Volume 16 Number 2 Spring 2021

Respiratory Therapy™

The Journal of Pulmonary Technique

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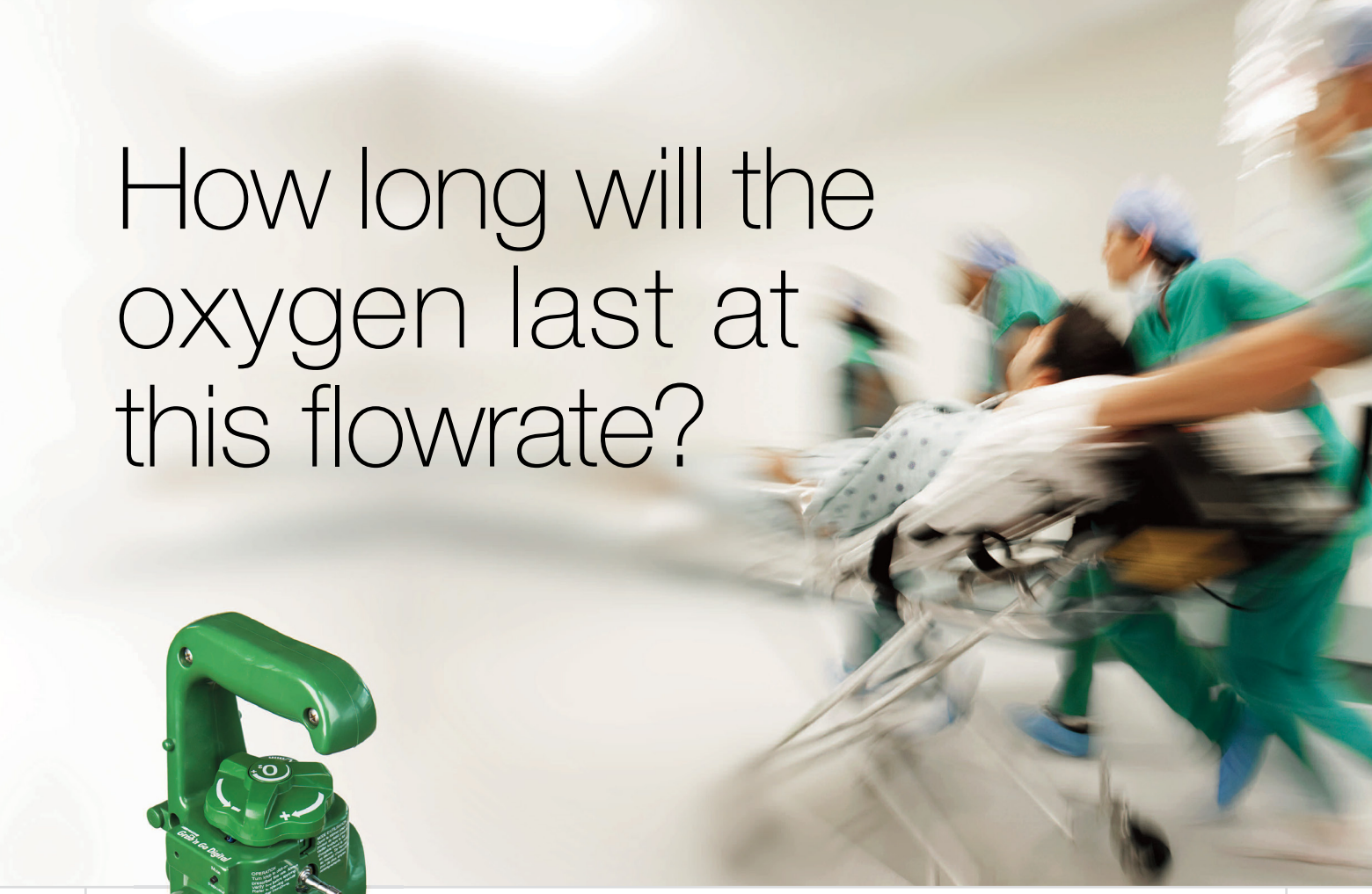

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Letter to the Editor

According to the CDC, half of COVID deaths involve secondary bacterial infections (VAP pneumonia). Per Dr Anthony Fauci, *"The majority of deaths in the 1918-1919 influenza (Spanish Flu) pandemic resulted directly from secondary bacterial pneumonia caused by common upper-respiratory-tract bacteria."*

Ventilated patients cannot swallow so infectious secretions seep from the upper airways into the lower airways causing secondary bacterial infection. By reducing seepage of these infectious secretions into the lower airways and lungs, we can significantly diminish the incidence of such infections and save lives.

Over 25 years of clinical research shows that removing secretions from the upper airways utilizing subglottic secretion drainage (SSD) is the most effective form of secretion management. This has been endorsed by the CDC, AHRQ, ATS, AARC, AACN and SHEA. Guidelines from Johns Hopkins cite RCTs with a 45% reduction in VAP rates and reduced time on ventilators when using SSD.

So why hasn't this been widely adopted in the US? For a variety of reasons, most facilities in the US have resisted making changes in set protocols even when the scientific evidence suggests otherwise. The challenge is to make SSD more user friendly to encourage its adoption.

Our company has developed a subglottic secretion management pump/device to simplify SSD protocols and maximize secretion removal via automation. It helps reduce the VAP incidence beyond the findings cited in the Johns Hopkins guidelines by removing up to 10x the volume of secretions versus traditional methods (ie wall suction or syringe). Secretions are collected in an integrated, disposable canister, eliminating cross-contamination in the ICU. It has been used successfully for many years in Europe and is routinely found in COVID ICUs there.

COVID is a catalyst for rethinking existing protocols and redefining best practices. Our company is committed to increasing SSD awareness and adoption across the United States.

Hamid Khosrowshahi
President
FloSure Technologies LLC
hkhosrow@flosuretechnologies.com
www.flosuretechnolongies.com

News

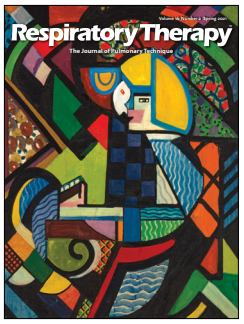
■ Spring 2021

Vivo 45 LS Ventilator Introduced to the US

Breas Medical USA announced the market introduction of the Vivo 45 LS, one of the smallest, full-featured Life Support devices on the market. The Vivo 45 LS is cleared by the US FDA to provide both invasive and non-invasive continuous or intermittent ventilatory support across the continuum of care in the home, post-acute, hospital and portable applications for pediatric through adult patients weighing more than 5 kg (11 lbs). "The ultra-portable Vivo 45 LS life support ventilator is designed to maximize independence and mobility to the patient thanks to its ultra-small footprint, utilizing the comfortable eSync trigger technology used in the Vivo 65 with added ultra-quiet operation," said Chris Southerland, General Manager, Breas Americas. "The Vivo 45 LS has the added benefit of offering patient monitoring of etCO2, SpO2, FiO2 and PtCO2 and can be connected to EveryWare, Breas' securely hosted, remote cloud-based application, which can help deliver an insightful approach to the care of respiratory patients in the home." Engineered in our founding Swedish and USA offices, Breas delivers leading edge innovations that can provide patient comfort and mobility needed to improve their quality of life. To learn more about the exclusive eSync™ technology, ultra-quiet operation, long battery life and integrated ventilation monitoring value for patients and caregivers alike visit https://breas.us/vivo45ls/ Breas Medical was founded in Gothenburg, Sweden in 1991 and has provided innovative respiratory medical device products to the global market for 30 years. Breas has long been known for its Swedish design, reliable technology and ease of use. Breas offers a comprehensive line of respiratory medical devices in Homecare Life Support Ventilation and Non-Invasive Ventilation, Airway Clearance and CPAP treatment.

New Study in Newborns Finds Nellcor Pulse Oximetry Technology Provides Fast Stable Oxygen Saturation Readings

Medtronic announced the results of an independent, prospective observational study comparing the efficacy and reliability of two pulse oximeters — Nellcor Bedside SpO2 Patient Monitoring System and Masimo Radical-7 Pulse CO-Oximeter, both set at the highest sensitivity ("Neonatal" and "Fast" for Nellcor pulse oximetry technology and "Max" for Masimo) — with electrocardiography (ECG) monitoring following the delivery of 60 term newborns by Caesarian section. Pulse oximetry is a simple, noninvasive bedside test that can accurately detect the percentage of blood saturated with oxygen and measure heart rate. According to the study, a stable signal was obtained from all 60 newborns with the Nellcor pulse oximeter but from only 55 newborns with the Masimo pulse oximeter. Of the 55



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newborns with stable signals from both monitors, the mean time to stable signal with the Nellcor pulse oximeter was 15 seconds compared with 27 seconds with the Masimo pulse oximeter. The average difference of 12 seconds between the monitors was statistically significant ($P < 0.001$). The results of this prospective observational comparative study were published online in the Journal of Perinatology, the official journal of the Section on Neonatal-Perinatal Medicine of the American Academy of Pediatrics and the Neonatal-Perinatal Association of the United States. The study was conducted at the Rabin Medical Center, Petach Tikvah, Israel, a university-affiliated tertiary care center with approximately 9,000 births annually. The principal investigator of the study is Professor Ruben Bromiker, MD, Department of Neonatology, Schneider Children's Medical Center of Israel, Petach Tikvah, Israel and Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel. The availability of a pulse oximeter for monitoring oxygenation and heart rate of newborns contributes to decision making during resuscitation and stabilization, and can help physicians minimize the risk of either too low or too high blood oxygen levels and associated morbidity and mortality, the authors state in the discussion section. Both the Nellcor and Masimo pulse oximeters provide relatively quick measurements of oxygen saturation and heart rate in most cases well before the so-called "golden first minute" of resuscitation. The results conclude that Nellcor showed a statistically significant difference in the time needed to deliver a stable signal between devices which could potentially impact the provision of care during neonatal resuscitation. With respect to heart rate, the study observed there was a difference of 12 beats per minute (BPM) between the Masimo monitor and the reference standard ECG in 18 of 51 (35%) newborns. In all 18 newborns, the ECG showed a heart rate >100 BPM versus <100 BPM with the Masimo monitor, which may be observed as false bradycardia with the Masimo device. In 16 of the 51 (31%) newborns, the difference in heart rate with the Masimo monitor was 40 BPM compared with the rate recorded by the comparator ECG. In contrast, the heart rate detected by the Nellcor pulse oximetry monitor correlated closely with that of the ECG, with no recording of false bradycardia and no reading having >40 BPM difference compared with the ECG. "A newborn's heart rate is a key component of physician assessment for resuscitation, and helps to identify not only those in need of intervention but also their response to treatment. Those who do not achieve a heart rate of 100 beats per minute by five minutes of life are at an increased risk of death," said Frank Chan, president, Patient Monitoring, which is reported as part of the Minimally Invasive Therapies Group at Medtronic. "This study demonstrates that physicians can rely on Nellcor pulse oximetry technology to post data quickly, offer consistency, perform well with these patients, and meet the requirements of the neonatal resuscitation program guidelines, which are especially important in the delivery room." These findings are important because, per the neonatal resuscitation program (NRP) guidelines, only one minute should be allotted for completing the initial monitoring steps to inform reevaluation and initiation of ventilation.

Device Gets Clearance

3B Medical, Inc. announced receiving FDA 510(k) clearance on its new third generation bi-level device, the Luna G3 Auto-BPAP. The Luna G3 Auto BPAP is a modern and technologically advanced Bi-Level PAP therapy device for the treatment of obstructive sleep apnea. This device is available with integrated heated tubing, cellular connectivity and 3B's advanced algorithm which automatically senses and adjusts pressure settings to ensure airway patency for a comfortable night's sleep. The Luna G3 Auto-BPAP provides a backup rate that reduces the work of breathing with pressure settings up to 25 cmH2O. "We are excited by FDA's recent action approving use of the Lumin G3 Auto-BPAP. The Luna G3 is 3B Medical's third generation platform and incorporates a new design, a smaller footprint, and more advanced functionality", said Justin Smith, 3B Medical's Chief Operating Officer. The Luna G3 Auto-BPAP delivers non-invasive ventilator support with all of the bells and whistles that DME's have come to expect from 3B Medical", said Smith. 3B Medical is a leader in the development, marketing and distribution of medical products for the treatment of sleep therapy, oxygen therapy and disinfection.

Maternal COVID Antibodies Cross Placenta, Detected in Newborns

Antibodies against SARS-CoV-2 cross the placenta during pregnancy and are detectable in most newborns born to mothers who had COVID-19 during pregnancy, according to findings from a study presented at the virtual Society

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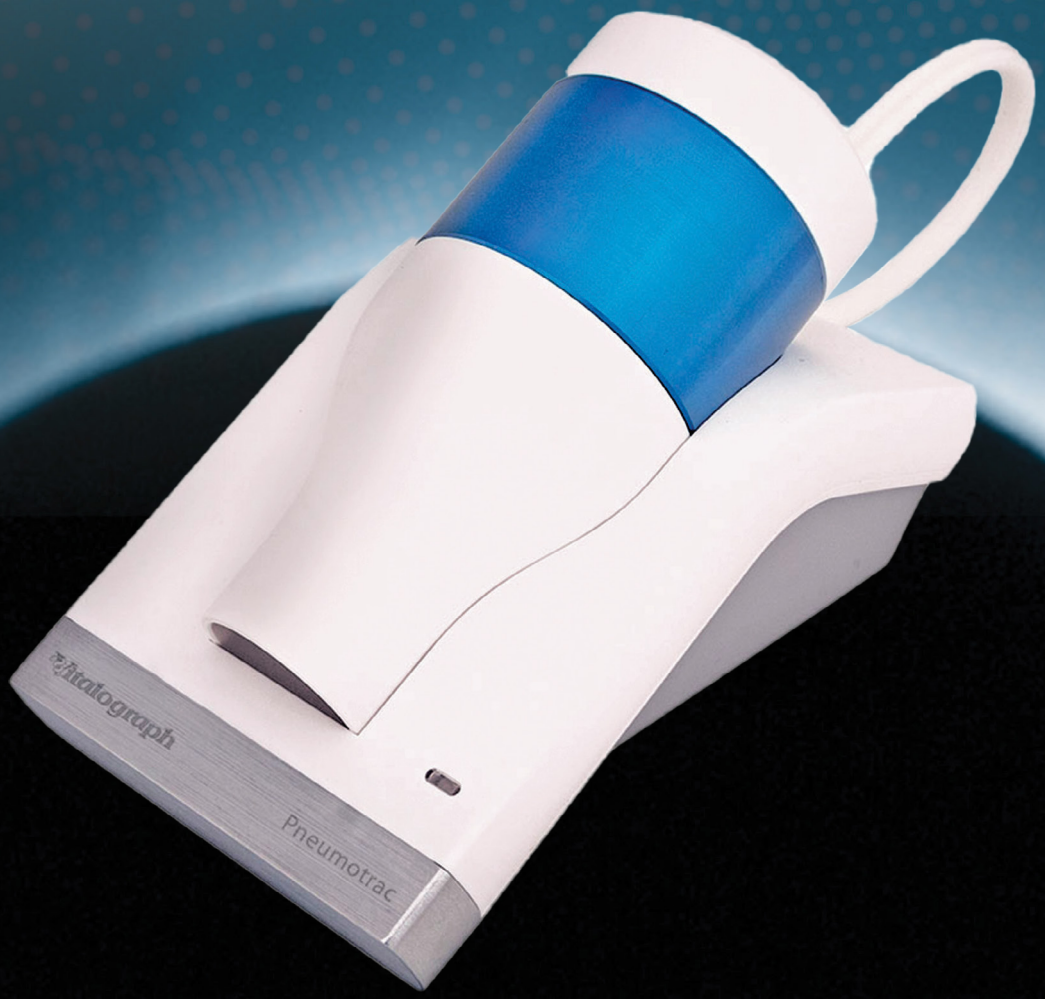
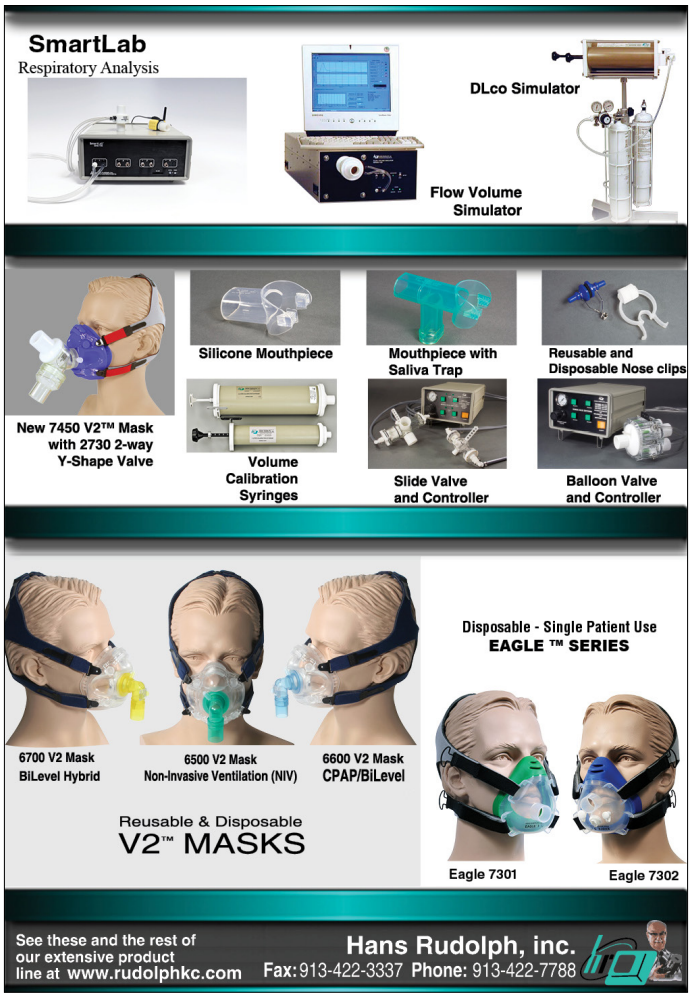


for Maternal-Fetal Medicine (SMFM) 2021 Annual Pregnancy Meeting. "I think the most striking finding is that we noticed a high degree of neutralizing response to natural infection even among asymptomatic infection, but of course a higher degree was seen in those with symptomatic infection," Naima Joseph, MD, MPH, of the Emory University School of Medicine, Atlanta, Georgia, said. "Our data demonstrate maternal capacity to mount an appropriate and robust immune response," and maternal protective immunity lasted at least 28 days after infection, Joseph said. "Also, we noted higher neonatal cord blood titers in moms with higher titers, which suggests a relationship, but we need to better understand how transplacental transfer occurs as well as establish neonatal correlates of protection in order to see if and how maternal immunity may also benefit neonates." The researchers analyzed the amount of immunoglobulin G (IgG) and immunoglobulin M (IgM) antibodies in maternal and cord blood samples prospectively collected at delivery from women who tested positive for COVID-19 at any time while pregnant. They used enzyme-linked immunosorbent assay to assess for antibodies for the receptor binding domain of the SARS-CoV-2 spike protein. The 32 pairs of mothers and infants in the study were predominantly non-Hispanic Black (72%) and Hispanic (25%), and 84% used Medicaid as their payer. Most of the mothers (72%) had at least one comorbidity, most commonly obesity, hypertension, and asthma or pulmonary disease. Just over half the women (53%) were symptomatic while they were infected, and 88% were ill with COVID-19 during the third trimester. The average time from infection to delivery was 28 days. All the mothers had IgG antibodies, 94% had IgM antibodies, and 94% had neutralizing antibodies against SARS-CoV-2. Among the cord blood samples, 91% had IgG antibodies, 9% had IgM antibodies, and 25% had neutralizing antibodies. "It's reassuring that so far, the physiological response is exactly what we expected it to be," Judette Louis, MD, MPH, an associate professor of ob/gyn and the ob/gyn department chair at the University of South Florida, Tampa, Florida, said. "It's what we would expect, but it's always helpful to have more data to support that. Otherwise, you're extrapolating from what you know from other conditions," said Louis, who moderated the oral abstracts session. Symptomatic infection was associated with significantly higher IgG titers than asymptomatic infection (P = .03), but no correlation was seen for IgM or neutralizing antibodies. In addition, although mothers who delivered more than 28 days after their infection had higher IgG titers (P = .05), no differences existed in IgM or neutralizing response.



Infection Control and Remote Patient Monitoring During Current Health Climate

As concern over the COVID-19 virus continues to grow and many pulmonary function labs remain open for testing, there is an increased scrutiny on patient safety and how patient health is monitored. These topics have always been on the forefront of MGC Diagnostics' commitment to their customers and they have complete health solutions to ensure you can provide the best care to your patients. Having clear and defined infection control policies is important for staff and patient safety. Infection control has seen a marked increase in the last year with augmented cleaning procedures to ensure the safety of staff and patients.

Pulmonary function labs have been vigorous in their attempts to clean any part or surface that might be contaminated. With MGC Diagnostics, changing patient testing supplies is complete in less than a minute with no warm-up time or recalibration of the system. With options to sterilize and reuse or dispose, you're able to make the choice that is right for you. MGC Diagnostics' preVent® flow sensor has a simple snap-in setup and is accurate and low cost. Also available are filters, mouthpieces and a patient circuit to complete your patient testing setup.

So, you're able to test patients safely, but how long before you can test the next patient? ATS recommendations state that you should have sufficient time between patients to allow for adequate room ventilation. They recommend a negative pressure room, if one is available. The time varies depending on whether the room is under negative pressure and whether there is a concomitant use of a high efficiency particulate air (HEPA) filter or ultraviolet light decontamination. According to the CDC, if you only have 10 air changes per hour in your lab, you need to wait 28 minutes for 99% efficiency for airborne-contaminant removal.

The AirPura UV614 HEPA filter offered by MGC Diagnostics is a system that combines both a Super HEPA filter and UV light to help decontaminate the air in your testing room and speed up the wait time between patients. With a maximum airflow of 560 CFM, the UV614 can provide up to 26 air changes per hour based on a 12'x12'x9' room. When combining the UV614 with the facility's HVAC system, this could bring the wait time to under 15 minutes. The Super HEPA filter has a 99.99% efficiency in removing airborne particles 0.3 microns in size or larger.

In order to maximize patient safety and potential harmful contacts, Remote Patient Monitoring should be considered, when possible. The GoSpiro® spirometer offered by MGC Diagnostics provides laboratory quality diagnostic testing that can be conducted outside of the clinic and in the comfort of a patient's home. After all, when a patient is comfortable you will

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Asthma-COPD Overlap: Patients Have High Disease Burden

Patients with asthma-chronic obstructive pulmonary disease overlap (ACO) experienced a higher burden of disease than patients with either asthma or COPD alone, a recent study has found. Approximately 20% of chronic obstructive airway disease cases are ACO, but data on these patients are limited, as they are often excluded from clinical trials, wrote Sarah A. Hiles, MD, of the University of Newcastle (Australia) and colleagues. "Comparing the burden of eosinophilic ACO, eosinophilic severe asthma, and eosinophilic COPD may also help contextualize findings from phenotype-targeted treatments in different diagnostic groups, such as the limited success of anti-IL [interleukin]–5 monoclonal antibodies as therapy in eosinophilic COPD," they said. In a cross-sectional, observational study published in Respirology the researchers recruited patients aged 18 years and older with a confirmed diagnosis of COPD only (153) severe asthma only (64), or ACO (106). Patients were assessed for demographic and clinical factors including health-related quality of life, past-year exacerbation, and other indicators of disease burden. In addition, patients were identified as having eosinophilic airway disease based on a blood eosinophil count of at least 0.3x109/L. Overall, eosinophilic airway disease was present in 41% of the patients; 55%, 44%, and 29% for those with ACO, severe asthma, and COPD, respectively. Reports of poor health-related quality of life and past-year exacerbations were similar for eosinophilic patients across all three conditions. However, patients with eosinophilic ACO experienced significantly more past-year exacerbations, notably those requiring oral corticosteroids, compared with patients with asthma alone. In addition, the cumulative number of past-year exacerbations in patient with eosinophilic disease was 164 in those with ACO, compared with severe asthma alone (44) and COPD alone (59). Patients with ACO also had significantly higher disease burden based on the St George's Respiratory Questionnaire (SGRQ), which assessed functional limitation. "For 100 patients, the cumulative SGRQ score attributable to eosinophilic airways disease in ACO was 2,872.8, which was higher than in severe asthma (1,942.5) or COPD (1,638.1)," the researchers said. The study was limited by several factors including the cross-sectional design and use of a single measurement to classify eosinophilia, the researchers noted. "The non-eosinophilic group likely included a mix of patients with treated eosinophilia and patients without eosinophilia, regardless of treatment, which is a limitation to consider when interpreting the disease burden estimates in this group," they added. However, the results add to the understanding of blood eosinophils in airway disease and the study "supports eosinophilia as a phenotype that spans across disease labels of severe asthma and COPD, and their overlap," they concluded. The study was supported by AstraZeneca; lead author Dr Hiles received a salary through a grant from AstraZeneca to the University of Newcastle while conducting the study. Other coauthors disclosed relationships with companies including AstraZeneca, GlaxoSmithKline, Menarini, and Novartis.

Benralizumab Improves Health-Related Quality of Life in Severe Eosinophilic Asthma

Severe eosinophilic asthma can cause airway hyperresponsiveness, worsening symptoms, and decreased lung function for patients, often leading to recurrent or maintenance corticosteroid use and deeply conditioning patients' quality of life. A team, led by Carla Maria Irene Quarato, University of Foggia, determined if and how an add-on treatment with benralizumab could improve the quality of life of patients with severe eosinophilic asthma in data at the European Respiratory Society International Congress 2020 (ERS 2020). The study included 10 outpatients with severe eosinophilic asthma, 7 of which were female. Each patient received treatment added-on with benralizumab and was followed-up with in an accredited outpatient clinic for severe asthma at 12 and 24 weeks. The investigators assessed quality of life during each visit using the Asthma Quality of Life Questionnaire (AQLQ), EuroQol-visual analogue scales (EQ-VAS), and EuroQol-5Dimensions-3Levels (EQ-3D-5L). The researchers found both a significant reduction in eosinophilic inflammation, exacerbations, and gaining in pre-bronchodilator FEV1 and symptoms control, with all the enrolled subjects experiencing an improvement in AQLQ [from 3.65±0.56 (baseline) to 4.61±0.67 (12 weeks) (P = 0.003) and to 5.17±0.87 (24 weeks) (P = 0.0002)]. This covered all 4 health domains — symptoms perception, activity limitation, emotional function, and environmental stimuli — investigated (P <0.05). The patients also saw an improvement in EQ-VAS (from 44.5±7.7% (baseline) to 60.5±6.6% (12 weeks) (P = 0.002) and to 86.7±7.2% (24 weeks) (P <0.001), with a statistically significant reduction in severe limitation in all dimensions — mobility, self-care, daily activities, pain/discomfort and anxiety/depression (P <0.001). "Our real life experience confirms the effectiveness of benralizumab as an add-on treatment in restoring patients with severe eosinophilic asthma to a better [quality of life] perception already after 12 weeks of treatment," the authors wrote. Recent study findings from the ANDHI trial further back the efficacy and safety of benralizumab for patients with severe asthma. The study extended knowledge and understanding of the efficacy and safety of benralizumab for severe eosinophilic asthma patients, including the onset of effect and additional health-related quality of life measures. They included adult patients with severe eosinophilic asthma with at least 2 prior-year exacerbations despite high-dosage inhaled corticosteroid plus additional controllers and screening blood eosinophil counts of at least 150 cells/μL. Patients were randomized 2:1 to either 24 weeks of benralizumab 30 mg every 8 weeks or placebo. Nasal polyposis was present for 34.2% of those in the benralizumab group and 35.8% of placebo patients, with a mean SNOT-22 of 51.5 for benralizumab versus 48.2 for placebo. The team found benralizumab significantly improved asthma exacerbation rate, with a 49% reduction versus placebo (.94 vs 1.86; P ≤.0001). There was also a clinically meaningful and statistically significant improvement in least-squares mean change in SGRQ total score at week 24 versus placebo (delta-8.11; P ≤.0001), with similar differences at earlier times throughout the study period. Benralizumab improved lung function, ACQ-6, and SNOT-22 at week 24 versus placebo.

