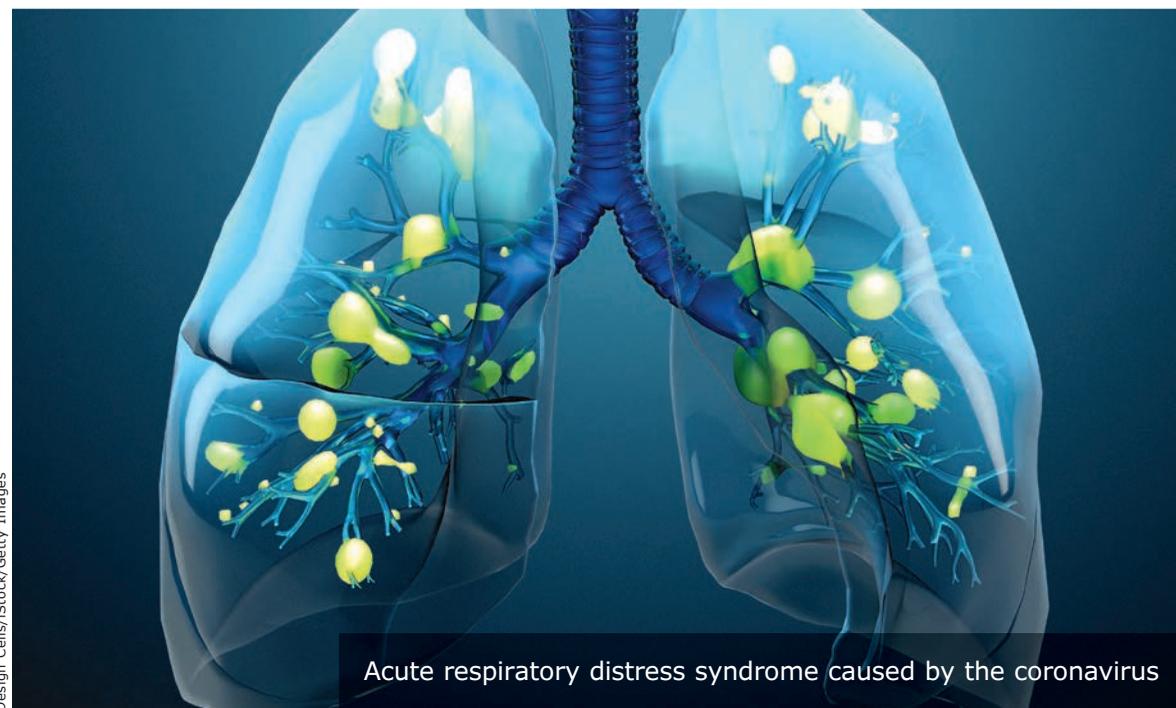




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Acute respiratory distress syndrome caused by the coronavirus

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'Exciting time' as researchers explore cellular repair in ARDS

BY RANDY DOTINGA

Scientists are beginning to unravel the secrets of acute respiratory distress syndrome (ARDS), the devastating disorder that floods the lungs with fluid and has ushered countless millions to death after infection with pneumonia, sepsis, and COVID-19.

Two centuries after the lung damage caused by the disorder was first described in medicine, it's now clear that ARDS is an autoimmune condition spurred by the body's overactive defenses. There's interest in disrupting "crosstalk" between cells, and rise of a new form of genetic analysis is allowing researchers to test their hypotheses more effectively than ever before. And, perhaps most importantly, recent findings reveal how stem cells in the epithelial lining of the lungs get

stalled in an intermediate stage before regenerating into new cells. Reversing this process could trigger repair and recovery.

There's still a ways to go before clinical trials can test therapies to turn things around at the epithelial level, acknowledged University of Michigan, Ann Arbor, professor of internal medicine Rachel L. Zemans, MD, in an interview. Still, "it's a pretty exciting time," said Dr. Zemans, who manages a lab that explores how the lung epithelium responds to injury.

A lung disorder's deep roots in human history

A British doctor first described the traits of ARDS in 1821, although this form of pulmonary edema had been described in "ancient writings,"

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TNF inhibitors may treat RA-associated interstitial lung disease

BY DOUG BRUNK

Patients with rheumatoid arthritis-associated interstitial lung disease (RA-ILD) who start a tumor necrosis factor (TNF) inhibitor appear to have rates of survival and respiratory-related hospitalization similar to those initiating a non-TNF inhibitor biologic disease-modifying antirheumatic drug (bDMARD) or Janus kinase inhibitor (JAKi), results from a large pharmacoepidemiologic study show. "These results challenge some of the findings in prior literature that perhaps TNF inhibitor should be avoided in RA-ILD," lead study investigator Bryant R. England, MD, PhD, said. The findings were presented at the American College of Rheumatology annual meeting.

Dr. England, associate professor of rheumatology and immunology at the University of Nebraska Medical Center, Omaha, said while RA-ILD carries a poor prognosis, a paucity of evidence exists on the effectiveness and safety of disease-modifying therapies in this population. It's a pleasant surprise

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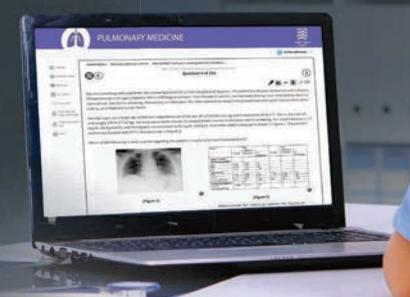
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according to a 2005 report by Gordon Bernard, MD, of Vanderbilt University Medical Center, Nashville, Tennessee. Sometimes called “double pneumonia,” ARDS was almost always fatal until the last few decades of the 20th century. “The advent of well-equipped ICUs, well-trained staff, and the availability of reliable positive pressure ventilators has allowed patients to be kept alive much longer and thus have the opportunity to heal the pulmonary injury and survive,” Dr. Bernard wrote.

According to the Mayo Clinic, there are many causes of ARDS. Sepsis is the most common, and others include severe pneumonia, head/chest injuries, massive blood transfusions, pancreatitis, burns, and inhalation of harmful substances. Since 2020, ARDS has been a hallmark of COVID-19.

University of Washington, Seattle, emeritus professor of medicine Thomas R. Martin, MD, explained that ARDS occurs when the epithelium barrier in the lungs breaks down. Unlike the permeable endothelial barrier, the alveolar epithelium is “like a brick wall or a big dam, keeping red cells and plasma out of the airspace.”

In cases of pulmonary edema due to heart failure, fluid can back up into the lungs, said Dr. Martin, who studies ARDS. However, pumps in the epithelium can clear that excess fluid pretty quickly because the epithelium remains in a normal state, he said. “Given enough time and enough medical support, people with heart failure and pulmonary edema can get better without lung injury.”

In ARDS, however, “the epithelium is damaged. Cells die in the alveolar wall, the scaffolding is exposed, and the fluid in the alveoli cannot be cleared out. You’ve got a disaster on your hands because all of the fluid and red blood cells and inflammatory products in the blood are going right into the airspace. The patient gets extremely short of breath because their oxygen level falls.”

