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Respiratory Therapy^{*}

The Journal of Pulmonary Technique

CDC Says COVID, Flu Vaccines Can Be Co-Administered

When the Centers for Disease Control and Prevention (CDC) released its latest round of recommendations regarding seasonal influenza vaccines, the document contained one notable update: flu vaccines and COVID-19 vaccines can now be given simultaneously.

This change stands in marked contrast to previous recommendations, in which the CDC said that other vaccinations should not be administered within a 2-week window before or after receiving the COVID-19 vaccine. "We believe flu vaccination is very important in the context of ongoing COVID-19 activity," said Lisa A. Grohskopf, MD, MPH, medical officer, Influenza Division, CDC, in an interview. "First, as COVID-19 cases continue to increase, our healthcare system is increasingly burdened by caring for COVID-19 patients. While flu activity has been unusually low since March of 2020, we are seeing the return of other common respiratory viruses, so we anticipate that we will experience an annual

epidemic of flu this season as we do during most winters. "Substantial flu activity occurring at the same time as COVID-19 activity could overwhelm our healthcare systems," she added. Grohskopf explained that the current recommendations-the product of regular meetings of the Advisory Committee on Immunization Practices' (ACIP's) Influenza Working Group—are intended to guide clinicians in the use of influenza vaccines for the upcoming flu season, from late fall through early spring. Not surprisingly, they recommend routine annual influenza vaccination for all people who are at least 6 months of age and who do not have contraindications. Following such precautions will not only reduce the prevalence of illness caused by influenza but will also reduce symptoms that might be confused with those of COVID-19, the authors say. In addition, preventing flu and mitigating the severity of its symptoms will likely result in a reduction of outpatient visits, hospitalizations, and intensive care unit admissions, which in turn may alleviate stresses on the healthcare system



caused by COVID-19. "ACIP and CDC's universal flu vaccine recommendation has not changed," Grohskopf noted. "Everyone 6 months of age and older should get a flu vaccine every season, with rare exception. There are some groups of people who are at higher risk of developing severe flu complications, and vaccination is especially important for them. This includes adults 65 years and older, people with certain chronic health conditions (for example, asthma, diabetes, heart disease), pregnant people, and children younger than 5 years old." In addition to the timing of COVID-19 vaccinations, the recommendations have other notable updates. First, the composition of flu vaccines has been updated such that all vaccines are now quadrivalent, designed to protect against four flu viruses. Additionally, licensure for the Flucelvax Quadrivalent flu vaccine has changed: the approved age indication for the cell culture-based inactivated vaccine has been increased from age 4 years or older to age 2 years or older.

Circadian System Implicated in Asthma Worsening at Night

For hundreds of years, people have observed that asthma severity often worsens in the nighttime. One longstanding question has been to what degree the body's internal circadian clock-as opposed to behaviors, such as sleep and physical activities-contributes to worsening of asthma severity. Using two circadian protocols, investigators from Brigham and Women's Hospital and Oregon Health & Science University have pinned down the influence of the circadian system, uncovering a key role for the biological clock in asthma. Understanding the mechanisms that influence asthma severity could have important implications for both studying and treating asthma. Results are published in The Proceedings of the National Academy of Sciences. "This is one of the first studies to carefully isolate the influence of the circadian system from the other factors that



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¹Hasani A et al. Chron Respir Dis. 2008;5(2):81-86.² Roca O et al. Respir Care. 2010;55(4):408-413.

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©2021 by Goldstein & Associates, Inc. All rights reserved. Reproduction in whole or in part without written permission is strictly prohibited. are behavioral and environmental, including sleep," said co-corresponding author Frank A.J.L. Scheer, PhD, MSc, director of the Medical Chronobiology Program in the Division of Sleep and Circadian Disorders at the Brigham. Co-corresponding author Steven A. Shea, PhD, professor and director at Oregon Institute of Occupational Health Sciences added, "We observed that those people who have the worst asthma in general are the ones who suffer from the greatest circadianinduced drops in pulmonary function at night, and also had the greatest changes induced by behaviors, including sleep. We also found that these results are clinically important because, when studied in the laboratory, symptomdriven bronchodilator inhaler use was as much as four times more often during the circadian night than during the day." As many as 75 percent of people with asthma-20 million people in the U.S. — report experiencing worsening asthma severity at night. Many behavioral and environmental factors, including exercise, air temperature, posture, and sleep environment, are known to influence asthma severity. Scheer, Shea, and colleagues wanted to understand the contributions of the internal circadian system to this problem. The circadian system is composed of a central pacemaker in the brain (the suprachiasmatic nucleus) and "clocks" throughout the body

and is critical for the coordination of bodily functions and to anticipate the daily cycling environmental and behavioral demands. To disentangle the influence of the circadian system from that of sleep and other behavioral and environmental factors, the researchers enrolled 17 participants with asthma (who were not talking steroid medication, but who did use bronchodilator inhalers whenever they felt asthma symptoms were worsening) into two complementary laboratory protocols where lung function, asthma symptoms and bronchodilator use were continuously assessed. In the "constant routine" protocol, participants spent 38 hours continuously awake, in a constant posture, and under dim light conditions, with identical snacks every two hours. In the "forced desynchrony" protocol, participants were placed on a recurring 28-hour sleep/wake cycle for a week under dim light conditions, with all behaviors scheduled evenly across the cycle.