Device Helps Make VAP Preventable

The issue of secondary bacterial infection during a pandemic is nothing new. Per Dr Fauci, *"The majority of deaths in the 1918-1919 influenza (Spanish Flu) pandemic resulted directly from secondary bacterial pneumonia caused by common upper-*

Continued on page 36…

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SPOTLIGHT ON BLOODGAS

Medtronic

Tell us about your oximetry products currently available.
Across the areas of respiratory care, we offer clinical and economic value through our range of market-leading brands. We provide several patient safety monitoring solutions like our Microstream™ capnography and Nellcor™ pulse oximetry technologies.

Microstream™ capnography responds fast, is accurate, and easy to use[1]—it lets you measure end-tidal CO2, respiration rate, and detect apnea accurately and reliably.[2-5] Microstream™ technology is used by more hospitals than any other capnography system.[6]

Nellcor™ pulse oximetry has shown to provide accurate, trusted SpO2 and pulse rate readings, including faster time to post in newborns than competitors, and better correlation in pulse rate compared to a reference standard.[15]

- Nellcor time to stable oximeter signal was significantly faster than a competing technology, by 12 seconds on average
- Nellcor pulse rate (PR) readings were strongly correlated with ECG heart rate
- Nellcor recorded no instances of false bradycardia (heart rate <100 beats per minute (bpm)), compared to other technologies that recorded false bradycardia in 18 of 55 (35%) newborns, with 16 of 55 (31%) newborns having a difference in heart rate that was over 40bpm lower than ECG heart rate

Nellcor™ pulse oximetry with OxiMax™ technology LoSat expanded accuracy feature:

- Offers industry-leading SpO2 accuracy during low saturation conditions, of ±3% within the range of 60% to 80% saturation.
- Enables informed clinical decisions for patients in low saturation range.
- Available across the entire line of Nellcor™ SpO2 adhesive sensors, including Nellcor™ SpO2 forehead sensors.

To take these a step further, we developed the Vital Sync™ remote surveillance monitoring and clinical decision support solution that connects with our Microstream™ capnography and Nellcor pulse oximetry technologies to give you smart, actionable data that your clinical teams can safely access anytime, anywhere. To learn more, visit: https://www.medtronic.com/covidien/en-us/products.html

Discuss the range of your oximetry products' applications.
Microstream™ capnography has been shown to be used in patient populations, ranging from neonates to adults across the continuum of care.[7-11] Continuously monitoring patients for extremes of etCO2 and respiratory rate, as measured by Microstream™ Capnography may provide clinicians with an early indicator of patient decline, facilitating early intervention to enhance patient safety.[12-13]

OxiMax™ technology enables the Nellcor™ pulse oximeter to deliver accurate, reliable SpO2 and pulse rate values even during low perfusion, patient motion and other forms of signal interference. By combining advanced technology with innovative sensor designs, the Nellcor™ pulse oximetry sensor with OxiMax™ technology platform allows clinicians to more effectively monitor a broader range of patients, from neonates to adults, including those who require long-term monitoring.

Note: Oxygen saturation accuracy can be affected by certain environmental, equipment, and patient physiologic conditions (as discussed in the operator's manual for the monitor) that influence readings of SpO2. Please consult the IFU and operator's manual for full safety information. To learn more, visit: https://www.medtronic.com/covidien/en-us/products.html

What oximetry products do you have in development?
As a company committed to innovation, we continue to look at how we further enhance and adapt our trusted Nellcor technology. We are committed to continued innovation in our core technology, meeting customer needs, and supporting the most critical patients that typically require the most attention, as well as disruptive innovation to ensure we are finding new and better ways to address the clinical & workflow issues seen in monitoring today. We will continue to focus on key areas, such as low saturation and low perfusion patients, reducing non-actionable alarms, and supporting the most critical neonatal patients.

What type of customer assistance and training do you offer?
We are committed to helping clinicians achieve procedural and clinical proficiency through clinical education. The online courses, continuing education, live events, webcasts, just to name a few, are all helpful in furthering clinical proficiency and patient care.

We offer complimentary continuing education courses through our Professional Affairs Clinical Education (PACE) program. Visit www.Medtronic.com.

Additionally, our knowledgeable field staff are here to partner with clinicians to help implement and train—at no charge—to new patient safety monitoring protocols.

How is your product helping with the treatment of COVID-19?
Unsure of what lay ahead, we started with our one constant—our Mission to alleviate pain, restore health, and extend life—as our guide. It was time to put our purpose into action. We virtually gathered our global leaders, biomedical engineers, and scientists to devise a plan.

1. How could we best help patients? Send ventilators to the places where they were needed the most—first China, later Europe, and then the United States.
2. How could we support innovation? Reposition our invention submission program to focus on virus-fighting technology.
3. How could we expand access to respiratory support for patients? Partner with academic institutions and others to design a light ventilator(opens new window).
4. How could we do it all faster? Work with the FDA to authorize emergency use of our compact ventilator(opens new window) for use in the United States.

As hospitals became flooded with critically ill patients, it quickly became clear that the global supply of ventilators would likely not meet the time-sensitive demand. New York Governor Andrew Cuomo estimated a need for 30,000 in his state alone.[14] So we started by increasing production.

FAST AND ACCURATE FOR NEONATAL ASSESSMENT

A new head-to-head study comparing two leading neonatal pulse oximeters showed Nellcor™ pulse oximetry to be faster, closer to ECG readings, and more accurate than Masimo Radical-7™* technology.[1]

Read the press release to find out how Nellcor™ pulse oximetry can help identify neonatal patients in need of resuscitation or treatment: **https://bit.ly/2LDTUay**

Learn more at **Medtronic.com/PulseOxForNeonates**

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The Nellcor™ pulse oximetry monitoring system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

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Medtronic
Further, Together

Our Ireland facility doubled capacity and introduced 24/7 operations. We fortified our supply chain, brought in new partners, and trained new employees.

We're here for you, as your partner in responding to COVID-19, with respiratory monitoring solutions that may help you enhance safety—for your patients—and for you. Our comprehensive respiratory care and patient monitoring portfolio offers the solutions you need to provide the highest level of care. To learn more, request a demo, or speak to a sales rep, visit www.Medtronic.com/COVIDCapnography. To learn more about our mission as a blueprint, visit: https://www.medtronic.com/us-en/about/covid19-stories/mission-as-blueprint.html

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The Microstream™ capnography monitoring system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

Instrumentation Laboratory

Tell us about your oximetry products currently available.
Instrumentation Laboratory's (IL) GEM® Premier™ 5000 analyzer with integrated CO-Oximetry panel is a revolutionary analyzer for point-of-care and centralized laboratory testing, offering Arterial Blood Gas (ABG), Electrolytes, Glu, Lac, Hct, tHb, O_2Hb, COHb, HHb, MetHb, sO_2, tBili, from a single sample. Self-contained GEM PAK cartridges incorporate all components for patient testing and are maintenance-free. Enhanced Intelligent Quality Management 2 (iQM®2) on the GEM Premier 5000 system is an active quality process control program designed to provide continuous monitoring of the analytical process; before, during, and after each sample measurement with real-time, automatic error detection, automatic correction and automatic documentation of all corrective actions.

Hemoglobin monitoring with CO-Oximetry provides complete oxygenation monitoring status and supports lung-protective strategies for the management of oxygenation therapy in acutely ill patients. Measuring tHb directly vs. calculating Hct can reduce red blood cell transfusions, hospital length-of-stay, comorbidities and mortality.[1] Measurement of tHb is performed by CO-Oximetry using multi-wavelength spectrophotometry in the GEM Premier 5000 analyzer, which is not affected by dilution of blood proteins and results in more consistent measurements of hemodilution during cardiopulmonary bypass.[2,3]

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Discuss the range of your oximetry products' applications.
IL's CO-Oximetry products have three main applications—

The Intelligent Analyzer.

Introducing GEM Premier 5000 with iQM2—for improved patient care.

GEM Premier 5000 blood gas testing system provides automated quality assurance with every whole-blood* sample. Now with next-generation Intelligent Quality Management (iQM2), featuring *new* IntraSpect™ technology, potential errors are detected not only before and after, but also *during* sample analysis, along with real-time correction and documentation. Plus, it's simple—just change the all-in-one GEM PAK once a month. So regardless of testing location or point-of-care operator, quality results and compliance are assured with every sample.

Real-time assurance and advanced simplicity. Now that's intelligent.

For more information in North America, call 1.800.955.9525 or visit **instrumentationlaboratory.com**
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*Heparinized.

GEM 5000 | iQM2

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supporting patient blood management with measured tHb in the Cardiovascular Operating Room (CVOR), supporting lung-protective strategies in intensive care patients on mechanical ventilation and detecting dyshemoglobinemia (elevated carboxyhemoglobin and methemoglobin).

Effective patient blood management is critical to optimizing patient care in the CVOR. Unnecessary transfusions increase risk of infection and ischemic complications, and can contribute to costly, prolonged hospital stays. Studies have demonstrated that the precision in hemoglobin measurement is critical; a difference of only 1 g/dL can impact the decision to transfuse. Up to 57% of transfusions are likely 'unnecessary' and initiated based on poor or inaccurate test results.[1] The GEM Premier 5000 system supports transfusion management with precise, measured tHb in the CVOR.

Oxygen therapy is one of the most common and beneficial interventions in medicine. It can promote significant improvements in quality of life and reduce morbidity and mortality in the treatment of critically ill patients.[2,3] Maintaining adequate oxygen delivery to vital organs often requires the administration of supplemental oxygen, sometimes at high concentrations. At these levels, oxygen therapy can be harmful, particularly when administered for prolonged periods.[4] ABGs and a measured CO-Oximetry (not affected by dyshemoglobins like pulse-oximetry) offered on the GEM Premier 5000 analyzer, align with guidelines and clinical best practices in providing safe and effective diagnostics and ensuring optimal patient management of oxygen therapy.

Additionally, CO-Oximetry on the GEM Premier 5000 system can detect carboxyhemoglobin (COHb) and Methemoglobin (MetHb). Elevation of these dysfunctional hemoglobin derivatives can profoundly affect tissue oxygenation. These conditions are not detectable with blood gas analysis alone. Accurate and measured tHb, rather than a calculated value derived from Hct or using pulse oximetry, is the gold standard methodology for detecting dysfunctional hemoglobins.

Further, IL also offers the Avoximeter™ 4000 CO-Oximeter, providing rapid, accurate assessment of oxygenation status in less than 10 seconds. Patented state-of-the-art optics ensure accurate determinations of: O_2Hb, HHb, MetHb, COHb, tHb, O_2Ct, SO_2, O_2Cap, from a single, whole-blood sample. A comprehensive and complete evaluation enables critical decisions and treatments, essential during Cardiac Catheterization, where timing is critical. Another IL system, the Avoximeter 1000E Oximeter is ideally suited for quantitative measurements to aid in the diagnosis and detection of intracardiac and great-vessel shunts. With no sample preparation needed, Avoximeter systems are fast and simple to use. The two-step test method, using easy-to-fill, room-temperature disposable cartridges, minimizes waste.

Additional applications for IL's CO-Oximetry products include: MetHb for nitric oxide (NO) in the Neonatal Intensive Care Unit, and COHb for CO poisoning in the Emergency Department.

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What oximetry products do you have in development?
All GEM Premier systems today and in the future are designed to address the critical clinical applications that benefit from lab-quality, measured CO-Oximetry.

What type of customer assistance and training do you offer?
iQM/iQM2 on the GEM Premier systems automatically detect, correct and document errors, eliminating the need for manual maintenance and troubleshooting. And, all GEM Premier systems feature the GEM PAK, the only all-in-one, multi-use cartridge on the market today. With all components for critical testing contained in the cartridge itself, there is virtually no need for maintenance or technical support, and thus training is minimal. A single GEM PAK, stored at room temperature at any testing site, is simply installed when needed.

IL offers Technical Support staff in the field for customers to ensure optimal product performance and customer satisfaction. In addition, the IL Technical Support group is available by phone, 24 hours a day, 7 days a week.

To assist customers with regulatory compliance, IL also offers a comprehensive document outlining how GEM Premier systems meet the regulatory requirement of each regulatory agency. Additionally, IL conducts educational seminars throughout the year at customer hospitals and at national conferences. These seminars include experts in diagnostics, quality control and clinical practice, and provide Continuing Education Units (CEU) for attendees.

How Is Your product helping with the treatment of COVID-19?
Arterial blood gas analysis remains the gold standard for accessing oxygenation status in acutely ill patients. Oxygen saturation measured by pulse oximetry (S_pO_2) is shown to be consistently lower than arterial oxygen saturation (S_aO_2) measured by blood gas analysis through CO-Oximetry on the GEM Premier 5000 analyzer, in COVID-19 patients in the Intensive Care setting. The discrepancy may lead to administration of a higher inspired oxygen fraction than necessary, when using S_aO_2 to guide oxygen titration.[1]

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Nova Biomedical

Tell us about your oximetry products currently available.
Nova's Stat Profile Prime Plus is a 22-test critical care analyzer that includes a 5-test CO-Ox panel consisting of the following tests: O2Hb, COHb, MetHb, HHb, tHb. Prime Plus incorporates a new, patented, multi-wavelength optical system that scans a continuous spectrum of wavelengths to produce a

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High Frequency Chest Wall Oscillation Therapy

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Now is the time to promote pulmonary and bronchial hygiene for at-risk pulmonary patients to be in the best health possible.

Airway Clearance Therapy is a cornerstone for the prevention and treatment of pulmonary disease and neurorespiratory dysfunction.[1] The goal of Airway Clearance Therapy is to provide a preventative treatment option for at-risk pulmonary patients that results in reduced, recurring hospitalizations and better overall health.[2,3]

Who is the "At-Risk" Respiratory Patient?

- History of Pneumonia
- Bronchiectasis
- Chronic Respiratory Conditions
- COPD
- Bronchitis, Emphysema
- Disorders of The Diaphragm

TAILORED THERAPY

MOBILITY DURING USE

COMFORTABLE DESIGN

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AffloVest requires a doctor's prescription for treatment by High Frequency Chest Wall Oscillation (HFCWO). The AffloVest has received the FDA's 510k clearance for U.S. market availability, and is approved for Medicare, Medicaid, and private health insurance reimbursement under the Healthcare Common Procedure Coding System (HCPCS) code E0483 – High Frequency Chest Wall Oscillation. The AffloVest is also available through the U.S Department of Veterans Affairs/Tricare. Patients must qualify to meet insurance eligibility requirements.

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INTERNATIONAL BIOPHYSICS CORPORATION

comprehensive CO-Oximetry panel without lysing the sample. The optical components in contact with blood are contained in a disposable sensor card, which is replaced every 16 days.

- Cleaning and deproteinizing are completely eliminated.
- Lysing and all its required mechanical components are eliminated, along with lysing and deproteinizing reagents.

This new technology reduces maintenance costs and improves analyzer reliability.

Discuss the range of your oximetry products' applications.

The Prime Plus has a broad range of clinical applications, providing a complete CO-Oximetry profile as well as unique critical calculated values like Plasma Volume Status, Oxygen Index and A-v DO_2 to name a few. Clinical areas where the Prime Plus analyzers are critical to the patient care continuum include but are not limited to: Emergency Department, Pulmonary Cardiac Surgery, Cath Lab, MICU, SICU, CTICU, NICU and PICU.

What oximetry products do you have in development?

Nova Biomedical has a robust pipeline of diagnostic products in development including unique point of care CO-Oximetry products. We are unable to provide any additional information or specifications.

What type of customer assistance and training do you offer?

Nova's training for users and administrators consists of E-learning modules and hands-on group sessions customized for each hospital. Administrator/Super User training continues with analyzer configuration and communications using the NovaNet data manager. User training includes:

- Instrument overview
- Analyzing Patient, QC and Proficiency Samples
- Consumable Replacement
- Warranty Program/Process
- Recall and review of test data

Additional administrator training includes:

- User privileges and certification management
- QC and Inventory management
- Facility and location management
- Quality Assurance Program (QAP) participation

GO-LIVE Support

A customer success manager (CSM) is assigned to optimize the customers experience from the point of sale, coordinate installation/training and transition to GO-LIVE. After go-live Nova staff proactively visits the site over the next few months to ensure success in all aspects of implementation and customer satisfaction.

How Is Your product helping with the treatment of COVID-19?

Stat Profile Prime Plus has many unique tests that assist clinicians in diagnosing and treating patients with COVID-19.

a. BUN and Creatinine.
b. Ionized magnesium (iMg)
c. Measured hematocrit and measured hemoglobin
d. Plasma Volume
e. Lactate and SO2%

BUN and creatinine become elevated with acute kidney injury and COVID-19 patients have been shown to develop AKI as the disease progresses. Prime Plus can provide BUN and creatinine results to allow clinicians to monitor and address kidney function in these patients.

Acute respiratory failure requiring mechanical ventilation has been shown to increase with dysmagnesemia. Prime Plus uniquely provides iMg, the biologically active component of Mg, which is a better indicator of dysmagnesemia.

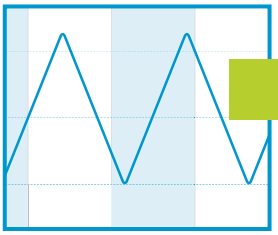
Patients at high risk for COVID-19 feature heart disease, obesity, diabetes, and hypertension. The plasma volume calculation (derived from Hct and Hb) is used by clinicians to assess a patient's heart congestion or heart failure status and is useful in treating COVID-19 patients. Prime Plus provides the best measure of plasma volume status (PVS) through measured hematocrit and measured hemoglobin. Other analyzers measure only one of these parameters, making the PVS calculation less useful.

The WHO states that "markers of total body oxygenation — SO2 and lactate — should be tracked to ensure adequate perfusion and oxygen delivery to the end-organs" when initiating ECMO. Prime Plus offers these tests that can help when administering ECMO to COVID-19 patients.

Chronic respiratory patients getting treatment **but not feeling better?**

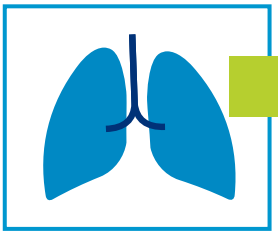
Three great reasons to try the Philips InCourage system:

1 The Philips InCourage system triangle waveform technology **clears more mucus than** competing technology[1]



Triangle waveform

2 RespirTech bronchiectasis patients reported **62% reduction in hospitalizations** and a **14% reduction in antibiotic use** one year after initiating Philips InCourage vest therapy[2]



Outcomes

3 "I was on antibiotics every month of the year for the last 40 years... **Since I've had the InCourage machine, I haven't had to take antibiotics* in over a year**..."
-Marjorie M., CA
*Individual results may vary.

Patient results

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1. Milla CE, Hansen LG, Weber A, Warwick WJ. High frequency chest compression: effect of the third generation waveform. Biomed Instrum Technol 2004; 38:322-328. Note: 8 CF comparing triangular waveform vs. sine waveform technology.
2. Data from RespirTech's bronchiectasis patient outcomes program. Methodology: As of 6/30/19, self-reported data from over 16,000 bronchiectasis patients.

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Subglottic Suctioning: Benefits, Covid-19 Considerations and Manual versus Automatic

Nicole DePalma, MS, CCC-SLP

Subglottic Suctioning: Overview

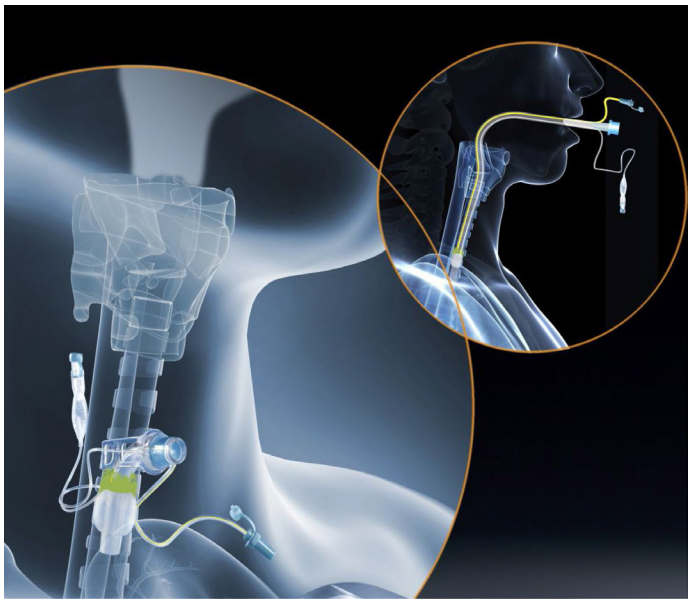
When an endotracheal or tracheostomy tube is inserted, there is a disruption in airflow, pressure differentials and swallowing. Complications include difficulty managing secretions due to a disruption in normal protective reflexes, impaired coughing, a lack of airflow and a lack of sensation through the upper airway.

Endotracheal tubes (ETTs) and tracheostomy tubes have a balloon-like structure or cuff attached to the distal end of the tube. The cuff is located below the level of the vocal folds. When the cuff is inflated, secretions collect on top of the cuff and can ultimately leak around the cuff and into the lungs. When material pools on top of the cuff or passes around the cuff, there is potential for infection. Aspiration is the term for when material (secretions, food, liquid) passes the level of the vocal folds.

Aspiration of oral and/or gastric secretions is the primary route of bacterial entry into the lungs and is believed to be a primary factor in the development of ventilator-associated pneumonia (VAP). Ventilator-associated pneumonia (VAP) is defined by infection of the pulmonary parenchyma in patients exposed to invasive mechanical ventilation for at least 48 hours. VAP is among the highest incidence hospital-acquired infections in intensive care units and has a high rate of mortality.

What is Subglottic Suctioning?

Some endotracheal tubes and tracheostomy tubes have a subglottic suction, which is a small hole in the shaft of the tube, just above the cuff. A channel runs up inside the endotracheal or tracheostomy tube and is connected to a suction port to remove secretions that pool above the cuff. Secretions have been traditionally removed manually with a syringe or wall suction, but there are complications with these techniques. An automated intermittent subglottic suction device can remove more secretions, without manual needs of clinical staff.



The Centers of Disease Control (CDC) recommends an ETT dorsal lumen above the endotracheal cuff to allow drainage by continuous or frequent intermittent suctioning of tracheal secretions that accumulates in the patient's subglottic area. Subglottic suctioning is recognized as an effective method to prevent ventilator-associated pneumonia (VAP) in critically ill patients. Other organizations that recommend subglottic suctioning include: American Thoracic Society (ATS), Infectious Diseases Society of America (IDSA), American Association for Critical Care Nurses (AACN) and Agency for Healthcare Research and Quality (AHRQ).

According to A Compendium of Strategies to Prevent Health-Care Associated Infections in Acute Care Hospitals, it is best practice to use endotracheal tubes with subglottic secretion drainage ports to prevent VAP for patients likely to require greater than 48-72 hours of intubation (Klompas, M. et al, 2014).

Covid-19 and Secondary Bacterial Infections

Patients with Covid-19 may require mechanical ventilation and are at risk for VAP and secondary bacterial infections. These

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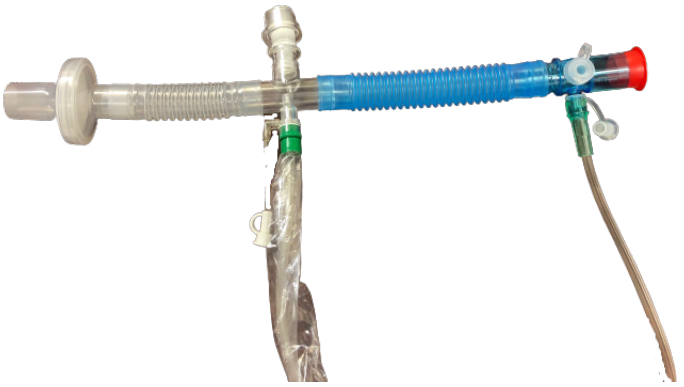
secondary bacterial infections are a major risk factor for adverse Covid-19 outcomes. A retrospective study from China found that 27 out of 28 patients with secondary bacterial infections died (96%). Half of non-survivors experienced a secondary bacterial infection (27 out of 54); ventilator-associated pneumonia occurred in 10 out of 32 patients (31%) requiring invasive mechanical ventilation (Zhou et al, 2020). More recent reports of VAP rates in mechanically ventilated patients with Covid-19 are between 40-86%. Patients with Covid-19 were significantly more likely to develop VAP than patients without Covid-19 (Maes, M. et al, 2021). Prevention of VAP and secondary bacterial infections is paramount to patient safety and survival.

Post-mortem studies of patients with a confirmed diagnosis of Covid-19 have revealed extensive pulmonary mucous secretions and plugging (Fox et al, 2020; Tang et al, 2020). Therefore aggressive pulmonary hygiene including tracheal and subglottic suctioning is beneficial for removing secretions and may help to optimize oxygen supplementation.

Aerosol Generating Procedures and Suctioning

On April 13, 2020, the Centers for Disease Control (CDC) updated their guidance to indicate that aerosol generating procedures (AGPs) are medical procedures that are "more likely to generate higher concentrations of infectious respiratory aerosols than coughing, sneezing, talking, or breathing" and result in "uncontrolled respiratory secretions." AGPs produce airborne particles (aerosols/droplets) that can lead to the spread of respiratory infections.

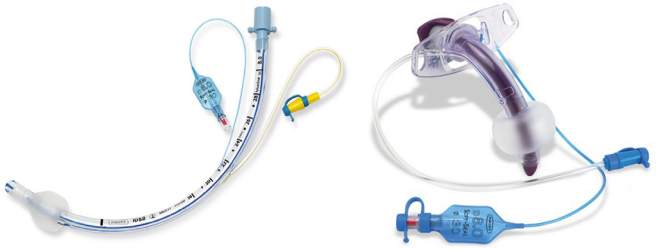
Open suctioning is listed as an aerosol generating procedure (Centers for Disease Control, 2020). Closed tracheal suctioning is recommended to reduce the likelihood of contamination. Closed suction catheters are therefore recommended at this time, even if the patient with tracheostomy has been weaned from mechanical ventilation. It is also recommended to use cuffed, non-fenestrated tracheostomy tubes during the pandemic. The cuff should be left inflated to maintain a closed system in patients with known or suspected Covid-19. This allows secretions and aerosols to stay in the tubing system and not dispersed into the air. Subglottic suctioning can be considered a closed system with use of an automated suction device.



Benefits of Subglottic Suctioning

Subglottic suction drainage (SSD) reduces the volume of secretions that can potentially seep around the cuff and into the lungs. Evidence has shown that subglottic suctioning drainage has repeatedly lowered the risk of ventilator-associated pneumonia (Papazian LK et al, 2020; Pozuelo-Carrascosa, D. et al, 2020).

Recent meta-analysis has also shown a significant decrease in mortality with the use of subglottic suction drainage (Pozuelo-Carrascosa, D. et al, 2020). The review did not show a significant reduction of duration of mechanical ventilation or hospital length of stay.



Images courtesy of Smith's Medical.

Other reviews have shown to significantly reduce the need for mechanical ventilation, ventilator associated pneumonias, and time spent in the ICU. A systematic review and meta-analysis of 13 randomized controlled trials evaluated subglottic secretion drainage in 2,442 patients. Overall, implementing subglottic suction drainage endotracheal tubes (ETTs) caused a 45 percent VAP reduction, shortened patient length of stay in ICUs by 1.5 days, and shortened the length of mechanical ventilation necessary for patients by 1.1 days. The review also demonstrated that using SSD-ETT had no effect on adverse events or on hospital or ICU mortality (Muscedere et al, 2011). One study found that subglottic suction drainage was associated with less antibiotics and another study did not find an association (Bouza, E. et al, 2008; Lacherade, JC, 2010). There may also be potential to reduce aerosol generating particles when used with an automated closed-suction device.

SSD is widely recommended to prevent VAP. National guidelines in the Unites States, Canada and parts of Europe propose using endotracheal tubes with subglottic suctioning (Lacharade, JC, 2018).

Manual Subglottic Suctioning

Subglottic suctioning may be an open system for a brief time during opening of the port when performed manually. Manual subglottic suctioning involves placing a syringe into the subglottic suction port to aspirate the secretions. Subglottic and tracheal suctioning may result in coughing and small aerosol particles may be dispersed into the air. Clinicians are in close contact with the patient during manual suctioning, and appropriate safety measures and PPE should be worn. An automated intermittent subglottic suction device can solve the infection control issues of an open system, allow for safe distancing during suctioning and potentially reduce the spread of infection.

Automated Intermittent Subglottic Suctioning

An automated intermittent subglottic suction device eliminates the need for manually suctioning of subglottic secretions and reduces tracheal suctioning needs, thereby maximizing staff productivity. It also provides the ability to suction the patient in a closed system, to prevent cross-contamination.