COVID-19 virus finds a weak spot in the lungs

COVID-19 is “a classic example of an attack on the alveolar epithelium,” Dr. Martin said. By chance, the virus evolved to recognize receptors in the epithelium, allowing it to enter and propagate. “To make matters worse, defense mechanisms in the body attack those dying epithelial cells because the virus is visible on the surface cells. So lymphocytes from the immune system

and macrophages attack the outer walls and cause further damage.”

Other scientists agree about this general picture of ARDS. “Studies of human lung tissue support the notion that failure of alveolar repair and regeneration mechanisms underlie the chronic lung dysfunction that can result from ARD,” wrote researchers from Cedars-Sinai Medical Center, Los Angeles, California, and Icahn School of Medicine at Mount Sinai, New York, in a 2022 report.

According to Dr. Martin, researchers and clinicians have discovered a pair of strategies to help vanquish COVID-19: Control viral entry through antiviral medication and dampen the body’s inflammatory response via steroids. Still, “although we’ve learned lessons from COVID-19, we’re not good at all at promoting repair,” Dr. Martin said. While new drugs have dramatically improved treatment for lung diseases such as cystic fibrosis, he said, “we don’t have good examples of new therapies that promote repair in ARDS.”

Looking for a way to turn the tide of fluid buildup

Dr. Zemans and colleagues have uncovered a crucial obstacle to repair: the failure of stem cells to fully differentiate and become functional alveolar epithelial cells.

Researchers only began to understand a few years ago that the stem cells go through a transitional stage from type 2 to type 1, which make up 98% of cells in the epithelial surface, Dr. Zemans said. In patients with ARDS who don’t get better quickly, “it looks like the cells get hung up in this intermediate state. They can’t finish that regeneration.”

As a 2022 study by Dr. Zemans and colleagues put it, this process can lead to “ongoing barrier permeability, noncardiogenic pulmonary edema, and ventilator dependence, and mortality.” In fact, she said, “when we look at the lungs of people who died of ARDS, their cells were all in that intermediate stage.”

The discovery of the intermediate state only came about because of new technology called single-cell RNA sequencing, she said. “Now, these transitional cells are being found in other organs.”

Why do the epithelial cells get only part way through the regeneration process? It’s not entirely clear, Dr. Zemans said, but researchers are intrigued by the idea that “cross-talk” between cells is playing a role.

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Angel Coz, MD, FCCP, is Editor in Chief of CHEST Physician.

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“to see the investigators were unable to demonstrate a significant difference in the risk of respiratory hospitalization or death between people with RA-ILD initiating non-TNF inhibitor/JAKi versus TNF inhibitor. Here is a unique situation where a so called ‘negative’ study contributes important information. This study provides needed safety data, as they were unable to show that TNF inhibitors result in worsening of severe RA-ILD outcomes,” Sindhu R. Johnson, MD, PhD, professor of medicine at the University of Toronto, said when asked for comment on the study.



Dr. England

“While this study does not address the use of these medications for the treatment of RA-ILD, these data suggest that TNF inhibitors may remain a treatment option for articular disease in people with RA-ILD,” said Dr. Johnson, who was not involved with the study.

For the study, Dr. England and colleagues drew from Veterans Health Administration data between 2006 and 2018 to identify patients with RA-ILD initiating TNF inhibitors or non-TNF inhibitor biologic/JAKis for the first time. Those who received ILD-focused therapies such as mycophenolate and antifibrotics were excluded from the analysis.

The researchers used validated administrative algorithms requiring multiple RA and ILD diagnostic codes to identify RA-ILD and used 1:1 propensity score matching to compare TNF-inhibitor and non-TNF inhibitor biologic/JAKi factors such as health care use, comorbidities, and several RA-ILD factors, such as pretreatment forced vital capacity, obtained from electronic health records and administrative data. The primary outcome was a composite of time to respiratory-related hospitalization or death using Cox regression models.

Dr. England reported findings from 237 TNF-inhibitor initiators and 237 non-TNF inhibitor/JAKi initiators. Mean age was 68 years and 92% were male. After matching, the mean standardized differences of variables in the propensity score model improved, but a few variables remained slightly imbalanced, such as two markers of inflammation, inhaled corticosteroid use, and

body mass index. The most frequently prescribed TNF-inhibitor drugs were adalimumab (51%) and etanercept (37%), and the most frequently prescribed non-TNF inhibitor/JAKi drugs were rituximab (53%) and abatacept (28%). Researchers observed no significant difference in the primary outcome between non-TNF inhibitor/JAKi and TNF-inhibitor initiators (adjusted hazard ratio, 1.22; 95% confidence interval, 0.92-1.60). They observed no significant differences in respiratory hospitalization, all-cause mortality, or respiratory-related death at 1 and 3 years. In sensitivity analyses with modified cohort eligibility requirements, no significant differences were observed between non-TNF inhibitor/JAKi and TNF-inhibitor initiators.

At the meeting, Dr. England posed the question: Are TNF-inhibitor drugs safe to be used in RA-ILD? “The answer is: It’s complex,” he said. “Our findings don’t suggest we should be systematically avoiding TNF inhibitors with every single person with RA-ILD. But that’s different than whether there are specific subpopulations of RA-ILD for which the choice of these therapies may differ. Unfortunately, we could not address that in this study. We also could not address whether TNF inhibitors have efficacy at stopping, slowing, or reversing progression of the ILD itself. This calls for us as a field to gather together and pursue clinical trials to try to generate robust evidence that can guide these important clinical decisions we’re making with our patients.”

He acknowledged limitations of the analysis, including its observational design. “So, despite best efforts to minimize bias with pharmaco-epidemiologic designs and approaches, there could still be confounding and selection,” he said. “Additionally, RA-ILD is a heterogeneous disease characterized by different patterns and trajectories. While we did account for several RA- and ILD-related factors, we could not account for all heterogeneity in RA-ILD.”

Dr. England reports receiving consulting fees and research support from Boehringer Ingelheim, and several coauthors reported financial relationships from pharmaceutical companies and medical publishers. Dr. Johnson reports no relevant financial relationships. Dr. Pope reports being a consultant for several pharmaceutical companies. She has received grant/research support from AbbVie/Abbott and Eli Lilly and is an adviser for Boehringer Ingelheim. ■



Dr. Johnson

Corinne Young, MSN, FNP-C, FCCP, comments: Although there are many limitations in this study, it provides some hope in growing treatment options for patients with RA-ILD. Although randomized controlled trials will likely be needed before official recommendations can be made, the preliminary findings are encouraging and will undoubtedly inspire future research in this area.



Ms. Young is a member of the CHEST Physician Editorial Board.

When asked for comment, session moderator Janet Pope, MD, MPH, professor of medicine in the division of rheumatology at the University of Western Ontario, London, said that the study findings surprised her. “Sometimes RA patients on TNF inhibitors were thought to have more new or worsening ILD vs. [those on] non-TNF inhibitor bDMARDs, but most [data were] from older studies where TNF inhibitors were used as initial bDMARDs in sicker patients,” she said. “So, data were confounded previously. Even in this study, there may have been channeling bias as it was not a randomized controlled trial. We need a definitive randomized controlled trial to answer this question of what the most optimal therapy for RA-ILD is.”

