normal, tidal breathing. The lung's structural and mechanical properties react to this external, oscillating pressure allowing the device to measure the Impedance (Zrs) of the respiratory system (Rrs = resistance and Xrs = reactance) which represents how easy is for the air to flow in and out through the airways and the lungs.

Thanks to the different contribution of large, small airways and lung parenchyma to the measured Rrs and Xrs, FOT can localize the site of obstruction as peripheral, central or heterogeneous.

The **Forced Oscillation Technique** (FOT) has evolved significantly over the years, the culmination of innovation and the latest technological advances are incorporated in a new series of devices, the Resmon Pro Full and now the V3 (see figure 1). The popularity of this new, diagnostic device is reflected by numerous peer-reviewed publications every month.

The Resmon Pro Full is a recent device in the market, result of more than 25 years of research started by the Medical Engineering Department of the Politecnico di Milano University (Prof. Raffaele Dellaca' et al), alongside several clinical centers from Europe, the US and Australia, now brought to a simple, understandable diagnostic instrument, widely used all over the world in more than 450 centers.

Roberto "Roby" Perissin is the Vice President, Worldwide FOT and Asthma Management Business Development, MGC Diagnostics, St. Paul, MN.

Figure 1. Resmon™ Pro Full V3

Use of Oscillometry since the inception of the latest ERS International Technical Standards, in the daily clinical routine

The 2020 international document *Technical standards for respiratory oscillometry* have brought FOT closer to Forced Spirometry recommending to perform, as for spirometry, 3 acceptable FOT measurements in one session, with an established CoV % (coefficient of variation, repeatability index) criteria that the Resmon Pro Full devices shows, ensuring test quality and acceptance, assisting the operator with helpful warnings.

The document also defines thresholds for the significative response to treatment (ie Bronchodilator), that can be applied to oscillometry pre-post sessions. With these published and accepted criteria, Resmon PRO FULL may now be used daily on all patients during clinical routine testing.

Clinical and research uses

The Resmon Pro Full system is based on established, standardized methodologies while incorporating the latest technology and novel patented algorithms. Ease-of-Use and simplified data evaluation result in a quick & easy diagnostic

test suitable for use in a diverse patient population from young children to the elderly, from research to clinical.

Figure 2. the Resmon™ Pro in use, tidal breathing testing in children and adults.

This specialized device allows quick, sensitive, reliable airway assessment via a unique 'within-breath' real-time analysis (200 Hz sampling frequency) of both inspiratory and expiratory Resistance (Rrs) and Reactance (Xrs) to determine, with a few tidal breaths:

- Presence and location of airways obstruction
- Quantitative assessment when compared to available published, standard normative data
- Tidal Expiratory Flow Limitation at rest (EFL_{VT})
- Reversibility of the airflow obstruction (pre-post testing)
- Hypersensitivity of the airways (bronchial challenge)

What does Resmon Pro Full measure

Resmon Pro FULL features 3 modes of measurement to optimize the results according to the degree of obstruction of the patient, all extremely well tolerated by patients:

1. Validated "enhanced optimized" multi-frequency 5-11-19 Hz mode for all adults and pediatrics, with moderate to severe obstruction
2. Single frequency modes suitable for very young children, severe COPD and Asthmatic adults with very high airways resistance
3. Non-prime Pseudo-Random Noise multi-frequency mode

The device features a special algorithm, which identifies and discards non-physiological breaths and artefacts, so that only technically acceptable breaths, typically 10, are sufficient to obtain a reliable measurement.

Central and Peripheral Components of Airway Obstruction

Resistance (Rrs) provides information about airway caliber reflecting the degree of airway obstruction but measured at rest during normal, tidal breathing. Due to the morphology of the airways, Rrs mainly reflects central airways obstruction as FEV1 would in forced spirometry. Rrs can be measured at different oscillating frequencies and if increased at low frequencies and decreased at the higher ones ("frequency dependent"), is indicative of heterogeneous (mixed) obstruction.

Reactance (Xrs) enables to determine how effectively the deep lung is ventilated, or simply, how well air reaches the peripheral airways. Xrs may be affected by changes in peripheral obstruction and/or airway compliance. Xrs falls below predicted values at low oscillating frequencies in conditions such as peripheral obstruction, tidal expiratory flow limitation, alveolar gas trapping and chest wall restrictions (i.e. Obesity, kyphoscoliosis, pregnancy, etc).

Resistance (Rrs) and Reactance (Xrs) are both measured by Resmon Pro Full "within-breath" modes and are reported as inspiratory, expiratory and total components.

Figure 3.

The literature demonstrates that improvement in traditional FOT indices after bronchodilator may be variable, particularly true if a patient has expiratory flow limitation. Inspiratory resistance provides a sensitive measurement of obstruction and may be used for therapeutic treatment assessment.

Resmon Pro Full measures and calculates the tidal **Expiratory Flow Limitation Index (EFL_{VT})** or Delta Reactance (ΔXrs) which is the difference between INSP and EXP reactance at 5Hz: if this difference is greater than a published and validated threshold, the presence of EFL — expiratory flow limitation — may exist and can be quantified (FL %). This patented index is now extensively used in COPD and rehabilitation programs.

Breathing pattern parameters: During FOT testing Resmon Pro Full measures all essential parameters of the "breathing pattern", such as VE, VT, RR, Ti/Tot, VT/Ti etc. and reports them, even as changes to treatment.

Also available (not US FDA approved at this time) is the Slow Vital Capacity (SVC) and Inspiratory Capacity (IC) test to measure changes in lung volumes and hyperinflation in COPD and severe asthma. That measurement enables the calculation of volume independent sGrs, specific conductance of the respiratory system.