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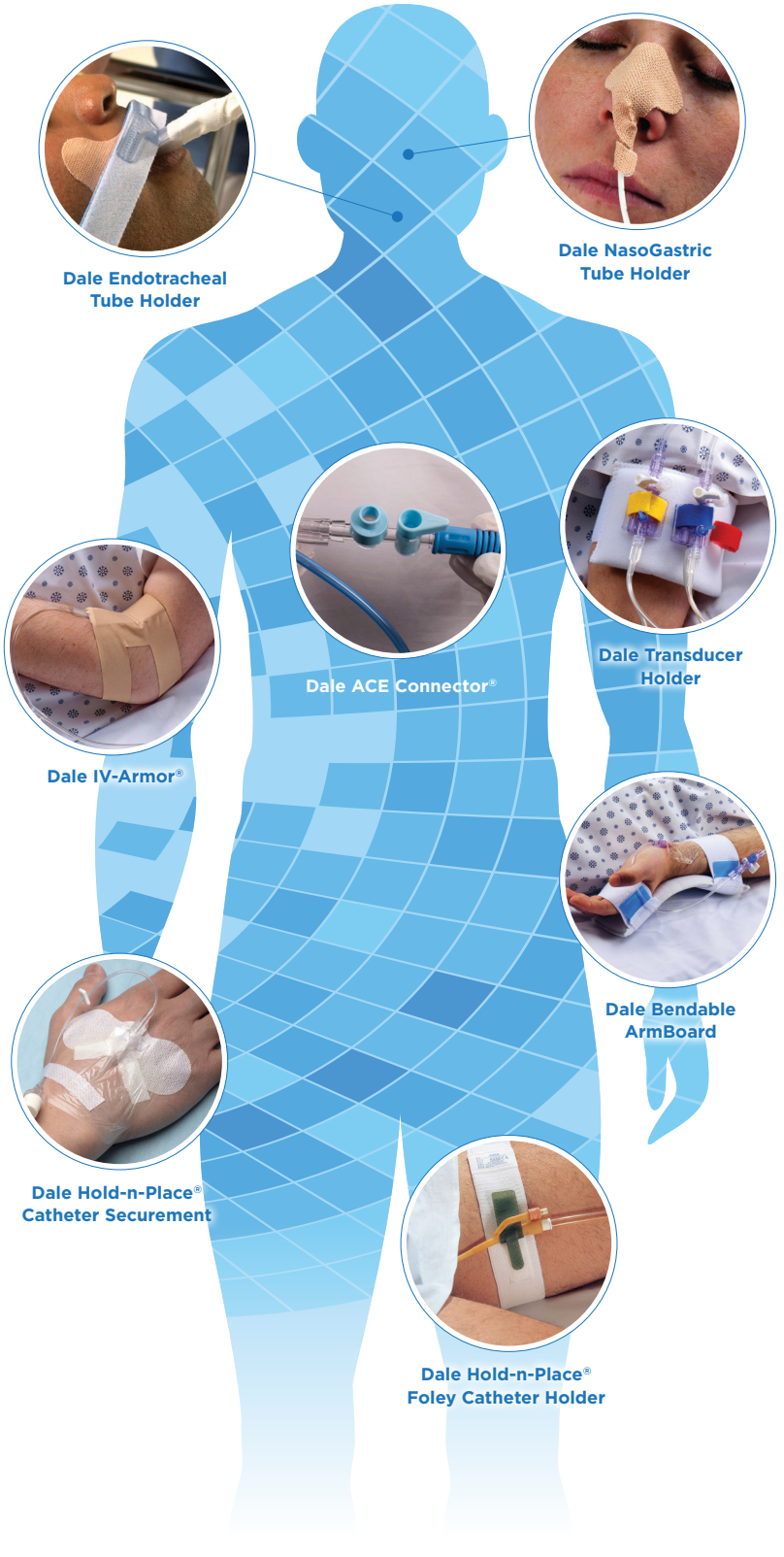

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The SIMEX subglottic suctioning system is the only FDA approved device for removal of subglottic secretions. There may be a reduction in cross-contamination through use of the SIMEX device as care providers do not have to manually suction via subglottic suctioning and it may reduce tracheal suctioning needs. The SIMEX is a closed system, so that infectious secretions are aspirated into a self-contained disposable collection canister.

Another advantage to the automated subglottic suctioning system is the volume of secretions that are able to be removed from the patient's subglottic region and the reduction in secretions that may leak out of the stoma. If a patient presents with Covid-19, these secretions can be minimized with the device to prevent exposure to healthcare workers.

The SIMEX device has three different settings that can be customized, including negative pressure, suction frequency and duration. Negative pressure settings for the automated intermittent aspiration system range from -60 to -300 mbar (-45 to -225 mmHg). There is a suction interval setting from 10-60 seconds (ON), and from 3-60 minutes (OFF). The pressures fall in line with the subglottic suction drainage guidelines from the AARC, with recommended negative pressures from -80 to-150mmHg. Manual syringes and wall suction regulators have been shown to exert more force on the airways than recommended guidelines.

Cost Savings of Subglottic Suctioning

Even though the benefits for subglottic suctioning are well documented, its use is not widespread. Issues include cost of the subglottic suctioning tube. Facilities consider the immediate costs of the subglottic suction tube at $17.16 compared to a standard tracheostomy tube at $3.07 (Branch-Elliman, W. et al, 2015). However these costs are minimal in comparison to cost savings from reducing VAP rates. Each new VAP leads to an increased estimated cost of $10,000 to $60,000. In a cost-benefit analysis, subglottic endotracheal tubes were cost effective for preventing VAP from the societal and hospital perspectives (Branch-Elliman, W. et al, 2015). It may also have been impractical to perform subglottic suctioning due to staffing issues to manually suction secretions. An intermittent subglottic suction device such as SIMEX provides the benefits of subglottic suctioning with reduced staffing needs and a closed system to prevent cross contamination of infectious secretions.

Summary

Subglottic suctioning is an effective method of removing secretions from above the cuff of the endotracheal or tracheostomy tube. Evidence has demonstrated a reduction in ventilator associated pneumonia rates with use of subglottic suctioning devices. This is particularly important during the Covid-19 pandemic, as secondary bacterial infections and pneumonias are associated with mortality. An automated subglottic suctioning device is beneficial in removing large volumes of secretions with less staffing needs. It also maintains a closed positioning to reduce the spread of infection.

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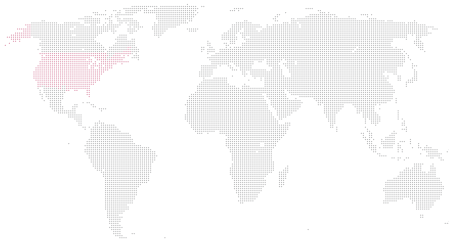
Recommendations for Use of Single-Use Bronchoscopes and Safe Bronchoscopic Sampling During the COVID-19 Pandemic

The benefits of single-use bronchoscopes to prevent and control infection are woven into many new industry guidelines in a world forever changed by COVID-19. As the virus demands attention to safety and forces shifts in patient volume and care, single-use devices safeguard the frontline. Read the latest guidelines here.



U.S. Guidelines & Publications

Society for Advanced Bronchoscopy Consensus Statement and Guidelines for Bronchoscopy and Airway Management Amid the COVID-19 Pandemic (Pritchett and others, 2020)

"[I]t could be hypothesized that the use of a single-use, disposable bronchoscope might offer specific advantages. In addition to avoidance of reprocessing equipment, there may be other advantages to using a single-use bronchoscope. As most of these bronchoscopes are attached by a single cord to a monitor, less equipment is involved in set-up, post-procedure disinfection and transport. Additionally, most single-use bronchoscopes would only need a single user to operate, which may decrease the number of personnel required to assist with the procedure."

American Association for Bronchology and Interventional Pulmonology (AABIP): Statement on the Use of Bronchoscopy and Respiratory Specimen Collection in Patients with Suspected or Confirmed COVID-19 Infection (Wahidi and others, 2020)

"Disposable bronchoscopes should be used first line when available in patients with suspected or confirmed COVID-19 infection."

Performing Tracheostomy During the COVID-19 Pandemic: Guidance and Recommendations from the Critical Care and Acute Care Surgery Committees of the American Association for the Surgery of Trauma (Michetti and others, 2020)

"If available, use of disposable, single-use bronchoscopes is recommended."

Tracheotomy in Ventilated Patients with COVID-19: Guidelines from the COVID-19 Tracheotomy Task Force, a Working Group of the Airway Safety Committee of the University of Pennsylvania Health System (Chao and others, 2020)

Percutaneous dilatational tracheotomy: ''A disposable percutaneous dilational tracheotomy kit should be used, as well as a disposable flexible bronchoscope with monitor (if using)."

Performing Percutaneous Tracheostomy in a Viral Pandemic (CHEST Bronchoscopy Domain Task Force American College of CHEST Physicians, 2020)

On the equipment list to perform percutaneous tracheostomy in a viral pandemic: disposable bronchoscope.

Bronchoscopy in the Era of COVID-19: Providing Timely Care, Minimizing Exposures (CHEST Bronchoscopy Domain Task Force American College of CHEST Physicians, 2020)

"Consider use of disposable bronchoscopes" for bronchoscopy in suspected or COVID positive patients.

Consensus Guidelines for Managing the Airway in Patients with COVID-19 (Cook and others, 2020)

"Where practical, single-use equipment should be used."

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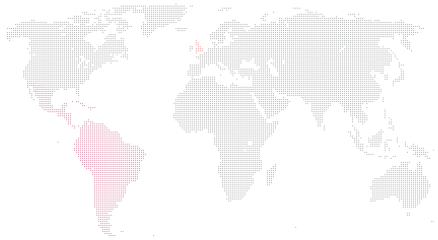


South American and Central American Guidelines & Publications

Latin America and Brazil Overview: What Has the COVID-19 Pandemic Taught Us About Adopting Preventive Measures? (Cristina De Oliveira, 2020)

"It immediately implemented control measures … and investment in single-use equipment such as disposable bronchoscopes for bronchoscopy and percutaneous tracheostomy."

Argentina: Tracheostomy in the Intensive Care Unit: Guidelines During COVID-19 Worldwide Pandemic (Smith and others, 2020)

Materials: "Disposable flexible video bronchoscope with remote display."'

U.K. Guidelines & Publications

Guidelines: Infection Prevention and Control 2020 (Association of Anaesthetists, 2020)

"Single-use flexible fiber-optic bronchoscopes (FOBs) could potentially eliminate the risk of cross-infection. The cable attached to the FOB is also single-use. The monitor can be disinfected and reused."

"The use of single-use FOBs may be cost effective as expenses related to processing, maintenance, repairs and any potential litigation are avoided."

Multidisciplinary Guidance for Safe Tracheostomy Care During the COVID-19 Pandemic: the NHS National Patient Safety Improvement Programme (NatPatSIP) (B A McGrath and others, 2020)

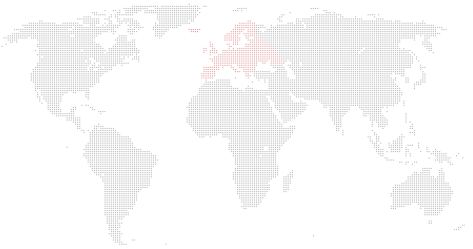
"The choice of using bronchoscopy during percutaneous tracheotomy in a patient with COVID-19 should reside with the operative team. If used, single-use bronchoscopes with a sealed ventilator circuit are recommended."

Multidisciplinary COVID-19 Tracheostomy Guidance (National Tracheostomy Safety Project, 2020)

"If used, single-use endoscopes with a sealed ventilator circuit are recommended."

Should We Be Switching from Reusable Bronchoscopes to Disposable Due to the Risks of Cross-Contamination? A reply: (Bailey, 2020)

"Single-use, flexible, fiber-optic bronchoscopes could potentially eliminate the risk of cross-infection and may be cost effective, as expenses related to processing, maintenance, repairs and any potential litigation are avoided. However, costs and benefits need to be weighed carefully by individual hospitals and intensive care units."



European Guidelines and Publications

Bronchoscopy During SARS CoV-2 Pandemic: Recommendation of the Swiss Society for Pneumology (Franzen, Plojoux and Widmer, 2020)

"If possible, if the SARS infection is proven or suspected, the use of disposable bronchoscopes (e.g. from Ambu) should be considered. This means avoiding operations with SARS-contaminated instruments with CoV-2, although proper preparation would kill the virus."

Irish Thoracic Society Statement on Bronchoscopy and SARS COVID-19 (Irish Thoracic Society, 2020)

"Single-use bronchoscopes have a number of clear advantages:

1) Staff shortages: Where staff are absent there is no requirement to clean scopes
2) Out-of-hours bronchoscopy: No requirement to prepare or clean scope
3) Portability: Small portable screen and scope – reduced requirement for staff
4) Cross-contamination: No risk of cross-contamination
5) Cost: Single-use bronchoscopes are not expensive."

Single Use Bronchoscopes: Applications in COVID-19 Pandemic (Barron and Kennedy, 2020)

"We … endorse the statement that 'disposable bronchoscopes should be used first line when available' in patients with suspected or confirmed COVID-19 infection. "Prior to COVID-19, single-use bronchoscopes had a number of potential advantages including cost, risk of nosocomial infection spread and portability.

"In the current COVID-19 era … single-use bronchoscopes are associated with less staff handling of bronchoscopes prior to bronchoscopy which should reduce the risk of contamination also.

"Single-use bronchoscopes have also advantage in 'out-of-hour' bronchoscopy and bronchoscopy outside of the endoscopy or bronchoscopy unit."

The Italian Coronavirus Disease 2019 Outbreak: Recommendations from Clinical Practice (Sorbello and others, 2020)
"Single-use flexible bronchoscopes should be used as they are associated with a reduced risk of cross-contamination, and a separate screen is strongly advised."

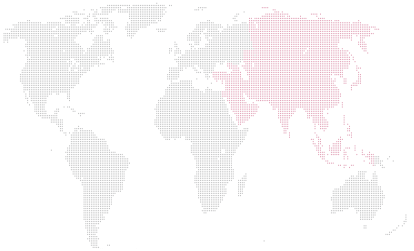
The Italian National Association of Critical Area Nurses (Associazione Nazionale Infermieri di Area Critica) Recommends Single-Use Fiberscopes in COVID-19 Patients (Associazione Nazionale Infermieri di Area Critica, 2020)
"Particular attention should be paid to refreshing the internal safety rules aimed at limiting the dispersion of contaminants containing SARS-Cov2 viruses, particularly for procedures at risk. … Prefer the use of single-use fiberscopes."

Hospital Surge Capacity in a Tertiary Emergency Referral Center During the COVID-19 Outbreak in Italy (Review) (Carenzo and others, 2020)
"These items were left in the unit at all times. These included: disposable bronchoscopes …"

Special Precautions for Performing a Bronchial Endoscopy During the COVID-19 Epidemic Phase Recommendations of the French-Speaking Pneumology Society (SPLF) (French-speaking Pneumology Society, 2020)
"The use of a disposable endoscope must be considered and proposed to reduce the risk of aerial and manual exposure when cleaning the soiled endoscope."

Spanish Society of Pulmonology and Thoracic Surgery (SEPAR) and the Spanish Society of Respiratory Endoscopy (AEER): Consensus Recommendations on the Use of Bronchoscopy and Airway Sampling in Patients with Suspected or Confirmed COVID-19 Infection (Cordovilla and others, 2020)
"Equipment: Of choice: disposable bronchoscopes for single use with electronic screen for visualization of the bronchoscopy. The bronchoscope is discarded in the container arranged for it and the screen is cleaned like the rest of the surfaces in the room."

The Cutting Edge of Thoracic Anesthesia During the 2019 Coronavirus Disease (COVID-19) Outbreak (Fiorelli and others, 2020)
"If bronchoscopy is required, a disposable tool should be preferred."



Asian Guidelines & Publications

Perioperative Management of Patients Infected with the Novel Coronavirus: Recommendation from the Joint Task Force of the Chinese Society of Anesthesiology and the Chinese Association of Anesthesiologists (Chen and others, 2020)
"One disposable fiberscope should be dedicated to a single patient."

Pre-intubation preparation: "(5) if available, preparation of a disposable flexible video bronchoscope; ..."

Surgical Considerations for Tracheostomy During the COVID-19 Pandemic: Lessons Learned from the Severe Acute Respiratory Syndrome Outbreak (Review) (Tay, Khoo and Loh, 2020)
"Percutaneous tracheotomy involves more extensive airway manipulation, such as bronchoscopy and/or serial dilations during trachea entry. …Whenever possible, disposable equipment should be used."

Intubation of the Patient with a Suspected or Confirmed COVID-19 Infection (Wong, Ong and Ang, 2020)
"For rescue ventilation, a disposable, second-generation supraglottic airway device that allows direct fiber-optic intubation using a disposable bronchoscope is recommended."

Expert Recommendations for Tracheal Intubation in Critically Ill Patients with Novel Coronavirus Disease 2019 (Zuo and others, 2020)
"If available, prepare disposable flexible video bronchoscope."

International Consensus Recommendations

Thoracic Anesthesia of Patients with Suspected or Confirmed 2019 Novel Coronavirus Infection: Preliminary Recommendations for Airway Management by the EACTA Thoracic Subspecialty Committee (Sentürk and others, 2020)
"It is recommended to prepare a dedicated trolley for tracheal intubation of this special group of patients. …Disposable devices (e.g. single-use blades, laryngoscopes, video laryngoscopes with remote screens, and flexible bronchoscopes) should be preferred."

"In cases intubated with ETT and BB, the position of the BB (and the tube) should be confirmed with a disposable flexible bronchoscope or an ETT with an embedded camera." "The position of the DLT should be confirmed with a disposable flexible bronchoscope."

"Ideally, disposable bronchoscopes are the best option to avoid the need for decontamination after the procedure."

International Pulmonologist's Consensus on COVID-19 (International pulmonologist's consensus group, 2020)
"It can be performed to suction out mucous plugs in ventilated patients; consideration for use of a disposable bronchoscope if available."

Performing Bronchoscopy in Times of the COVID-19 Pandemic: Practice Statement from an International Expert Panel (Luo and others, 2020)
"Where possible utilize disposable single-use bronchoscopes if timely and validated reprocessing of the bronchoscopes is not ensured."

Tracheostomy in the COVID-19 Era: Global and Multidisciplinary Guidance (Brendan. A. McGrath and others, 2020)
"Single-use bronchoscopes with a sealed ventilator circuit are preferable when doing percutaneous tracheostomies."

Clinical Guidelines Relevant to Safe Bronchoscopic Sample Collection

American Association for Bronchology & Interventional Pulmonology (AABIP): Statement on the Use of Bronchoscopy and Respiratory Specimen Collection in Patients with Suspected or Confirmed COVID-19 Infection (Wahidi and others, 2020)
"If bronchoscopy is being performed for COVID-19 sample collection, a minimum of 2-3ml of specimen into a sterile, leak-proof container for specimen collection is recommended in suspected COVID-19 patients."

Performing Bronchoscopy in Times of the COVID-19 Pandemic: Practice Statement from an International Expert Panel (Luo and others, 2020)
"Bronchoscopy in intubated COVID+ patients: Connect the BronchoSampler to the scope; connect the scope to aView monitor."

SEPAR and AEER Consensus Recommendations on the Use of Bronchoscopy and Airway Sampling in Patients with Suspected or Confirmed COVID-19 Infectio (Cordovilla and others, 2020)
"Perform a mini BAL better than a regulated BAL, since it minimizes the risk of contagion of the personnel who perform the endoscopy. It is recommended to collect 2-3ml in a sterile, sealed and dry container."

Bronchoscopy, Laryngoscopy, and Esophagoscopy During the COVID-19 Pandemic (Review) (Reddy, Nguyen and Deschler, 2020)
"To obtain bronchoscopy sample for testing: 2-3ml of specimen should be collected into a sterile, leak proof container."

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- Flexible design and intuitive user interface with 180-degrees rotation options
- Live image within seconds and over 3 hours battery time
- Upgradeable and repairable repairable this is in development and to be finalized within the next few months

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Pasteurization: Ultimate High-Level Disinfection For Respiratory Therapy Devices

Robert Straub

The topic of cleaning and disinfecting respiratory care devices has not been widely covered in respiratory therapy publications, nor have many clinical studies been completed specifically for this specialty. Yet when RT teams had to face the 2020 coronavirus pandemic, the attention of healthcare providers, government leaders and the media were all placed on therapists and their life-saving ventilators and respiratory care equipment. The crisis also brought to light the supply constraints for this equipment when it was needed in unusually high numbers. Furthermore, the exponential increase in seriously ill patients intensified the need to consider device reuse and reprocessing whenever possible to make up for inadequate supplies in affected geographic areas.

Even in non-pandemic times, however, there are many valid reasons to reprocess and reuse RT medical devices. Healthcare organizations that employ reusable RT components and perform best reprocessing practices consistently stand to gain multiple benefits. These include reducing device supply and per-use costs, reducing infection risk, reducing facility/system costs, improving compliance and regulatory/survey reporting, and reducing the facility and environmental medical waste burden.

Single Use Device		**Reusable Device**
• Anesthesia circuit: $8 • Disposal in hospital: $1 • Storing medical waste in facility: $1 • Picked up by waste management company: $2 • Waste disposed at landfill: $3	**vs**	• Anesthesia circuit: $20 • 10 uses: $2 per use plus $1 to reprocess (washer/HLD-pasteurizer) = $3 per use • 1/10 the waste and disposal costs: 70¢ per use if not recycled
Total: $15 per use		**Total: $3.70 per use**

Figure 1. Cost comparison between Single-use Device and Reusable Device.

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National medical device reprocessing standards

All classified medical devices, including those used in respiratory therapies, are subject to guidance and standards from national regulatory and professional bodies such as FDA, CDC, Joint Commission, ANSI/AAMI, AORN, APIC and IAHCSMM, governing how they must be processed if they are to be reused. These authorities apply the Spaulding Classification to determine the minimum level of disinfection needed to reduce risk to patients and reprocessing technicians. The non-critical, semi-critical and critical classifications are based on the infection risk posed by each device's intended use (whether it touches intact skin, contacts intact mucous membranes or non-intact skin, or is used to enter sterile or vascular areas of the body).

Standards bodies also refer users to the manufacturers' instructions for use for all relevant medical devices, and they recommend strict adherence to these IFU as part of each facility's reprocessing practices. The objectives of standards and manufacturers' IFU are to help reprocessing teams establish consistent practices that optimize reprocessing quality and patient safety. They are based on research, testing and evidence that validate the effectiveness of their recommendations and instructions. Each healthcare facility or system is responsible for documenting its own policies, procedures, training, and continuous quality improvement program in alignment with the national guidelines and manufacturers' IFU.

Guidance for respiratory therapy reprocessing

Respiratory therapy equipment, components and accessories are typically classified as semi-critical devices and are therefore subject to high-level disinfection to render them safe for handling and reuse. HLD is defined as a process for complete elimination of microorganisms on or in a device, except for small numbers of bacterial spores.[6] Guidance for reprocessing devices used in respiratory therapy, anesthesia, sleep labs and pulmonary procedures includes:

- ANSI/AAMI ST58, Chemical sterilization and high-level disinfection in health care facilities
- ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- APIC: Infection Prevention and Control Essentials for Ambulatory Care, 2020
- CDC (APIC): Guideline for Disinfection and Sterilization in Healthcare Facilities 2008

These advisory tools provide evidence-based guidance to help hospital reprocessing departments and ambulatory center teams

establish their protocols for reprocessing respiratory therapy devices. They include recommendations for cleaning and disinfecting devices, training personnel, selecting compatible cleaning methods and products, and following all equipment, device and disinfectant IFU.

Reprocessing challenges RT departments face

Although they must follow the same reprocessing standards as their counterparts, RT technicians face challenges that are different from those of hospital central services technicians. For example, ambulatory care departments, sleep labs and remote facilities often lack specific documented policies and procedures for device reprocessing in their particular environments, which creates the risk of inconsistency and the potential for error. Also, regardless of where they are disinfected, RT components must be reassembled into ventilators and other equipment for the next use, and this is typically the responsibility of trained RT technicians who complete the task in their labs and clinics. They also deal with disinfection workflow challenges such as less counter space, smaller equipment footprints and a lack of defined clean and dirty areas. And finally, they often lack reliable non-manual device tracking, process control and cycle documentation capabilities, which creates more work to assure compliance to device reprocessing limits and regulatory reporting. Proper cleaning and disinfection are still attainable, however, if these constraints are taken into account in location-specific policies and procedures, and if reprocessing equipment is optimized to facilitate the process.

High level disinfection methods

CDC lists the following, among others, as properties of an ideal disinfectant: it should have a wide antimicrobial spectrum; should be nontoxic for users and patients; should be compatible with all device surface materials; should be easy to use; should have a pleasant odor or no odor; should be economical; and should be environmentally friendly.[8] Even though many disinfectants in current use do not meet all these aspirations, healthcare providers must use what is available to them.

Currently marketed high level disinfection methods include automated and manual processes using chemicals such as hydrogen peroxide, peracetic acid and aldehydes. Although they all achieve high level disinfection when used as directed, these chemicals also pose potential risks, including one or more of the following:

- Corrosion, staining and other damage to the processed devices[4]
- Sensitivity and injury to staff during use[7]
- Sensitivity and injury to patients from residues[7]
- Survival of organisms within accumulated biofilms[4]
- Organisms developing reduced susceptibility to the chemical[4]
- Chemical solutions becoming contaminated[4]

These are not the only challenges for users; healthcare providers incur associated ongoing consumable disinfectant supply costs, chemistry monitoring requirements, inventory management responsibilities (to assure expiration dates are coordinated) and waste management costs (for neutralizing chemicals).

Pasteurization raises the bar

In addition to chemical methods, the CDC formally recognizes pasteurization as an effective high-level disinfection method. Studies also confirm its effectiveness even for drug-resistant bacteria.[12] Pasteurization involves the full immersion of devices in heated water at a specific temperature for a specified time period. CDC lists "wet pasteurization at 70°C [158° F] for 30 minutes with detergent cleaning"[3] as a useful method for a variety of devices, and specifically for respiratory therapy and anesthesia equipment and accessories. Global standards (ISO 15883) recommend that to achieve HLD, pasteurization should be performed at a minimum 65° Celsius (149° Fahrenheit). In the United States, pasteurization must achieve a 6-log reduction of the original population of organisms (99.9999%) for HLD.

Table 1. Devices Compatible with a Washer-Pasteurizer/High Level Disinfector*

Healthcare Department	Items
Anesthesiology	• Manual resuscitation bags (auto-inflatable) • Humidifiers • Anesthesia gas machine bag arm rebreathing bags • Laryngoscope blades • Oxygen administration masks and head bands • Non-invasive blood pressure cuffs • Reusable endotracheal tubes • Stylettes • Ventilator breathing circuits • IV arm boards • Pulse oximeter probes • Airways • PEEP valves • Blood pressure cuffs • Ventilator inhalation/exhalation check valve assemblies • End-tidal CO_2 sample line adapter ports • Oxygen sensor circuit "T" • Velcro poseys
Cardiopulmonary Lab	• Pulmonary function testing hoses and pneumo-tachometer • Masks • Mouthpieces • Circuits
Respiratory and Sleep Lab	• CPAP masks, tubing and headgear • Tubing, smooth bore and corrugated • Manual resuscitation bags (auto-inflated) • Hyperinflation bags (Nursery & NICU) • Humidifiers • Ventilator component parts • Laryngoscope blades • Oxygen administration masks and head bands • Blood pressure cuffs • Treatment nebulizers and wall oxygen humidifier bottles • Large bore tubing • Ventilator breathing circuits and water condensation traps • Croup tent components • Airways • PEEP valves • Ventilator inhalation/exhalation check valve assemblies • End-tidal CO2 sample line adapter ports • Oxygen sensor circuit "T" • Velcro poseys • Incentive spirometers • Aero Chambers

*Check each device manufacturer's instructions for use for specific processing instructions.

There are numerous benefits for healthcare facilities that use pasteurization rather than chemical HLD processes. For example, the heated water used in the cycle is ecologically

beneficial since it does not discharge chemical solutions or contamination into drains. Also, the process is economical—it requires fewer chemistries and costs less per cycle (one study estimated annual savings of $30,000 using pasteurization[14]). In addition, pasteurization is compatible with most RT devices (see Table 1). Since the system facilitates a commitment to reusable devices, it helps reduce a facility's single-use inventory, as well as its environmental medical waste footprint and associated costs.