Dr. England reports receiving consulting fees and research support from Boehringer Ingelheim, and several coauthors reported financial relationships from pharmaceutical companies and medical publishers. Dr. Johnson reports no relevant financial relationships. Dr. Pope reports being a consultant for several pharmaceutical companies. She has received grant/research support from AbbVie/Abbott and Eli Lilly and is an adviser for Boehringer Ingelheim. ■



Dr. Pope

ARDS continued from previous page

“When the cells are in that stage, they also activate neighboring cells, including inflammatory cells, like macrophages, and fibroblasts,” she said. “And once those cells become activated, they become pathologic. What we think is that those cells then can talk back to the epithelial cells and prevent the epithelial cells from finishing that differentiation. It’s really hard to snap out of that positive feedback loop.”

This interaction probably evolved “for a good reason,” she said, “but it also became pathologic.” If the cells stay in the intermediate stage too long, she said, fibrosis develops. “They have scar tissue that never goes away. It takes a lot of work to

expand the lungs when they’re so stiff when they should be stretchy like a rubber band. Scar tissue also gets in the way of the oxygen absorption, so some people have low oxygen levels.”

Future directions: Teaching cells to get “unstuck”

What’s next for research? One direction is exploring the variety of types of cells in the epithelium. Recent findings are revealing “new cell subpopulations that maintain alveolar homeostasis, communicate injury signals, and participate in normal and maladaptive repair. Emerging data illuminate the complexity of alveolar physiology and pathology to provide a more complete picture

of how alveoli maintain health and respond to injurious stimuli,” write the researchers from Cedars-Sinai Medical Center and Icahn School of Medicine at Mount Sinai in their 2022 report.

Meanwhile, “we’re trying to look at the signaling pathways, the proteins or molecules, to understand the signals that tell a cell how to get unstuck,” Dr. Zemans said. And researchers are exploring whether knocking out certain genes expressed by transitional cells in mice will lead to better outcomes, she said.

The 2022 study by Dr. Zeman and colleagues described the potential ramifications of better understanding of the entire process: “Ultimately,

investigation of the cellular and molecular mechanisms underlying ineffectual alveolar regeneration in ARDS and fibrosis may lead to novel therapies to promote physiological regeneration, thus accelerating restoration of barrier integrity, resolution of edema, liberation from the ventilator and survival in ARDS, and preventing fibrosis in fibroproliferative ARDS and [idiopathic pulmonary fibrosis].”

To put it more simply, Dr. Zemans said, “if you can seal the barrier, you can get the fluid out of the lungs, and you can get the patients off the ventilator, get out of the ICU, and go home.”

Dr. Zemans and Dr. Martin have no disclosures. ■

Conditional recommendations rule in new SARD-associated interstitial lung disease guidelines

BY DOUG BRUNK

SAN DIEGO – In the spring of this year, the American College of Rheumatology is expected to release guidelines to help inform the screening, monitoring, and treatment of interstitial lung disease (ILD) in people with systemic autoimmune rheumatic diseases (SARDs).

The guidelines, which were previewed during a session at the ACR's annual meeting, will include 50 recommendations, 3 of which met criteria for a strong rating:

- For people with SARDs at increased risk of developing ILD, the authors strongly recommend against screening with surgical lung biopsy.
- For people with systemic sclerosis (SSc)-related ILD, the authors strongly recommend against glucocorticoids as a first-line ILD treatment.
- For people with SSc-related ILD progression despite an initial ILD treatment, the authors strongly recommend against using long-term glucocorticoids.

Elana J. Bernstein, MD, MSc, a rheumatologist who directs the Columbia/New York-Presbyterian Scleroderma Center, and Sindhu R. Johnson, MD, a rheumatologist who directs the Toronto Scleroderma Program at the University of Toronto, provided a sneak peek of the recommendations to attendees before anticipated publication in *Arthritis & Rheumatology* and *Arthritis Care & Research*. For now, guideline summaries for screening and monitoring and treatment are currently available, and three manuscripts are under peer review: one about screening and monitoring, one about treatment, and one about the patient panel that participated in the effort.

"ILD is a significant cause of morbidity and mortality in people with SARDs," said Dr. Bernstein, who is co-first author of the guidelines. "People with systemic sclerosis, rheumatoid arthritis, idiopathic inflammatory myopathies, mixed connective tissue disease, and Sjögren's disease are at greatest risk of developing ILD."

Pediatric patients with SARDs excluded

The guidelines' population of interest was people 17 years of age and older who were diagnosed with SARDs with a high risk of ILD. Pediatric patients with SARDs were excluded from the endeavor, as were those with systemic lupus erythematosus, antineutrophil cytoplasmic antibody-associated vasculitis, sarcoidosis, ankylosing spondylitis, undifferentiated connective tissue disease, interstitial pneumonia with autoimmune features, and unclassifiable ILD.

In the realm of screening, the guideline authors conditionally recommend two screening tests for patients considered at increased risk of ILD: pulmonary function tests and high-resolution chest CT (HRCT). Pulmonary function tests should include spirometry, lung volumes, and diffusion capacity. "Office spirometry alone is insufficient," said Dr. Johnson, who served as lead author of

the guidelines. And while a HRCT scan is recommended, "some patients may present to the emergency room with acute-onset shortness of breath, and they may receive a CT angiogram to screen for pulmonary embolism," she said. "It's important to note that CT angiograms are performed in incomplete inspiration to maximize pulmonary artery enhancement. This may produce atelectasis that may obscure or mimic ILD. As a result, CTA studies are often inadequate to screen for ILD."



Dr. Bernstein

Once a patient is diagnosed with ILD, three tests are recommended for monitoring: pulmonary function testing (every 3-6 months the first year in patients with IIM and SSc, then less frequently once stable, and every 3-12 months in the first year in patients with RA, SjD, and MCTD, then less frequently once stable); ambulatory desaturation testing every 3-12 months; and HRCT as needed. Dr. Johnson noted that, while the screening of ILD lies within the realm of rheumatologists, "once a patient is diagnosed, we are encouraged to co-manage these patients with pulmonologists," she said. "Ambulatory desaturation testing is not an infrequent test in the hands of pulmonologists. This is where co-management can be helpful." She characterized a 6-minute walk test with continuous oximetry as "insufficient and is not synonymous with ambulatory desaturation testing. Ambulatory desaturation testing includes uptitration of oxygen if a patient desaturates."

The guidelines conditionally recommend against using chest radiography, 6-minute walk test distance, ambulatory desaturation testing, and bronchoscopy for ILD screening, and there is a strong recommendation against surgical lung biopsy. "However, there are unique circumstances where these tests may be considered," Dr. Johnson said. "For example, ambulatory desaturation testing may be helpful if a patient is unable to perform a pulmonary function test. Bronchoscopy may be used to rule out infection, sarcoidosis, lymphoma, or alveolar hemorrhage, and surgical lung biopsy may be considered if you're trying to rule out a malignancy."

Similarly, several tests are conditionally recommended against for the monitoring of ILD, including chest radiography, the 6-minute walk test distance, and bronchoscopy. "But there are unique circumstances where they may be considered," she said. "The 6-minute walk test may be used if a patient is unable to perform a pulmonary function test or if they're being assessed for lung transplantation. Bronchoscopy may be used to rule out infection or alveolar hemorrhage."