New Study Evaluates the Feasibility of Using Masimo EMMA Capnography on Mechanically Ventilated Neonates

Masimo announced the findings of a study published in the European Journal of Pediatrics in which Dr. Masashi Hotta and colleagues at the Osaka Women's and Children's Hospital in Japan found that the



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Masimo EMMA Portable Capnograph "may be considered an effective monitoring device" for mechanically ventilated preterm infants (neonates). Noting the importance of maintaining an appropriate range of partial pressure of arterial carbon dioxide (PaCO2) in preterm infants, especially while undergoing mechanical ventilation in the neonatal intensive care unit (NICU), the researchers sought to evaluate whether noninvasively monitoring end-tidal carbon dioxide (EtCO2) with EMMA could help clinicians maintain neonatal PaCO2 in the delivery room. They chose EMMA not only because of its portability but because it offers a solution with a small dead space (1 mL). The researchers enrolled 40 neonates (gestational age of 26+0 to 31+6 weeks) who required intubation in the delivery room (the EMMA monitoring group) and compared their PaCO2 value, either at admission to the NICU or 2 hours after birth, with that of 43 infants who did not undergo EMMA monitoring (the historical control group). They defined "appropriate" PaCO2 as 35-60 mmHg, as measured using a blood gas analyzer. The researchers found that the proportion of infants with appropriate PaCO2 was greater in the EMMA group than in the control group (80% vs. 42%, p = 0.001). Stratified according to birth weight (< 1000 g vs. > 1000 g), they found that in smaller neonates, there was no significant difference in the proportion of infants with appropriate PaCO2 between groups, but in the larger cohort, the rate of appropriate PaCO2 was significantly higher in the EMMA group: 93% vs. 44%, p < 0.001. The study authors concluded that EMMA "facilitated the maintenance of an appropriate PaCO2 for mechanically ventilated pre-term infants, especially infants with birth weight ≥ 1000 g, in the delivery room." They noted that the main strength of their study was that they "collected intervention data prospectively and showed the feasibility of using a portable capnometer during resuscitation of intubated preterm infants"-the first study of its kind. EMMA provides seamless mainstream capnography for patients of all ages in a compact, easily portable device. The instrument requires no routine calibration and minimal warm-up time, with accurate EtCO2 and respiration

rate measurements and continuous EtCO2 waveforms displayed within 15 seconds.

Company Expands Facility

Siemens Healthineers announced it will invest more than \$32 million in its Glasgow Laboratory Diagnostics Manufacturing Facility located in Newark, Delaware. The investment extends over 24 months and will enable the company to position in Delaware manufacturing capabilities for more than 20 diagnostic tests. This project is part of an initiative to drive greater efficiency, productivity, and stability across the company's diagnostics supply chain. "The Glasgow manufacturing facility expansion will further increase our manufacturing footprint in the United States-the largest healthcare market in the world," said Deepak Nath, PhD, President of Laboratory Diagnostics, Siemens Healthineers. "As part of the expansion, we will relocate important test manufacturing to this facility, which will streamline some of our processes and further improve the efficiency with which we can deliver these important tests to healthcare providers and their patients." The

Newark, DE facility employs more than 1,300 employees and manufactures more than 120 assays that run on certain instrument platforms, including the Atellica Solution, ADVIA Chemistry, Dimension, Dimension Vista, Syva Drug Testing, and Stratus CS instruments-providing tests that help physicians diagnose, monitor, and/ or treat diseases. The Glasgow manufacturing facility is one of several manufacturing facilities Siemens Healthineers operates for its diagnostics portfolio.

Patients With More Severe PH in COPD May Respond to Treatment

Patients with pulmonary hypertension (PH) as a complication of chronic obstructive pulmonary disease (COPD) have worse functional impairment and higher mortality, compared with patients who have idiopathic pulmonary arterial hypertension (IPAH). Despite these factors, some patients with more severe PH in COPD may respond to treatment and show clinical improvement after treatment, according to recent research published in the journal CHEST Carmine Dario Vizza, MD, of the pulmonary hypertension unit, department of cardiovascular and respiratory diseases at Sapienza University of Rome, and colleagues evaluated patients in the Comparative, Prospective Registry of Newly Initiated Therapies for Pulmonary Hypertension (COMPERA) database, enrolled up to August 2020, identifying 68 patients with moderate PH and COPD and 307 patients with severe PH and COPD. The researchers compared the PH and COPD groups with 307 patients who had idiopathic pulmonary arterial hypertension. Overall, mostly older men made up the group of patients with moderate (50%; mean, 68.5 years) and severe PH in COPD (61%; mean 68.4 years), compared with those who had IPAH (37%; mean 61.7 years. Oral monotherapy