It's important to note, however, that all pasteurizers are not equally effective. CDC noted that "Some data challenge the efficacy of some pasteurization units."[8] However, there is a washer-pasteurizer/high level disinfector available to RT departments that is specifically designed for semi-critical medical device processing. The only such system to be FDA cleared to date, it has undergone extensive testing and provides data to back up its efficacy claims. It meets all HLD standards and offers enhanced patient safety and process control features. The system's full immersion cycle at a temperature of 72° C (161.6° F) for 30 minutes has been shown to achieve a 6-log reduction of all required test organisms for typical medical devices used for anesthesia, pulmonary procedures, sleep labs and respiratory care. It offers accessories and trays to accommodate a wide variety of devices and components.

This particular system also has additional process control and monitoring features and functions to verify effective operation and provide audit records:

- Monitors cycle parameters during cycles to assure thorough cleaning and HLD
- Meters out cleaning agent for consistent dosing during the optional wash cycle
- Documents and prints out verification of each wash/pasteurize cycle step and condition alerts and diagnostics
- Provides condition alerts for insufficient cleaning agent, lid not locked, heat system failure, preventive maintenance, system cleaning, system failure

By performing two automated functions in one, this washer-HLD pasteurizer helps to reduce space and workflow needs while potentially streamlining reprocessing functions. If combined with customized and compliant reprocessing protocols, it can add significant value and time savings to an RT department.

Time to consider safe, economical, ecological options

Pasteurization is a validated method for disinfecting immersible semi-critical medical devices. For specialties like anesthesia, RT and sleep labs, all of which use many semi-critical devices in their therapeutic regimens, a validated automated washing/pasteurization system, when used as part of specific documented high-level disinfection policies and procedures, would help eliminate unnecessary steps and functions, streamline workflows and facilitate audit reporting. When compared to chemical disinfection, the benefits for patients, staff, devices, healthcare budgets and the environment would be significant.

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introduction.html
4 https://www.cdc.gov/infectioncontrol/guidelines/disinfection/healthcare-equipment.html
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14 APIC workbook: IPC Essentials for Ambulatory Care https://secure.apic.org/web/ItemDetail?iProductCode=SLS7001P-WB&Category=DIGITAL
15 Pasteurization is effective against multidrug-resistant bacteria. AJIC https://www.ajicjournal.org/article/S0196-6553(06)00002-2/abstract
16 https://www.hpnonline.com/sterile-processing/reprocessing-equipment/article/21128198/cenorin-receives-updated-510k-for-pasteurization-and-disinfection-systems
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respiratory-tract bacteria." Today, half of the COVID problem is *actually* COVID. The other half is pneumonia or secondary bacterial infections which is preventable if hospitals use proper secretion management equipment. An estimated 150k+ COVID deaths involve VAP. VAP is preventable. The SIMEX device reduces VAP risk.

"Sadly, this is a very serious problem that is not going away and is getting worst and worst by the minute especially in California where the percentage of COVID ventilated patients dying due to VAP pneumonia is at 56% (10% higher than the national average)," said Hamid Khosrowshahi, President, FloSure Technologies' LLC.

Long-COVID Cases Rise as Stigma of Chronic Fatigue Taunts

When Margot Gage-Witvliet began feeling run down after her family returned from a trip to the Netherlands in late February, she initially chalked up her symptoms to jet lag. Three days later, however, her situation went from concerning to alarming as she struggled to breathe. "It felt like there was an elephant sitting on my chest," she said. Her husband and daughters also became ill with COVID-19, but Gage-Witvliet was the only one in her family who didn't get better. After an early improvement, a rare coronavirus-induced tonic-clonic seizure in early April sent her spiraling back down. Gage-Witvliet spent the next several weeks in bed with the curtains drawn, unable to tolerate light or sound. Today, Gage-Witvliet's life looks nothing like it did 6 months ago when she first got sick. As one of COVID-19's so called long haulers, she continues to struggle with crushing fatigue, brain fog, and headaches—symptoms that worsen when she pushes herself to do more. Across the country, as many as one in 10 COVID-19 patients are reporting illnesses that continue for weeks and months after their initial diagnosis. Nearly all report neurologic issues like Gage-Witvliet, as well as shortness of breath and psychiatric concerns. For Avindra Nath, MD, a neurologist at the National Institutes of Health, the experience of these long-haul COVID-19 patients feels familiar and reminds him of myalgic encephalomyelitis, also known as chronic fatigue syndrome. Nath has long been interested in the lingering neurologic issues connected to chronic fatigue. An estimated three-quarters of all patients with chronic fatigue syndrome report that their symptoms started after a viral infection, and they suffer unrelenting exhaustion, difficulties regulating pulse and blood pressure, aches and pains, and brain fog. When Nath first read about the novel coronavirus, he began to worry that the virus would trigger symptoms in a subset of those infected. Hearing about the experiences of long-haulers like Gage-Witvliet raised his suspicions even more. Unlike COVID-19 long haulers, however, many patients with chronic fatigue syndrome go at least a year with these symptoms before receiving a diagnosis, according to a British survey. That means researchers have had few opportunities to study the early stages of the syndrome. "When we see patients with myalgic encephalomyelitis, whatever infection they might have had occurred in the remote past, so there's no way for us to know how they got infected with it, what the infection was, or what the effects of it were in that early phase. We're seeing them 2 years afterward," Nath said. Nath quickly realized that studying patients like Gage-Witvliet would give physicians and scientists a unique opportunity to understand not only long-term outcomes of COVID-19 infections, but also other postviral syndromes, including chronic fatigue syndrome at their earliest stages. It's why Nath has spent the

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Study Finds Benefits of Home Monitoring for High-Risk Opioid, Post-Operative, Orthopedic Patients

Chris Campbell

When a patient is in a hospital, there is an entire team set up to monitor their progress and deal with any emergencies that may occur. But what happens when a patient is discharged, but is still dealing with a complex medical condition in a home setting.

A team of researchers out of Utah set out to study post-operative and post-discharge risks in relation to opioid-induced respiratory depression (OIRD). The team of Kimberly J. Bennion, Zeek Tyler, Megan Jensen, Megan Hepworth and Robert L Mazzola MD, MSPH, FCCP out of Intermountain Healthcare received an Intermountain Research and Medical Foundation grant to conduct a quantitative, prospective, non-randomized, single cohort study.

"Patients receiving opioids are at risk of morbidity and death due to opioid-induced respiratory depression (OIRD)," wrote the authors of the study, called Preliminary Post-Survey Outcomes of High-Risk Opioid, Post-Operative, Orthopedic Patient Home Monitoring: An Intermountain Research and Medical Foundation Grant Supported Study.

The authors asserted in the study that some patients are being discharged faster than ever before and study was needed to see how home monitoring would help when OIRD occurred.

"Time to discharge is decreasing, pushing these risks into the home setting," they wrote. "Monitoring systems with alarms may avert post-discharge OIRD. The feasibility of such systems for home monitoring has limited study. It is our impression rather than just obstructive sleep apenea (OSA), an inadequate minute ventilation induced by opioids and/or polypharmacy of central nervous system depressing drugs, may be contributing factors to OIRD."

Opioids, according to the authors, can:
1) directly inhibit respiratory musculature function from the upper airway to the diaphragm,
2) impair hypoxic/hypercapnic ventilatory response,
3) alter control of breathing at the medulla and pons, and,
4) impair arousal response.

The study took place at TOSH, the stand-alone hospital for orthopedic care within Intermountain Healthcare. The researchers used Masimo RAD 97 monitoring devices to test the feasibility of 4-day, home monitoring. The research team worked with Masimo to report issues and provided evidence to which Masimo engineers revised software, said the authors.

Table 1. High-Risk Opioid Orthopedic Patient Home Monitoring Post-Study Patient Survey Outcomes

Post-Study Results of Patients: September 23, 2019 through May 13, 2020	Total Pts n=235# (%)
Post-surveys Completed & Returned	235 (100)
Pts Who Felt Safer While Using the Monitoring Device	89 (38)
Caregivers OR Family Members That Felt Safer When Pts Were Using the Monitoring Device	98 (42)
Pts Who Felt Discomfort Wearing Oximetry Sensor on the Finger	46 (20)
Pts Who Felt Discomfort Wearing ETCO2 Cannula	53 (23)
Pts Who Called the Number Provided OR Went to the ER/ Urgent Care in Response to An Alarm	27 (11)
Pts at Home Who Used Naloxone/Narcan (Reversal) Medication Given to Them Prior to Discharge	1 (<1)
Pts or Caregivers Feeling Monitor Had Too Many False Alarms	115 (49)*
Pts Who Would Undergo Home Monitoring in The Future If It Was Felt to Be Needed to Ensure Safety	149 (63)
Pts Who Think That Having A Healthcare Provider Who Can Respond to Alarms by Seeing/Speaking Them Through A Remote Camera Would Make Them Feel Safer/More Comfortable Than the Current Monitoring System	85 (36)

*Research team worked with Masimo to report issues & provided evidence to which Masimo engineers revised software.

"Oxygen saturation (SpO_2), HR, RR and capnography ($ETCO_2$) were recorded," the authors wrote. "Patients meeting high-risk opioid inclusion criteria and prescribed opioids were included. Patients were educated about risks of OIRD and other CNS depressing medications, alarm response, Narcan administration and when to call 911. They were given a 24/7 number to call with questions/concerns. Upon device return, all recorded data were analyzed including pre-/post-study surveys given to patients."

The researchers set a target of 500 enrolled patients or 6-months, or whichever comes first. As of May 13, 2020, 235 patients have been enrolled in the study. Detailed post-study patient survey results are reported in Table 1.

Chris Campbell is the Senior Editor of Neonatal Intensive Care.

Conclusions

What the study authors discovered was the risks patients faced after being discharged and the conditions that revealed.

"The majority of patients were willing to participate in additional studies but were split on allowing camera/video for communication in homes," says the study. "Patients reported $ETCO_2$ over-alarming. Masimo coordinated with researchers to identify a software issue and adjusted to allow for actionable alarming. One patient used Narcan after discharge, was aroused and caregivers called 911. Two patients with frequent alarms sounding during the night were admitted to the hospital and diagnosed with 'opioid induced non-ST elevated myocardial infarction' and 'opioid induced renal hypoxia/failure' respectively. It is our impression without this study raising the awareness of opioid risks and alarms alerting, these patient conditions may have gone unalerted, unrecognized, and delayed treatment."

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past several months scrambling to launch two National Institutes of Health (NIH) studies to examine the phenomenon. Although Nath said that the parallels between COVID-19 long haulers and those with chronic fatigue syndrome are obvious, he cautions against assuming that they are the same phenomenon. Some long haulers might simply be taking a much slower path to recovery, or they might have a condition that looks similar on the surface but differs from chronic fatigue syndrome on a molecular level. But even if Nath fails to see links to chronic fatigue syndrome, with more than 92.5 million documented cases of COVID-19 around the world, the work will be relevant to the substantial number of infected individuals who don't recover quickly.

Microsoft, Cigna Form Coalition for Digital Records of COVID-19 Vaccination

Tech giants including Microsoft Corp, Oracle Corp and healthcare companies Cigna Corp and Mayo Clinic are part of a coalition pushing for digital records of people who get vaccinated against COVID-19. The project, called Vaccination Credential Initiative, aims to help people get encrypted digital copies of their immunization records stored in a digital wallet of their choice, the companies said in a statement. Individuals without smartphones would receive paper printed with QR codes containing the credentials, they said. In the United States, where vaccines from Pfizer Inc and Moderna Inc have been authorized for emergency use, vaccinated individuals receive a vaccination card or printout. The current system does not readily support convenient access, control and sharing of verifiable vaccination records, the companies said.

Disinfecting During Pandemic Puts Asthmatics at Risk

Increased cleaning by people with asthma during the pandemic may be triggering flares of their disease, a new report suggests. Researchers who surveyed 795 US adults with asthma between May and September found the proportion who disinfected surfaces with bleach at least five times a week rose by 155 percent after the pandemic started. Use of disinfectant wipes, sprays and other liquids also increased, the researchers reported in the Journal of Allergy & Clinical Immunology: In Practice. After accounting for other behaviors and risk factors, higher odds of having uncontrolled asthma were linked with greater household use of disinfectant wipes, disinfectant sprays, bleach and water solutions, and other disinfecting liquids. The study does not prove that increased frequency of disinfecting caused uncontrolled asthma. Still, the authors say, people with asthma need safer cleaning options. The Centers for Disease Control and Prevention advises asthmatics to ask someone else to clean and disinfect surfaces and to stay in another room when cleaners or disinfectants are used and right afterward. It also said soap and water may be sufficient for surfaces and objects that are seldom touched.

Asthma Inhaler Sensors Improve Pediatric Asthma Control

Sensor-based inhaler monitoring with clinical feedback may improve asthma symptom control in children, as well as caregiver quality of life, according to a randomized trial evaluating a sensor-based electronic monitoring system. Such a system would work well in racially and economically diverse pediatric populations, researchers found. However, this intervention was also associated with higher health care usage, suggesting that further "platform refinement" is

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Dysphagia: Dispelling the Myths

Carmin Bartow, MS, CCC-SLP, BCS-S

There are numerous healthcare providers who care for patients with dysphagia. It is helpful for these providers to have a basic understanding of normal and disordered swallowing and to recognize the signs and symptoms of aspiration. It is also important that attempts to manage dysphagia are not arbitrary or based on assumptions, but instead are based on objective evidence and individualized needs. The purpose of this article is to provide basic information about swallowing and swallowing disorders, to refute some common dysphagia myths, and to provide supporting truths.

Swallowing Terminology

- Deglutition: the act of swallowing.
- Dysphagia (dis-ˈfā-j(ē-)ə): impaired swallowing.
  - May be oral stage, pharyngeal stage, or esophageal stage
  - Not to be confused with dysphasia or aphasia (language impairment)
- Odynophagia: pain when swallowing.
- Bolus: ball-like, rounded mass of material, usually a mixture of food and saliva that forms in the mouth during the process of chewing.
- Stasis or residue: food or liquid left on surfaces and in the cavities of the oral and pharyngeal structures after swallowing.
- Laryngeal vestibule penetration: when food enters the airway but does NOT pass below level of vocal folds.
- Aspiration: entry of secretions, food, or any foreign material into the airway that travels below the level of the vocal folds.
- Silent aspiration: aspiration of material below level of vocal folds that does not stimulate cough or other response.
- Aspiration pneumonia: an infection that develops after inhaling oropharyngeal or gastric contents into the lungs.

Normal Swallowing

Swallowing is a pressure-driven event requiring coordination of sensorimotor actions to transition the bolus from the oral cavity to the esophagus and to prevent material from entering the airway. The act of swallowing is typically divided into three phases; the oral phase, which includes the oral preparatory phase and the oral transit phase; the pharyngeal phase; and the esophageal phase. To swallow efficiently and safely, all phases of swallowing must be intact, and breathing and swallowing must be coordinated.

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.

Disordered Swallowing

In a recent article by Spronk et al. (2020), the prevalence of dysphagia in hospitalized patients was reported to be 30.7%. Medical conditions and iatrogenic causes such as stroke, traumatic brain injury, progressive neurologic disease, respiratory disease, prolonged intubation, and tracheostomy may disrupt normal swallowing. When dysfunction in any phase of swallowing occurs, complications may arise. Some of the complications of dysphagia include malnutrition, dehydration, prolonged hospitalization, aspiration pneumonia, poor quality of life, and even death. Due to the possibility of dire consequences from dysphagia, efforts to remediate dysphagia appropriately are essential. It also is essential that healthcare professionals understand the basics of dysphagia management, including dispelling some of the myths that have been perpetuated over time.

Myths and Truths

Myth

- **If a patient is coughing during a meal, they are aspirating.**

Truth

- **Patients cough for a myriad of reasons, and coughing during a meal may not be caused by aspiration.**

Mealtime coughing may be an attempt to clear secretions or may be a normal response to clear deep laryngeal vestibule penetration, protecting the airway and preventing aspiration (Watts, Tabor, & Plowman, 2017). Healthcare providers should be watchful for signs and symptoms of aspiration, such as a cough, but should not base decisions about the safety of swallowing solely on the presence of a cough during meals. If there are concerns for aspiration, an instrumental swallowing assessment such as the videofluoroscopic swallowing study (VFSS) or the fiberoptic endoscopic evaluation of swallowing (FEES) should be conducted by a speech language pathologist. These objective examinations can determine if the cough is or is not related to aspiration.

Myth

- **If a patient is not coughing during a meal, they are not aspirating.**

Truth

- **Some patients aspirate and do not cough.**

Velayutham et al. (2018) studied 1,286 pediatric patients who underwent a VFSS. Authors found that 34% of patients demonstrated aspiration. Within the aspiration group, 89% demonstrated silent aspiration. Laryngeal cleft, laryngomalacia, unilateral vocal fold paralysis, developmental delay, epilepsy/

seizures, syndrome, and congenital heart disease were all associated with silent aspiration. Garon et al. (2009) evaluated 2,000 adult patients via VFSS. Authors found that 51% of patients demonstrated aspiration. Of the patients who aspirated, 55% had silent aspiration. Diagnoses of brain cancer, brainstem stroke, head-neck cancer, pneumonia, dementia/Alzheimer, chronic obstructive lung disease, seizures, myocardial infarcts, neurodegenerative pathologies, and right hemisphere stroke resulted in the highest rates of silent aspiration. Disease and injury processes may change the sensorimotor response which may then contribute to silent responses (Watts et al., 2017). Silent aspiration is considered a greater risk factor for the development of pneumonia compared with aspiration with a cough response (Pikus et al., 2003). Healthcare providers should be aware that the absence of cough does not preclude the possibility of aspiration. Use of FEES or VFSS may reveal silent aspiration, and findings may guide swallowing recommendations and the overall management of aspiration.

> "It is very likely that the early return of swallowing ability in the setting of mechanical ventilation, even in a small volume, may contribute to better recovery of the health and general well-being of inpatients in the ICU setting"
>
> – Rodrigues et al., 2015

Myth

- **When patients aspirate thin liquids, thickened liquids are always better and safer.**

Truth

- **Thickened liquids are not always better for patients who aspirate thin liquids.**

The rationale for using thickened liquids is that they move more slowly through the pharynx than thin liquids, allowing the patient more time to protect the airway. The theory is that this may improve airway protection and lower the risk of developing aspiration pneumonia. While there are reports of less aspiration of thickened liquids than thin liquids (Clave et al., 2006), this strategy may not have the desired outcome of reducing aspiration pneumonia and may have more risk than benefit. Kaneoka et al. (2017) conducted a systematic review and meta-analysis investigating pneumonia associated with thin liquid versus thickened liquid intake in patients who aspirate. Authors found no significant difference for pneumonia risk between patients who drank thin liquids with safety strategies and patients who drank thickened liquids. Additionally, it has been reported that patients who are only allowed to have thickened liquids have increased risk for dehydration and patients' perceived quality of life is also lower when on thickened liquids (Carlaw et al., 2012; Chichero, 2013). There are instances when thickened liquids may be appropriate, but arbitrary use of thickened liquids is discouraged and may be detrimental in some cases. Decisions to use thickened liquids should be based on the patient's goals of care, current evidence, objective findings about swallow function, and conference with the medical team.

Myth

- **A chin tuck always makes swallowing safer.**

Truth

- **Swallowing with a chin down posture may worsen swallowing ability, resulting in increased aspiration for some patients.**

The chin tuck or chin down strategy is commonly used with the goal of promoting upper airway protection during swallowing; however, varying degrees of success with this strategy are reported in the literature. Saconato et al. (2016) studied use of the chin tuck in patients with neurogenic dysphagia and found that it was beneficial for patients who had a delay in triggering a swallow and difficulties swallowing liquids; however, it was not the best compensatory strategy for patients with severe dysphagia. Fraser & Steele (2012) studied chin down swallowing in a group of heterogenous patients and found reduced penetration and aspiration during cup drinking of thin liquids. However, the chin down posture worsened swallowing safety when using a teaspoon for liquids in all instances and one time with cup drinking, causing more deep penetration and aspiration than with the head in a neutral position. The authors concluded that clinicians should not recommend the chin down maneuver or other postural modifications without first ruling out detrimental effects and seeing visual evidence of its effect in videofluoroscopy.

Myth

- **An inflated tracheostomy cuff prevents aspiration.**

Truth

- **An inflated cuff does not prevent aspiration.**

There are several important points to consider regarding this myth. First, if material passed between the vocal folds and is sitting above the cuff, the patient has already aspirated since the cuff sits well below the vocal folds. Second, the cuff does not provide a watertight seal. The trachea expands and contracts with respiration; and therefore, material sitting above the cuff will most likely seep around the cuff into the lower airways. Third, research has shown that patients exhibit increased silent aspiration in the cuff inflated vs. cuff deflated conditions (Ding and Logemann, 2005). Last, patients who have an inflated cuff experience dystussia. A normal cough requires vocal fold adduction during the compression phase of the cough followed by high expiratory flow through the upper airway during the expiratory phase of the cough. With the cuff inflated, the patient is not able to cough normally. Since patients with tracheostomies have a high risk of aspiration (Ding & Logemann, 2005), the ability to cough to clear the airway is imperative. One way to facilitate improved swallowing and improved cough is by deflating the cuff and placing the Passy-Muir® Valve (Ding & Logemann, 2005; Blumenfeld, 2011).

Myth

- **Patients requiring a tracheostomy tube and mechanical ventilation should not eat or drink.**

Truth

- **Some patients requiring mechanical ventilation via tracheostomy may eat and drink safely.**

Waiting to assess swallowing ability until after patients are weaned from mechanical ventilation is not only unnecessary, it also may result in further dysfunction due to disuse atrophy (Burkhead et al., 2007). Research has demonstrated that early implementation of a swallowing rehabilitation program is feasible for patients with tracheostomy tubes requiring mechanical ventilation (Rodrigues et al., 2015). In this study, patients underwent a swallowing rehabilitation program which included: cuff deflation, in-line Passy-Muir Valve (PMV) use, and swallowing therapy. They found improved swallow scores after

the swallowing rehabilitation program and no adverse events related to swallowing intervention were reported.

One of the first steps in dysphagia intervention in this patient population is to restore positive airway pressure and airflow into the upper airway. This may be accomplished by cuff deflation and use of the Passy-Muir Valve. It requires teamwork between the speech language pathologist and respiratory therapist. Once the PMV is in place, patients may experience benefits, such as restored breathing and swallowing pattern (Prigent et al., 2011); improved secretion management and less aspiration (Blumenfeld et al., 2011); restored subglottic pressure and improved swallow efficiency (Gross et al., 2003); and improved cough function.

Myth

- **Aspiration always causes aspiration pneumonia.**

Truth

- **Aspiration does not always lead to aspiration pneumonia.**

In a landmark study, Langmore et al. (1998) reported that the best predictors for the development of aspiration pneumonia were dependency for feeding, dependency for oral care, number of decayed teeth, and tube feeding. Dysphagia was concluded to be an important risk for aspiration pneumonia, but generally not sufficient to cause pneumonia unless other risk factors are present. A more recent study by Komiya et al. (2015) corroborated these findings and reported poor oral hygiene, overuse of sedative medications, impaired immunity, reduced mucociliary transport, and depressed lung function due to aging are risk factors for aspiration pneumonia. Therefore, the presence of aspiration alone does not lead to aspiration pneumonia.

Conclusion

Dysphagia, aspiration, and aspiration pneumonia are complex, multi-factorial medical conditions which require individualized and evidence-based assessment and treatment. Healthcare providers should be aware that signs and symptoms of aspiration vary amongst patients and there are no universal swallowing strategies to ameliorate dysphagia. While careful attention to patients' swallow function is important, practitioners' interpretations of swallowing ability and dysphagia management recommendations should be grounded in evidence and truth, not myth and conjecture. Referrals to speech language pathology, use of instrumental swallowing evaluations, and focus on patient-centered care leads to objective and individualized dysphagia management decisions.

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warranted. The study, from Ruchi S. Gupta, MD, MPH, Feinberg School of Medicine, Northwestern University, Chicago, Illinois, and colleagues, was published in *Pediatrics*. One of the issues associated with managing asthma in school aged children is adherence to preventive therapies such as daily inhaled corticosteroids (ICS) — And poor adherence leads to complications. For example, research shows that about 1 out of every 4 asthma exacerbations and more than half of asthma-related hospitalizations are due to nonadherence to ICS. The need to improve ICS adherence among children has resulted in interventions involving sensor-based inhaler monitoring, giving clinicians the chance to assess and intervene on the basis of real-time adherence and usage data. Furthermore, Gupta and colleagues pointed out, "the integration of sensor-based inhaler monitoring with mobile applications may reduce asthma-related health care use by assisting asthma patients between health care provider visits." The Improving Technology-Assisted Recording of Asthma Control in Children (iTRACC) trial was designed to determine the effectiveness of clinically-integrated, sensor-based inhaler monitoring on symptom control and outcomes in racially and socioeconomically diverse children with moderate-to-severe asthma. Children were eligible for inclusion in the study if they were 4 to 17 years of age, had moderate-to-severe persistent asthma, had a prescription for daily ICS for 1 or more years before enrollment, and at least 1 exacerbation requiring oral corticosteroids the year before trial enrollment. In this study, 125 caregiver and child pairs were randomly assigned to inhaler sensors that allowed for caregiver and clinician electronic monitoring of medications, while 127 pairs served as controls. One primary end point of the study was the change in asthma symptom control as measured by the Asthma Control Test (ACT), a five-item questionnaire, with scores ranging from a low of 5 for poorly controlled asthma, to 25 for well-controlled asthma, and the Childhood Asthma Control Test (c-ACT), a 7-item validated questionnaire for children aged 4 to 11 years, with scores ranging from 0 for poor asthma control to 27 for well-controlled asthma. Any score under 19 on either test indicated uncontrolled asthma. The other primary end point was health care usage, which included emergency department visits, hospitalizations, and oral corticosteroid prescriptions during the course of the 12-month trial. Daily ICS use and caregiver quality of life (QoL) were also assessed. Gupta and colleague found that by the end of the trial the mean adjusted ACT scores increased from 19.1 to 21.8 in the intervention group (a 2.7-point increase), and from 19.4 to 19.9 in the control group (a .5 point increase). They also found the change in adjusted mean ACT scores from baseline was significantly greater in the intervention group than in controls at all time points of the trial, with the greatest difference at 12 months.

Mercury Medical Announces New Director of Sales

Mercury Medical, Inc., has announced the appointment of David L. McLaughlin as Director of Sales - Western Region. McLaughlin will be responsible for increasing the sales growth of Mercury's products in the Western United States and galvanizing the sales infrastructure to better serve this essential customer base. "We are delighted to have David join the company at this juncture. Our product pipeline in the critical care markets has never been stronger. David is an 18-year veteran in our industry and previously worked at Mercury Medical as a Territory Sales Manager before joining Edwards Lifesciences in 2010. David brings significant commercial experience to Mercury Medical,
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Safe Delivery of Aerosolized Medications in the Age of COVID

Peter Antevy, MD

Early in the COVID pandemic, aerosolized medications were removed from all of the ambulances across my EMS agencies. The sick, asthmatic or elderly patient suffering from COPD unfortunately could not receive the gold standard treatment of nebulized medications for fear of transmitting COVID-19 to the treating paramedics in the small confines of an ambulance. In order to protect the EMS professionals on the front lines, the decision was made by me that all nebulizations had to stop until further notice. For similar safety reasons, the avoidance of nebulization treatments also became common in hospitals and urgent care centers.

Now, one year later, protocols across the country do not allow for aerosolized medications. With all of the media attention, even the lay person has become familiar with various aspects of the SARS-CoV-2 virus and its primary mechanisms of spread: respiratory droplets and aerosols. These have become household terms and now carry a negative connotation, but it's not the aerosol itself that is concerning. It is the viruses that attach to them for a free ride and ultimately travel to the depths of the airways that pose a danger to others in the same confined space, such as paramedics in ambulances, or healthcare professionals in emergency departments and intensive care units across the country.

An aerosol is simply defined as a fine mist that is suspended in air. Due to their optimal delivery to the depths of the lungs, aerosolized medications are some of our main weapons against respiratory diseases such as asthma, bronchitis and COPD exacerbations. Once an aerosol combines with living organisms such as viruses or bacteria it becomes a *bioaerosol*, a process that occurs when the patient coughs, sneezes, speaks or simply breathes out.