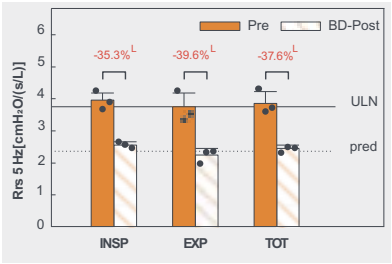
Using these parameters, the Resmon Pro Full allows a very simple FOT results "evaluation" scheme, see Figure 3 below.

Clinical Applications of Resmon Pro Full

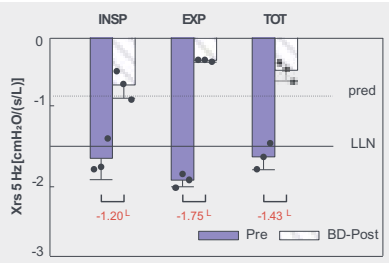
- **Asthma** (adult and pediatric):
  - Early identification of functional impairment
  - Screening programs for asthma
  - Quantify bronchodilator and broncho-provocation response
  - All patients that cannot easily perform a technically acceptable FVC set of maneuvers.
- **Use of FOT with FeNO** (Exhaled Nitric Oxide): Used in combination with FeNO (a widely employed, validated biomarker of eosinophilic inflammation) for early detection of asthma even when spirometry is normal or symptoms are not present. Also used for medication control over time in asthma management programs, see figures 4a and 4b:

1. PRESENCE OF RESPIRATORY IMPAIRMENT AND REVERSIBILITY

5 Hz | 8 Hz | 5, 11, 19 Hz



Resistance (Rrs) graphs for Inspiratory, Expiratory and Total inspiratory cycle parameters at the lowest measured frequencies (for adult and pediatrics). Predicted dotted line and ULN (Upper Limit of Normality).



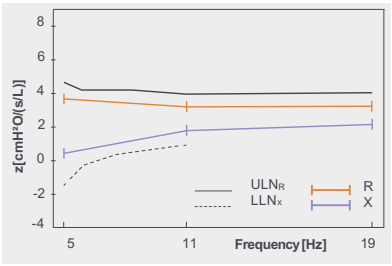
Reactance (Xrs) graphs for Inspiratory, Expiratory and Total inspiratory cycle parameters at the lowest measured frequencies (for adult and pediatrics). Predicted dotted line and LLN (Lower Limit of Normality)

RRS > ULN and/or XRS < LLN are indicative of an anomaly in respiratory mechanics.

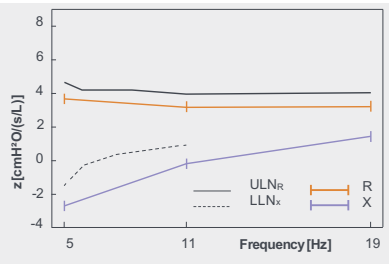
Differences between tests that are above those expected in a reference healthy population are highlighted in red

2. LOCALIZATION

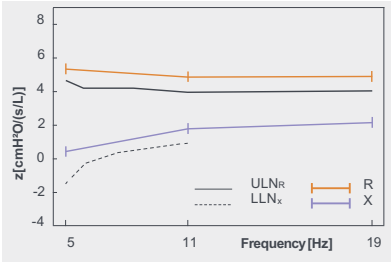
5, 11, 19 Hz



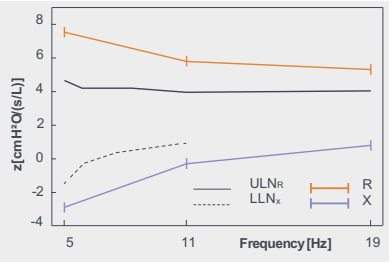
NORMAL
Both Resistance (**Rrs**) and Reactance (**Xrs**) do not present anomalies (**Rrs < ULN** and **Xrs > LLN**).



PERIPHERAL DISEASE
Resistance (**Rrs**) does not present anomalies (**Rrs < ULN**), Reactance (**Xrs**) is below its lower limit of normality (**Xrs < LLN**), for possible small airway obstruction, excluded alveoli, disomogeneity of ventilation, or possible restriction.



CENTRAL OBSTRUCTION
Resistance (**Rrs**) is above its upper limit of normality (**Rrs > ULN**) and Reactance (**Xrs**) does not present anomalies (**Xrs < LLN**) for diseases affecting central airways.



SEVERE OBSTRUCTIVE DISEASE
Both Resistance (**Rrs**) is above its upper limit of normality (**Rrs > ULN**) and Reactance (**Xrs**) is below its lower limit of normality (**Xrs < LLN**). Resistance (**Rrs**) tends to decrease at higher frequencies (i.e. severe asthma, severe COPD).

3. TIDAL EXPIRATORY FLOW LIMITATION, ΔXRS INDEX

5, 11, 19 Hz | 5 Hz

ΔXrs is the patented index of expiratory flow limitation during tidal breathing.*

ΔXrs> 2.8 → LIMITATION

* Dellacà et al. Eur Resp J 2004, Eur Respir J 2007.

Figure 3. the test evaluation pathway of Resmon™ Pro. Notice in Panel 3 above the tidal EFL evaluation with its established threshold.