for patients with PH and COPD was the main treatment, consisting of phosphodiesterase-5 inhibitors, while most patients with IPAH received endothelin receptor antagonists. On functional tests, patients in the PH and COPD group tended to perform poorer on the 6-minute walking distance (6MWD) and World Health Organization functional class (WHO FC) than patients with IPAH. Specifically, among 42.7% of patients in both group for whom follow-up data were available, there was a similar frequency of improvement for 6MWD of 30 meters or more from baseline for both PH and COPD and IPAH groups (46.9% vs. 52.6%; P = .294), but there were significant differences between 6MWD between patients with moderate and severe PH and COPD (51.6% vs. 31.6%; P = .04). There was a nonsignificant improvement in WHO FC improvement of one or more classes for 65.6% of patients with PH and COPD and 58.3% of patients with IPAH with follow-up data available, with 28.5% of patients with PH in COPD improving compared with 35.8% of patients with IPAH (P = .078) and nonsignificant differences between moderate and severe PH and COPD (19.0% vs. 30.4%; P = .188). Follow-up data were available for 84% of patients with IPAH and 94% of patients with PH and COPD. Dr. Dario Vizza and colleagues found 45.7% of patients in the PH and COPD group and 24.9% of patients in the IPAH group died during follow-up, while 1.1% in the PH and COPD group and 1.5% of patients in the IPAH group underwent lung transplantations. For patients with moderate PH and COPD, 31.3% died and none underwent lung transplantation, while 49.0% of patients in the severe PH and COPD group died and 1.4% underwent lung transplantations.

Masimo CEO Joe Kiani Appointed to President's Council of Advisors on Science and Technology

Masimo announced that Founder, Chairman, and CEO Joe Kiani has been appointed by President Joe Biden to the President's Council of Advisors on Science and Technology (PCAST). Since 1933, with the creation by President Franklin D. Roosevelt of a Science Advisory Board, each President has established an advisory committee of scientists, engineers, and health professionals. Created by Executive Order, President Biden's PCAST will advise him on matters involving science, technology, education, and innovation policy. The Council also provides the President with scientific and technical information needed to inform public policy relating to the American economy, the American worker, national and homeland security, and more. In particular, President Biden has asked PCAST to consider such pressing topics as how the pandemic can inform public health needs and how scientific and technological breakthroughs can help address climate change. The 30 members of the Council, the most diverse in history, include distinguished individuals from sectors outside the Federal Government with diverse perspectives and expertise in science, technology, education, and innovation, including 20 elected members of the National Academies of Sciences, Engineering and Medicine, five MacArthur "Genius" Fellows, two former Cabinet secretaries, and two Nobel laureates. Joe Kiani commented, "Thank you, President Biden, for this appointment. I am excited to work with this incredible PCAST group and others to explore ways that science and technology, and policies that can shape them, can improve healthcare, the environment, innovation, and equity in our country and the world."

Obese Children With Asthma Are Resistant to ICS

Obese or overweight children with asthma could be using inhaled corticosteroids (ICS) to no avail, combined results from observational studies suggest. Using Mendelian randomization, a method for reducing bias in observational studies, investigators from the University of Amsterdam Medical Center performed an analysis of data from four crosssectional studies and one cohort study on a total of 1,511 children with asthma. They showed that every 1-unit increase in the body mass index (BMI) z score was associated with a more than twofold higher odds ratio for exacerbation, reported Cristina Longo, PhD, a former postdoctoral fellow at AMC, and assistant professor of medicine at the University of Montreal. "In this large, multicenter Mendelian randomization study, our findings support current evidence that children with higher BMI status respond inadequately to inhaled corticosteroids, and that this association is likely not explained by measured confounding or reverse causation," she said in an oral abstract presentation during the European Respiratory Society International Congress. The obese-asthma phenotype in children is characterized by reduced lung function, high symptom expression, poor response to ICS, and high health care utilization. "While most observational studies suggest that weight status is associated with asthma exacerbations, despite using inhaled corticosteroids, it's unclear whether these associations may be due to unmeasured confounding or reverse causation, which captures the idea that perhaps obesity is a



consequence rather than a cause of uncontrolled severe asthma," she said. Traditional observational studies of the obesity-asthma link rely on comparing data on asthma in a target population and comparing nonobese patients with obese patients. The problem with this method, Dr Longo contended, is that the exposure assignment-weight status-is not random, and could lead to bias from potential imbalance of confounders, leading to unintentionally biased results. In contrast, Mendelian randomization uses genetic data to approximate random assignment of exposures, using a risk score for BMI based on genetic susceptibility. The score is based on the accumulation of genetic variants (single-nucleotide polymorphisms, or SNPs) that predispose individuals to obesity, with higher numbers of variants results in a higher risk score. The scores are then used to determine the comparison groups for evaluating the obesity-asthma association.

Courageous RT Stories Told on Podcast

Vitalograph (USA) Inc. has created a series of special editions for their Exhale podcast focused on the front lines of the great pandemic. The next several episodes we will be titled "Ask the Respiratory Therapist." This special series will interview multiple Respiratory Therapists and PFT technicians in different healthcare situations caring for COVID-19 infected patients. They share their experiences with the public, what they endured during this pandemic, and what they expect of the future. The host of Exhale is Mark Russell, Marketing Communications Manager and Janson Lanier, National Sales Manager and Respiratory Therapist for Vitalograph US, a global leader in respiratory diagnostics. The most recent interview is with Kimberly Wins Koldoff a Respiratory Therapist working at a Medical Center outside of Atlanta, Georgia. Exhale connected with her when she posted on LinkedIn an emotional cry after a long shift and a plea to get vaccinated. Here's her message: "My shifts this weekend confirmed my fears...Covid is indeed back. Today was one of the most exhausting days I've ever worked. I'm grieving. I'm angry. I'm scared. I'm tired. What can we do? Please consider getting vaccinated if you haven't already." These interviews of Respiratory Therapists and their colleagues on the frontlines say a lot about the pressure and the courage of the past 18 months. The days have been long, the breaks have been few, and the urgency has been unrelenting. The intent of these interviews is to shed some light of these medical heroes and what they endure day after day during the COVID pandemic. Vitalograph is a world-leading provider of the highest quality respiratory diagnostic devices, clinical trial services and medical equipment servicing. With a pioneering heritage of excellence spanning over



half a century, Vitalograph continues to make valuable contributions to effective medical care and enhanced quality of life.