Preferred treatment options described

First-line treatment recommendations for ILD were based on the best available published

Corinne Young, MSN, FNP-C, FCCP, comments: These new guidelines are an excellent resource for managing these complex and often rapidly progressive patients. For those of us in private practice and/or in rural areas where ILD multidisciplinary committees or conferences don't exist and access to our rheumatology colleges is limited, these guidelines provide an essential framework.

Ms. Young is a member of the CHEST Physician Editorial Board.

evidence, voting panel expertise, and patient preferences. For SSc, the preferred treatment options include mycophenolate (CellCept), tocilizumab (Actemra), or rituximab (Rituxan and biosimilars), while additional options include cyclophosphamide, nintedanib (Ofev), and azathioprine. For myositis, the preferred treatment options include mycophenolate, azathioprine, rituximab, or calcineurin inhibitors, while additional options include a Janus kinase (JAK) inhibitor or cyclophosphamide. For MCTD, the preferred treatment options include mycophenolate, azathioprine, or rituximab, while additional options include cyclophosphamide. For RA and Sjögren's, the preferred treatment options include mycophenolate, azathioprine, or rituximab, while additional options include cyclophosphamide. Dr. Johnson emphasized that there was low-certainty evidence to recommend one treatment over another. "Many situations might lead a provider to choose a different option for ILD treatment, such as the presence of comorbidities or extra-pulmonary disease," she said. "So, while our guidelines were focused on effectiveness for ILD, providers may choose therapies that will help ILD and other disease manifestations."

The guidelines conditionally recommend a short course of glucocorticoids as a bridging therapy or for treatment of a flare of ILD in patients with myositis, MCTD, RA, and Sjögren's. The panel strongly recommends against the use of glucocorticoids in patients with SSc due to the concern for inducing a scleroderma renal crisis. "While this may be common knowledge for rheumatologists, it may not be common knowledge for pulmonologists," she said. "So here is an opportunity to educate our pulmonology colleagues in our consultation notes."

The guidelines also include recommendations for progression of ILD, which was defined using the INBUILD trial criteria (N Engl J Med 2019;381[18]:1718-27. doi: 10.1056/NEJMoa1908681). Mycophenolate is conditionally recommended to be the first ILD treatment for all SARDs when progression occurs, if it wasn't the first ILD treatment used. "If it was, then other medications that rheumatologists are used to can be considered as the next ILD treatment in the

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Psoriasis and obstructive sleep apnea linked

BY DOUG BRUNK

Patients with psoriasis had a 1.77-fold increased risk of having obstructive sleep apnea (OSA), in a study comparing patients with psoriasis with controls. Prior studies found a link between psoriasis and OSA, but suggested confounders may drive the association. Using a case-control design, researchers analyzed data from 156,707 participants in the National Institutes of Health's (NIH) All of Us Research program: 5,140 with psoriasis and 151,567 controls. They used Pearson's χ^2 test to compare the prevalence of OSA, logistic regression to calculate odds ratios (ORs) in multivariable analysis, and two-sided t-tests to evaluate continuous variable significance.

OSA and psoriasis

Compared with controls, patients with psoriasis were older (62.4 vs 57.3 mean years, respectively), more often White (86.1% vs 70.6%), reported higher annual household incomes (59.9% vs 52.6%), and were more likely to smoke (48.2% vs 43.4%). The OSA rate was significantly higher among patients with psoriasis compared with controls (29.3% vs 17.1%; $P < .001$). On unadjusted multivariable logistic

regression controlling for age, gender, and race, psoriasis was significantly associated with OSA (OR, 1.77, 95% confidence interval, 1.66-1.89; $P < .001$). Psoriasis was also significantly associated with OSA in the adjusted model controlling for age, gender, race, body mass index, and smoking status (OR, 1.66, 95% CI, 1.55-1.77; $P < .001$) and in the adjusted model controlling for age, gender, race, BMI, smoking status, type 2 diabetes, congestive heart failure, hypertension, history of myocardial infarction, angina, and peripheral artery disease (OR; 1.45, 95% CI, 1.35-1.55; $P < .001$).

NIH-funded research

Jeffrey M. Cohen, MD, of the department of dermatology at Yale University, New Haven, Conn., led the research. The study was published in the *Journal of the American Academy of Dermatology* (2023 Nov 24. doi: 10.1016/j.jaad.2023.11.031). Study limitations included the use of electronic health record data, a potential lack of generalizability to the US population, and reliance on survey data for certain variables such as income and smoking status. The All of Us Research Program is supported by the NIH. Dr. Cohen serves on a data safety and monitoring board for Advarra. ■

Air pollution associated with stroke risk

BY ANTARA GHOSH

Exposure to air pollutants is linked to emergency hospital admissions for stroke shortly after the exposure, with the risk highest in men and individuals younger than 65 years. Limited studies have investigated the association between hourly exposure to air pollutants and specific stroke subtypes, especially in regions with moderate to high levels of air pollution. The multicenter case-crossover study evaluated the association between hourly exposure to air pollution and stroke among 86,635 emergency admissions for stroke across 10 hospitals in three cities. Of 86,635 admissions, 79,478 were admitted for ischemic stroke, 3,122 for hemorrhagic stroke, and 4,035 for undetermined type of stroke. Hourly levels of fine particulate matter (PM_{2.5}), respirable PM (PM₁₀), nitrogen dioxide (NO₂), and sulfur dioxide (SO₂) were collected from the China National Environmental Monitoring Center.

Risk related to exposure

Exposure to NO₂ and SO₂ increased the risk for emergency admission for stroke shortly after exposure by 3.34% (95% confidence interval, 1.41%-5.31%)

and 2.81% (95% CI, 1.15%-4.51%), respectively. Among men, exposure to PM_{2.5} and PM₁₀ increased the risk for emergency admission for stroke by 3.40% (95% CI, 1.21%-5.64%) and 4.33% (95% CI, 2.18%-6.53%), respectively. Among patients aged less than 65 years, exposure to PM₁₀ and NO₂ increased the risk for emergency admissions for stroke shortly after exposure by 4.88% (95% CI, 2.29%-7.54%) and 5.59% (95% CI, 2.34%-8.93%), respectively.

Local data on exposure

The study was led by Xin Lv, MD, department of epidemiology and biostatistics, School of Public Health, Capital Medical University, Beijing, and published Oct. 30 in the journal *Stroke* (2023. doi: 10.1161/STROKEAHA.123.044191). Study limitations include localized variations in pollution concentrations due to using data from the nearest monitoring site to the hospital. There may be a possibility of residual confounding resulting from time-varying lifestyle-related factors. The study was supported by the Zhejiang Provincial Project for Medical Research and Health Sciences. No disclosures were reported. ■

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face of progression: rituximab, nintedanib, tocilizumab, and cyclophosphamide," she said. The guidelines include a conditional recommendation against long-term glucocorticoid use in myositis, MCTD, RA, and Sjögren's, plus a strong recommendation against long-term glucocorticoid use in SSc. Finally, there is a conditional recommendation of referral for lung transplant evaluation at the appropriate time at experienced centers.