The bad reputation aerosolized medications have received is linked to their suspension in the environment from minutes to hours depending on their size and the surrounding conditions.[1,2,8] When treating patients with aerosolized medications, up to 50% of the intended treatment is not inhaled by the patient, instead a large number of particles are released into the surrounding atmosphere. These un-inhaled aerosols are called *fugitive emissions*. Scientists believe that through the mechanism of bioaerosols combining with fugitive medication aerosols, COVID-19 has spread and infected others nearby.[3,4,10] This is the main reason healthcare professionals have stopped using aerosolized medications.[5]

The particles produced by aerosolized treatments range from 1-5 microns in size,[6,8] compared to the 0.06-0.14 micron size range of the SARS-CoV-2 virus.[7] One study showed the size of fugitive emissions ranging between 0.86-1.4 microns across all nebulizer combinations.[8] Vibrating mesh nebulizers (VMN) are reported to generate smaller micron size distributions than those generated by jet nebulizers, improving medication delivery, but due to their smaller size, lighter particles are reported to remain suspended longer in in the air.[8]

Experiments with a human patient simulator have shown that significant quantities of exhaled droplets exit through the side vents of a typical facemask.[9] The risk of exposure to these exhaled droplets being accompanied by COVID-laden bioaerosols has led healthcare workers to take extra protective measures if within 0.8 meters of patients with febrile respiratory illnesses of unknown etiology, even in isolation rooms under negative pressure.[10]

The avoidance of nebulized medications — a mainstay of respiratory therapy — has made the standard treatment of shortness of breath particularly challenging during the pandemic. Some practitioners have adopted the use of breath-actuated nebulizers (BANs) as a safer option since they produce less aerosols and increase the concentration of medication delivered. However, breath-actuated nebulizers do NOT reduce fugitive bioaerosols. As all respiratory therapists know, the first thing that a "tight" asthmatic or COPD patient does when bronchodilators open up their airways, is cough! Further, the work of breathing and respiratory rate are both increased due to the patient's dyspnea, and lung compliance is decreased. The combination of dyspnea and coughing are forceful mechanisms which expel bioaerosols into the air and increase the risk to front line healthcare personnel.

Researchers have confirmed that viruses are contained in the patients' exhaled breath.[4,11] Practitioners treating patients with shortness of breath should be keenly aware of this and should

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take the necessary precautions. Common sense suggests that the best way of minimizing bioaerosols is to filter the patient's exhaled breath.[9] CPAP creates a tight seal, and when used in conjunction with a filter, provides significant aerosol reduction. However, this modality is uncomfortable and expensive. VMNs and breath-actuated nebulizers produce less aerosols but do not have a means for the containment of bioaerosols. The solution we sought out provided aerosol delivery while simultaneously preventing the release of patient-expelled pathogens into the immediate atmosphere.

Such a mask was recently introduced into the medical device market and after conducting a validation study, we've added a new type of nebulizer back into our respiratory distress tool kit. The SafetyNeb™ is a new product that uses high efficiency filters and a CPAP-like seal that allows for safer aerosol delivery, even in confined spaces. Now, instead of reverting to archaic methods for treating bronchospasm such as terbutaline and intramuscular epinephrine, we can resume the use of modern nebulized and targeted medications while dealing effectively with the problem of fugitive bioaerosols.

Our data has confirmed that use of the SafetyNeb™ can drastically reduce the presence of environmental bioaerosols during treatment. This effectively eliminates the risk of bioaerosol-contaminated fugitive emissions to the healthcare professionals who risk their lives each and every day to treat others. This type of innovation will undoubtedly be effective for the next superbug which many experts fear will not wait another century to develop.

As we move past the current COVID-19 pandemic into the future, medical professionals will continue to be confronted with patients presenting with cough, fever and shortness of breath due to unknown causes. Safety will always take priority, but it shouldn't be at the expense of quality of care. A mask that can filter out over 99% of exhaled bioaerosols allows us to strike the perfect balance between safety and quality of care so we can get back to the work we are here to do.

The author of this article pays tribute to our Frontline Workers, especially our Respiratory Therapists, EMTs and nurses for their dedication, tenacity, and bravery as they approach each patient with care and compassion despite the dangers of viral transmission. See "Lost on the Frontline".

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Supplement: Graphics Analysis During MIE and Implications for Improving Cough Effectiveness

Detailed Discussion Based on Six Step Graphics Analysis Sequence

Jon O Nilsestuen, PhD

Step#1 Mask Leaks

In clinical practice we have found that mask leaks represent one of the biggest impediments to successful use of MI-E. While this seems to be rarely discussed in the clinical literature, there is one bench study evaluating different MI-E devices that found leaks were a significant deterrent affecting tidal volume to varying extents and PCF in the majority of devices.[1]

Step#2 Target Inspiratory Pressure

There is a large variation in MI-E pressures reported in the literature with target inspiratory pressures ranging from +20 to +60, and target expiratory pressures ranging from -20 to -60. Some papers have reported reasonable increases in PCF with lower pressures.[2,3,4,5] while other studies suggest higher pressures are required for supporting clearance.[6,7,8,9,10,11] Overall balanced pressure settings of +40 and -40 seem to be the most commonly cited values, and Bach[12] reports that "while some patients find MI-E to be most effective at pressures of equal to or greater than 60 cmH2O, the great majority of patients in clinical practice receive it at 40 to -40 cmH2O. Thus, these are the widely preferred pressures in clinical practice for both comfort and effectiveness in many of hundreds of patients and thousands of applications in patients with neuromuscular weakness over the last 50 years". In addition, much of the manufactures literature[13,14] suggests starting the initial settings at lower pressures of 10 to 15 cmH2O to acclimate the patient to the device and then gradually increasing the pressures to a target of 35 to 45 cmH2O, once the patient is better accustomed to the device. The Philips training materials also reference Wink & Colleagues[10] that therapeutic PCF may not be reached unless pressures of 40 cmH2O are used. It is also worth mentioning that in bench models[15,16] in order to achieve the clinically relevant PCF value of 160 L/min, inspiratory and expiratory pressures settings on the MI-E needed to be at least +30/-30 suggesting that for clinical efficacy pressures needed to be at least that much, while pressures of 35 to -35 and 40 to -40 were the most effective in achieving higher PCF values. In clinical studies Wink[10] evaluated the effect of different pressure settings of 15, 30 and 40 cmH2O on several different patient populations including COPD and patients with neuromuscular disorders. This study found that only the higher pressure of 40 cmH2O improved Oxygen saturation and PCF.

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Based on the collective findings from the literature we have adopted a similar approach and recommend setting target pressures in the 35 to 40 cmH2O range. We try to achieve an initial pressure of 30 to 35 by the end of the set-up/training session and then increase the pressure to 40 cmH2O during the monthly follow-up visit, once the subject has more experience with the device. In some instances where subjects are too weak to maintain the mask seal at these pressures and are unsupported in the home (without caregiver support) we will accept the lower limit of 30 cmH2O, otherwise we coach the subject and the caregiver to target the 40cmH2O.

Step#3 Setting Inspiratory Time

Few clinical studies have been designed specifically to address the timing issues (T_I and T_E) associated with MI-E. In general, the times selected seem to be the result of prior practice, but unsupported by specific logic. So for example Sancho and colleagues[17] used an inspiratory time of 2 seconds and an expiratory time of 3 seconds, but used as their rational that these were the settings previously used by Bach[18] and Gomez.[15] Note that the Bach paper[18] does not say what settings were used — except for pressures of 40 or more and that patients were trained to use the device for which he referenced Kang & Bach[19] Note this later paper was a retrospective review of patients over ten years from 1990 to 2000. More recently Sancho[20] also used these same settings T_I=2, T_E=3 in their studies involving the addition of high frequency oscillation to MI-E. We suspect that the time settings were general adaptations to the manufactures recommendations for using T_I in the 2 to 3 second range and are intended to achieve a maximum inspiratory volume by observing and communicating with the patient.

Volpe & colleagues[21] in one of their bench model scenarios used settings of T_I=3 and T_E= 2 to simulate what they said were the "usual settings applied in the clinic" however, they did not provide an explanation for where this information originated. In their bench model they were able to achieve very low inspiratory flows by manually adjusting a variable inspiratory flow switch. However, the device they used for bench testing (Cough Assist, Model CM-3200, Philips Respironics) is no longer on the market making application of their findings to the current clinical market difficult. To our knowledge the current devices on the market while allowing adjustment of pressure rise time are not flow controllers and do not allow the amount of flow adjustment necessary to effectively reduce inspiratory flows to the degree achieved in their bench model. Even so their concept of using lower inspiratory flows and longer inspiratory times to support

flow bias in favor of outward secretion movement is reasonable. Applying this concept to the current Philips T-70 device suggests that the low flow setting should be used on current models whenever possible.

Chatwin[22] offered a CME educational activity approved by the European Respiratory Society in which he recommended using inspiratory times of "approximately 2 sec or longer if required and should be titrated to patient comfort". Our findings from graphics analysis also support customizing the inspiratory times to the subject to maximize the inspiratory volume, and when possible using the objective feedback associated with on-sight graphics analysis. Application of the pressure algorithm will determine how long it takes for the inspiratory flow to decay back to zero indicating the "true time" needed to fill the subject's lung. This "true time" depends on the subject's system compliance, their relative size (similar to predicting FVC in pulmonary functions), the set target pressure, the flow setting (or rise time), and the subject's inspiratory effort; although we prefer to set pressures high enough so that the subject can let the device do the work. To this end we suggest that pressures that achieve maximal inspiratory capacity (MIC) should be used; and as Bach noted "Maximal insufflations are extremely important to increase PCF in adult patients who have VCs of Less than 1500 ml."[23] The low flow setting should be selected based on the bias flow theory; and when possible inspiratory times should be determined by graphic analysis and adjusted to the point where inspiratory flow has returned to base line indicating achievement of the target pressure and the MIC associated with the pressure setting. In this manner maximal inspiratory volume should be achieved and the patient should be at the optimum moment in time to synchronize their effort with the onset of negative pressure.

Step#4B Repetitive Coughs

Cough technique, especially in view of progressive neuromuscular weakness is an important issue. Frequently these patients are inclined to use multiple (repetitive) coughs. We have found invariably that the first cough (first glottic closure) results in the highest PCF supporting clearance. King & Colleagues[24] found that effective mucous clearance was largely dependent on the magnitude of the "PCEF"(PCF). From a mechanics standpoint this is supported in theory since the first cough effort is initiated at the highest lung volume, with the best length tension relationship for active expiratory muscle contraction, and the greatest amount of lung recoil. We have found that subsequent coughs beyond the first one or two are often below the threshold for clearance. The implication being that subsequent attempts are unlikely to meet the flow requirements to move secretions in the central airways. At this point we are unable to determine if these smaller later efforts have any influence on secretion movement in the peripheral airways.

While we are not aware of studies in the neuromuscular population that support a single cough, there are several inferences from clearance in chronic lung disease. Mcilwaine & colleagues[25] made the following recommendation in which they also cited Fink: "When repeated coughs are used, bronchial wall instability may result from recurrent compression of the airways, thereby reducing the expiratory flow and limiting the effectiveness of the cough (Fink[26]). Therefore, we recommend that airway clearance techniques (ACT's) be used as the primary method of mobilizing secretions from the middle and small airways to the larger airways. Then one effective cough be used to clear secretions from the larger airways, thereby preserving the integrity of the larger airways."

Step#4C Synchrony & Gas Decompression Spike

During the cross over phase -meaning the switch from application of positive pressure to application of negative pressure, there are two timing/synchrony factors that affect the resulting PCF: 1) the inspiratory time setting -either too short -preventing an optimal inspiratory capacity from which to start the cough, or too long impacting the patient's ability to time or synchronize their cough effort, and 2) the patient's own skill/response time in coordinating their cough effort with the machine. This effort can be facilitated by watching the dial on the face of the device, but may also be affected by neurological impairment associated with the later stages of ALS.

In laymen's terms we have used the analogy to the professional golf swing, with a maximal back swing and instant transition to the forward swing for best results. This analogy, however, is rooted in muscle physiology and influenced by the optimal length tension relationship, which in this setting would equate to the achieving MIC in preparing the expiratory muscles for forceful contraction. In addition, the ability to synchronize the cough effort at the moment the MIC is achieved and to rapidly transition from the inspiratory effort to the expiratory effort is supported by the analogous FVC maneuver in pulmonary functions and described in the ATS-ERS Test Procedure Guidelines for Spirometry.[27] This would include the patient instructions to use maximal vs passive effort and to exhale forcibly. It is interesting that the literature for MI-E rarely discusses the effort and synchrony issue, although this may be due in part to the lack of a live graphic display on current MI-E devices vs the advantage of having an active flow/volume loop displayed during spirometry.

Related to the synchrony issue is the frequent appearance of a gas decompression spike that occurs immediately at the beginning of expiration. We have observed this in a large percentage of our subjects and believe that it represents gas decompressing from the tubing at the onset of the expiratory phase of the Cough Assist Device (CAD). We have found that it exists during cough assist therapy in subjects regardless of diagnosis including normal subjects; and it exists in our bench models. This same feature is also found on ventilator graphics[28] both on patients and also replicated using test lungs when the lung model has a high resistance which slows the expiratory flow from the test lung and allows the decompression spike from the tubing (which exits the circuit first) to exceed the expiratory flow from the test lung. Two other sources also support this observation: Sancho and colleagues[11] observed a large increase in the flow wave reaching a maximal value at the beginning of the exsufflation cycle, "this maximal value represents cough peak flow generated by MI-E". Philips/Respironics also produced a white paper[29] developed specifically to show how the software engineers designed the Direct View Software to eliminate the spike so that the software displayed the digital peak flow associated with expiratory flow from the test lung rather than the peak flow corresponding to the decompression gas. From our observations this filtering correctly displays the PCF as long as the subject or test lung expiratory flow is a continuation of the decompression spike, however when there is a time delay between the occurrence of the spike and the subject's PCF (what we have referred to as asynchrony of the subject expiratory effort), then the software interprets the waveform as

two separate coughs and reports the highest PCF regardless of how it was initiated (either from decompression gas or from the subject). In our study a high percentage of subjects had difficulty timing their cough with the onset of negative pressure. The synchrony issue is very likely the reason that the manufacturers have a pie shaped graphic and both a blue-inspiratory bar and a yellow-expiratory bar to help patients time their cough effort.

Step#5 Expiratory Pressure-Upper Airway Collapse & Huff

During the expiratory phase one of the most important considerations for bulbar patients is the loss of the ability to control their pharyngeal and laryngeal muscles.[30] This results in two potential problems: the first is a decreased ability to inspire as a result of inspiratory obstruction/adduction. While this is an inspiratory issue, it often complicates PEF in bulbar patients because it severely diminishes their MIC leaving little volume to expire. This inspiratory obstruction can be caused by passive posterior or downward movement of supraglottic structures in response to MI-E imposed flow and pressure,[31] or receptor initiated reflex adduction that is thought to become hyper-responsive or dysregulated in patients with bulbar ALS[32,33] and may be triggered by rapid inspiratory airflow.

The second potential problem is upper airway collapse that results from exposure to negative pressure during the expiratory phase of MI-E. This expiratory airway collapse has been confirmed by Sancho and Colleagues using computed tomography.[17] They performed CT scans on three patients to evaluate the degree to which upper airway collapse occurred during MI-E. These scans confirmed two things: 1) some narrowing of the upper airway occurs (45% reduction) even in patients without bulbar involvement but not to the extent that it limits achieving effective PCF; and 2) the greatest amount of collapse or narrowing (77% reduction) occurred in the patient with the greatest degree of PCF limitation and presumed greatest bulbar impairment. More recently Anderson et al. have also observed both inspiratory obstruction and expiratory narrowing in ALS patients using videography during transnasal fiber-optic laryngoscopy.[31,34]

Glottic closure is essential for the compression phase of the cough, however in bulbar ALS patients, this loss of control eliminates the closure with the result that their spontaneous PCF is reduced to a peak expiratory flow (PEF) maneuver[35] and significantly reduces the effectiveness of MI-E. Their peak expiratory flow then becomes reliant on their ability to huff. During the expiratory phase the negative pressure imposed by MI-E encroaches into the upper airway and rapidly moves the equi-pressure point down into the lung[36] resulting in upper airway collapse. This dynamic airway collapse has been reported in prior studies involving bulbar patients.[17,37] For emphasis, it is worth mentioning the relative ease with which exposure to negative pressure can result in upper airway collapse since several papers[31,38,39,40] indicate that collapse occurs even in normal subjects when exposed to negative expiratory pressure. This finding would also resonate with sleep studies that demonstrate a significant occurrence of upper airway collapse in otherwise healthy subjects that present with obstructive sleep apnea.[41] Our initial findings indicate that titration of the negative pressure towards ambient can reduce the amount of narrowing or even prevent the upper airway collapse. The extension of this logic to severe bulbar patients that collapse with application of even small amounts of negative pressure would be to remove the negative pressure phase of MI-E and only use slow positive inflation to support MIC followed by huff or by manually assisted cough. In so doing the luminal pressures in the upper airway would always remain positive preventing upper airway collapse.

As noted previously for patients with bulbar impairment, the ability to huff greatly improves their peak expiratory flow rate (PEFR) and often allows them to reach PEFR's above that required for clearance — in the range of 200 to 250 L/Min, even without glottic control. In support of this Cecins and colleagues[42] noted in reference to active cycle of breathing techniques that "the main driver of expiratory airflow is huffing" and "the peak expiratory flow rate, with a huff at high lung volume, is similar to a cough". This is further supported by a clinical study conducted by Hasani and Colleagues[43] in subjects with airways obstruction that evaluated the effect of a huff vs a cough on regional lung clearance. "The mean PEFR for the cough was 288 ±29L/min and for the huff was 203±25L/min. Both were sufficient to increase tracheobronchial clearance by 44% and 42% respectively," and the article concluded that both techniques "were equally effective in clearing lung secretions". Increased expiratory flows above the threshold for clearance should extend the length of ventilator independence. These findings have important implications when teaching patients with bulbar impairment how to maximize their PEFR. Further studies are needed to verify whether this can reduce recurrent respiratory infections and if there are ways to predict the amount of negative pressure to use.

Step#5 Setting Expiratory Pressure: Expert Panel Recommendation for Asymmetrical Pressures

Recently an International Expert Panel[44] organized by the European Neuromuscular Center and convened in March of 2017 recommended that higher expiratory pressures than inspiratory pressures (asymmetrical pressures) should be used during MI-E. This recommendation seems to be founded on bench tests involving rigid tubes[21,45] that would be analogous to clinical circumstances during which patients were intubated. In contrast to this finding, by far our predominant subject population uses noninvasive ventilation (NIV) and has collapsible upper airways. As mentioned above even normal subjects have collapsible airways, and especially in our ALS subjects and even more so in our bulbar ALS group we frequently see upper air collapse during the negative pressure phase of MI-E.

To address this contrasting finding we developed a bench model with a collapsible upper airway (previously published in this Journal).[46] The model includes a modified Michigan Instruments Training Test Lung (TTL) with an overhead support bar with attached rubber bands that mimic the addition of a chest wall and create an FRC for the test lung. This allows the model to illustrate the influence of negative pressure in reducing FRC during the negative pressure phase. The model also has an attached collapsible upper airway created using a section of flexible tubing from the Philips Dream Wear Headset (Respironics Ref# 1116747). Specifically, the collapsible airway simulates the physiology of the subjects in our study group who are using the CAD as non-invasive therapy, as opposed to patients that are already intubated or trached.

Our findings from the bench model indicate that in every combination of positive and negative pressures from +20 to +50, and -20 to -50 (tested in increments of 10 cmH2O); that whenever the negative pressures are greater in magnitude than the positive pressures -asymmetric pressure settings (eg +20/-30 or +30/-40) that the resulting PCF is less than the corresponding

opposite pair. So for example the PCF for +20/-30 is less that the opposite pair +30/-20; and the PCF for +30/-40 is less than the opposite +40/-30 even though the pressure difference (PI-PE) or magnitude of the driving pressure in the pairs is the same. We postulate that the lower flows obtained by the asymmetric pressure combinations are a result of the influence that greater negative pressure has in narrowing the collapsible airway — in essence creating high expiratory resistance to flow or even completely collapsing the airway during exhalation.

The bench study also supports our initial graphic findings that indicate if we maximize the inspiratory positive pressure on bulbar subjects and then titrate the negative pressure towards ambient in stepwise increments, that the luminal pressure in the upper airway at some point moves towards a positive value and the collapse is prevented.

Step#6 Setting Expiratory Time-Implications for Lung De-recruitment

With regard to exsufflation times we are surprised again with the times reported in the literature because there does not appear to be sound rationale for the selection. From a physiologic standpoint PCF is a function of several items: the maximum inspiratory capacity achieved during inspiration; this affects the optimum respiratory muscle length tension relationship and results in an associated respiratory system recoil pressure from which exhalation is initiated;[35] the patients expiratory muscle strength affecting the degree of volume compression; the pressure gradient between the peak alveolar pressure achieved during the compression phase of the cough and the negative pressure setting; and the airway caliber influenced by the degree to which negative pressure collapses or narrows the upper airway (the resistance factor associated with the airflow outlet).

If we assume for the moment, from normal pulmonary function studies, that 80% of the FVC can be expired in one second then extending expiratory times beyond one second should place the patient's lung volume below their FRC. In support of this assumption bench studies originally performed by Gomez-Merino & colleagues[15] (2002) and more recently by Volpe & colleagues[21] (2018) found that after a 2 sec exsufflation time that the test lung would inspire to return the test lung to functional residual capacity. In addition, extending expiratory times beyond this no longer effects the PCF -which occurs much earlier. Gomez-Merino[15] also noted that increasing insufflation times resulted in greater exsufflation flows -presumably because longer inspiratory times allowed attainment of greater inspired volume, however lengthening exsufflation time did not increase exsufflation flow. Striegl et al.[45] found similar results in an infant lung model where maximum expiratory flow increased with insufflation time, insufflation pressure and exsufflation pressure, but not with exsufflation time. These bench models support what we observe clinically -namely that the peak expiratory flow value, whether occurring from actual glottic closure in patients that can cough (PCF) or from bulbar patients that can only huff (PEFR) always occurs very early on at the transition from insufflation to exsufflation, and the prolongation of expiratory time has no effect on this value.

Surprisingly Chatwin[22] in his European Respiratory Society CME offering recommended using negative pressures that were 10 to 20 cmH2O greater than the positive pressure and holding the negative pressure for 3 to 6 seconds — noting that "the best indicator of efficacy is an increase in the sound of the cough". Based on our findings prolonged expiratory times such as this would only reduce the lung volume significantly below FRC and likely increase the risk of lung de-recruitment. Furthermore, based on our findings in ALS subjects, expiratory times of 3 to 6 sec are likely to result in upper airway collapse; the resulting sounds in our estimation are more likely to be the result of the groaning created by vibration of the collapsed upper airway. This vibration (groan) has been a fairly common occurrence in our subjects when titrating the negative pressure to prevent upper airway collapse in bulbar subjects.

While there are no clinical studies using MI-E so far that have addressed this issue, a more practical approach regarding the selection of expiratory time would be to use insp/exp ratios of 1/1 or 2 /1 or greater which would still give patients plenty of time to maximize a single cough effort. In rare instances there may be a need to extend exhalation times beyond this for patients that cannot synchronize and have significantly delayed cough efforts. One additional consideration is for patients that have COPD; in the circumstances of invasive mechanical ventilation, the expiratory time setting is often extended to prevent air-trapping and auto-peep. However, in the context of spontaneous breathing and MI-E, the application of negative pressure during the expiratory phase would likely result in pushing the equi-pressure point deeper into the lung and exacerbate already existing air-trapping and hyperinflation. With this in mind MI-E is generally not recommended in this group of patients (American Association for Respiratory Care Clinical Practice Guideline 2013[47]) and is considered to be contradicted in patients with bullous emphysema with the associated risk of pneumothorax.[13]

What our findings contribute to this discussion is the clinical inference that extending expiratory times beyond the initial cough attempt or in patients without cough beyond the time at which FRC has been reached will not impact the critical flows required for clearance. Extending exsufflation time beyond this increases the potential for lung de-recruitment. While we only have one case study demonstrating de-recruitment, the fact that the PCF's and the inspired lung volume declined in every sequence for a period of 30 days is significant. In light of this finding we recommend that expiratory times should not exceed 2 seconds. In addition, we recommend ending the session with positive pressure breaths (with no negative phase) to return the patient to their FRC level and alleviate potential lung de-recruitment. Ending the treatment with insufflation is also supported by the British Thoracic Society guideline for management of children with neuromuscular weakness,[48] and the 2018 Expert Panel Review.[44]

Additional Discussion of Inspiratory and Expiratory Flow Reduction

In our sample population, the majority of our subjects with bulbar type symptoms (regardless of onset) were able to inspire adequate volumes sufficient to support PCF above the minimal threshold of 160 L/min, despite evidence of mild to moderate inspiratory flow reduction (only 2 subjects were unsuccessful despite changes in the pressure settings). This result is in contrast to the Anderson papers[31,34] in which visual fiberoptic observation indicated that all bulbar subjects experienced inspiratory flow obstruction and that this factor was the major contributor to impaired use of the MI-E. There may be a couple of reasons why their findings differ from ours: 1) in our study we used the graphic from the flow transducer to evaluate

both inspiratory and expiratory flows; this represents a more objective measurement of flow than photographic visualization; in many subjects there was evidence of initial inspiratory flow reduction that was immediately followed by opening. Apparently this allowed patients to inspire enough air to support adequate PCF; 2) our subjects were instructed to sit in the upright position or lean slightly forward to reduce the effects of gravity on passive laryngeal obstruction; this is in contrast to the semi recumbent position that is likely to be required for trans nasal fiberoptic observation; and 3) in our experience subjects that had evidence of mild to moderate inspiratory obstruction frequently also had evidence of expiratory collapse. In these subjects titration of the negative pressure to prevent upper airway collapse improved the success of MI-E and suggests that these patients were able to inspire adequate volumes to support cough.

As a final consideration we used the low flow setting on the device to help reduce inspiratory obstruction. While this helped in some subjects there are still some bulbar subjects that have severe inspiratory flow limitation that was not relieved by reducing the flow. As it relates to active reflex adduction it is physiologically reasonable to assume that if design adjustments were made to allow for flow control, that the flow could be reduced to a level below the threshold for reflex adduction. This lower flow would potentially allow bulbar patients the capability to slowly inspire adequate volumes from which to huff cough.

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The Incremental Additional Costs of a Tank-Based System for Delivering Inhaled Nitric Oxide

Ricky W Bowen, MPM, RRT, RCP, FAARC, Jeff Thompson, MBA, RRT-NPS, Charles V Pollack, Jr, MA, MD

In 1999, the United States Food and Drug Administration (FDA) approved inhaled nitric oxide (iNO) gas, a selective pulmonary arterial vasodilator, "to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents."[1] This mirrored earlier, similar approved indications in other regulatory jurisdictions around the world.

The physical delivery of iNO in the hospital setting — usually in the neonatal intensive care unit (NICU) — is also regulated by FDA guidance. Published in January 2000 (https://www.fda.gov/media/71766/download), the definition of a complete "nitric oxide delivery system (NODS)" includes three component devices: an NO "administration apparatus," an NO gas analyzer, and a nitrogen dioxide (NO_2) gas analyzer. The NO administration apparatus is a device used to add NO to gases that are to be inhaled by a patient. The NO may be added to a ventilator circuit or other gas delivery system, such as nasal cannula. The apparatus must allow reliable maintenance of an approximately constant concentration of iNO during patient (or ventilator) inspiration, regardless of variation in flow rates, as set typically in the range of 0 to 80 parts per million (ppm).

The administration apparatus must also include a pressure regulator and connectors with fittings which are specific for nitric oxide gas cylinders. These cylinders, which weigh around 45 pounds each, typically contain 400 to 1000 ppm NO dissolved in nitrogen gas. The apparatus must be designed to limit the time that NO is mixed with oxygen, thus minimizing the production of NO_2, which is the toxic product of the chemical reaction of nitric oxide with oxygen.

The apparatus further must include an NO gas concentration analyzer with alarms, an NO_2 gas analyzer with alarms, and an oxygen analyzer with alarms. Importantly, the delivery system must include or indicate a separate, redundant apparatus for use as a "backup" system to supply iNO when the primary administration apparatus cannot be used. For this reason, the NODS that must be delivered to the bedside in a typically crowded NICU bed space includes *two* of these 45-pound tanks. This design was the only physical option available to hospitals for the administration of iNO until December 2019, when the FDA approved the first "tankless" system for iNO delivery that met FDA standards for a NODS.[2] This device (GENOSYL® DS, VERO Biotech, Atlanta, GA USA) is portable, includes two consoles (primary and standby [redundant]), within which cassettes containing dinitrogen tetroxide/nitrogen dioxide (N_2O_4/NO_2) liquid produce NO gas at the bedside. The redundant console is for complete backup capability for delivery of iNO. The entire NODS weighs about 70 pounds (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202860s000lbl.pdf), versus about 176 pounds for a tank-based system (https://www.inomax.com/wp-content/themes/inomax-website/dist/downloads/INOMAX-DSIR-Plus-MRI-Manual.pdf).