Long COVID Symptoms Can Persist for More Than 1 Year, Study Shows Nearly one half of people who are hospitalized with COVID-19 suffer at least one lingering symptom 1 year after discharge, according to the largest study yet to assess the dynamic recovery of a group of COVID-19 survivors 12 months after the illness. The most common lingering symptoms are fatigue and muscle weakness. One third continue to have shortness of breath. Overall, at 12 months, COVID-19 survivors had more problems with mobility, pain or discomfort, and anxiety or depression, and had lower self-assessment scores of quality of life than matched COVIDfree peers, the investigators report. The study was published online August 26 in The Lancet.

"While most had made a good recovery, health problems persisted in some patients, especially those who had been critically ill during their hospital stay," Bin Cao, MD, from the National Center for Respiratory Medicine at the China-Japan Friendship Hospital and Capital Medical University, both in Beijing, said in a Lancet news release.

"Our findings suggest that recovery for some patients will take longer than one year, and this should be taken into account when planning delivery of healthcare services post-pandemic," Cao said.

Antidepressant Helps Prevent Hospitalization in COVID Patients: Study

A handful of studies have suggested that for newly infected COVID-19 patients, risk for serious illness may be reduced with a short course of fluvoxamine (Luvox), a decades-old pill typically prescribed for depression or obsessivecompulsive disorder (OCD). But those were small studies involving just a few hundred people. Researchers reported promising data from a large, randomized phase 3 trial that enrolled COVID-19 patients from 11 sites in Brazil. In this study, in which 1472 people were assigned to receive either a 10-day course of fluvoxamine or placebo pills, the antidepressant cut emergency department and hospital admissions by 29%. Findings from the new study, which

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have not yet been peer reviewed, were published August 23 in MedRxiv. Around the globe, particularly in countries without access to vaccines, "treatment options that are cheap and available and supported by good-quality evidence are the only hope we've got to reduce mortality within high-risk populations," said Edward Mills, PhD, professor in the Department of Health Research Methods, Evidence and Impact, McMaster University, Ontario, Canada.

The new findings came from TOGETHER, a large platform trial coordinated by Mills and colleagues to evaluate the use of fluvoxamine and other repurposed drug candidates for symptomatic, high-risk, adult outpatients with confirmed cases of COVID-19. The trial's adaptive format allows multiple agents to be added and tested alongside placebo in a single master protocol - similar to the United Kingdom's Recovery trial, which found that the common steroid dexamethasone could reduce deaths among hospitalized COVID-19 patients. In platform trials, treatment arms can be dropped for futility, as was the case with hydroxychloroquine and lopinavir-ritonavir, neither of which did better than placebo at preventing hospitalization in an earlier TOGETHER trial analysis.

Children's Upper Airways Primed to Combat SARS-CoV-2 Infection

Epithelial and immune cells of the upper airways of children are pre-activated and primed to detect a COVID-19 infection, which may contribute to a stronger early immune responses to a COVID infection than in adults, new research suggests. The findings may help to explain why children have a lower risk of developing severe COVID-19 illness or becoming infected with SARS-CoV-2, the novel coronavirus, in the first place, the researchers say. The study was published online August 18 in Nature Biotechnology Children appear to be better able than adults to control SARS-CoV-2 infection, but, until now, the exact molecular mechanisms for this have been unclear. A team of investigators from Germany did an indepth analysis of nasal swab samples obtained from 24 children and 21 adults who tested positive for SARS-CoV-2, as well as a control group of 18 children and 23 adults who tested negative for SARS-CoV-2. "We wanted to



understand why viral defense appears to work so much better in children than in adults," Irina Lehmann, PhD, head of the molecular epidemiology unit at the Berlin Institute of Health Charité-Universitätsmedizin Berlin, explains in a news release. Single-cell sequencing showed that children had higher baseline levels of certain RNAsensing receptors that are relevant to SARS-CoV-2 detection, such as MDA5 and RIG-I, in the epithelial and immune cells of their noses. This differential expression led to stronger early immune responses to SARS-CoV-2 infection in children than in adults. Children were also more likely than adults to possess distinct immune cell subpopulations, including KLRC1+ cytotoxic T cells, involved in fighting infection, and memory CD8+ T cells, associated with the development of long-lasting immunity. The study provides "clear evidence" that upper airway immune cells of children are "primed for virus sensing, resulting in a stronger early innate antiviral response to SARS-CoV-2 infection than in adults," the investigators say. Primed virus sensing and a pre-activated innate immune response in children leads to efficient early production of interferons (IFNs) in the infected airways, likely mediating substantial antiviral effects, they note. Ultimately, this may lead to lower viral replication and faster clearance in children. In fact, several studies have already shown that children do eliminate the virus quicker than adults, consistent with the concept that they

shut down viral replication earlier, the study team says.