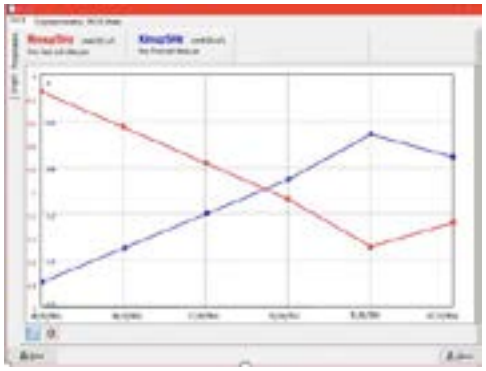


Figure 4a. A FOT Trend of Rrs and Xrs over time, during a therapy monitoring period, notice the increase of Rrs and decrease of Xrs before the last visit, due to non-compliance to therapy.

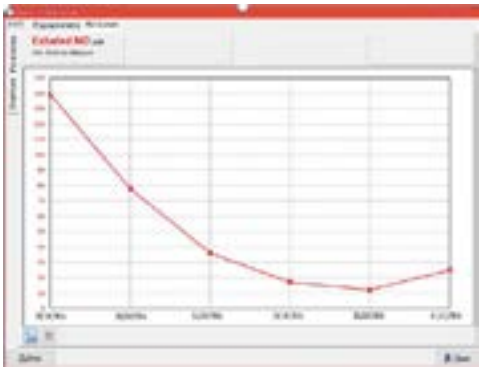


Figure 4b. A FeNO trend over time, during a therapy monitoring period, notice decrease of FeNO before the last visit, due to non-compliance to therapy.

The Resmon Pro V3 can be used in combination with a portable bronchial FeNO analyzer, such as the new MGCD FeNOBreath, (Figure 5) the results of both, FOT and FeNO are now widely employed in the Asthma lab.

Figure 5. A portable FeNO analyzer, the FeNObreath.

- **COPD**
  - Early identification of functional impairment
  - Evaluate pharmacological and therapeutic treatment
  - Quantify functional improvement to rehabilitation sessions, secretion mobilization procedures and during recovery process from exacerbations.
  - During exacerbations of COPD to quantify severity of the impairment, even in Emergency Department settings
  - Assessment of resting Expiratory Flow Limitation (EFL) in severe and acute COPD patients
  - COPD patients that cannot easily perform a technically acceptable FVC set of maneuvers.
  - Lung hyperinflation monitoring by the SVC and IC measurement (not US FDA approved at this time)
- **Airway Clearance Evaluation**
  (Pulmonary and Neurological Rehabilitation, Cystic fibrosis), Physiotherapy
  - Objectively quantifies lung functional improvement to rehabilitation sessions
  - Allows treatments evaluation in all patients, single measurements and over time periods.
  - All patients that cannot easily perform a technically acceptable FVC set of maneuvers.
  - Tidal Expiratory Flow Limitation (EFL) has been shown to be useful for tracking rehabilitation progression and effectiveness of treatment.
- **Testing Post-Covid Subjects**
  An important novel application to safely measure patients who have or have had Covid-19, tracking their progress over time of small airway and lung recruitment at tidal breathing, minimizing particles dispersion in the testing environment.

Trending Graphs

A useful function available in the Resmon Pro Full is the TRENDING of any parameter, user defined, that helps in the follow up over time of patients in rehabilitation, asthma management, medication control and POST-COVID subjects during the course of therapy, see Figure 6.

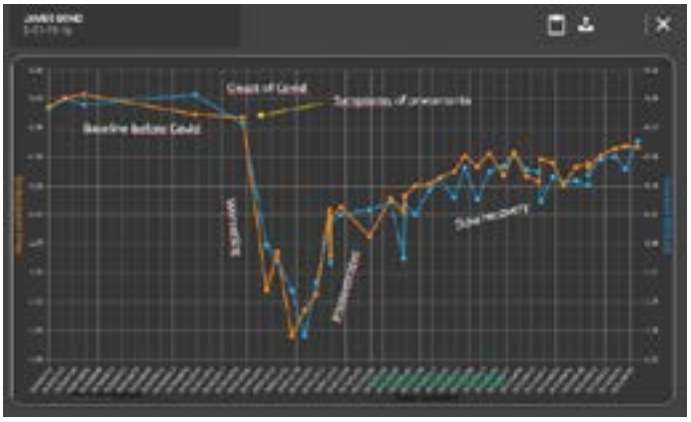


Figure 6. Trend of 12 months monitoring of Xrs (reactance at 5Hz, small airways and lung recruitment) one FOT test/week, patient before COVID (baseline of 2 months) onset of Covid pneumonia, recovery.

Use with or instead than Forced Spirometry (Flow Volume Loop, FVL)

Recently Oscillometry is being employed in combination or instead than forced spirometry or Flow Volume Loop (FVL), in routine clinical uses. With the latest international ERS "*Technical standards for respiratory oscillometry*" oscillometry (FOT) can be used in the daily clinical routine, both methods have advantages and disadvantages:

- FVL requires forced, prolonged expiratory maneuvers, which may be difficult, particularly when the subject is impaired or during acute phases. The Resmon Pro FOT needs a few accepted breaths at tidal breathing.
- One of the major drawbacks of FVL is the operator and patient dependency, FOT has minor or no dependency from the operator and from patient effort, providing sensitive, repeatable results.
- FVL cannot accurately estimate the site of airflow obstruction (large or small airways) and hence the presence and extent of small airways disease. FOT can assess the extent of large and/or small airways disease, which may help the choice of inhaled medication, prescribed.
- It is known that FVL is rather insensitive to mild disease conditions and doesn't have optimal correlation with symptoms.
- FOT has been shown to be more sensitive than spirometry in detecting mild disease even when not present in FVL.
- Forced spirometry can classify severity (mild, moderate, severe) of disease with FEV1/FVC (GOLD, GINA guidelines and ATS/ERS statement). Standard FOT based severity classification is not available yet but clinical studies are on-going and may provide the obstruction classification soon.