Another group of recommendations has to do with cases of rapidly progressive ILD, which is characterized by rapid progression from no oxygen or a patient's baseline oxygen requirement to a high oxygen requirement or intubation usually within days to weeks without a documented cause, such as infection or heart failure. "In cases of rapidly progressive ILD, which typically occurs in the setting of anti-MDA5 antibodies, there is a conditional recommendation for IV glucocorticoids plus two additional therapies: traditionally rituximab and mycophenolate," Dr. Johnson said. "However, what may be new to some clinicians is combination IVIG [intravenous immunoglobulin] and a calcineurin inhibitor, notably tacrolimus," she said. "This is the situation where

experience at expert centers is influencing our guidelines in advance of data."

A patient panel provided input

For the undertaking, a core team that included six rheumatologists; one pulmonologist; one thoracic radiologist; one expert on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology; and two literature review experts developed clinically relevant population, intervention, comparator, and outcomes (PICO) questions. The literature review team included 13 rheumatologists, 8 pulmonologists, and 3 methodologists. Finally, a 21-member patient panel was convened to share their values and preferences regarding screening, monitoring, and treatment of SARD-related ILD. Of these, Dr. Bernstein said that 4 were at risk for ILD and 17 had been diagnosed with ILD. Next, the literature review team conducted a systematic review and used the GRADE methodology to rate the available evidence as high, moderate, low, or very low. Then, a voting panel comprising 13 rheumatologists, 10 pulmonologists, 1 radiologist, and 3 patients from the patient panel cast votes for each PICO question and made final recommendations.

The review of evidence left the guidelines authors with 241 PICO questions, "which is a lot," Dr. Bernstein said. "To put this in perspective, some guidelines address only 10 or 15 PICO questions. Fortunately, we had a dedicated group of experts who were up to the challenge." Dr. Johnson emphasized that the forthcoming guidelines should not be used by insurers to mandate a specific order of prescribing. "Clinicians must retain the latitude to prescribe medications based on individual patient factors and preferences," she said.

Dr. Bernstein disclosed that she is an adviser to, a consultant for, and has received grant or research support from Boehringer Ingelheim and has also received grant or research support from Kadmon and Pfizer. Dr. Johnson disclosed that she has received research support from the American College of Rheumatology to develop these guidelines. She has also been an investigator for trials sponsored by Bristol-Myers Squibb, Roche, and Boehringer Ingelheim and has mitigated these relevant conflicts of interest 1 year prior to the development of these guidelines, and will continue to do so for the foreseeable future. ■



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SLEEP MEDICINE

The prospect of a medication to treat OSA is getting closer

BY BERTRAND HERER, MD

For researchers involved with sleep disorders, developing a pharmacologic treatment for obstructive sleep apnea (OSA) is a bit like searching for the holy grail. P.K. Schweitzer and colleagues have published the results of the randomized MARIPOSA study assessing a combination of two medicinal products known as AD109, one of the products having an antimuscarinic effect (aroxybutynin), and the other a noradrenergic effect (atomoxetine), in treating OSA. These molecules increase the activity of the dilator muscles in the upper airways by activating the genioglossus muscle with a synergic effect on the upper respiratory tract during sleep.

MARIPOSA methodology

The trial included 209 patients, 176 of whom completed the 4-week protocol. The trial was double-blinded according to four parallel arms: participants in the first and second arms received AD109 containing doses of 2.5 mg/75 mg and 5 mg/75 mg of aroxybutynin and atomoxetine, respectively. The third arm received atomoxetine alone (75 mg), and the fourth arm was given a placebo.

Two polysomnograms (PSGs) were carried out at the start and end of the trial, allowing researchers to calculate the apnea-hypopnea index (AHI) and to quantify nocturnal desaturation. The impact of these variables is now being deemed as the primary marker of the risk for cardiovascular complications secondary to OSA. Finally, questionnaires that evaluated excessive daytime sleepiness, fatigue, and sleep quality were completed.

The median age varied from 5 to 57 years, depending on the arm of the study, and body mass index varied between 31.2 and 34.5 kg/m². Inclusion criteria comprised an AHI between 10 and 45 events per hour, of which, at least 75% were described as obstructive. Where continuous positive airway pressure (CPAP) was used (21%-30% of cases), it was abandoned during the trial (in a time frame that is perhaps too short to consider these patients as treatment naive).

Combination brought improvements

After the 4 weeks of treatment, the AHI measured via follow-up PSG went from a median of 20.5 to 10.8 (in arm one and from 19.4 to 9.5 in arm two ($P < .0001$ vs placebo in these two arms)). For participants in arm three, AHI went from 19.0 to 11.8 ($P < .01$ vs placebo).

The rate of nocturnal desaturation (in percentage per hour) declined from -12.7 in arm one ($P = .03$), from -16.6 in arm two ($P = .005$), and from -5.2 in arm three ($P = .003$) compared with the placebo. The fatigue score was significantly improved by AD109 2.5 mg/75 mg. The use of atomoxetine alone slightly worsened the sleep disturbance score. The main side effects were dry mouth sensation (which was markedly more common with AD109 5 mg/75 mg), difficulty passing urine in 7%-22% of cases, tachycardia in all trial arms, and

These molecules increase the activity of the dilator muscles in the upper airways by activating the genioglossus muscle with a synergic effect on the upper respiratory tract during sleep.

increased diastolic blood pressure at the 2.5-mg/75-mg dose. The authors concluded that AD109, a combination of noradrenergic and antimuscarinic molecules, is effective in correcting mild to severe OSA.

The 2.5-mg/75-mg dose was as effective as the 5-mg/75-mg dose. Atomoxetine alone is less effective, has more side effects, and is associated with lower quality sleep. Finally, it is reported that compliance with oral treatment was not checked, yet the argument of patient noncompliance with CPAP is largely used by the authors in their presentation of their study. A phase 3 trial is underway.

Nevertheless, these results herald important scientific benefits considering Colin Sullivan's original 1981 research paper, which ushered in the CPAP era, presented the results of just five participants. ■

CHEST introduces five core organizational values

Looking ahead to 2024, one notable accomplishment of the past 12 months that will guide our organization for years to come was to establish CHEST organizational values. The result of a collaborative process that was led by the Value-Setting Work Group and informed by CHEST leaders, members, and staff, the CHEST values are **Community, Inclusivity, Innovation, Advocacy, and Integrity.**

The process to arrive at these values was intentionally designed to ensure input from all corners of the organization. Over the course of 5 months, CHEST members had the opportunity to participate in focus groups or submit written feedback about the proposed values. The feedback shaped subsequent iterations of the values that the work group produced, finally arriving at these five.

“These values are meant to be reflective of the CHEST organization and all of its leaders, members,

and staff,” said Co-Chair of the Value-Setting Work Group and CHEST Board of Regents Member Nneka Sederstrom, PhD, FCCP. “As a society, we’ve come to a point where we can’t pretend that real life issues don’t matter to our patients and to our members. It’s become a pivotal point in our world for our systems to be clear on who they are. All too often, the question of, ‘Is this our lane?’ comes up. These values are a succinct way to show not only what falls into our ‘lane,’ but that we celebrate where we stand. It was a big undertaking, but seeing the collaboration and passion was exceptional.”