EAACI Review Urges Reduction in Antibiotic Overuse With Allergy

Urgent recommendations from a European Academy of Allergy and Clinical Immunology (EAACI) task force are aimed at reducing antibiotic overuse with allergic disease. Top recommendations include limiting antibiotic therapy in pregnancy and early childhood to help reduce the allergy epidemic in children, and restricting antibiotic therapy in exacerbations and chronic treatment of allergic diseases, especially asthma and atopic dermatitis. The review, by lead author Gerdien Tramper-Stranders, MD, PhD, Department of Pediatrics, Franciscus Gasthuis & Vlietland Hospital, Rotterdam, the Netherlands, and colleagues, was published online August 13 in the journal Allergy. The authors note that several studies have shown that use of antibiotics in childhood and during pregnancy is associated with disturbing the intestinal and respiratory microbiome, which in turn leads to dysbiosis and an increased risk of acquiring allergic diseases. In addition, patients with allergic diseases such as asthma have a higher risk of being prescribed antibiotics for infections compared with the general population, despite lack of clear clinical benefit. "In fact, there are no clear data supporting antibiotic prescriptions for acute exacerbations; and clinical and/ or laboratory criteria are lacking," the

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authors write. Despite that lack of data, antibiotics are often prescribed for exacerbations along with oral corticosteroids, Tramper-Stranders told Medscape Medical News. Some patients may benefit from antibiotics in a flare-up, she said, but more research is needed to determine which ones. Tramper-Stranders said Franciscus has begun a large study that includes patients with asthma exacerbations to find biomarkers that might predict the type or origin of exacerbation to personalize treatment.

AHA Targets Rising Prevalence of Obstructive Sleep Apnea in Children

Obstructive sleep apnea is becoming more common in children and adolescents as the prevalence of obesity increases, but it may also be a preventable risk factor for cardiovascular disease, according to a new scientific statement from the American Heart Association. The statement focuses on the links between OSA and CVD risk factors in children and adolescents, and reviews diagnostic strategies and treatments. The writing committee reported that 1%-6% of children and adolescents have OSA, as do up to 60% of adolescents considered obese. The statement was created by the AHA's Atherosclerosis, Hypertension, and Obesity in the Young subcommittee of the Council on Cardiovascular Disease in the Young and was published online in the Journal of the American Heart Association. Carissa M. Baker-Smith, MD, chair of the writing group chair and director of pediatric

preventive cardiology at Nemours Cardiac Center, Alfred I. duPont Hospital for Children, Wilmington, Del., explained the rationale for issuing the statement at this time, noting that the relationship between OSA and CVD in adults is well documented. "There has been less focus on the importance of recognizing and treating sleep apnea in youth," she said in an interview. "Thus, we felt that it was vitally important to get the word out to parents and to providers that paying attention to the quality and duration of your child's sleep is vitally important to a child's longterm heart health. Risk factors for heart disease, when present in childhood, can persist into adulthood." For making the diagnosis of OSA in children, the statement provides clarity on the use of polysomnography and the role of the apnea-hypopnea index, which is lower in children with OSA than in adults. "One controversy, or at least as I saw it, was whether or not polysomnography testing is always required to make the diagnosis of OSA and before proceeding with tonsil and adenoid removal among children for whom enlarged tonsils and adenoids are present," Dr Baker-Smith said. "Polysomnography testing is not always needed before an ear, nose, and throat surgeon may recommend surgery." The statement also noted that history and physical examination may not yield enough reliable information to distinguish OSA from snoring. In areas where sleep laboratories that work with children aren't available, alternative tests such as daytime nap polysomnography, nocturnal oximetry, and nocturnal video recording may be

used-with a caveat. "These alternative tests have weaker positive and negative predictive values when compared with polysomnography," the writing committee noted. Home sleep apnea tests aren't recommended in children. Questionnaires "are useful as screening, but not as diagnostic tools." Pediatric patients being evaluated for OSA should also be screened for hypertension and metabolic syndrome, as well as central nervous system and behavioral disorders. Diagnosing OSA in children and adolescents requires "a high index of suspicion," the committee wrote. Pediatricians and pediatric cardiologists should exercise that high index of suspicion when receiving referrals for cardiac evaluations for attention deficit hyperactivity disorder medication, Dr. Baker-Smith said. "Take the time to ask about a child's sleep-snoring, apnea, etc. - especially if the child has obesity, difficulty focusing during the day, and if there is evidence of systemic hypertension or other signs of metabolic syndrome," she said.

Vapotherm Announces FDA Clearance for HVT 2.0 Next Generation Platform

Vapotherm, Inc. announced it has received 510(k) clearance from the US Food and Drug Administration for HVT 2.0. This next generation system is designed to provide high velocity therapy using an integrated air source, eliminating the need for wall air or any pressurized air source. It is estimated that 50% of U.S. hospital beds don't have wall air. When paired with an oxygen source, the HVT 2.0 will support patients whether they need respiratory support in the hospital or home setting. The Company is planning a limited commercial release of HVT 2.0 in the United States in the fourth quarter of 2021. "Clearance of HVT 2.0 enables us to provide high velocity therapy to Patients throughout the hospital, which is very important when ICU beds become scarce. It will allow hospitals to leverage their general care floors and potentially reduce emergency room crowding and wait times. We will also use this next generation platform, combined with the Vapotherm Access digital remote Patient monitoring platform, to begin learning how to treat complex lung disease Patients in the home," said Joe Army, President and CEO of Vapotherm. Vapotherm,

Inc. is a publicly traded developer and manufacturer of advanced respiratory technology based in Exeter, New Hampshire, USA. The company develops innovative, comfortable, non-invasive technologies for respiratory support of patients with chronic or acute breathing disorders. Vapotherm is focused on the development and commercialization of its proprietary Vapotherm high velocity therapy® products which are used to treat patients of all ages suffering from respiratory distress. Over 3.0 million patients have been treated with the use of Vapotherm high velocity therapy systems. For more information, visit www.vapotherm.com.