Conclusions and Future Prospectives

FOT has come a long way since the 1950s, started as a pulmonary physiology tool with limited use, mostly on subjects unable to perform forced spirometry or research.

In the last years the clinical applications of FOT have become widely employed and, thanks to the publication of the ERS international technical standards, FOT is becoming an important part of the pulmonary medical routine, in adults and pediatrics.

Specifically in Asthma management, along with FeNO, a well accepted technique to monitor pulmonary inflammation, FOT can be safely, easily and effectively used in asthma monitoring programs.

The future of FOT includes portable handheld devices that will add even more interest and uses, for screening and for home monitoring.

Also coming, on the Resmon devices, are capabilities for testing neonates and infants.

The Resmon Pro Full will also include in the future, complementary measurements, such as Closing Volume, a widely recognized parameter for early detection and monitoring of PAD (Peripheral Airways Disease), maldistribution of ventilation with impaired gas exchange within the lung and peripheral lung injury, measured by FOT.

Roberto "Roby" Perissin is currently the Vice President, Worldwide FOT and Asthma Management Business Development, MGC Diagnostics, St. Paul, MN, has been working internationally in the field of pulmonary function testing since 1984, first from the US where he was based for several years, then in Italy where he currently resides, and from where now he works worldwide.

He was trained in Respiratory Therapy and Pulmonary Function Technologies in the US and Italy in the 80's, is a renowned international expert in the field of respiratory diagnostics marketing and clinical applications as well as devices design and development for adults, pediatrics and neonatal applications.

Roby has worked and consulted for the industry and for several clinical and research international medical centers, contributed to the development of several commercial clinical devices and methods such as the Negative Expiratory Pressure (NEP), respiratory mechanics monitor for ventilated patients, physical activity monitors, wearable armband for COPD etc. and other PFT devices, including now Forced Oscillatory Technique. He travels and lectures worldwide in 4 languages, on topics such as FOT in adults and pediatrics and Pulmonary Function testing, while maintaining extensive contacts with many international Key Opinion Leaders in pediatric and adult asthma, COPD, rehabilitation, pulmonary physiology.

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Useful Respiratory Calculations in the NICU

Estephanie Rivero, MD, Faiza Javed, MD and Shabih Manzar, MD

Most neonatal intensive care unit (NICU) admissions consist of preterm infants. More than half of these infants require respiratory support in some form. We describe here a few quick calculations that assist with the respiratory management of these infants.

Respiratory Severity Score (RSS)[1]

RSS = Mean airway pressure (cmH_2O) × Fraction of supplemental oxygen (FiO_2 0.21–1.00). RSS could be used to predict the chances of successful extubation. It could be used in conjunction with the extubation calculator (http://extubation.net/).[1,2]

Pulmonary Acuity Score (PAS)

PAS score could help in assessing the severity of the respiratory disease. PAS score = (FiO_2) (support) + medication, where the support score is: 2.5 for the ventilator, 1.5 for continuous positive airway pressure, and 1 for NC. The medication score is 0.20 for systemic steroids, 0.10 for a diuretic or inhaled steroids, and 0.05 for methylxanthines or intermittent diuretics.[3,4]

Effective FiO_2 (E-FiO_2)

Based on weight and NC flow, obtain the factor, then look at that factor on the table to see the precalculated effective FiO_2 for the corresponding FiO_2.[5,6] E-FiO_2 helps in weaning the NC support.

BPD outcome/NIH calculator

Bronchopulmonary dysplasia (BPD) is common among extremely premature infants. The outcome calculator could help with making decisions on treating with steroids.

https://neonatal.rti.org/index.cfm

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Author contribution

Dr Rivero, Dr Javed, and Dr Manzar conceptualized the study and wrote the draft.

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None

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Patient Reported Outcomes Support the Use of High-Frequency Chest Wall Oscillation

Gary Hansen, Sarah Daignault, and Pritesh Pandya[a]

Introduction

High-frequency chest wall oscillation (HFCWO or "vest therapy") is a method of chest physiotherapy used for airway clearance therapy. These devices use an inflatable vest attached to a base unit that creates rapid pulsations to the chest, helping to loosen, thin, and mobilize mucus. This therapy is prescribed for a large number of pulmonary disorders where the normal mechanisms for clearing mucus are impaired or lacking; these patients often experience an excess of secretions in the bronchi and small airways that limit the effectiveness of respiration. Additionally, sputum accumulation can facilitate the growth of bacteria, leading to serious complications including degradation of pulmonary function[1] and increased infections.[1,2] Uncleared secretions can promote chronic inflammation, repeated infections, irreversible lung damage, and impaired respiratory function.[3,4] HFCWO therapy is intended for patients who are unable to clear excess mucus without external intervention.

HFCWO was developed almost 30 years ago to address the unmet airway clearance needs of patients with cystic fibrosis (CF).[5] The use of HFCWO therapy has expanded well beyond CF to include a long list of hereditary and acquired conditions that impair normal breathing, primarily non-cystic fibrosis bronchiectasis (referred to as BE or "bronchiectasis" in this paper).[6-8] Less commonly, HFCWO has also been used to treat patients with COPD who have excess respiratory secretions[9] and an undifferentiated population of symptomatic patients during the COVID healthcare emergency.[10] Despite being a commonly accepted treatment, there have been calls for more studies that demonstrate the effectiveness of HFCWO.[11,12] Such evidence would support what many clinicians have seen in everyday practice—the need for maintenance and improvement of lung health in individuals with chronic respiratory conditions.