The work group was co-chaired by Dr. Sederstrom and Elizabeth Stigler, PhD, and was supported by David Zielinski, MD, FCCP; Bravein Amalakuhan, MD; Alisha Young, MD; Steven Simpson, MD, FCCP; Nehan Sher, MD; and CHEST staff members, Teresa Rodriguez, Manager, CHEST Annual Meeting; Terri Horton-O’Connell, MSW, Director,

Grant and Proposal Development; and Vanessa Rancine, Recruiting Specialist.

“These values are a succinct way to show not only what falls into our ‘lane,’ but that we celebrate where we stand.”

– CHEST Board of Regents Member Nneka Sederstrom, PhD, FCCP

Beyond solidifying the five succinct values, the work group strategically defined each value to clarify its intent.

- **Community:** We invest in the support, growth, and development of everyone involved with CHEST, both individually and collectively, and are tireless champions for one another.
- **Inclusivity:** We cherish the diverse perspectives and experiences of our community members and

amplify their unique voices.

- **Innovation:** We strive for excellence in all that we do with an adaptable and ever-evolving perspective. We pursue bold, future-oriented possibilities for constant improvement and continual growth.
- **Advocacy:** We courageously and intentionally create and foster positive changes for our patients and their families, our members and staff, and the next generation of CHEST clinicians.
- **Integrity:** We take pride in acting responsibly with respect, honesty, and accountability that engenders trust.

“With the new values in place, hopefully, our members will feel a shift in how we, as an organization, show up when anything occurs,” Dr. Sederstrom said. “The values will be reflected through community engagement and support and will be deeply integrated into the CHEST Annual Meeting. When someone asks CHEST, ‘Who are you?’-we can now answer it with certitude.” ■

CRITICAL CARE COMMENTARY

Should intensivists place PEG tubes in critically ill patients?

BY JOHN P. GAILLARD, MD, FCCP

The practice of initiating early and adequate nutrition in critically ill patients is a cornerstone of ICU management. Adequate nutrition combats the dangerous catabolic state that accompanies critical illness. A few of the benefits of this practice are a decrease in disease severity with resultant lessened hospital and ICU lengths of stay, reduced infection rates, and a decrease in hospital mortality. Enteral nutrition (EN) is the route of nutritional support most associated with safe and effective provision of enhanced immunologic function and the ability to preserve the patient’s lean body mass while avoiding metabolic and infectious complications.

PEG tube placement by intensivists is a procedure that will undoubtedly benefit patients in the ICU and assist in offloading the operation costs of critical care units.

Since its inception in 1980, percutaneous endoscopic gastrostomy (PEG) tubes have become the preferred method for delivering EN in ICUs across the United States. When comparing PEG and nasogastric tubes (NGTs), evidence shows reduced bleeding events, less tube dislodgement, and decreased tube obstructions with a faster rate

of recovery of previous swallowing function that prevents delays in medical care and increased mortality rate. Although PEG tubes do not entirely prevent acid reflux or aspiration events, they are positively correlated to significantly reduced rates of both which result in a survival benefit seen in a 2012 study (*Psychiatry Clin Neurosci.* 2012 Aug;66[5]:418).

The majority of PEG tubes placed in the United States has unquestionably shifted to the ICU patient population since 2014 according to the largest health care database search on this topic published in 2019 (*Ann Am Thorac Soc.* 2019 Jun;16[6]:724). The safety and efficacy of this procedure has only improved, yet the delayed timing of placement remains problematic and often exceeds what is medically necessary or financially feasible.

To understand this issue, it is important to consider that despite intensivists being globally recognized as procedurally sound with enhanced ultrasound expertise, their endoscopic experience is usually limited to bronchoscopy without formal training in upper gastrointestinal endoscopy. This is the leading theory to explain why intensivists are performing their own percutaneous tracheostomies but not gastrostomies. Fortunately, the FDA-approved Point of Care Ultrasound Magnet Aligned Gastrostomy (PUMA-G) System has shown analogous safety and efficacy when compared with the traditional endoscopically placed PEG tube technique (*J Intensive Care Med.* 2022 May;37[5]:641).

A case series was recently published in 2021



Dr. Gaillard is Associate Professor in the Departments of Anesthesiology, Section on Critical Care, Internal Medicine, Section on Pulmonology, Critical Care, Allergy, and Immunologic Diseases, Wake Forest University School of Medicine, Winston-Salem, NC.

that included three intensivists who underwent a 3-hour cadaver-based training course for the PUMA-G System with a mandatory minimum successful placement of three gastric tubes (*J Clin Ultrasound.* 2021 Jan;49[1]:28). Once they demonstrated competence in the technique, the procedure was performed on mechanically ventilated and sedated patients without any reported complications peri-procedurally or over the next 30 days. The evidence that intensivists can use their current skillset to rapidly become competent in this ultrasound-guided bedside procedure is without question.

PEG tube placement by intensivists is a procedure that will undoubtedly benefit patients in the ICU and assist in offloading the operation costs of a significant number of critical care units and their associated organizations. This is an area ripe for growth with further education and research. ■

CHEST grant winners to study health inequities related to air pollution, medication nonadherence, and more

In 2023, CHEST awarded \$300,000 in clinical research and community impact grants to 15 individuals. Grant recipients are recognized for their scientifically meritorious achievements, with rigorous metrics to track their project's progress, and have innovative, novel approaches to addressing their research topic.

CHEST grants have made a difference in patients' lives by leading to breakthroughs in the treatment and/or management of chest diseases and patient care. This year's grant-funded projects run the gamut of topics within chest medicine, ranging from lung cancer and COPD to tuberculosis and idiopathic pulmonary fibrosis.

Here's a glimpse into two of this year's grant winners and their projects.

For a full list of the 2023 grant winners, visit chestnet.org/grant-recipients.

Air pollution in sarcoidosis

This year, the John R. Addrizzo, MD, FCCP Research Grant in Sarcoidosis was awarded to Ali Mustafa, MD, of the Johns Hopkins Hospital in Baltimore, MD, for his project "Air Pollution in Sarcoidosis."

The project's aim is to investigate the feasibility of studying indoor and outdoor air pollution in patients with pulmonary sarcoidosis.

According to Dr. Mustafa's application, pulmonary sarcoidosis is one of the most common interstitial lung diseases in the United States, and mortality due to sarcoidosis has risen by more than 3% in recent decades.



Dr. Ali Mustafa



Dr. Stephanie LaBedz

While the etiology of sarcoidosis remains elusive, evidence points toward a combination of genetic predisposition with external environmental triggers affecting disease onset. One small study of 16 individuals with fibrotic pulmonary sarcoidosis assessed the association between local levels of outdoor air pollutants to clinical outcomes. This study found that increased short-term exposure was associated with increased respiratory symptom severity and worse health-related quality of life.

Additionally, significant health disparities exist in sarcoidosis. Black individuals with sarcoidosis have worse pulmonary function, higher rates of multiorgan disease, and as much as a 12-fold increase in mortality compared with non-Hispanic White individuals with sarcoidosis. Socioeconomic status and Black race have

also been associated with increased exposure to air pollution and closer proximity to high toxic emission facilities, suggesting higher exposure to outdoor air pollution.