Masimo SafetyNet Alert Launches in Western Europe

Masimo announced the CE marking and launch in western Europe of Masimo SafetyNet Alert, an arterial blood oxygen saturation monitoring and alert system designed for use at home. Masimo SafetyNet Alert features Signal Extraction Technology wearable fingertip pulse oximetry sensor that communicates wirelessly to an accompanying Home Medical Hub and smartphone app. Masimo SafetyNet Alert monitors blood oxygen saturation (SpO2) and pulse rate (PR) using clinically proven Masimo SET Measurethrough Motion and Low Perfusion pulse oximetry and perfusion index (Pi). The system provides escalating alerts when drops in oxygen levels are detected, designed to wake up the person suffering from opioid overdose and if they do not, to send alerts to others when help may be needed. Over 200 million people are monitored with Masimo SET pulse oximetry in hospitals each year. In hospitals, continuous Masimo SET oxygen saturation monitoring has been shown to reduce harm associated with opioids in multiple clinical trials, including a 10-year study in which researchers at Dartmouth-Hitchcock Medical Center found that the use of Masimo SET-based continuous patient surveillance monitoring resulted in zero opioid-related preventable deaths or brain damage in their postsurgical wards. The researchers also found there was a reduction in rapid rescue events by 60%, a reduction in ICU transfers by 50%, and an estimated \$7 million annually in cost savings. Opioids are powerful painkillers, and are commonly used as part of recovery

after surgery and for patients with chronic pain, but they can also slow or stop one's breathing, potentially leading to heart attack, brain damage, and even death. In 2020 the number of drug-related deaths recorded in England and Wales rose to 4,561, the highest since records began, and around half of these involved opioids.5 Worldwide, that number is even worse, with an estimated more than 100,000 people dying from opioid overdose each year. Whether taking prescription or nonprescription opioids, people can suffer from the condition known as opioidinduced respiratory depression (OIRD) to varying degrees.6 Opioid overdose may occur while a person is particularly vulnerable, while asleep, and the risk of opioid overdose-related death is heightened for people taking opioids for the first time, those who have sleep apnea, COPD, or asthma, along with those who combine opioids with alcohol or other sedatives, amongst other factors. By monitoring a person's oxygen saturation level, especially while asleep, and providing escalating alerts when help may be needed, Masimo SafetyNet Alert can help identify life-threatening opioid overdose before it causes lasting harm or even death. Masimo SafetyNet Alert leverages the same SET pulse oximetry technology and a similar notification escalation policy used in hospitals to bring hospital-proven monitoring to the home setting. The system provides escalating visual and

audible alerts on the smartphone app and at the Home Medical Hub station, which are designed to alert the patient or anyone nearby to help prompt action. If oxygen levels continue to decline, designated emergency contacts, such as friends and family members, are also notified via text messages, so that they can intervene or involve Emergency Medical Services as needed. Masimo SafetyNet Alert brings to the home the breakthrough Masimo SET pulse oximetry used in hospitals around the world. SET has been clinically proven to help care teams enhance patient safety and improve patient outcomes; in fact, more than 100 independent and objective studies have shown that Masimo SET outperforms other pulse oximetry technologies during motion and low perfusion conditions, providing clinicians with increased sensitivity and specificity to make critical care decisions. Dr Mike Durkin, a Senior NHS Advisor on Patient Safety Policy and Leadership for the National Institute for Health Research (NIHR) Imperial College Patient Safety Translational Research Centre, said, "Patients recovering from surgery still need pain relief using opioid drugs after they are discharged from hospital and return home. However, these drugs have significant side-effects, particularly on the depression of breathing, which without urgent intervention can result in serious harm or death. The technology is now available to monitor the impact



of opioids on breathing and it is vital that patients are given the opportunity to easily and continuously monitor their oxygen levels and vital signs while taking these medications at home. This will greatly improve the safety of patients while rehabilitating at home." Yvonne Gardner, mother of 21-yearold Parker Stewart, who died of an opioid overdose after taking only half of the prescribed dose of painkillers following a tonsillectomy, said, "I've had so many people call me personally and say, what would you do differently? My son needs a tonsillectomy, or my daughter is going into surgery. I tell them: make sure your doctor gives you a monitor." Joe Kiani, Founder and CEO of Masimo, said, "30 years ago, we had the dream of improving patient outcomes and reducing the cost of care by taking noninvasive monitoring to new sites and applications. Bringing our measure-through motion and low perfusion pulse oximetry to the home to monitor patients taking opioids is fulfilling that dream in a way that I could not have imagined at the time. I hope tens of thousands of lives will be saved each year from opioid overdose with the launch of Masimo SafetyNet Alert."