The availability of a tankless and portable system markedly alters the logistics of delivering iNO. The impact of changing to a tankless system has potential economic consequences that include ease of iNO delivery, ergonomic improvement, labor costs, need for storage space, and other issues. Some of these differences are apparent, while others are less obvious. It is our goal in this focused, qualitative comparison between a tank-based and a tankless system for iNO administration, to identify key distinctions between them from the perspective of both the treating practitioner and of the hospital facility where care is delivered.

Labor Costs

Set-up by a qualified respiratory therapist (RT) of a NODS at the patient's bedside is a function of apparatus availability and the RT's familiarity with it. The former is in turn a function of storage location and the ergonomics of moving the NODS into place; the latter is particularly important in facilities where the volume of iNO use is low. We will address storage and ergonomic issues below. Familiarity with the apparatus is dependent upon initial and ongoing refresher training, which constitutes a labor cost because it diverts the RT from clinical responsibilities. Regularly scheduled calibration also constitutes a labor cost. The currently available tankless system is simpler to use, with fewer steps to initiate and monitor therapy. Ease of use also contributes to quicker and less frequent refresher training, which limits nonclinical time for RTs involved in delivering iNO therapy.

Many institutions designate an individual to manage the supply chain and maintenance for gas cylinders. This workload may consume two or three hours/week in larger facilities, as that

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individual must maintain inventory counts and must order, receive, and distribute supplies and cylinders. The cassettes that provide iNO in a tankless system are about the size of a can of soda and weigh 16 ounces, enabling supplies to be maintained closer to the treatment area and simplifying inventory control.

Storage and Logistics

Space is always in short supply in today's healthcare facilities. The primary gas cylinder storage areas in most facilities are located near the loading dock due not only to footprint and weight but also to ventilation requirements for cylinders and oxidizing gases. Unfortunately, the loading dock is generally not convenient to intensive care units, bringing both labor costs and ergonomic considerations to storage and deployment logistics. A practitioner must both move fresh cylinders to the point of care and return empty cylinders. In addition, some loading docks have access restrictions that may complicate a clinician's round-the-clock access. There is of course the additional opportunity cost of reserving this space for NO tank storage, making it unavailable for other uses.

Storage of NO cylinders is governed by a number of regulators, but primarily by the National Fire Protection Association (NFPA; see current regulations at https://www.nfpa.org/~/media/4B6B534171E04E369864672EBB319C4F.pdf). While NO is not an oxidizing gas, there are still multiple storage specifications, including square footage, ventilation, ceiling clearance, and sprinkler system, that must be met. A tankless system avoids these requirements for NO storage.

The logistics of delivering a tank-based NODS to the bedside vary from institution to institution, but cylinder storage requirements and ergonomic demands in the setting of care of critically ill neonates are a disadvantage compared to a tankless system. The two systems occupy approximately the same bedside footprint, but replacement cassettes for the tankless system can be easily maintained in the unit close to delivery of care, and spent cassettes can be disposed of in routine trash receptacles.

Ergonomics

In a tank-based NODS, the weight of the two cylinders alone is approximately 90 pounds, which is replaced in a tankless system by two 16-ounce cassettes. While the ergonomic differences these numbers represent are obvious, there are also actual regulations that govern them, from both the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH).

Lifting

- A single cylinder of NO gas weighs 45 pounds. OSHA recommends that when lifting loads heavier than 50 pounds, two or more people should jointly lift the load. NIOSH has a lifting equation for calculating a recommended weight limit for one person under different conditions. The lifting equation establishes a maximum load of 51 pounds as a load that, under ideal conditions, is safe for 75% of females and 90% of males. This is then adjusted to account for how often the weight is being lifted, the degree of twisting of the back during lifting, the vertical distance the load is lifted, the distance of the load from the body, the distance moved while lifting the load, and how easy it is to hold onto the load (https://www.cdc.gov/niosh/docs/94-110/pdfs/94-110.pdf?id=10.26616/NIOSHPUB94110). One can easily imagine that in a "rush" situation where a cylinder is needed immediately in the NICU environment, there may be a tendency to overlook sound lifting mechanics. The ability to generate a rolling initiation force for a wheeled piece of equipment is also dependent on the body weight and strength of the mover, leaving employees with lower body weights and/or muscle mass at a disadvantage for wheeling a cart carrying two NO tanks plus an administration apparatus.[3] This is not a concern with a tankless system.
- In fact, musculoskeletal injuries (MSI) are the leading category of occupational injury in health care. In one study, such injuries accounted for 83% of all employee injuries, and 55% of those MSI were due to material/equipment handling activities.[4]
- Ergonomic testing on college students—younger than the typical RT—indicated that the heaviest load subjects were willing to lift was 41.5 pounds with back lifting, 39.4 pounds with front lifting, and only 25.5 pounds with side lifting.[5] In the healthcare worker injury study described above, the MSI rate per 100 person-years for employees younger than 30 years was 4.6, but for employees 60 years of age and older increased to 7.4.[4]

Design and Drop Risk

- The typical NO cylinder is designed with a small protective enclosure around the metering regulator that makes gripping the tank for lifting more challenging for personnel with larger hands, and also makes opening or closing the partially covered valve difficult for those who require two hands to turn it. The tankless system has no such issues.
- According to one study of injuries to hospital workers, the most common injuries related to cylinder handling result from falling cylinders. The most prevalent are contusions and fractures in the lower extremities, including breaks in the phalanges, metatarsal, tibia, and fibula.[6] These potential injuries and the associated economic cost and lost productivity comprise a cost of using a tank-based system.

Economics

Reconciliation of gas use is less transparent to customers of tank-based systems. The contracts for these systems tend to be more complicated than that for the simpler, tankless system. The hospital may also incur cost for inadvertently incompletely closed tanks, which may continue to leak NO and accrue usage charges; this cannot occur with the tankless system.

Data from a longitudinal registry of iNO use at a 300+ bed children's hospital suggest that hospitals incur substantial expense maintaining and managing a tank-based NODS, especially for the "line items" of procurement, storage, data management, and labor costs for training and for response to frequent alarms (such as NO_2 and wet sample line alerts). From these data it is estimated that the incremental cost of a tank-based system in a hospital where 250 patients receive 30,000 hours of iNO treatment/year is approximately $148,000.

In summary, there are both obvious and relatively hidden real and opportunity costs with the use of tank-based iNO delivery systems versus the tankless alternative. The most frequently cited explanation for limited use of iNO in hospitals is cost,[7] but that reflects acquisition cost and not total expense. The light weight, portability, ease of use, greatly decreased and simplified storage space requirements,

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- The most common adverse reaction is hypotension.
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and ergonomic and economic advantages of the tankless system warrant quantitative evaluation, including a formal time-in-motion study.

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which will be of great benefit for our customers," said Executive Vice President - Sales and Marketing, Ray Mundy. While at Edwards Lifesciences, McLaughlin held various leadership positions and was instrumental in developing strategic methodologies for sales and clinical training. "I am honored again to be joining Mercury Medical as their Director of Sales - Western Region. My focus will be on doing what is best for our customers and providing leadership and enhanced training to the sales organization," said McLaughlin. Mercury Medical is a global provider of medical device systems for healthcare providers bringing a legacy of innovation through high quality, cost-efficient solutions for better patient outcomes. As both a manufacturer and distributor, the company provides its products to critical care, neonatal, anesthesia, and EMS markets in more than 58 countries.

Grant Issued to Develop Vaccine

GeoVax Labs, Inc., a biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases, announced that the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), has awarded the company a Small Business Innovative Research (SBIR) grant in support of its development of a vaccine against SARS-CoV-2, the virus that causes COVID-19. The Phase 1 grant, titled, "*Preclinical Development of GV-MVA-VLP Vaccines Against COVID-19,*" will support the ongoing design, construction and preclinical testing of GeoVax's vaccine candidates in preparation for human clinical trials. The efficacy testing will be performed in collaboration with the University of Texas Medical Branch (UTMB). GeoVax is leveraging its GV-MVA-VLP platform to address the global need for an effective and safe SARS-CoV-2 vaccine. Unique among other vaccines under development, the experimental GeoVax candidates are specifically designed to provide a broader and more long-lived level of protective immunity against SARS-CoV-2 while avoiding the potential side effects that can limit vaccine utility and acceptance. GeoVax's vaccine candidates will be tested for antigen expression and genetic stability under conditions designed to simulate those in manufacturing, which will demonstrate the likely suitability of each vaccine construct as a candidate for full-scale production and clinical testing. Mark Newman, Ph.D., GeoVax's Chief Scientific Officer, commented, "The first generation of SARS-CoV-2 vaccines are based on the 'Spike (S)' protein and are designed to induce antibodies that block infection of human cells, an effect referred to as virus neutralization. The GV-MVA-VLP platform provides the opportunity to design and test vaccine candidates that differ significantly through the inclusion of multiple SARS-CoV-2 proteins that are presented to the immune system as virus-like particles (VLPs). Our goal is to safely increase vaccine potency and efficacy by inducing both neutralizing antibody and cellular immune responses to optimize the level of protection against existing and potential new variants of COVID as well as establish immunological memory to provide multi-year protection. Vaccines using the GV-MVA-VLP platform developed for other pathogens have proven to be efficacious with a single dose, having strong durability which would be a significant advantage for SARS-CoV-2 global vaccination campaigns." David Dodd, GeoVax's Chairman and CEO, added, "We are pleased to receive this Phase 1 SBIR funding award, which will supplement the internal resources allocated to our COVID-19 vaccine program and accelerate our progress toward human clinical trials. We

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System Availability Analysis of the GEM® Premier™ 5000 with Intelligent Quality Management 2 (iQM®2)

Cervera J, Conant J

Introduction

Reporting results on-demand is a key requirement for blood gas analyzers utilized in acute care settings. Delays due to lack of analyzer availability can impact quality of care. Factors contributing to blood gas analyzer downtime include: manual, hands-on troubleshooting or maintenance, consumable replacement, instrument service, quality management processes, and other manual corrective actions.

The GEM Premier 5000 system with iQM2 was designed to minimize user maintenance and troubleshooting with its all-in-one GEM PAK. Upon insertion into the GEM Premier 5000 analyzer, the GEM PAK automatically initiates a warm-up process of approximately 45 minutes, followed by Automatic PAK Validation (APV) of less than 15 minutes to validate its Process Control Solution calibrations. After APV is complete, iQM2 assumes control of the analytical system throughout the 31-day use-life of the GEM PAK, and manages sensor stability, error detection (systemic and transient) and automatic error correction.

Many discussions of blood gas analyzer uptime are theoretical, based on ideal conditions. This study aimed to evaluate system availability of the GEM Premier 5000 system under real-world conditions, such as those observed in a clinical setting.

Methods

An evaluation was performed on a GEM Premier 5000 system in the IL Customer Simulation Laboratory (CSL), where a clinical environment is reproduced with a variety of sample types, sample devices and non-laboratory-trained operators.

System availability (uptime) was defined as readiness of the analyzer, and all analytes, for sample analysis throughout the entire GEM PAK use-life (31 days).

Sensor or analyzer availability can be impacted by sample or systemic issues encountered during routine testing. The GEM Premier 5000 analyzer with iQM2 automatically detects errors through Pattern Recognition technology and performs corrective actions for any errors (sensor, sample or transient) encountered, continuously. The time to automatically resolve such issues was calculated as downtime. Use-life (lifetime) was defined as total operating time of the GEM PAK while onboard the instrument. A total of 126 GEM PAKs (>55,000 samples) run for the complete use-life, were examined. All GEM PAKs were exposed to the maximum number of samples (n=450) and use-life. The measurement of uptime (MUT) was calculated using the equation uptime/lifetime.

The authors are with the Instrumentation Laboratory (IL), Bedford, Massachusetts, USA.

Results

The GEM Premier 5000 system with iQM2 demonstrated a MUT of 99.8% overall (Table 1), with excellent individual analyte performance (Figure 1).

Table 1. System unavailable (%)* due to time required to automatically correct pre-analytical or systemic errors

pH	pCO_2	pO_2	Na^+	K^+	Cl^-	Ca^{++}	Hct	Glu	Lac	CO-Ox
0.004	0.004	0.026	0.009	0.003	0.006	0.005	0.003	0.028	0.011	0.042

*Downtime due to automatic correction of pre-analytic or system errors

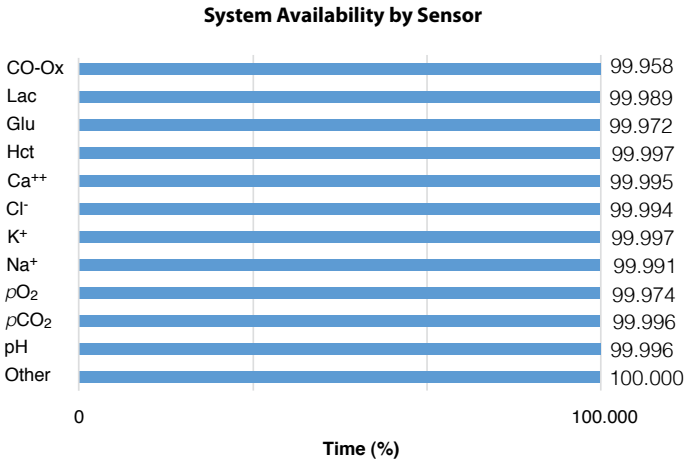

Figure 1. System availability (MUT) by sensor

Conclusion

The GEM Premier 5000 system with iQM2, through its automatic error-detection and correction capabilities and all-in-one GEM PAK, minimizes many of the skill-, labor- and time-intensive tasks that can impact system availability in blood gas testing.

By conducting five automatic and continuous quality checks, iQM2 detects errors in real-time, and through its Pattern Recognition technology makes immediate, appropriate corrections, prior to subsequent sample analysis. iQM2 eliminates dependence on user intervention, a significant contributing factor to the increased downtime experienced with other systems. This analysis demonstrates that the GEM Premier

5000 system with iQM2 offers maximum uptime in clinical use conditions, making it optimal for use in acute care settings.

For more information, contact your local Instrumentation Laboratory sales representative or distributor.

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appreciate and welcome this support from NIH/NIAID, which follows our signing of a Patent and Biological Materials License Agreement providing GeoVax with access to key NIAID patent rights, and which provides GeoVax with nonexclusive rights to develop, manufacture and commercialize our COVID-19 vaccine. While we continue to advance our COVID-19 vaccine program, we remain in discussions and negotiations related to additional funding support that will further accelerate our progress into clinical testing and supply chain preparation. We anticipate that additional vaccines, such as ours will be necessary against COVID-19, as well as potentially new strains and variants, requiring broader immune response, strong durability, exquisite safety within various cohort populations and minimal refrigeration for distribution and supply throughout the world. These attributes represent the focus of our overall 'COVID-X' vaccine program (think 'COVID-20, -21', etc.)."

Company Signs Distribution Agreement

Dräger, an international leader in the fields of medical and safety technology, today announced that it has entered into an agreement with Breas Medical, a global medical device company delivering respiratory care solutions throughout the continuum of care. Together, they will provide long-term acute care (LTAC) and skilled nursing facilities (SNF) in the US access to both Dräger and Breas Medical mechanical ventilator technologies. Both Dräger and Breas Medical offer solutions specifically designed to address the challenges faced by many LTACs and SNFs, most notably the complexity and costs associated with caring for chronically ill patients after requiring mechanical ventilation following intensive care. This new agreement with Breas Medical, effective January 6, 2021, will extend the reach of high-quality ventilation, along with the company's unparalled service and support, into these and other non-acute settings. "In an effort to reduce costs, the care of stable but chronically ill patients is increasingly being pushed from the hospital out to extended care settings with many of these patients relying on mechanical ventilation," said Dräger Senior Vice President of Sales, Hospital Solutions, Steve Menet. "Administrators at these alternative care facilities continue to deliver quality care with limited resources. This distribution agreement with Breas Medical offers a more comprehensive solution with the combined goals of positively impacting patient and financial outcomes." "Quality and patient comfort are Breas' top priority; we put great focus into these core values using innovation in all of our devices. This agreement with Dräger will improve the experience for patients, operators and clinicians while creating more effective access and support for Breas ventilators in the LTAC and SNF markets," said Chris Southerland, General Manager of Commercial Operations, Americas Region at Breas Medical. "Dräger is known throughout the healthcare industry and respiratory community for its state-of-the art mechanical ventilation technology. We are proud to partner with Dräger in their efforts to care for more clinically complex patients."

AerosoLess Medical Has Introduced a New Nebulizer Mask

According to a recent estimate, more than 2,900 US healthcare workers have died in the COVID-19 Pandemic since March 2020. The gravity of the pandemic has heightened awareness of the necessity of preventing patients' pathogens from infecting front-line medical personnel. In the case of nebulizers, which are the recommended treatment protocol for medical conditions

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A Modern Approach to Spirometry Training

Amanda K Clark, RRT

Respiratory medicine focuses on breathing, an essential life function for us all. It also differs from that of any other type of medicine; from medication administration to therapeutics, diagnostic testing, and the list goes on. They are all dependent on good (and proper) technique to generate successful (quality) outcomes. Take for instance most oral or injected medications, when administered, goes to the same place, and follows the same process in the body every time. However, when administering inhaled respiratory medication, to successfully deliver the medication into the distal airway, proper technique is required. When that technique is varied, it statistically decreases medication deposition and ultimately results in suboptimal treatment.[1] From a diagnostic perspective, a corelating argument could be made, drawing blood, or performing a radiological scan, yields a relatively definitive result every time. However, to perform respiratory diagnostic procedures, such as pulmonary function testing, the clinician must be highly skilled in technical knowledge of respiratory anatomy and physiology, familiar with the equipment (and specifications) being used, understand the test being performed and theory behind it to then communicate simple instruction clearly to the patient to ensure proper technique is used (and recognize when it's not). Since spirometry is firmly established as an essential diagnostic and monitoring tool for chronic respiratory disease across the globe, it has become increasingly important to promote confidence in its use and ensure high-quality spirometry testing.[3] As with the medication example, varying technique, leads to variable data, making it challenging to perform accurate testing. To increase the complexity, imagine adding an unpredictable variable to this mix, the patient.

Spirometry is defined as an objective and quantifiable measurement of lung function and is considered a lab exam.[2] As with any lab test, a quality-control process or procedure should be established to ensure accurate measurements are reported. When assessing the quality assurance and quality control (QA/QC) of spirometry testing, the clinician has several points to consider such as device maintenance, adherence to American Thoracic Society (ATS) guidelines, and technical skill level needed to perform the test. Basically stated, proper training consists of far more than just "buttonology" (knowledge of what button to push to generate an image and numbers for a report).

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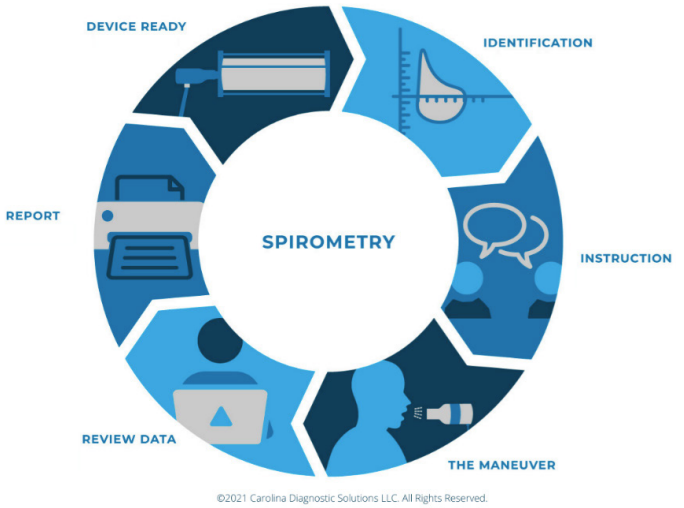

Figure 1. Image showing the process to perform spirometry

Let's take a look at published training program outcomes to better understand what has been done to date to educate clinicians. In Parons et al,[3] a study was conducted in Welsh practices in 2019 which measured the effects of the Spirometry Learning Module, their proprietary program, to evaluate clinician's confidence, experience, and understanding of spirometry beyond "buttonology". The authors concluded that participants who completed the course showed significant improvements in knowledge of spirometry, perceived confidence, and understanding after twenty weeks and retained this when assessed again at twelve months. A drawback from this study was that they did not track or document the technical quality of spirometry performed, thus only assuming that their efforts yielded this as a by-product.[3] The participants conveyed a preference for online, self-paced training in place of traditional methods like face-to-face.[3] Closing thoughts from the authors further indicated that online case-based examples would likely increase retention of concepts in the future.[3] However, in another study, Borg et al[4] concluded that good training does not necessarily guarantee valid results. This group enrolled participants in a 14-hour spirometry training course, using a blended learning method of traditional and online instruction, and periodically reviewed their progress at 5, 7, and 9 months following the course. Despite the course and follow-up training, results in the spirometry quality reported did not reach a desired level.[4]

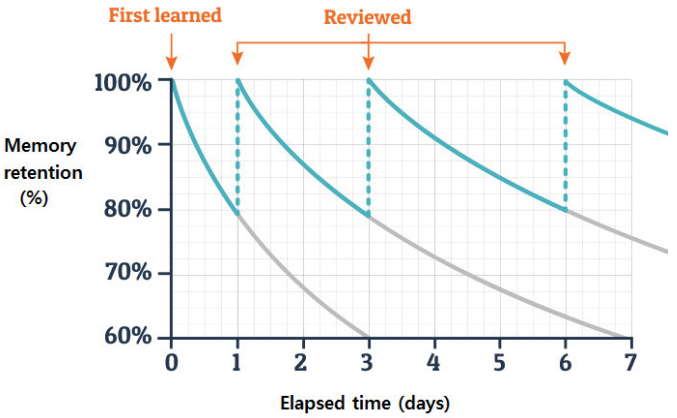

Figure 2. Chart showing the Ebbinghaus Forgetting Curve and Review Cycle[6]

To analyze failures from the prior examples, perhaps the length of instruction played a role in the subpar outcomes. For example, the average attention span of most Americans when learning was found to be 10-15 minutes.[5] Thus, a 14-hour training course would likely prove to be quite overwhelming to the learners. What was the reason for not retaining or just forgetting the information presented? In 1885 Dr Herman Ebbinghaus published his studies regarding this very concept. He was interested in understanding how the human brain absorbs and retains information. His research led to a concept that is still used today, the forgetting curve. Basically, the forgetting curve is a mathematical formula that shows the decline of memory over time.[8] Variables that effect memory retention include: the difficulty of the material, how meaningful the material is to the learner, the method used for learning, and physiological factors such as sleep.[6] He hypothesized that the base forgetting rate differs very little between individuals. Figure 1 demonstrates that memory retention is highest the day that information is presented but declines rapidly over time. To put things into perspective, six days after initial presentation, without any additional review, people retain only about 25% of information.[6] To ensure retention, the learner should review the information learned on a regular basis to be able to recall more quickly the concepts learned.[6] A suggested frequency is review at least four or five times; directly after the lesson, several hours later, one week later, and one month later to maintain a high rate of retention.[7,8] According to professional development research on the topic of retention it is suggested that most **adults lose nearly 30% of skills annually** that are **not routinely reinforced** and that this decreases less when skills are routinely performed **correctly**.[7]

This brings us to another concept that has become popular recently, microlearning. Microlearning is defined as learning small bits of information in a short amount of time and focusing on short term strategies for higher retention. Educators and professionals use this concept in many instances from elementary ages to professional development. Using this concept to build additional value in E-learning environments has been paramount to their success during the COVID pandemic. For optimal outcomes, information should be presented in multiple small, consumable, and repetitive methods. The success rate from microlearning, in conjunction with eLearning, as compared to traditional methods are promising and even more engaging when available in an anytime learning availability (Figure 3). According to Neuhauser's study,[10] "Ninety-six percent of the online students found the course to be either as effective or more effective to their learning than their typical face-to-face course." In a cross-literature review of microlearning for healthcare professionals (both digital and traditional content), Gagne et al.[11] concluded that "Microlearning as an educational strategy has demonstrated a positive effect on the knowledge and confidence of health professions students in performing procedures, retaining knowledge, studying, and engaging in collaborative learning." Imagine if this was available anytime for learners to access on demand.

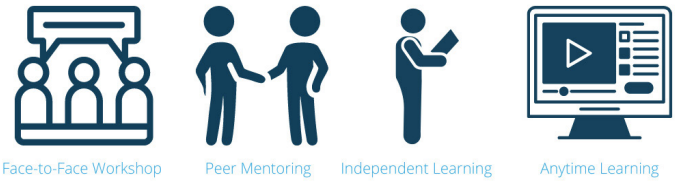

Figure 3. Image showing examples of Professional Learning Methods.

In regions outside the US, spirometry competency assessments are required to ensure quality care is delivered and built upon existing framework. For example, the Association for Respiratory Technology and Physiology (ARTP), a UK professional organization that produces guidelines and standards for their Department of Health, requires clinicians to complete competency assessments every three years with annual renewal and to be a member of the 'Register of Spirometry Practitioners' as part of their continuing professional development standards.[12] This statement from their document on pulmonary function testing puts things in perspective, "it cannot be pre sumed that individuals who have achieved their qualifications in the past continue to be competent without ongoing assessment. **The performance of practitioners has been shown to decline over time**".[12] For the purpose of this article, further discussion and

Spirometry Training Source	Required Training for Reimbursement	Recertification Required	Complies with 2019 ATS/ ERS Standards	Online/ Mobile Capabilities for Anytime Learning
American Lung Association Course			Unknown	
OSHA NIOSH Course *(occupational health only)*	●	●	●	
AARC Office Spirometry Certification *(for non-RT professionals)*			Unknown	
Spirometry 360			Unknown	
SpiroTutor™			●	●
CACPT Spirometry Certification	Unknown	Unknown	Unknown	●
ARTP Spirometry Certification	●	●	●	●

Table 1. Table showing comparison of multiple spirometry training programs.

comparison of learning methods and depth of content provided are limited, Table 1 provides a snapshot. However, the question of additional requirements in the US have been presented in professional circles. Perhaps this is something that should be revisited to ensure quality of care provided.

As stated previously, there have been many solutions attempted to improve quality and training, and while some have contributed to change, they may still be missing the mark … Vitalograph®, as a global respiratory diagnostic industry leader for decades, is keenly aware of the quality issues surrounding pulmonary function testing. This is why Vitalograph® is working with CDS to address the pervasive issue of affordable and timely training surrounding quality testing and monitoring, head on. We developed SpiroTutor™ to provide thorough and consistent training to clinicians of all skill levels online and in an anytime learning environment to meet demand. To further break down the barriers, this service (currently available in the US) is designed to build confidence in clinicians which will create a positive impact for the patients they serve. Through SpiroTutor™ we have the capability to provide training access to users for learning 24/7, making training and maintaining critical skills sets easier and more convenient than ever. To ensure that clinicians are confident using their devices, Vitalograph® provides a free enrollment with each new device purchased. Upon the completion of the training content, a manufacturer's certificate of completion is added to the user's training record and is available for download. Training content includes all Vitalograph diagnostic software, spirometers, respiratory monitors, and screeners. Additional training seats are available for purchase. More information is available at www.SpiroTutor.com

Figure 4. Image showing attributes of SpiroTutor™

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HFCWO Therapy: A Change in Plan

Gary Hansen, PhD

The adoption of high frequency chest wall oscillation (HFCWO) or vest therapy has changed rapidly in recent years. Usage for several traditional disease states has remained stable during the last six years, while several more have experienced remarkable growth. It should surprise no one that these growth patterns were disrupted by the emergence of the COVID-19 pandemic. While the number of new HFCWO patients suffered a steep decline in 2020, a few non-traditional diagnoses, chronic obstructive pulmonary disease (COPD) and chronic bronchitis, experienced strong growth. Many of these patients received their devices under regulatory flexibilities put in place by The Centers for Medicare and Medicaid Services (CMS) during the public health emergency (PHE). These flexibilities allowed for CMS coverage of respiratory devices, such as HFCWO, based on the physicians' determination of medical need of the respiratory device for their patient.[36] Our preliminary examination of outcomes for this group shows a 70% reduction in hospitalizations compared to the prior year, while self-reported ability to clear pulmonary secretions improved 51%.[1]

Key Points

- HFCWO usage patterns have changed in recent years.
- Originally used for cystic fibrosis and neuromuscular disease, this therapy has seen rapid adoption for non-CF bronchiectasis since 2015.
- COVID-19 has drastically changed these practice patterns in a single year.
- Flexibility put in place by CMS has allowed consideration of HFCWO therapy for respiratory patients who might not otherwise have received it.
- Self-reported outcomes from these patients show a robust improvement in hospitalization and the ability to clear mucus since initiating HFCWO therapy.