Key Points

- HFCWO may be associated with improvements in hospitalization rate, antibiotic usage, and self-reported level of symptoms in four different patient cohorts.
- Patients with bronchiectasis and COPD, as well as diverse patients covered by the VA and under COVID-era reimbursement rules, typically see improvements upon initiating HFCWO therapy.
- The results are robust: both statistically and clinically significant, potentially supporting the extension of reimbursement for symptomatic patients.
- These real-world outcomes illustrate what may be expected by patients and clinicians.

There are many reasons for this state of affairs; primarily that conventional studies of HFCWO are intrinsically difficult to perform.[13] Nonetheless, a large and growing body of real-world evidence supports the use of HFCWO for a variety of symptomatic respiratory patients. Traditional randomized control studies may help to isolate the therapeutic intervention from its environmental context but do not illuminate how the therapy operates in actual practice. In a real-world setting, the success of a therapy that depends on the ongoing cooperation of patients cannot easily be separated from issues of support and adherence. Furthermore, traditional studies necessarily involve small numbers of patients with a narrow range of underlying conditions, thus limiting the generalizability to wider populations. Real-world studies have their own limitations,[14] but they often include thousands of patients with diverse backgrounds and conditions drawn from large registries or claims databases. While randomized control trials remain the gold standard for generating clinical knowledge, it is increasingly recognized that results from such studies are difficult to translate to real-world clinical practice.[15] Real-world evidence derived from real-world data better reflects the actual clinical settings or situations in which an intervention is applied, including patient demographics, adherence, and concurrent treatments. Additionally, real-world studies are the only way to gather patient self-reports on symptoms and attitudes.

Real-world evidence for the effectiveness of HFCWO has received growing attention in recent years with abstracts[16-30]

[a]Gary Hansen, Sarah Daignault, and Pritesh Pandya are employees of Respiratory Technologies, Inc. dba RespirTech, a Philips Company. This educational information offers general coverage, coding and payment information for procedures associated with use of HFCWO, which is indicated when external manipulation of the chest is the prescribed treatment to increase the clearance of mucus in patients with pulmonary disorders. This is not legal guidance, nor is it advice about how to code, complete, or submit any particular claim for payment. It is always the provider's responsibility to determine coverage and submit appropriate codes and charges for services rendered. This is based on the medical necessity of the services and supplies provided, the requirements of insurance carriers and any other third-party payers, and any local, state or federal laws that apply to the products and services rendered. Given the rapid and constant change in public and private reimbursement, we cannot guarantee the accuracy or timeliness of this information.

and papers[31,32] from a variety of objective and independent data sources, principally healthcare claims databases and patient-reported outcomes from clinical registries. Many of these studies utilized the High-Frequency Chest Wall Oscillation Outcomes Registry (HFCWO-OR), a large repository of self-reported data from patients who were prescribed HFCWO therapy using the InCourage system (RespirTech, a Philips company, Plymouth, MN, USA). Preliminary results have been reported for patients with bronchiectasis (BE),[18,19,21,31] COPD,[20] coverage under the veterans administration (VA),[17] and COVID-era respiratory illnesses ("COVID Waiver" or "CW").[22] Collectively, this evidence provides valuable insights about critical outcomes of interest such as hospitalizations, quality of life, and antibiotic usage.

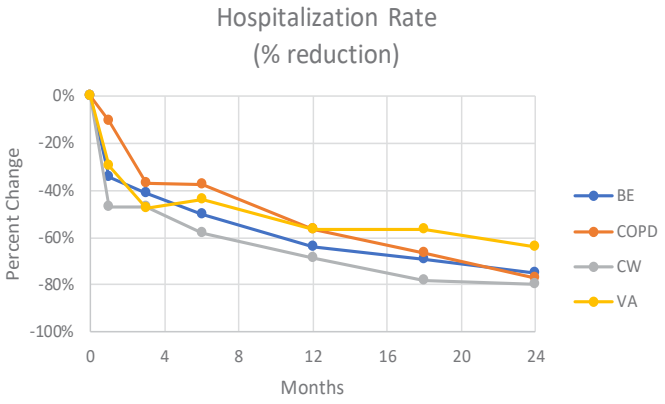

Figure 1. Reductions in hospitalization rate relative to baseline for the four cohorts described in this paper: bronchiectasis (BE), COPD, COVID waiver (CW), and veterans administration (VA). Results are compared to the hospitalization rate for the 12 months prior to initiation of HFCWO therapy (zero months).

In general, the results consistently showed a reduction in hospitalization rate as well as improvements in patient-reported symptoms after the initiation of HFCWO therapy. This registry started in 2015 and is still actively gathering data and patient counts have grown considerably since the earlier reports. Therefore, it is timely to revisit the results for various patient cohorts with much larger numbers. Moreover, considerable insights may be gathered from comparing the findings across different disease states. The remarkable consistency and convergence of these findings in the patient populations reported herein suggest that the broader implementation of this therapy will be beneficial to patients with airway clearance concerns.

Methodology

The RespirTech Outcomes Registry consists of self-reported outcomes by patients categorized by disease state or selected reimbursement status (Table 1). Patients were enrolled in the registry at the time of prescription; thereafter they were surveyed by phone at periodic intervals of 1 month, 3 months, 6 months, 12 months, 18 months, and 24 months. During each survey, patients were asked how many hospitalizations for respiratory causes had occurred since starting therapy. In addition, patients were asked about the number of antibiotic treatments received for respiratory purposes and also rated their respiratory health and ability to clear secretions on a five-point Likert scale. All patient data were self-reported, with prior research validating the correspondence between patient self-reports and medical records.[31]

Successive records were extracted, de-identified, and delivered to North American Science Associates, LLC "NAMSA" (Minneapolis, MN) for statistical analysis. This analysis was performed on SAS Version 9.3 or later (SAS Institute, Cary, NC). Western Institutional Review Board's (WIRB) IRB Affairs Department has confirmed that this study meets the conditions for IRB exemption under 45 CFR 46.101(b)(4). Additionally, informed consent was obtained from all patients.