Racial disparities are present and particularly important in sarcoidosis. Black individuals are more likely to have more advanced disease at diagnosis, have a six-fold increase in hospitalization, and a 12-fold increase in mortality compared with non-Hispanic White individuals with sarcoidosis. Little is known about the drivers of these disparities; however, environmental exposure has been implicated in sarcoidosis pathogenesis and incidence and may be an important contributor.

Dr. Mustafa's preliminary work suggests disparities in exposure to air pollution among individuals with sarcoidosis may be contributing to inequities in clinical outcomes.

Determinants of medication non-adherence among adults with chronic obstructive pulmonary disease

The CHEST/ALA/ATS Respiratory Health Equity Research Award was given to Stephanie LaBedz, MD, of the University of Illinois Chicago. The Respiratory Health Equity Research Award is jointly supported by the American Lung Association, the American Thoracic Society, and CHEST.

Dr. LaBedz's project, "Determinants of Medication Non-Adherence Among Adults With Chronic Obstructive Pulmonary Disease," aims to

GRANTS *continued on following page*

This month in the journal CHEST®

Editor's picks

BY PETER J. MAZZONE, MD, MPH, FCCP

Editor in Chief

Read these articles and more by visiting journal.chestnet.org.

Indicators of Neighborhood-Level Socioeconomic Position and Pediatric Critical Illness

By *Carlie N. Myers, MD, et al.*

Restrictive Visitation Policies and Related Post-Traumatic Stress Among Families of Critically Ill Patients With COVID-19

By *Katherine R. White, MD, et al.*

Central and Peripheral Hemodynamics in Young Adults Who Use Water Pipes and the Acute Effects of Water-Pipe Use

By *Hassan A. Chami, MD, et al.*

Multiplex Polymerase Chain Reaction Assay to Detect Nasopharyngeal Viruses in Immunocompromised Patients With Acute Respiratory Failure

By *Alexis Maillard, MD, et al.*

The Economic Burden of Bronchiectasis: A Systematic Review

By *Jack M. Roberts, et al.*

Emotional Distress, Anxiety, and General Health Status in



Patients With Newly Identified Small Pulmonary Nodules: Results From the Watch the Spot Trial

By *Michael K. Gould, MD, et al.*

Antithrombotic Therapy in Arterial Thrombosis and Thromboembolism in COVID-19: An American College of Chest Physicians Expert Panel Report

By *Tatjana Potpara, MD, PhD, et al.*



In memoriam

CHEST has been informed of the following deaths of CHEST members. We remember our colleagues and extend our sincere condolences.

- Ali Massoumi, MD, MS
- Venkat Kondragunta Rao, MBBS, FCCP
- Naorem I. Singh, MD
- Glenn J. Williams, MD, PhD

Coding & Billing: A look into bronchoscopic codes and digital evaluations

BY MIKE NELSON, MD, FCCP
CHEST AMA CPT® Representative; Member,
ATS/CHEST Joint Clinical Practice Committee

Pulmonary physicians and particularly interventional bronchoscopists have been receiving denials when CPT® codes **31628** Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe and **31629** Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i) are billed during the same procedure.

While the difference between a transbronchial forceps biopsy and transbronchial needle biopsy are obvious to bronchoscopists, there has been confusion with payers. This could have been partly on the basis of a CPT Assistant article from March 2021 describing the use of both codes that stated, “Note that performing two types of lung biopsy (forceps and needle aspiration) on the same lesion would be considered unusual and documentation of medical necessity should clearly describe why both types of biopsy were clinically necessary.” This may have been interpreted by coders and/or payers to mean that the two codes should be billed together rarely or not at all. It is also possible that computer-based coding programs (eg, Optum/Encoder Pro, etc) are responsible for these inappropriate denials. There are, however, no NCCI edits that disallow this nor was this the intent of the CPT codes when they were developed.

The previous statement from the CPT Assistant article was clarified in the following sentences, “For example, if needle aspiration were performed and immediate screening of the sample were insufficient for diagnosis, a forceps biopsy would be



appropriate and reported separately. On the other hand, if a physician performed a needle aspiration out of concern that the lesion was vascular and found that it was not and proceeded with a forceps biopsy, then the needle aspiration would be integral to the forceps biopsy and not separately reported.” Importantly, with the increasing use of navigational bronchoscopy and robotic bronchoscopy, these codes will be used together more frequently, appropriately, and correctly, especially on distal lesions.

Remember, these codes are used for procedures in a single lobe. If multiple lobes are sampled then CPT codes **31632** and **31633** would be added to **31628** and **31629**, respectively. If one is receiving denials for these procedures, coders and payers should be notified of these errors, and denials should be appealed.

Q&A

Question: My practice is wondering if we can use the newer codes for online digital E/M services? We know they are time-based, but we are confused about when they cannot

be used. Can you please help? For example, I had an established COPD patient send a message through the electronic health record’s patient portal reporting new symptoms of headache, cough, and sputum production. They asked me to review the chest x-ray that was done two days prior when they went to urgent care. The patient is asking for an assessment and management plan. We message back and forth over the next day for a total of 13 minutes. Three days later, the patient developed more symptoms and then scheduled an office visit. How would I bill for this? **99212-99215** (Established Office E/M) or **99422** (Online digital E/M 11-20 minutes)?

Answer: Online Digital E/M services (**99421**, **99422**, **99423**) are to be used for established patients, only. They are time-based codes and cumulative up to seven days. They are to be reported for asynchronous communication via HIPAA-compliance secure platforms, such as through the electronic health record portal, portal email, etc. They may not be reported if an E/M occurs within seven days before or after, though

the time may be incorporated into the subsequent E/M. These codes are not to be used for communication of test results, scheduling of appointments, or other communication that does not include E/M. In your example, you would report the appropriate Office/Outpatient Established CPT code (**99212-99215**).

99421 – Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes

99422 – Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes

99423 – Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes

Question: Is Cardiopulmonary Resuscitation in the Intensive Care Unit considered to be part of Critical Care services? (**99291-99292**)? There appears to be confusion in our billing department on this issue.

Answer: **92959** Cardiopulmonary resuscitation is not bundled into **99291-99292**. Consider it as a procedure. To code for this service in addition to Critical Care, the time for the CPR must be separate from the time for Critical Care (**99291-99292**). A separate procedure note must also be documented. There is no minimum time for this service, and a 25 modifier must be included, as well. **92950** reimburses at 4.00 wRVUs and may be reported two times per calendar day. ■

Originally published in the September 2023 issue of the American Thoracic Society’s ATS Coding & Billing Quarterly. Republished with permission from the American Thoracic Society.

GRANTS *continued from previous page*

use behavioral science theory to identify barriers and facilitators to COPD medication adherence.

Studies suggest racial minorities and individuals of low socioeconomic status (SES) are less likely to be adherent to COPD medications compared with White and high SES patients with COPD. Interventions designed to improve COPD medication adherence must

address barriers to adherence experienced by these groups to avoid perpetuating disparities in adherence and downstream outcomes disparities.

For her project, Dr. LaBedz will focus on examining barriers and facilitators of COPD medication adherence, including social determinants of health and other structural barriers faced by these vulnerable populations. She will use the

information gained from the qualitative study to design interventions that address the barriers to adherence faced by these groups.