High frequency chest wall oscillation, also known as vest therapy, is indicated for respiratory patients who require airway clearance. Such patients often experience accumulation of secretions in the bronchi and small airways that may limit gas exchange in the lungs. Inadequately cleared secretions can become a culture medium for pathogens, leading to serious complications including degradation of lung function[2] and increased lung infections.[2,3] By providing periodic compressive pulses to the chest wall, the device transmits therapeutic vibrations to pulmonary airways; these vibrations thin and loosen the secretions, driving them upward to the mouth where they can be expectorated.[4] Acute illness and a progressive decline in lung function can occur when the normal mucus-clearing function is impaired or disrupted on a chronic basis.[5] Secretions that are not cleared can promote chronic inflammation, repeated infections, irreversible lung damage and impaired respiratory function.[6,7] Conditions that result in chronic mucus hypersecretion are considered candidates for airway clearance therapy, including HFCWO. These therapies are intended for patients who are unable to clear excess secretions without external manipulation or therapeutic intervention, and the range of such conditions is wide and often overlapping.

Since its invention almost 30 years ago, prescribing patterns for HFCWO have evolved, driven by changing medical practice and availability of new evidence. The number of prescriptions for many of its customary diagnoses — cystic fibrosis (CF) and neuromuscular disorders — has remained largely unchanged, mostly because patients with these diseases are readily identified and prevalence is small to begin with. Another diagnosis, non-CF bronchiectasis (hereafter referred to as "bronchiectasis") experienced explosive growth as it became clear that there was a large, underserved population of patients with this condition.[8] Comparatively, use of HFCWO for chronic obstructive pulmonary disease has grown more slowly, despite emerging evidence that many of these patients have excess sputum production and could also benefit from airway clearance therapy.[9,10]

HFCWO Adoption Grows

The Centers for Medicare and Medicaid Services (CMS) in the United States covers HFCWO for a number of diagnoses. These diagnoses may be categorized into four broad categories: *cystic fibrosis*, *neuromuscular disease*, *"other" respiratory illnesses*,

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. Gary Hansen is the Director of Scientific Affairs, Respiratory Technologies, Inc. dba RespirTech, a Philips Company.

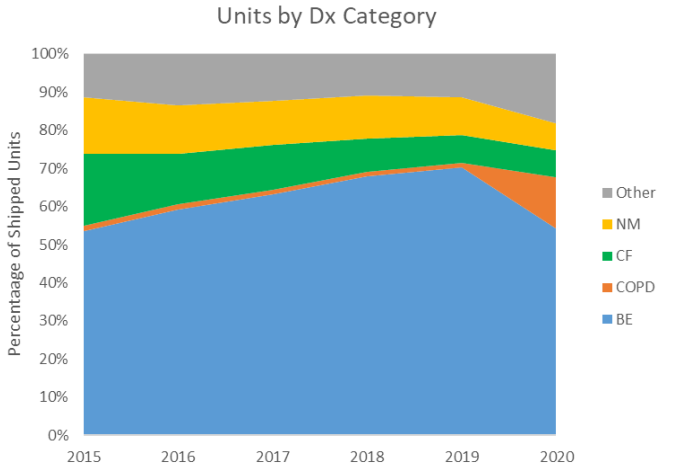

Figure 1. The proportion of HFCWO devices shipped to patients within five major diagnosis categories. "NM" is neuromuscular conditions, "CF" is cystic fibrosis, "COPD" is chronic obstructive pulmonary disease, "BE" is bronchiectasis. Data sourced from a proprietary business database of RespirTech, a Philips company.

and bronchiectasis. The proportionate share of these categories has changed considerably in the last six years, as shown by data from a proprietary customer database for one HFCWO manufacturer, RespirTech, a Philips company. (Figure 1)

HFCWO was originally designed to treat cystic fibrosis, a genetic disease that results in thickened pulmonary secretions that are difficult to mobilize without artificial methods of airway clearance. Numerous studies have shown HFCWO equivalent[11-18] or superior[19-23] to other airway clearance methods; accordingly, its use is now accepted as standard of care in the US.[24]

Within the neuromuscular category, HFCWO has long been used for patients who have an insufficient cough due to a variety of neurological and neuromuscular conditions.[25] (Figure 2) These disorders often result in respiratory muscle disability, making patients more susceptible to pneumonia and infection due to the inability to clear accumulated secretions through coughing.[26] Studies with these patients have found that HFCWO therapy can result in reduced hospital days,[27] a reduction in pneumonias,[28] and an overall reduction in healthcare utilization and costs.[29]

The "other" category contains a large number of uncommon respiratory diseases unrelated to the categories listed above. The RespirTech database shows that no single condition predominates the mix; unfortunately, there is little evidence regarding HFCWO use in this area, largely because they are low incidence conditions or else present other difficulties for doing clinical studies.

Among all diagnoses, bronchiectasis, has been the largest contributor to HFCWO adoption in recent years. This pulmonary disorder is characterized pathologically by permanent bronchial dilatation and severe bronchial inflammation. The clinical picture may include chronic productive cough, excessive sputum production, and recurrent infectious exacerbations. Once thought to be an orphan disease,[30] research has shown that a large population of undiagnosed and untreated individuals exists with this condition.[8] Further research has highlighted the value of HFCWO therapy in addressing the airway clearance needs for these patients.[31,32] Increasing awareness of the importance of recognizing and treating bronchiectasis has driven the adoption of international guidelines, which include recommendations for airway clearance.[33-35]

The results in this paper are from a single company, but nonetheless reflect a revealing snapshot of changes in medical practice as seen in the adoption of HFCWO for various diagnoses. Within this data set, distinct trends may be observed. Significantly, Figure 1 shows the impressive growth of bronchiectasis relative to other disease states. It may appear that the CF and neuromuscular categories have declined, but actual numbers have remained largely unchanged since 2015, probably due to low incidence rates and a relatively few undiagnosed patients with these conditions. In contrast, the "other" category has experienced a modest but steady annual growth rate of about 18% in the years before COVID-19, 2015-2019. The true driver of HFCWO has been the bronchiectasis category (J47.0, J47.1, J47.9), with an annual growth rate of 26% during the same period. This remarkable increase is attributable to the factors mentioned previously: more clinical evidence documenting the need for airway clearance therapy, more awareness of the disease, a large reservoir of undiagnosed patients, and a growing number of physicians who focus on it. The last issue we have not discussed is COVID-19, which of course has had a major impact on who has received HFCWO therapy in the year 2020.

COVID Intervenes

Since the recognition of the COVID-19 virus in late 2019, and its subsequent emergence into a worldwide pandemic, the lives of millions have been upended; this inevitably affected medical practice in many ways. Initial reports suggested that HFCWO therapy could have a role in addressing airway clearance needs of COVID-19 patients. An estimated 34% of hospitalized COVID-19 patients have excess sputum production.[36] In practice, HFCWO use for the COVID-19 diagnosis has comprised only a tiny fraction of all HFCWO patients in 2020 (about 0.2%).

Nonetheless, COVID-19 has radically changed HFCWO prescribing patterns in 2020, driving bronchiectasis numbers down, but COPD numbers up. This is explainable, at least in part, by the temporary changes put in place by CMS in response to the PHE. These provided greater flexibility for physicians to determine the medical need for respiratory devices, such as HFCWO therapy for their patients who might not otherwise

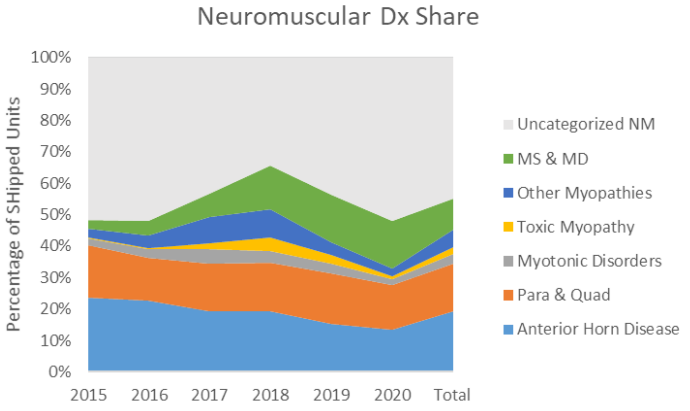

Figure 2. The proportion of HFCWO devices shipped to patients within the Neuromuscular category, with leading diagnoses called out separately. "MS" is multiple sclerosis, "MD" is muscular dystrophy, "Para" is paraplegia, "Quad" is quadriplegia, "anterior horn disease" includes amyotrophic lateral sclerosis. Data sourced from a proprietary business database of RespirTech, a Philips company.

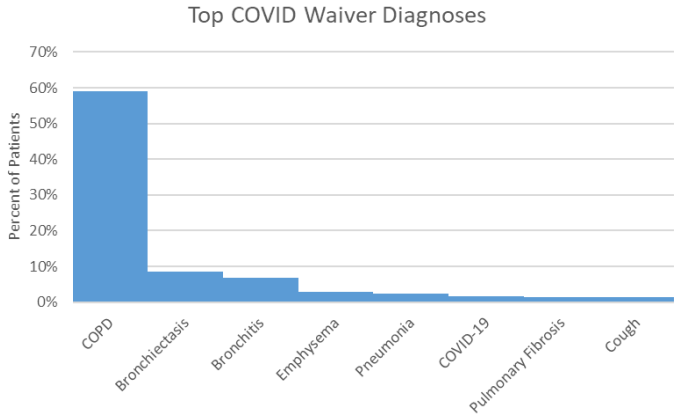

Figure 3. The proportion of various diagnoses for patients receiving HFCWO therapy under the COVID waiver. The top 8 diagnoses make up almost all of such patients. Data sourced from a proprietary business database of RespirTech, a Philips company.

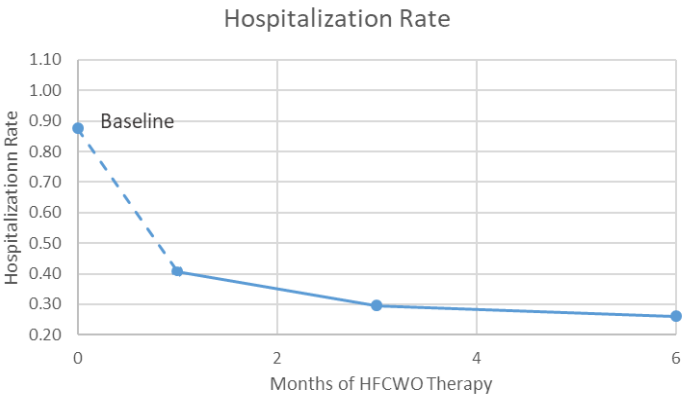

Figure 4. The reduction of annualized hospitalization rate for COVID waiver patients initiating HFCWO therapy. The baseline value is the hospitalization rate for the prior 12-month period. Data sourced from RespirTech Outcomes Registry.

qualify under CMS' medical polices for such devices [36] (referred to as "COVID waiver" in this paper). The intent was to make access to therapy less onerous during a time when clinic access is extraordinarily difficult. At the time of this writing (February 2021), the temporary changes are set to last until the PHE expires on April 20, 2021, but the PHE may be extended.[37]

Significant changes in prescribing may be seen for patients who have a preexisting respiratory disease. Figure 1 shows a steep drop in bronchiectasis prescriptions, perhaps reflecting reluctance on the part of physicians to subject patients to a High Resolution CT scan, which is normally required for a definitive diagnosis of bronchiectasis. In addition, concerns about visiting a clinic may have inhibited a number of patients from seeking medical assistance that is not immediately urgent. Many cases of bronchiectasis in the U.S. are found among patients with already-diagnosed chronic obstructive pulmonary disease; under the COVID waiver, patients with airway clearance issues may receive HFCWO directly, without the need for an additional diagnostic procedure. It seems clear that some patients who might have otherwise received a diagnosis of bronchiectasis found coverage in 2020 under the diagnosis of COPD. In fact, we do see a large increase in COPD diagnoses in 2020, an unknown number of which might also have bronchiectasis. We will now turn to the question of whether patients from this expanded population will actually benefit from HFCWO therapy.

Outcomes for COVID Waiver Patients

While the pandemic is certainly unwelcome, it does create a unique opportunity to evaluate the outcomes of HFCWO in otherwise non-covered patients. By providing vest therapy to a large number of new patients with respiratory illness, it is possible to track their outcomes and demonstrate that this form of therapy provides positive patient-reported benefits to otherwise non-covered patients. The RespirTech Outcomes Registry has followed COVID waiver patients since the beginning of the pandemic, finding among them a large number of patients with respiratory diseases, including COPD, that are not typically covered under CMS guidelines.

In fact, COPD makes up the largest proportion of diagnoses covered under the COVID waiver (Figure 3). A few bronchiectasis patients may be seen here, but the rest comprise a number of diagnoses that are not commonly covered: chronic bronchitis, emphysema, pneumonia, pulmonary fibrosis, and simple cough. This situation creates the unusual opportunity to assess the effectiveness of HFCWO therapy for this population. Two groups, in particular, experienced substantial growth in 2020: during that year, the number of chronic bronchitis prescriptions grew by 6.6 times, and COPD prescriptions grew by 9.9 times, compared to average of the prior five years.

There is reason to believe that vest therapy would be effective for these groups, particularly COPD patients who demonstrate a need for airway clearance therapy. The use of HFCWO for COPD has been the topic of some research.[38-40] A 2011 study compared the use of HFCWO to conventional treatment for patients with COPD.[41] The results showed the vest therapy device was well tolerated with good reported compliance, reduced symptoms and improved quality of life. More recently, results from RespirTech's registry of self-reported outcomes data found 54.4% reduction in the annualized hospitalization rate for respiratory causes, and a 51.9% increase in patients with favorable rating for "ability to clear lungs".[9] This last study was limited to 219 patients, while new patients covered by the COVID waiver represent the chance to greatly expand this patient count.

The RespirTech Outcomes Registry has been described in detail elsewhere,[32] but briefly it consists of self-reported outcomes by patients in certain diagnostic categories: originally bronchiectasis, but since enlarged to include COPD, Veterans Administration (VA) patients, and in 2020, COVID waiver. Once a new patient receives and is trained on their HFCWO device, they are enrolled in RespirTech's Outcomes Registry. At periodic intervals for the subsequent two years, they receive a phone-based survey asking about their hospitalization, antibiotic use, and several quality of life questions. Results are then compared to the prior 12-month period (hospitalization) or to the patient responses when they first receive the device (all other questions). The data shown in Figure 4 represent all COVID waiver patients from February through December 2020 (N=812, mean age 72.8 ±10.3).[1] After six months of HFCWO therapy, the hospitalization rate dropped by 70% (Figure 4), while the proportion those reporting their "ability to clear lungs" as good-excellent improved 51% and those reporting their "overall respiratory health" as good-excellent improved 41%. Finally, a point estimate of antibiotic use dropped 15%.

Conclusion

It is clear that HFCWO usage patterns have changed in recent years. No longer just for cystic fibrosis and neuromuscular disease, the field has seen the rapid adoption of vest therapy for non-CF bronchiectasis, with a number of other specific disease states growing at a more modest rate. The emergence of COVID-19 has changed these practice patterns in a single year, with the COVID waiver allowing physicians the flexibility to determine the medical need for respiratory devices like HFCWO, resulting in patients who might not otherwise be considered for HFCWO being evaluated and prescribed therapy. Our data shows that the majority of these patients had diagnoses that are not normally covered by CMS, primarily COPD. While past evidence suggests that HFCWO is beneficial for symptomatic COPD patients, the preliminary analysis of our outcomes data for COVID waiver patients implies a robust response to vest therapy.

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where patients present with shortness of breath, the pandemic has compromised physicians' options in treating their patients. Nebulizers are being underused due to concerns that they facilitate the spreading of patient-generated viral particles into the environment.

AerosoLess Medical is producing the SafetyNeb, an aerosol delivery device fitted with water-resistant viral filters over its vent holes. These highly effective viral filters are designed to prevent both patient exhaled pathogens and fugitive emissions from entering into the environment and thereby endangering Healthcare Workers. In addition to the viral filters, the SafetyNeb uses patent-pending technology to create a CPAP-like tight seal with the patient's face. Unlike other devices which were designed primarily for optimizing the delivery of aerosolized medications, the AerosoLess SafetyNeb was designed from the very beginning with the utmost focus on protecting the safety of healthcare personnel without compromising medication delivery. The unique design of the SafetyNeb drastically reduces the ability of pathogens contained in patients' exhaled breath and coughs to escape into the environment.

Siemens Healthineers IL-6 Test Receives Emergency Use Authorization

The US Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for Siemens Healthineers' laboratory-based IL-6 assay to measure the presence of Interleukin-6 (IL-6) in human serum or plasma. IL-6 is an indicator of potential severe inflammatory response in patients with confirmed SARS-CoV-2 infection. This simple blood test may be used to assist in identifying a severe inflammatory immune response in patients confirmed to have COVID-19, to aid in determining the risk of needing intubation with mechanical ventilation, in conjunction with clinical findings and the results of other laboratory testing. Emergency use of this test is limited to authorized laboratories. Approximately five percent of COVID-19 patients develop a systemic dysregulated cytokine response known as cytokine storm. IL-6 is a type of cytokine (intercellular messenger molecule) that plays a central role in the immune response to infection and can evoke many different actions when it is released. It is substantially elevated in patients presenting with cytokine storm. Cytokine release is a normal part of the body's immune response when fighting off a virus. However, a severe immune response can cause overproduction of cytokines leading to potential wide-scale cellular and organ damage, and ultimately death. IL-6 levels were found to be higher in COVID-19 patients with severe disease. "The Siemens Healthineers' IL-6 assay is an important tool for the care of hospitalized COVID-19 patients. This assay expands Siemens Healthineers' already comprehensive portfolio of tests available to aid in fighting the COVID-19 pandemic," said Deepak Nath, PhD, President of Laboratory Diagnostics, Siemens Healthineers. Siemens Healthineers' IL-6 assay is currently available across the US on the ADVIA Centaur Immunoassay Systems, the largest installed base of instruments in the US, with a time-to-result of 18 minutes. The IL-6 assay is also available outside the US with the CE mark on the ADVIA Centaur Systems, Atellica IM Analyzer and IMMULITE Systems. Siemens Healthineers has distinguished itself as a provider of quality assays to aid the COVID-19 pandemic. In addition to antibody, antigen, and molecular SARS-CoV-2 tests, Siemens Healthineers offers a broad diagnostics portfolio to aid in the prognosis, treatment and follow-up of COVID-19 patients. The company's broad and

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Validation of a Novel Compact System for the Measurement of Lung Volumes

Summary of a paper published in CHEST

Abstract

In a groundbreaking, multi-center study just published in CHEST,[1] lung volumes measured with the MiniBox+™ were shown to be equivalent to body plethysmography (body box) in both healthy participants as well as those with lung disease. MiniBox+ lung volumes were more reproducible and correlated better with body plethysmography than the other office-based techniques.

Study Overview

A systematic, multi-center study compared total lung capacity (TLC) measured by body plethysmography (TLC_{Pleth}) with TLC measured by the MiniBox+ (TLC_{MB}). Collaborating researchers from 5 medical centers in the US and Europe contributed comparative data from 266 participants — 197 with obstructive disorders, 33 with restrictive disorders, and 36 healthy.

For robustness, several body plethysmograph devices were used in the study, manufactured by Medisoft, MGC Diagnostics, and Vyaire. All measurements conformed with ATS/ERS guidelines.

Results

The normalized standard deviation (NSD) between the TLC_{Pleth} and TLC_{MB} was 7.0% in healthy participants. For patients with obstructive disease, the NSD ranged from 7.7 to 9.1% depending on disease severity. For patients with restrictive disease, the overall NSD was 10.3%. In all groups there was no significant difference between the measurements taken by the MiniBox+ vs the body box.

In 14 cases in this study, the patient's final clinical diagnosis differed by device. In 10 of these cases, the final diagnosis correlated better with the physiologic pattern characterized by the TLC_{MB} than by TLC_{Pleth}.

Current methods for measuring lung volumes

Five methods are currently recommended by ATS/ERS for measuring lung volumes: whole body plethysmography, multi-breath helium dilution (He), nitrogen wash-out (N2), computerized tomography (CT), and chest radiography (CXR). Each of these techniques has pros and cons to the clinical user and the patient. For example, CT and CXR are not utilized in PFT labs and incur radiation exposure, while He and N2 may underestimate lung volumes, as gas may not fully distribute to poorly ventilated areas.

Why plethysmography is the gold standard

The choice of technique depends on availability, cost, convenience and accuracy. Each of the existing methods is capital intensive and technically challenging, requiring a skilled technician for calibration, operation and maintenance. Of these however, body plethysmography requires less time to demonstrate repeatability between measurements, especially in patients with obstructive airway diseases.

MiniBox+ lung volumes correlate better with the body box than other office-based methods

In this study, TLC measurements taken with the MiniBox+ correlated more favorably with the body box than measurements taken with helium dilution and nitrogen washout in other comparative studies.

Mean Normalized Standard Difference (NSD)		
	%	# published studies
Helium Dilution	15.3	6
Nitrogen washout	14.2	1
Computerized Tomography	13.1	4
MiniBox+	8.9	1

Table 1. Mean Normalized Standard Difference (NSD) for TLC data when compared with body plethysmography

Why the MiniBox+ outdoes the body box on a practical level

The body box can be intimidating and uncomfortable for the patient enclosed within it. Testing requires complex respiratory maneuvers, which can be particularly exhausting for obstructed patients. In contrast, the MiniBox+ measures lung volumes using normal breathing. In addition, as a desktop device, the MiniBox+ is less costly, mobile, and simpler to operate and disinfect when compared to other lung volume measurement systems.

Conclusions

In light of the data in the present study, the authors state that the MiniBox+ should be considered equivalent to plethysmography for measurement of lung volumes in clinical practice.

For more information about the MiniBox+ please visit www.pulm-one.com or email rt@pulm-one.com.

Reference

1 Berger KI, Adam O, Kaminsky DA, Shiner RJ et al. Validation of a novel compact system for the measurement of lung volumes. In press. DOI:https://doi.org/10.1016/j.chest.2021.01.052.

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PFT Outside The Box

Benefits to Patients Being Initiated on NIPPV Using GO2VENT

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Dr. Hugo Espejo, Deputy Director of Critical Care Medicine for Hospital del IESS Quito Sur about using the GO_2VENT.

On December 5, 2017**,** the Ecuadorian government proudly opened its newest hospital. **Hospital General del Sur de Quito del Instituto Ecuatoriano de Seguridad Social (IESS)** began full operation in 2019 as a 375-bed secondary care and referral hospital offering 40 different specialties in addition to full emergency medical care. Dr. Hugo Espejo is the Deputy Director of Critical Care Medicine for the hospital.

On February 29, 2020, Ecuador's COVID-19 pandemic began. Despite the government's best efforts to limit and contain the virus, case numbers rapidly rose. The government was prepared to the best of its ability and expected an eight-fold increase in fatalities within the first two weeks of the pandemic. No one expected that they would experience unprecedented demand for mechanical ventilation support and that they would suffer a massive shortfall in mechanical ventilator resources.

Dr. Espejo and his skilled team utilized conventional therapies to manage the rapid influx of COVID-19 patients but many deteriorated, requiring more aggressive treatment. High flow oxygen and proning became common but many patients, nonetheless, deteriorated to the point that intubation and ventilatory support became necessary. Ventilator resources were quickly depleted with no hope of getting additional units, and the medical team was faced with coming up with therapies that could offer some hope of saving lives.

The Hospital del IESS Quito Sur had received GO_2VENTs (manufactured by VORTRAN Medical) in preparation for the possibility of ventilator shortages and began to utilize them to provide ventilator support. As soon as it was shown that mechanical ventilation in COVID-19 patients led to a much higher failure/fatality rate, the new recommendation was to avoid it, if possible. Faced with these challenges, Dr. Espejo and his team developed a patient care protocol to triage patients and initiate an innovative treatment.

VORTRAN Medical: Dr. Espejo, at what point did you come to the realization that conventional ventilation strategies were failing? Once you reached this point, what actions did you initiate to support the rapid influx of patients needing respiratory support?
Dr. Espejo: We developed a screening protocol that allowed clinicians to triage the patient to the level of support and care required. This protocol utilized initial physical examination, oxygen saturation/oxygen requirements, and arterial blood gases to categorize the patient into a treatment limb. Using the HACOR scoring and P/F ratio, we were able to direct patients to the variety of care options available.

VORTRAN Medical: Can you explain HACOR scoring?
Dr. Espejo: The article that introduced this concept was published in the Annals of Intensive Care (Duan, J, Wang, S, Liu, P et al. Early prediction of noninvasive ventilation failure in COPD patients: derivation, internal validation, and external validation of a simple risk score. Ann. Intensive Care 9, 108 (2019). https://doi.org/10.1186/s13613-019-0585-9). This scoring system uses heart rate, acidosis, consciousness (Glasgow Coma Score), oxygenation, and respiratory rate to provide an indicator of the likelihood of success or failure following the implementation of NIPPV. Patients scoring >5 had a high likelihood of failure of NIPPV and provided an early indicator of needing intubation and mechanical ventilation.

VORTRAN Medical: Using the HACOR and P/F ratio, you and your team directed patients to an NIPPV arm. What did you use to provide NIPPV?
Dr. Espejo: We utilized the GO_2VENT to provide NIPPV while the patient was proned, to avoid intubation.

VORTRAN Medical: Using the GO_2VENT, how did you determine which pressure settings were optimal?
Dr. Espejo: Between 5 to 8 mm-HG**.** Looking at the protocol, the pressures were titrated upward until normalized saturation was achieved and the HACOR score was <5.

VORTRAN Medical: What interface was utilized to deliver the NIPPV using the GO_2VENT?
Dr. Espejo: We utilized a non-vented clear cushioned face mask held in place with straps used to stabilize masks during mask anaesthesia. A non-vented CPAP mask with headgear is also an option.

VORTRAN Medical: How did you determine when a patient should be weaned from the GO_2VENT (NIPPV)?
Dr. Espejo: Criteria for equipment withdrawal:
- ***Clinical Condition:*** constant and stable, no tachypnea, no tachycardia, saturation greater than 90%, neurological integrity.
- ***Gasometry parameters:*** P/F greater than 200.

The GO_2VENT is then set to 50% FiO_2. Only in this way can we

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

change to another oxygen therapy device such as the Venturi system.

VORTRAN Medical: What clinical success came from this protocol that surprised you?
Dr. Espejo: Patients that were initiated on NIPPV using the GO2VENT and having respiratory alkalosis had the shortest stay once weaned off versus patients with normal or acidotic pH (9-day average vs >19 day average).

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differentiated menu includes hematology, coagulation, cardiac, respiratory, inflammation and infectious disease panels. Blood gas and imaging solutions from Siemens Healthineers deliver actionable results that aid clinicians in caring for COVID-19 patients.