Pre and post-data were considered in aggregate for each survey interval considered. Calls were planned to occur within a time window that depended on the survey interval: +10 days for the 1-month interval, and +15 days for all subsequent intervals. Information was sometimes unavailable for pre or post-survey intervals due to the inability to contact the patient, in other cases, surveys may have been incomplete. In these cases, patient data were included in the analysis where available. Mean values were calculated for hospitalization rate for each survey interval (baseline through 24 months), with statistical significance based on a repeated measures negative binomial model comparing baseline to each follow-up survey. The ability to clear lungs and respiratory health outcomes were converted to dichotomous variables by defining a negative outcome (Fair/Poor) and a positive outcome (Good/Very Good/Excellent) for each patient for each survey interval. The proportion of patients with a positive outcome was then tracked over time and compared to the baseline value. Similarly, the proportion of patients using antibiotics for breathing issues at the time of the survey was tracked over time and compared to the baseline value. For dichotomous variables, statistical significance was assessed using a repeated measures model comparing the baseline to each follow-up visit. Comparisons between baseline and subsequent results (e.g., 12-months and 24-months) were determined as statistically significant when *P*-values were less than 0.05.

Results

This paper shows, for the first time, the comparative results of the four different patient cohorts under the same protocol (Table 1). By far the largest cohort was bronchiectasis with n=20,738; these patients (ICD-10 codes J47.9 and J47.1) were confirmed to have BE via CT imaging. They were 37% male with a mean age of 71 years, minimum age of 20, and maximum age of 102.

The second cohort, COPD, included only patients with this primary diagnosis (ICD-10 codes J44.0, J44.1, and J44.9); these patients were confirmed not to have BE via high-resolution-computed tomography (HRCT) imaging. They were 47% male with a mean age of 66 years, minimum age of 32, and maximum age of 95 (n=358).

The third cohort contained patients who received HFCWO devices under the "COVID Waiver", relaxed coverage guidelines under regulatory flexibilities put in place by The Centers for Medicare and Medicaid Services (CMS) during the COVID public health emergency in early 2020. These flexibilities allowed for CMS coverage of respiratory devices, such as HFCWO, based on the physician's determination of the medical need of the patient. It should be noted that the vast majority of these patients did not have a diagnosis of COVID, but rather consisted of a mix of pulmonary patients whose common feature was a demonstrated need for airway clearance therapy, most frequently COPD.[22] Other diagnoses were included that are also not traditionally covered (e.g., chronic bronchitis and emphysema) and diagnoses that, prior to the CMS COVID Waiver, required the presence of anatomic changes documented by CT scan (bronchiectasis). Therefore, the actual presence or absence of bronchiectasis

Cohort	Description	Date Range	Cohort Size		
			Baseline	12 month	24 month
BE	Patients with bronchiectasis confirmed by a high-resolution CT scan	April 1, 2013 to January 1, 2021	18,995	7,398	6,185
COPD	Patients with COPD confirmed not to have radiographic evidence of bronchiectasis	April 1, 2013 to January 1, 2021	302	90	71
CW	Patients with a mix of diagnoses covered under the "COVID Waiver"	February 1, 2020 to September 30, 2022	2,851	404	114
VA	Patients with a mix of diagnoses covered by the Veteran's Adminstration	February 1, 2020 to September 30, 2022	632	90	41

Table 1. The four patient cohorts comprising the High Frequency Chest Wall Oscillation Outcomes Registry (HFCWO-OR). Data collection for each cohort began on a different date but collection continues at the time of this writing. Cohort size at 12 months and 24 months is typically smaller than baseline because some patients return units, are lost to follow-up, or have not been in the database for enough time to reach these time-points.

is unknown for the vast majority of these patients. Patients in the cohort had a mean age of 73 years, minimum age of 21, and maximum age of 97 (n=3,123).

The fourth and last cohort was comprised of patients who received HFCWO therapy through the Veterans Administration healthcare system. The VA also allows substantial flexibility in prescribing and often covers HFCWO therapy for patients requiring airway clearance therapy regardless of the underlying diagnosis. Unfortunately, the prescribing information provided to the registry does not usually include diagnosis, so we were unable to define the mix of disease states in this cohort. Patients in the cohort had a mean age of 72 years, minimum age of 26, and maximum age of 97 (n=672).

All four cohorts converged towards similar improvements in both hospitalization rate and quality of life outcomes with only small variations. All improvements were statistically significant