Study Shows Positive PVi Results

Masimo announced the findings of a study published in the Turkish Journal of Emergency Medicine in which Drs Seda Da[°]gar and Hüseyin Uzunosmano[°]glu at the Kecioren Training and Research Hospital in Ankara, Turkey investigated the role that noninvasive, continuous Masimo PVi might play in monitoring volume status

and volume changes in spontaneously breathing patients undergoing hemodialysis (HD). The researchers found that there was a "strong correlation" between change in PVi and the volume of fluid removed, concluding that "PVi may provide clinicians with useful information for monitoring the volume status in critically ill patients with spontaneous breathing." More than 100 independent studies have demonstrated the utility of PVi as an indicator of fluid responsiveness. Noting that PVi has been studied mostly in mechanically ventilated patients, the researchers sought to investigate its ability to help assess volume changes in spontaneously breathing patients. They enrolled 60 adult patients with end-stage renal disease who received routine HD (during which fluid is removed simultaneously with the removal of waste solutes) and had a median of 3,500 cc of fluid removed during HD. PVi was measured using a Masimo pulse oximetry sensor attached to a Masimo Root monitor, before and after HD, and changes in PVi were compared to the amount of fluid removed during the session. The researchers found that mean PVi showed a statistically significant increase after HD, from $20.7\% \pm 5\%$ to $27.7\% \pm 6\%$ (p < 0.001). Based on the amount of fluid removed during HD, the change in PVi was statistically significant (p = 0.015) and was strongly correlated to the volume of fluid removed (r = 0.744, p < 0.001). The researchers concluded, "In the present study, we found that the fluid removed by HD in spontaneously breathing patients caused an increase



in PVi and that this increase was strongly correlated with the amount of volume change. Bedside monitoring of PVi, which is a noninvasive, fast, reproducible measurement parameter, may provide the clinicians with useful information for monitoring the volume status and evaluating the effectiveness of volume-restoration therapy in critically ill patients with spontaneous breathing." The accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure, and device-related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi. In the US, PVi is cleared as a noninvasive, dynamic indicator of fluid responsiveness in select populations of mechanically ventilated adult patients.

Biologics for Asthma Also Improve Chronic Rhinosinusitis

Biologics used as an asthma treatment also appear to improve symptoms of coexisting chronic rhinosinusitis in some patients, according to results from a real-world study published in the International Forum of Allergy & Rhinology. Although patients with asthma commonly have coexisting chronic rhinosinusitis (CRS) with nasal polyps (CRSwNP) or without nasal polyps (CRSsNP), research on the effect of biologics has focused on CRSwNP, according to Devyani Lal, MD, of the Department of Otolaryngology, Division of Rhinology, Mayo Clinic, Phoenix, Arizona, and colleagues. The researchers evaluated how the use of omalizumab, mepolizumab, benralizumab, reslizumab, and dupilumab affected a group of 181 patients with asthma and CRSwNP and 66 patients with asthma and CRSsNP in a retrospective review of electronic health records at the Mayo Clinic. Over a period of at least 12 months, most patients in the study received omalizumab (51%), mepolizumab (46.6%), benralizumab (10.5%) or a combination of omalizumab and mepolizumab (6.9%). Of the 247 patients studied, 206 (84.1%) underwent endoscopic sinus surgery (ESS) and 189 of those patients had the surgery

performed prior to receiving biologic therapy. Matched-pair analyses were performed to identify changes from baseline in Lund-Mackay CT scores, SNOT-22 scores, serum eosinophil counts, and serum immunoglobulin E (IgE) levels. Lal and colleagues found treatment with an antiinterleukin-5 (anti-IL-5) biologic such as mepolizumab, benralizumab, or reslizumab significantly improved Lund-Mackay CT scores when analyzing the proportion of patients with both CRSwNP and CRSsNP, and SNOT-22 scores for patients with CRS overall and CRSwNP. Patients who received the anti-IgE biologic omalizumab had improved Lund-Mackay CT scores, but SNOT-22 scores did not significantly improve at any follow-up time, including the longest follow-up at mean 23.7 months. Aaron N. Pearlman, MD, an otolaryngologist at Weill Cornell Medicine and NewYork-Presbyterian in New York City, said the finding of objective and subjective improvement in a real-world study is important. "It shows you that these monoclonal antibodies are having a positive effect on diffuse chronic inflammatory conditions," said Pearlman, was not involved in the study. "Where asthma and chronic sinusitis with nasal polyps in many patients have a similar inflammatory pathway, we think that these medications would work on both systems. With this retrospective data, they've shown that there is some improvement even in patients [where] the indicated use was not for nasal polyps."

New Digital Features Available to Make Set Up Easier for Parents

ResMed, a global leader in digital health and sleep apnea treatment, launched AirSense 11, available first in the US, the company's next-generation PAP (positive airway pressure) device designed to help hundreds of millions of people worldwide with sleep apnea start and stay on therapy to treat and manage obstructive sleep apnea. AirSense 11 includes new features like Personal Therapy Assistant and Care Check-In designed to provide tailored guidance to PAP users, helping ease them into therapy and comfortable nightly use. Other features include the availability of remote software updates so users can enjoy the latest version of these tools every night. "AirSense 11's new tailored