Capsule and Retia Medical Collaborate on Argos Cardiac Monitor

Retia Medical is the first company to utilize Capsule Technologies' new Device Driver Interface (DDI) development strategy to integrate its Argos Cardiac Monitor, the companies announced. Capsule's new DDI development strategy uses the Integrating the Healthcare Enterprise-Patient Care Device (IHE-PCD) framework to speed device connectivity to other systems, improve clinician workflow efficiency, and to protect patient safety through rapid and accurate identification. IHE is a consortium of healthcare and industry experts focused on improving healthcare information sharing. The IHE framework fills the gaps between device communication standards such as HL7 without site-specific interface development so hospitals can more easily connect devices to their IT networks and capture data that drives safe and effective clinical decisions. "Medical devices, such as Retia Medical's Argos Cardiac Monitor, are indispensable for delivering safe and high-quality patient care," said John McHutcheon, vice president of operations at Capsule Technologies. "Yet effectively capturing and protecting the data generated from these life-saving devices, while enabling them to access EHR data, can be complicated. That is why we are very pleased to collaborate with Retia Medical on this first utilization of our Device Driver Interface that helps speed the development of highly interoperable, easily connected medical devices using an industry-recognized standard." By leveraging the new DDI development strategy, Retia Medical expedited the integration of its updated Argos Cardiac Monitor, saving engineering time and improving customer satisfaction. Using this strategy also enables the Argos Cardiac Monitor to take advantage of Capsule Technologies' Rapid Patient Identification (RPI) capability, which empowers clinicians at the point of care to more rapidly send patient demographic information to the device for faster identification confirmation, streamlining workflows, and promoting safer care. Likewise, the agreement with Capsule also supports Retia Medical's ability to develop its device output following Rosetta Terminology Mapping (RTM) and to receive patient demographics on its device using an IHE Patient Demographics Query (PDQ) request. Incorporating RTM and IHE profiles improves the interoperability of Retia Medical's device across a variety of different IT systems while also enabling clinicians to identify patients accurately and easily to protect their safety. "Our vision is to help prevent cardiovascular and other major complications from surgery and critical care by providing consistently accurate hemodynamic data to guide diagnosis and therapy. A key component of this approach is to help implement physiology-based, data-driven protocols through streamlined connectivity to the electronic health record (EHR) using modern communication protocols," said Marc Zemel, co-founder and CEO of Retia Medical. "We are pleased to collaborate with Capsule to make this vision a reality."

Pfizer to Complete Supply of COVID-19 Vaccines to EU by September

The distribution of an initial 200 million doses of the COVID-19 vaccine developed by Pfizer and BioNTech across the European
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Additional Work of Breathing From Trigger Errors in Mechanically Ventilated Children

Robert G T Blokpoel[1*] , Alette A Koopman[1], Jefta van Dijk[1] and Martin C J Kneyber[1,2]

Background

Mechanical ventilation (MV) is one of the most common practiced interventions in the paediatric intensive care unit (PICU).[1] In the absence of severe lung injury, there are several advantages associated with maintaining spontaneous breathing during MV including amongst others a lower need for sedation and a more even tidal volume (Vt) distribution towards the well-perfused lung-dependent zones thereby reducing shunting and lower lung inflammation.[2-5]

When allowing for spontaneous breathing, it is imperative to achieve good interaction between patient demand and ventilator delivery. Patient-ventilator asynchrony (PVA) arises when the patient and ventilator are out-of-sync at any time point throughout the breathing cycle.[6,7] It may lead to an increased use of sedatives and neuromuscular blocking agents, sleep disturbance, ventilator induced diaphragmatic dysfunction, and dynamic hyperinflation and volutrauma resulting from double triggering with subsequent breath stacking.[8-13] These detrimental effects may explain association between PVA and increased mortality and morbidity, albeit that a direct causative relationship has yet to be demonstrated.[9,14,15]

It has also been proposed that patients may experience increased work-of-breathing (WOB) related to PVA (WOB_{PVA}), especially when there are trigger errors.[16,17] This increased work comes from excessive pleural pressure swings (ΔP_{pl}) generated during an inspiratory effort with subsequent additional lung stress, a phenomenon known as self-inflicted lung injury.[18] Two small studies in adults have shown that PVA can contribute up to 13-21% of the total WOB.[19,20] Due to different respiratory mechanics these findings cannot be extrapolated to paediatrics. To date, it has not been studied if PVA in children is associated with increased WOB. Traditionally, total WOB is calculated using the Campbell diagram.[21] However, with ineffective triggering the flow generated by a patient is by definition insufficient to trigger the ventilator. Hence, the Campbell diagram cannot be constructed. The Pressure-time product (PTP) may be used as WOB surrogate because it does not require any volume measurements but instead makes use of respiratory rate and duration of respiratory muscle contraction[21-23] (Figure 1).

Previously, we reported that PVA is common in ventilated children, with ineffective triggering being the predominant type of PVA.[24] The objective of this exploratory study therefore was to calculate the added WOB_{PVA} caused by trigger errors in relation to total WOB by calculating the PTP, and to study the peak-to-through oesophageal pressure swing during ineffective and delayed triggering events.

Methods

Study population

This study was performed at the PICU of the Beatrix Children's Hospital, University Medical Center Groningen. Patients ventilated >24 h and <18 years old able to trigger the ventilator were studied. Patients with neuromuscular disorders, premature birth with gestational age corrected for post-conceptional age less than 40 weeks, severe traumatic brain injury (i.e. Glasgow Coma Scale <8), congenital or acquired damage to the phrenic nerve, congenital or acquired paralysis of the diaphragm, use of neuromuscular blockade, chronic lung disease (i.e. tracheostomy ventilation) and severe pulmonary hypertension were excluded. The Institutional Review Board waived the need for consent. Patients remained subjected to standard-of-care during the study (see Additional file 1).

Data collection and variables

Patient baseline characteristics included age, gender, weight, admission diagnosis. Ventilator settings including mode, set positive end-expiratory pressure (PEEP) pressure above PEEP (PAP), mean airway pressure (Pmean), pressure support (PS), expiratory tidal volume (Vte ml/ kg), mandatory breath rate, inspiratory time and fraction of inspired oxygen (FiO_2) were recorded before start of the measurements. Clinical data included prior use of neuromuscular blockade (NMB), amount of analgesia-sedation in the 4 h preceding the recording, Comfort B score as measure of patient comfort, endotracheal tube (ETT) diameter and percentage of ETT leakage.[25]

Data acquisition and analysis

Ventilator settings were not changed during the study period unless the clinical condition of the patient dictated otherwise. Patients underwent a 5-min recording of the ventilator flow-time, pressure-time and oesophageal pressure-time scalar. Data were acquired through the Ventilator Open XML Protocol (VOXP) interface at a sampling rate of 100 Hz (Carefusion, Yorba

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Linda, CA, USA). All data was stored for offline analysis and subsequently processed using Polybench (Applied Biosignals GmbH, Weener, Germany).

For this study, we focused on ineffective and delayed triggering. First, we used three previously published studies to define the normal response time and trigger delay.[26-28] A normal response time was considered between 0 and 70 ms (ms) and a trigger delay was defined by a response time between 70 and 150 ms. Ineffective triggering (IT) was defined by the absence in ventilator pressurisation following a patient effort. Then, we identified IT and trigger delay in the recorded ventilator scalars. This is visualised by a simultaneous negative deflection in the Pressure-time scalar, increase in the flow-time scalar and a negative deflection in the oesophageal-time scalar. We then calculated the trigger error index (TE-index) by the number of trigger error events (TEE) divided by the total number of breaths plus TEE times 100. Severe asynchrony was defined by TE-index > 10% and by TE-index > 75th percentile as proposed by others (i.e. TE-index > 22.5%).[14,29]

PTP was calculated by integrating the area under the oesophageal pressure versus time scalar from the beginning until the end of inspiration.[23,30] For each patient median PTP for effective and ineffective breaths were calculated. We determined for the entire 5-min recording of all effective ($PTP_{CUMULATIVE\_BREATHS}$) and ineffective breaths ($PTP_{CUMULATIVE\_PVA}$). PTP_{TOTAL} was defined as the sum of $PTP_{CUMULATIVE\_BREATH}$ and $PTP_{CUMULATIVE\_PVA}$. The oesophageal peak-to-trough (ΔP_{oes}) was calculated by subtracting the end-inspiratory P_{oes} from the P_{oes} at the onset of inspiration.

We expected that patients with a lower number of ineffective triggering events would have lower PTP and ΔP_{oes}. To compare the PTP between ineffective and effective breaths in each individual patient, the ratio of PTP_{PVA} over PTP_{BREATH} (PTP_{PVA}/PTP_{BREATH}) and ΔPoes-ineffective over ΔPoes-effective (ΔPoes-ineffective/ΔPoes-effective) was calculated.

Statistical analysis

The Shapiro-Wilk test was used to test for normal distribution of the data. Normally distributed continuous data are presented as mean and standard deviation (SD). When the assumption of normality was not met, data are presented as median and 25-75 interquartile range (IQR). Categorical data are presented as percentage (%) of total. When comparisons between groups were made, continuous data were analysed using the Mann-Whitney *U* test. Spearman's rank correlation coefficient was used to measure dependence between two variables. All statistical analyses were performed using SPSS version 24 (IBM, Armonk, USA). *P* values below 0.05 were considered statistically significant.

Results

In total 6194 breaths from 31 randomly selected patients (17 boys, 14 girls) were analysed. Median breaths during the 5-min recording was 180 [147; 249]. The median age was 3.0 [1.9; 18.5] months and median weight 5.6 [4.4; 9.8] kg. Median time patients were ventilated before data acquisition was 2.9 [1.9; 5.2] days. Median duration of MV was 5.9 [4.4; 9.5] days. NMB was used in 19 (61%) patients for a median duration of 31.8 [20.3; 51.2] hours. At the moment of data acquisition, NMB was stopped for a median duration of 25 [17.5; 48.9] hours. Twenty-three (74%) patients were admitted with primary respiratory failure, five

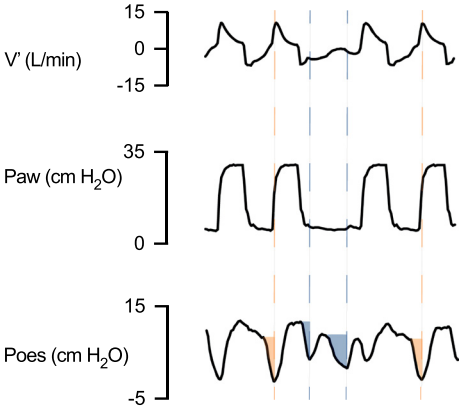

Fig. 1 Example of ineffective and effective triggering in a mechanical ventilated child. Recording of airway pressure (Paw), oesophageal pressure (Poes) and ventilator flow (V') versus time. Orange interrupted lines are showing effective triggering with in the orange shaded area an oesophageal pressure swing. Blue interrupted lines are showing ineffective triggering. Both ineffective errors are showing a different oesophageal pressure swing (blue area) with a concomitant different pressure–time–product (PTP) calculation

(16%) after cardiac surgery, two (7%) for septic shock and one (3%) patient was admitted after trauma. Cuffed ETTs were used in 23 (74%) patients. Twenty-four (77%) patients were ventilated using pressure controlled (PC) / assist control (AC), 6 (19%) were supported with continuous positive airway pressure (CPAP) plus pressure support (PS) and one patient was on pressure-regulated volume control (PRVC/SIMV) + PS. During the recordings, median Vte was 6.9 [6.2; 7.6] mL/kg actual bodyweight, median end-tidal CO_2 6.42 [5.81; 7.18] kPa and median Comfort B score 12 [10; 12] (Table 1).

Nine-hundred-and-fifty-nine trigger errors in 28 (90%) patients were identified, yielding a median TE-index of 9.7% [1.3; 22.5]. Patients had significantly lower TE-index when they were ventilated with a higher set inspiratory pressure ($r = 0.537$, $p = 0.006$), higher measured PIP ($r = 0.644$, $p < 0.001$) and higher Pmean ($r = 0.435$, $p = 0.015$). Patients had significantly lower TE-index if they had higher spontaneous breath rate ($r = -0.443$, $p = 0.13$) and higher PTP_{BREATH} ($r = -0.365$, $p = 0.044$).

The median $PTP_{CUMULATIVE\_PVA}$ was 4.7 cm H_2O*s [0.5; 17.7]. The percentage of PTP_{TOTAL} caused by trigger errors was 11.5% [0.5; 34.3]. This percentage was significantly greater when patients were ventilated with higher set inspiratory pressures ($r = 0.479$, $p = 0.015$), PIP ($r = 0.587$, $p = 0.001$), Pmean ($r = 0.383$, $p = 0.033$) and higher mandatory breath rate ($r = 0.667$, $p < 0.001$), especially when there spontaneous breath rate was significantly lower ($r = -0.357$, $p = 0.049$).

PTP_{TOTAL} significantly increased if patients were breathing more spontaneously ($r = 0.489$, $p = 0.005$) and mandatory breath rate was reduced ($r = -0.394$, $p = 0.029$). Patients able to generate a higher PTP for a single effective breath ($r = -0.384$, $p = 0.033$) and had higher levels of PTP_{TOTAL} ($r = -0.372$, $p = 0.039$) spent less time on the ventilator.

Median ΔP_{oes} was 2.93 cm H_2O [1.18; 5.56] when the triggering was effective and 1.94 cm H_2O [0.69; 3.03] ($p = 0.06$) when there was a trigger error. This resulted in a median $\Delta P_{oes\text{-}ineffective}$ / $\Delta P_{oes\text{-}effective}$ of 0.79 [0.32; 1.03]. The median work patients generated during effective triggering (PTP_{BREATH}) was 0.41 cm H_2O*s [0.14;

Table 1 Baseline demographics and ventilator settings

Variable	
N	31
Age (months)	3.0 [1.9; 18.5]
Weight (kg)	5.6 [4.4; 9.8]
Pulmonary diagnosis (n)	23
Surgical diagnosis (n)	5
Days on MV prior to study	2.9 [1.9; 5.2]
Duration of MV (days)	4.8 [3.6; 7.4]
Days on PICU	5.9 [4.4; 9.5]
NMB (h)	31.8 [20.3; 51.2]
NMB stopped prior to study (h)	25 [17.5; 48.9]
Cuffed endotracheal tube (%)	74
Comfort B score	12 [10; 12]
PAP (cm H_2O)	16 [13; 20]
PEEP (cm H_2O)	6 [5; 6]
Inspiration time (s)	0.6 [0.5; 0.68]
Set frequency (/min)	25 [20; 30]
Endtidal CO_2 (kPa)	6.42 [5.81; 7.18]
Expiratory tidal volume (ml/kg)	6.9 [6.2; 7.6]

MV mechanical ventilation, *PICU* paediatric intensive care unit, *NMB* neuromuscular blockade, *PAP* pressure above PEEP, *PEEP* positive end expiratory pressure

1.01]. This was significantly higher compared with the work generated during ineffective triggering PTP_{PVA} (0.23 cm H_2O*s [0.09; 0.53], $p = 0.03$). This resulted in a median $PTP_{PVA}/PTP_{BREATH\ of}$ 0.69 [0.17; 1.12]. We found that patients with a higher $\Delta P_{oes\text{-}ineffective}/\Delta P_{oes\text{-}effective}$ had a higher ITI ($r = 0.512$, $p = 0.003$) if they did not have spontaneous breaths outside the mandatory breath rate. ITI was significantly lower when patients had a total breath rate greater than the mandatory breath rate ($\Delta P_{oes\text{-}ineffective}/\Delta P_{oes\text{-}effective}$ $r = -0.577$, $p = 0.001$). Similar observations were made for PTP_{PVA}/ PTP_{BREATH} ($r = 0.541$, [$p = 0.002$] and $r = -0.630$ [$p < 0.001$] respectively).

Subgroup analysis; severe asynchrony

Analyzing the data set according to a paediatric and adult definition for severe asynchrony (i.e. TE-index > 75th percentile and > 10%) did not yield different results regarding patient discomfort, duration of MV or PICU stay.[9,30] In addition, a subgroup analysis was made for patients who spend the highest amount of work-of-breathing on ineffective triggering (i.e. $PTP_{CUMULATIVE\_PVA}$ > 75th percentile, > 17.7 cm H_2O*s) (Fig. 2). Subgroup analyses are shown in the online data supplement.

Discussion

To our best knowledge this is the first study investigating the physiological effects of trigger errors in a heterogeneous group of ventilated children. Our main finding was that the additional work-of-breathing caused by trigger errors showed great variability among patients. Overall we found that the more asynchronous breaths were present the higher the work-of-breathing of these breaths. Our data also suggested that preserved respiratory muscle strength and higher spontaneous breath rate led to a lower amount of trigger errors. Yet, in our study PVA was not associated with prolonged duration of MV or PICU stay.

MV is initiated to reduce the respiratory muscle workload until the clinical condition of the patient has at least partially improved. However, there is limited data on acceptable levels of PTP in mechanically ventilated children. In healthy adults, PTP varies between 50 and 150 cm H_2O*s/min.[21] Khemani et al. reported median PTP values of 41 cmH_2O*s/min [9; 82] during+ 10 cmH_2O pressure support ventilation, 101 cmH_2O*s/ min [61; 165] on CPAP+ 5 cmH_2O and 135 cmH_2O*s/min [84; 220] 5 min post-extubation without any positive pressure support in 409 children undergoing a spontaneous breathing trial (SBT).[31] Others reported PTP 23 cmH_2O*s/min [5; 89] before and 83 cmH_2O*s/ min [24; 110] during the SBT.[30] The PTP values observed in our study were lower than those previous reports. This might be explained by the fact that we also included patients early in the course of MV and not specifically during the weaning phase, thus our results may have been affected by the degree of respiratory muscle strength. We observed that that the additional energy expenditure from trigger errors was 11.5% [0.5; 34.3] and $PTP_{CUMULATIVE\ PVA}$ of 4.7 cm H_2O*s [0.5; 17.7]) during the 5-min recording. Taking the previously reported PTP values into consideration, the added work from trigger errors in our study may thus be interpreted as negligible and of little clinical importance.[30,31] Nonetheless, we did find that the percentage of the additional work caused by trigger errors could reach up to 34-42% of energy expenditure albeit that the PTP values still remained low. Although this high percentage of wasted energy might be interpreted as unwanted, we could not demonstrate an association with adverse patient outcome.

There is also very little data on ΔP_{oes} in mechanically ventilated children. In our study ΔP_{oes} during trigger errors for the entire population and for the patients with severe PVA were below values Mortamet et al. and Rubin et al. described in paediatric population receiving MV.[30,32] Because the ΔP_{oes} for trigger errors were below pleural pressure swings during conventional MV it may be supposed these pleural pressure swings did not contributed to patient self-inflicted lung injury. During the first 2 years of life there is a substantial reduction in chest wall compliance.[33] Hence, the question remains if paediatric patients can generate large pleural pressure swings, because of their compliant chest wall.

In our study, $PTP_{CUMULATIVE\ PVA}$ increased with more asynchrony. In addition, with an increase in asynchrony we found that also PTP and ΔP_{oes} for an individual trigger error increased. These observations may have clinical implications. If trigger errors are merely detected using flow- and pressure-time tracings and not by measuring true patient effort using oesophageal pressure tracings, differentiation between "acceptable" and "harmful" trigger errors is not possible. This differentiation might be important, because the variability in PTP and ΔP_{oes} for an individual ineffective breath could partially explain that PVA has different effects on patient outcome. To illustrate, de Wit et al. and Blanch et al. described that PVA in the first 24 h and throughout MV was associated with prolonged ventilation time and mortality.[14,15] In contrast, PVA during the weaning phase, using the same cut of values, was not associated with adverse clinical outcome.[34] It may be surmised that during the acute phase of disease causes patients generate more work and thus potentially injurious, larger pressure swings because respiratory system compliance (Crs) and respiratory muscle strength is reduced. Experimental work showed high pulmonary pressures swings generated by spontaneous breathing efforts worsened lung injury despite limiting plateau pressures.[35] When the clinical condition of the patient improves, the patient needs and is able to generate lower work to trigger the ventilator.

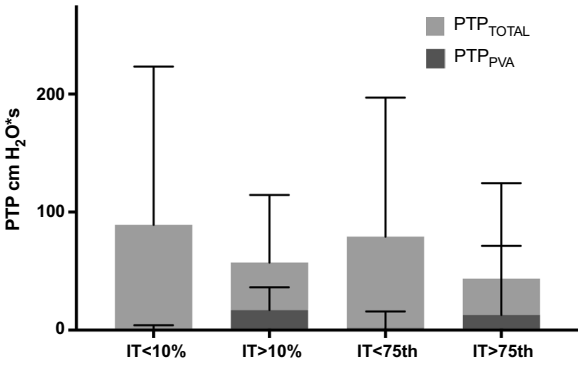

Fig. 2 Distribution of percentage PTP_{TOTAL} caused by trigger errors in patients with severe asynchrony. Distribution of percentage PTP_{TOTAL} caused by trigger errors in patients with severe asynchrony. Severe asynchrony was defined as an ineffective triggering index (IT) > 10% and > 75th percentile

Some limitations of our study must be addressed. First, our data represents a single-center study, limiting generalizability. Second, in this study we found a lower TE-index than we previously did.[24] This is probably due to a difference in methodology to detect PVA. In our previous study we detected PVA using ventilator scalars without oesophageal pressure tracings, thereby probably overestimating the actual prevalence of PVA. Also, in the present study, patients were ventilated with a different ventilator brand with potentially differences in triggering response time.[26] Lastly, patients were randomly selected (as we had previously done), thereby potentially under- or overestimating TE. Third, we performed 5-min recordings. Because the occurrence of PVA is variable during the course of mechanical ventilation and even during the day we may have over- or underestimated the prevalence of trigger errors.[15] Last, our study mainly included patients younger than 1 year of age with relative higher respiratory rates, limiting extrapolation of our findings to older children and adults.

Conclusion

The additional work-of-breathing caused by trigger errors in ventilated children can take up to 30-40% of the total work-of-breathing. Trigger errors were less common in patients breathing spontaneously and those able to generate higher PTP and pressure swings.

Supplementary information

Supplementary information accompanies this paper at https://doi. org/10.1186/s12931-020-01561-3.

Additional file 1. Data supplement to; Additional work of breathing from trigger errors in mechanically ventilated children. Data containing the local ventilation guideline. Subgroup analysis of patients with an TE-index >75th percentile and PTPCUMULATIVE_PVA >75th percentile.

Abbreviations

AC: Assist control; CPAP: Continuous positive airway pressure; Crs: Respiratory system compliance; ETT: Endotracheal tube; IT: Ineffective triggering; ITE: Ineffective triggering events; IT-index: Ineffective triggering index; IQR: Interquartile range; MV: Mechanical ventilation; NMB: Neuromuscular blockade; PAP: Pressure above positive-end-expiratory pressure; PC: Pressure controlled; PEEP: Positive end-expiratory pressure; Pmean: Mean airway pressure; PICU: Paediatric intensive care unit; P_{oes}: Oesophageal pressure; P_{pl}: Pleural pressure; PRVC: Pressure-regulated volume control; PS: Pressure support; PTP: Pressure-time product; PTP_{BREATH}: Pressure-time product of an individual effective breath; $PTP_{CUMULATIVE\_BREATHS}$: Pressure-time product of all effective breaths; $PTP_{CUMULATIVE\_PVA}$: Pressure-time product of all ineffective breaths; PTP_{TOTAL}: Total Pressure-time product; PTP_{PVA}: Pressure-time product of an individual ineffective breath; PVA: Patient-ventilator asynchrony; SBT: Spontaneous breathing trial; SD: Standard deviation; TE-index: Trigger error index; TEE: Trigger error events; VOXP: Ventilator open xml protocol; Vt: Tidal volume; Vte: Expiratory tidal volume; WOB: Work-of-breathing; WOB_{PVA}: Work-of-breathing related to Patient-ventilator asynchrony.

Authors' contributions

AAK and RGTB analysed the data. RGTB and JvD collected the data. RGTB drafted the manuscript. MK supervised the study and is responsible for the final version of the manuscript. All authors read and approved the final manuscript.

Availability of data and materials

The datasets analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The Institutional Review Board, University Medical Center Groningen Medical Ethics Review Committee, approved the study and waived the need for informed consent.

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News…continued from page 68
Union will be completed by September, a spokesman for the EU Commission said. The protracted timetable, which was previously unknown, confirms that the bloc, with a population of 450 million, will need vaccines from other suppliers to speed up inoculations against the coronavirus. Most EU countries began inoculating healthcare workers and vulnerable people on Sunday with the Pfizer vaccine, which is the only one so far authorised in the 27-nation bloc, and requires a two-dose regimen. "Distribution of the full 200 million doses is scheduled to be completed by September 2021," the spokesman said in an emailed statement. A spokesman for Pfizer declined to comment on specific schedules or whether the timeline indicated by the Commission represented a delay in planned supplies, adding: "Our timelines are aspirational and can shift based on capacity and manufacturing timelines. These considerations will in turn refine supply projections and delivery schedules". Talks are underway on delivery of a further 100 million doses which are optional under the contract sealed with the two companies, the EU spokesman said. The timetable for the additional doses is unclear. Pfizer's spokesman said the option for another 100 million doses had not been concluded. The EU spokesman said most supply contracts agreed by the EU with COVID-19 vaccine makers foresee the majority of deliveries completed by the end of next year. The EU has signed advance purchase agreements with Pfizer-BioNTech, AstraZeneca, Johnson & Johnson, Moderna, Sanofi and CureVac for a total of nearly 2 billion doses.

Complete Blood Count Scoring Can Predict COVID-19 Severity

A scoring system based on 10 parameters in a complete blood count (CBC) with differential within 3 days of hospital presentation predict those with COVID-19 who are most likely to progress to critical illness, new evidence shows. Advantages include prognosis based on a common and inexpensive clinical measure, as well as automatic generation of the score along with CBC results, note investigators in the observational study conducted throughout 11 European hospitals. "COVID-19 comes along with specific alterations in circulating blood cells that can be detected by a routine hematology analyzer, especially when that hematology analyzer is also capable to recognize activated immune cells and early circulating blood cells, such as erythroblast and immature granulocytes," senior author Andre van der Ven, MD, PhD, infectious diseases specialist and professor of international health at Radboud University Medical Center's Center for Infectious Diseases in Nijmegen, the Netherlands, said. Furthermore, van der Ven said, "these specific changes are also seen in the early course of COVID-19 disease, and more in those that will develop serious disease compared to those with mild disease." The study was published online December 21 in the journal *eLife.* The study is "almost instinctively correct. It's basically what clinicians do informally with complete blood count…looking at a combination of results to get the gestalt of what patients are going through," Samuel Reichberg, MD, PhD, associate medical director of the Northwell Health Core Laboratory in Lake Success, New York, said. "This is something that begs to be done for COVID-19. I'm surprised no one has done this before," he added. Van der Ven and colleagues created an algorithm based on 1587 CBC assays from 923 adults. They also validated the scoring system in a second cohort of 217 CBC measurements in 202 people. The findings were concordant—the score accurately predicted the need for critical care within 14 days in 70.5% of the development cohort and 72% of the validation group. The scoring system was superior to any of the 10 parameters alone. Over 14 days, the majority of those classified as noncritical (NC) within the first 3 days remained clinically stable, whereas the "clinical illness" (CI) group progressed. Clinical severity peaked on day 6. Most previous COVID-19 prognosis research was geographically limited, carried a high risk for bias and/or did not validate the findings, Van der Ven and colleagues note.

Vitamin D Fails to Help in Severe COVID-19

Vitamin D has gained immense popularity amid the coronavirus disease 2019 (COVID-19) pandemic. Several studies have tied vitamin D deficiency to the severity of COVID-19. Health experts are investigating if taking vitamin D may help protect against severe COVID-19. A team of researchers at the University of São Paulo in Brazil aimed to determine if vitamin D3 supplementation reduces length of stay in hospitalized patients with severe COVID-19. The researchers found that taking vitamin D3 was safe and effective in increasing 25-hydroxyvitamin D levels but did not reduce hospital length of stay or yield any other clinically-relevant outcomes compared with a placebo. In the current study, which appeared on the preprint server *medRxiv*, the team wanted to determine if vitamin D supplementation can reduce the hospital length of stay and improve clinical outcomes in hospitalized COVID-19 patients. The team conducted a multicenter, double-blind, randomized and placebo-controlled trial in two centers in Sao Paulo, Brazil. The trial included 240 hospitalized patients with severe COVID-19. The team randomly assigned patients to receive either a single oral dose of 200,000 IU of vitamin D3 or a placebo. The team wanted to determine the effects of vitamin D3 supplementation on the hospital length of stay, defined as hospital discharge or death. Other recognized outcomes were mortality, mechanical ventilation requirement, admission to the intensive care unit (ICU) and serum levels of 250-hydroxyvitamin D, calcium, creatinine, D-dimer and C-reactive protein. The team has found that of the 240 randomized patients, vitamin D supplementation markedly increased serum 25-hydroxyvitamin D levels compared to placebo. The supplement increased the serum vitamin D levels in 86.7 percent of the patients, compared to 11 percent in the placebo group. "There were no changes in any health-related laboratory markers following the intervention. Vitamin D3 supplementation was well tolerated, and no severe adverse events were reported throughout the trial," the researchers noted. However, vitamin D3 supplementation is ineffective in improving hospital length of stay or any other clinical outcomes among hospitalized patients with severe COVID-19. The single dose of 200,000 IU of vitamin D3 supplementation could not promote any clinically relevant effects among the study participants. "Thus, this trial does not support the use of vitamin D3 supplementation as an adjuvant treatment of patients with COVID-19," the team concluded.

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