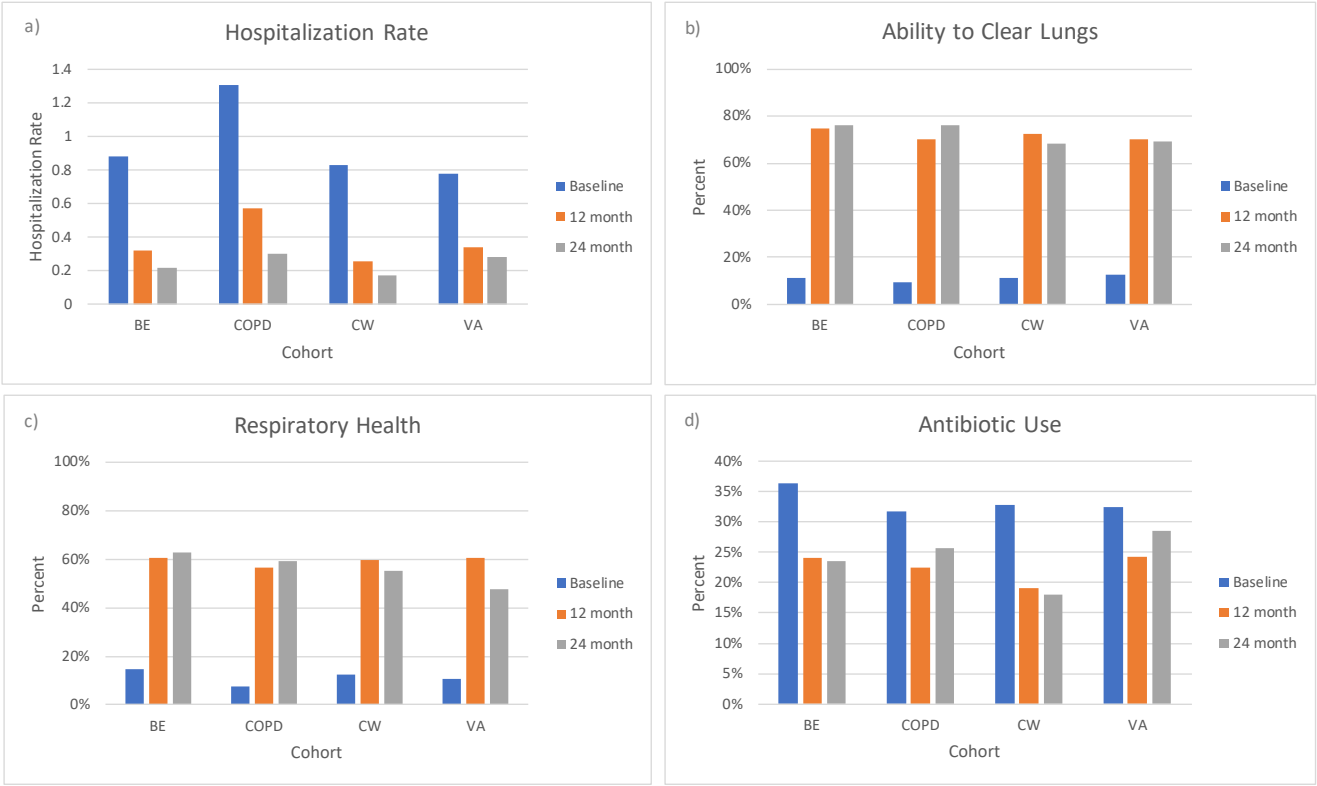

Figure 2. Results at baseline, 12, and 24-months for questions in the HFCWO-OR for the four cohorts described in this paper: bronchiectasis (BE), COPD, COVID waiver (CW), and veterans administration (VA). A) shows the hospitalization rate for the four cohorts at the baseline, 12-month, and 24-month time intervals. B) shows the percentage of patients who answered favorably to the question "How would you rate your current ability to clear your lungs of mucus?" C) shows the percentage of patients who answered favorably to the question "How would you currently rate your overall respiratory health". D) shows the percentage of patients who answered "yes" to the question "Are you currently taking any antibiotics for your breathing problems?"

($P<.05$) at 12 months and 24 months. As an example, relative hospitalization outcomes are shown in Figure 1. The first data point, zero months, is the baseline value for the 12 months before initiating vest therapy. Subsequent data show the annualized hospitalization rate up to the time later calls were made. In all cases, the hospitalization rate declined in the early months and then continued to fall for up to two years. It is notable that the baseline hospitalization rate for the COPD cohort started higher than the other cohorts (Figure 2).

Figure 2 also compares the results for the two quality-of-life questions: "how would you rate your current ability to clear your lungs of mucus?" and "how would you currently rate your overall respiratory health?" The percentages on the graph show the percentage of patients at any one point who chose the answers "good", "very good", or "excellent". For all cohorts, the number of such answers moved from a small percentage, typically less than 20%, to much higher values in subsequent months; the change was rapid and sustained from up to two years after the initiation of HFCWO. At the same time, the number of patients currently taking antibiotics for breathing issues also dropped and in most cases was also sustained for up to two years.

Discussion

There is striking convergence to these outcomes despite the differing populations and timeframes represented in the registry. Clearly, the implementation of HFCWO was associated with improvements in hospitalization rate and self-reported measures of symptoms. It is also notable that the basic pattern of outcomes did not depend on underlying diagnosis as much as the symptomatic need for airway clearance. Patients with excess secretions, regardless of cause, experienced a reduction in hospitalizations and an improvement in their symptoms. Although less clear, most results pointed to a reduction in antibiotic use as well.

The positive outcomes for COPD and COVID Waiver patients suggest that HFCWO provides considerable benefits to patients who have not been able to receive reimbursement under traditional rules. At this time (December 2022), the COVID Waiver is still in place. Therefore, many new patients could still be eligible for HFCWO therapy who would not otherwise be able to receive it. The knowledge that HFCWO benefits this range of patients should cause clinicians and policymakers to consider extending treatment to these underserved groups. Moreover, outcomes programs, such as the High-Frequency Chest Wall Oscillation Outcomes Registry, are designed to provide better communication between patients and healthcare teams. RespirTech's outcomes program staff are trained to provide support for better adherence as well as guidance on the proper setting and use of the device, with feedback from the calls delivered to the patient's physician, who is then empowered to have more productive conversations on the progress of therapy.