resmed.com

features along with our myAir patient engagement app help give people the support they need to use PAP - the gold standard for treating sleep apnea - comfortably and confidently every night," said Jim Hollingshead, ResMed president of Sleep and Respiratory Care. "And when digital health helps guide patients, it enables clinicians to provide great care to all their patients more efficiently." AirSense 11 features include: Personal Therapy Assistant provides interactive step-by-step tutorials via the myAir app for patients to set up their device and acclimate to therapy pressure. Care Check-In gives patients tailored guidance through key milestones in their treatment journey, based on patients' responses to simple questions like "How is your therapy" and "How sleepy did you feel this week?" It's available in the myAir app and on the device screen itself. With the patient's consent, healthcare providers can also see their patients' responses in AirView, providing another fast, virtual way to monitor patients. A sleek design, touch screen, and intuitive menu mimic a smartphone, making it easy to use, designed to support increased adherence to therapy. ResMed's proprietary therapy algorithms for AutoSet or APAP (auto-adjusting PAP) that delivers breath-by-breath therapy adjustments, the AutoSet for Her mode, a setting tailored to treat the female-specific characteristics of mild to moderate obstructive sleep apnea,

and CPAP (continuous PAP). The ability to make over-the-air upgrades directly to a user's device - just like you would get on a smartphone. AirSense 11 also gives access to myAir (patient engagement app) and AirView (remote monitoring platform for clinicians) - which together help bring overall patient adherence as high as 87%. The myAir app tracks the amount of time patients spend using CPAP therapy, number of sleep apnea events per hour, mask leak, and the number of times a mask was removed, providing nightly data on breathing, coaching tips, and support directly to their phone. AirView provides a secure, cloud-based patient management system for online patient monitoring that enables healthcare professionals to quickly access patient data, share clinical insights with other health professionals, improve care and reduce costs related to patient followup. AirSense 11 is available in the US, with other countries to follow, and is compatible with all ResMed masks. To learn more about AirSense 11, visit resmed.com/Air11 or speak with your healthcare provider.

New Solution to Impact the Future of Respiratory Simulation

IngMar Medical, LLC, a leading global provider of respiratory simulation solutions, launched their next generation solution for respiratory and ventilation training, RespiPro. With RespiPro, educators can train

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all levels of learners across multiple disciplines on the full scope of respiratory techniques using their own real ventilators and respiratory devices. The solution includes the most realistic breathing simulator, the ASL 5000, as well as easy-to-use software, a true-tolife patient monitor, and a respiratoryfocused manikin on a compact ICU bed. IngMar Medical President, Brian Linn, explains, "We have spent years talking to customers about how we can help them achieve better training outcomes, ultimately leading to better patient care. We understand that our customers want to immerse their learners in an environment that is indistinguishable from real life, while controlling the simulation with easy-to-use software. These are the key elements of our new RespiPro, and that is why we are thrilled to share it with respiratory educators all over the world." While the concept of RespiPro is the same as IngMar Medical's legacy RespiSim System solutions, this launch is particularly monumental due to the overhaul of both the software and hardware components. IngMar Medical worked closely with educators throughout the entire development process to ensure RespiPro meets their respiratory and ventilation training needs. "The launch of RespiPro marks a major step on our journey, and we couldn't be more excited to continue working with the respiratory simulation community to build off of this new foundation," stated Linn.

CPAP Device is Available for Acute Care Use and Surge Capacity Planning

The FDA issued recent guidelines indicating that Bilevel and CPAP devices can be used to effectively help treat COVID-19 patients in Respiratory Distress potentially avoiding mechanical ventilation. The patented Flow-Safe II+ is the first and only Disposable Bilevel CPAP ventilatory assist device available in the global market. This disposable Bilevel CPAP system includes a mask and manometer and optional filter that provides hospital and emergency clinicians with the components required to quickly set up the device and connect to an oxygen source for delivering verifiable Bilevel and CPAP therapies to patients in respiratory distress. A recent article published in the American Journal of Emergency Medicine

supports the use of the Flow-Safe product line concluding, "The Flow-Safe Disposable CPAP system can be as effective as NIMV in patients with Acute Cardiogenic Pulmonary Oedema (ACPO). Considering the overall improvement observed in the physiological blood gas and other parameters as well as the mortality and cost-related considerations, FSD-CPAP-S can be

preferred in emergency services if there are insufficient NIMV devices." The disposable advantage reduces the need for costly capital equipment and is the clinical solution for situations where backup Bilevel / CPAP equipment is scarce or unavailable. Flow-Safe II+ has been used extensively in pre-hospital EMS environments and in acute care emergency rooms. The disposable feature has the added advantage of assisting in preventing potential cross contamination. These advantages make it an ideal solution when planning surge capacity for pandemics or natural disasters. Flow-Safe II+ was introduced to the market in 2018 and has been awarded two prestigious industry awards, the 2018 EMS World Innovation Award and the 2019 JEMS Hot Products Award. This novel device was selected for both awards from over hundreds of submissions after a thorough review by panel of judges consisting of emergency medical services (EMS) product specialists, physicians, educators, managers and paramedics. The United States Patent and Trademark Office (USPTO) has issued Flow-Safe II+ US Patent No.10,258,759 in 2019. In March 2020, the USPTO issued two new utility



patents, US Patent No. 10,583,266 and 10,583,262 for the award-winning Flow-Safe II+ Disposable Bilevel CPAP device. John Gargaro MD, President and CEO at Mercury Medical, states: "Mercury Medical believes that Flow-Safe II+ is a unique superior solution designed to quickly improve patients in respiratory distress with a costefficient device. The disposable feature assists in reducing hospital infection rates that are associated with reusable equipment, Mercury Medical has a rich experience in introducing innovative, clinically differentiated medical devices to market. We are extremely pleased to extend this device to the acute care market where there is a need for Disposable Bilevel CPAP equipment."