While retrospective registry studies do not possess the rigor of randomized control studies, they have advantages of their own. Properly designed and executed, patient registries can provide an invaluable view of clinical practice, patient outcomes, and the effectiveness of a therapeutic method. Research such as this demonstrates what patients and caregivers may expect when choosing HFCWO in the real world. It also allows generalizability to standard clinical practice and elevates the voice of the patient regarding their own symptoms. The experience of thousands of patients provides a useful, practical demonstration.

Conclusion

HFCWO may be associated with improvements in hospitalization rate, antibiotic usage, and self-reported level of symptoms in four different patient cohorts. Patients with bronchiectasis and COPD, as well as patients covered by the VA and under COVID-era reimbursement rules typically see improvements upon initiating HFCWO therapy. The results are robust: both statistically and clinically significant, potentially supporting the extension of reimbursement for symptomatic patients so that this life-altering therapy can be made available to those who may benefit from it.

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What is RRP and Is There Any Way to Treat It?

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview is Dr Jeffrey Skolnik, Senior Vice President, Clinical Development at INOVIO Pharmaceuticals.

What is RRP and why is it considered a Rare Disease?
Recurrent Respiratory Papillomatosis (RRP) is a debilitating, often life-long disease caused by infection with the human papillomavirus (HPV), primarily HPV types 6 or 11. RRP can affect children, adolescents and adults. RRP is characterized by the development of small, wart-like growths, or papillomas, in the respiratory tract. Although they primarily occur in the larynx on and around the vocal cords, these growths may also affect the trachea, bronchi, and occasionally the lungs. While papillomas are generally benign, they can cause respiratory complications, and can significantly affect quality of life for patients by limiting the ability to speak effectively. Less often, RRP can result in severe, life-threatening airway obstruction. The standard of care primarily includes removal of the papillomas by surgery. In RRP, the papillomas tend to grow back after they have been removed surgically because the underlying HPV infection is not eradicated.

The Orphan Drug Act was passed in the United States in 1983 to facilitate development of drugs for rare diseases. The Orphan Drug Act defines a rare disease as a disease or condition that affects fewer than 200,000 individuals in the United States. The estimated prevalence of RRP within the US is well within this limit.

How large is the patient population with RRP?
Based upon information published by the RRP Task Force in 1995, there were around 14,000 active cases, and around 1.8 new cases per 100,000 adults each year in the US (Derkay C). However, because of vaccination against HPV, it is likely that those numbers are decreasing over time (Meites E). In other countries, the incidence (new cases per year) of RRP varies in part by the number of people who have similarly been vaccinated against HPV, among other factors (Seedat RY; Omland T; Novokovic D).

What are current treatment options for RRP?
Currently, there is no United States Food and Drug Administration (FDA) approved medical therapeutic for RRP. Surgery is the current standard of care. Other therapies have been used off- label, with some potential success.

What is INO-3107?
INO-3107 is INOVIO's clinical-stage DNA medicine product candidate being developed as a potential treatment for RRP. INO-3107 is designed to elicit a targeted T cell immune response against HPV 6 and HPV 11, the HPV types responsible for causing RRP. These targeted T cells are designed to seek out and kill HPV infected cells, leading potentially to a regression of existing papillomas and the possibility of clearing or reducing the levels of the virus which could prevent or slow the growth of new papillomas. The FDA granted Orphan Drug Designation for the candidate medicine INO-3107 in 2020.

How is INO-3107 designed to work and why might it benefit patients?
INO-3107 encodes for the E6 and E7 antigens associated with HPV-6/11, as well as for an immune adjuvant called interleukin (IL)-12, to harness the body's immune system to generate immune responses. We believe the ability to enable the body to generate T cell responses against disease-specific antigens, including memory T cell responses, may be important in the treatment of chronic viral diseases such as RRP.

INOVIO has experience in designing potential treatments for other HPV-associated diseases, such as cervical high-grade dysplasia (HSIL), where we have observed the ability of our DNA medicines to clear the underlying HPV virus infection and achieve regression of HPV-associated lesions. We believe our work with INO-3107 and RRP builds on our existing body of work on HPV-related diseases.

What is the status of INOVIO's Phase 1 / 2 clinical trial?
Initial data from this trial (NCT04398433) was announced in October 2022. The trial is a 32-participant open-label, multicenter Phase 1/2 trial to evaluate the safety, tolerability, immunogenicity and efficacy of INO-3107 in adult participants with HPV-6/11 RRP. The primary endpoint of the trial is to determine the safety and tolerability of INO-3107, and a secondary endpoint includes efficacy as measured by the change in the median number of surgical interventions in the year prior to treatment when compared with the year following treatment.

In the first cohort of 21 participants, INO-3107 showed a statistically significant improvement in the number of surgical interventions needed to control papilloma growth.

a. 16 of 21 (76%) participants saw a reduction in number of surgical interventions compared with the previous year, and of those 16 participants, six (6) required no surgical intervention during the year-long trial.

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

b. There was a median decrease of 3 surgical interventions (95% CI -3, -1).
c. INO-3107 was observed to be well tolerated and immunogenic.
d. INO-3107 generated CD4+ and CD8+ T cells against both HPV 6 and HPV 11.
e. T-cell activity was present at the study end, suggestive of a persistent cellular memory response.

Data from our second cohort of 11 participants are expected in first half of 2023. This cohort studies a modified delivery mechanism used to explore whether higher immune responses could be generated.

Who was included in the trial?

The participants were adults (≥18 years old) with histologically-documented HPV-6- or HPV-11-positive respiratory papilloma who have required at least two RRP surgical interventions in the prior year.

What is the pathway and timeline for approval?

Next steps are to discuss these data with regulators and determine the most expeditious path for potentially bringing INO-3107 to RRP patients as soon as possible.

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