Her long-term goal is to improve COPD medication adherence in vulnerable patients with COPD in order to improve the health status and reduce health disparities experienced by racial/ethnic minority and low SES patients with COPD. ■

Quitting tobacco can improve lung health in COPD

BY HEIDI SPLETE

Reducing exposure to tobacco smoke may reduce the burden of chronic obstructive pulmonary disease, and public health measures are needed, according to a new Tobacco Knowledge Summary from the World Health Organization (WHO). “Smoking is a major risk factor for COPD and leads to airway inflammation and remodeling associated with lung destruction,” and contributes to approximately 70% of COPD cases worldwide, according to the statement.

Tobacco exposure includes smoked tobacco products (cigarettes, cigars, pipes, water pipes, kreteks, and bidis), smokeless tobacco, heated tobacco products, and electronic nicotine delivery systems. Added chemicals and flavors can increase the appeal of tobacco products and promote addiction, the authors wrote, adding, hookahs and water pipes “are at least as detrimental to lung health as smoking cigarettes, and should not be considered as safe alternative[s].”

The risk of COPD includes e-cigarette products, the authors noted. A study in the *American Journal of Preventive Medicine* showed current users of e-cigarettes had a 75% increased risk of developing COPD compared never-users. Individuals with COPD face an increased risk of cardiovascular disease and type

2 diabetes. Smokers with COPD who quit improve their COPD and reduce their risk of developing these conditions, the authors said.

Mechanism of action explored

The authors noted how tobacco smoking may cause COPD when inhaled particles are deposited through the airway. Growing evidence suggests extracellular vesicles may play a role in the development of lung disorders such as COPD, and cigarette smoke can have an impact through this channel. A study published in the *American Journal of Respiratory and Critical Care Medicine* offered evidence of a potential link between exposure to cigarette smoke and the generation of a unique extracellular vesicle population that could promote the development of lung damage. In the study, Matthew C. Madison, MD, of the University of Alabama, Birmingham, and colleagues examined activity in extracellular vesicles from the bronchoalveolar lavage fluid of smoke-exposed mice and otherwise healthy human smokers.

The researchers found that airway extracellular vesicles in mice or humans exposed to cigarette smoke could cause rapid lung damage when transferred into naive recipient mice. The results provide a new model that can inform preclinical COPD research, they wrote.

Public health action needed

“The WHO emphasizes the impact of various forms of tobacco use on COPD,” Dharani Narendra, MD, FCCP, of Baylor College of Medicine, Houston, said in an interview. “This article focuses on the different types of tobacco exposure, the health care burden associated with COPD, and the risk of developing lung cancer. It also addresses the high-risk groups, especially youth, underscoring the importance of public education and the implementation of restrictions on tobacco use to combat these growing concerns,” she said. “Education, awareness, and targeted interventions are essential for smoking cessation and COPD management,” said Dr. Narendra. “These elements are key to informing the public about smoking risks, encouraging behavioral change, and ultimately reducing the incidence of smoking-related diseases,” she emphasized.

The WHO statement called for population-level interventions including brief advice to tobacco users, toll-free quit lines, pharmacological interventions, use of messaging and chatbots to provide quit support, and the WHO quit tobacco mobile app.

Finally, the authors emphasized the need to protect children and teens from the dangers of tobacco use through product regulation and to expose the tobacco industry’s

marketing tactics. “The article offers a comprehensive look at different types of tobacco exposure and their contribution to the development of COPD,” Dr. Narendra said. “Notably, it presents groundbreaking evidence of a strong association between the use of electronic nicotine delivery systems and heated tobacco products to development of COPD; additionally, it provides valuable guidance on smoking cessation resources for physicians to help patients quit smoking,” she said.

Looking ahead, Dr. Narendra said, more research is needed on “developing and sustaining state-specific or population-specific interventions for effective smoking cessation programs, and reducing the burden of COPD.”

The study by Madison and colleagues was supported by the National Heart, Lung, and Blood Institute, the National Institute of General Medical Science, the U.S. Veterans Affairs Administration, the Cystic Fibrosis Foundation Research Development Program, and the Veterans Affairs Merit grant. Additional financial support came from Imperial College London, a Wellcome Trust Senior Research Fellowship, and Rosetrees Trust/The Stonegate Trust. Dr. Narendra had no financial conflicts to disclose but serves as a member of the editorial board of *CHEST Physician*. ■

Smoking may alter salivary microbiota, raise disease risk

BY HEIDI SPLETE

Salivary microbiota changes caused by cigarette smoking may affect metabolic pathways and increase disease risk. Researchers analyzed health information and data on the composition of salivary microbiota from 1601 adult participants in the Cooperative Health Research in South Tyrol (CHRIS) microbiome study (CHRISMB); CHRIS is an ongoing study in Italy.

The average age of the study population was 45 years; 53% were female, and 45% were current or former smokers. The researchers hypothesized that changes in salivary microbial composition would be associated with smoking, with more nitrate-reducing bacteria present, and that nitrate reduction pathways would be reduced in smokers.

Salivary microbiota

The researchers identified 44 genera that differed in the salivary microbiota of current smokers and nonsmokers. In smokers, seven genera in the phylum Proteobacteria were

decreased and six in the phylum Actinobacteria were increased compared with nonsmokers; these phyla contain primarily aerobic and anaerobic taxa, respectively.

Some microbiota changes were significantly associated with daily smoking intensity; genera from the classes Betaproteobacteria (*Lautropia* or *Neisseria*), Gammaproteobacteria (*Cardiobacterium*), and Flavobacteriia (*Capnocytophaga*) decreased significantly with increased grams of tobacco smoked per day, measured in 5-g increments.

Smoking was associated with changes in the salivary microbiota; the nitrate reduction pathway was significantly lower in smokers compared with nonsmokers, and these decreases were consistent with previous studies of decreased cardiovascular events in former smokers.

However, the salivary microbiota of smokers who had quit for at least 5 years resembled that of individuals who had never smoked.

“Decreased microbial nitrate reduction pathway abundance in smokers may provide an additional explanation for the effect of smoking on

cardiovascular and periodontal diseases risk, a hypothesis which should be tested in future studies,” the researchers wrote.

Cross-sectional design

The lead author of the study was Giacomo Antonello, MD, of Eurac Research, Affiliated Institute of the University of Lübeck, Bolzano, Italy. The study was published online in *Scientific Reports* (a Nature journal) on November 2, 2023 (doi: 10.1038/s41598-023-42474-7).

The cross-sectional design and lack of professional assessment of tooth and gum health were limiting factors, as were potential confounding factors including medication use, diet, and alcohol intake.

The study was supported by the Department of Innovation, Research and University of the Autonomous Province of Bolzano-South Tyrol and by the European Regional Development Fund. The CHRISMB microbiota data generation was funded by the National Institute of Dental and Craniofacial Research. The researchers had no financial conflicts to disclose. ■

Asthma severity higher among LGBTQ+ population

BY NEIL OSTERWEIL

FROM CHEST 2023 ■ HONOLULU – Sexual and gender minority (SGM) people are at increased risk for asthma severity, compared with non-SGM people, and asthma is especially exacerbated in SGM persons who use e-cigarettes compared with heterosexuals.

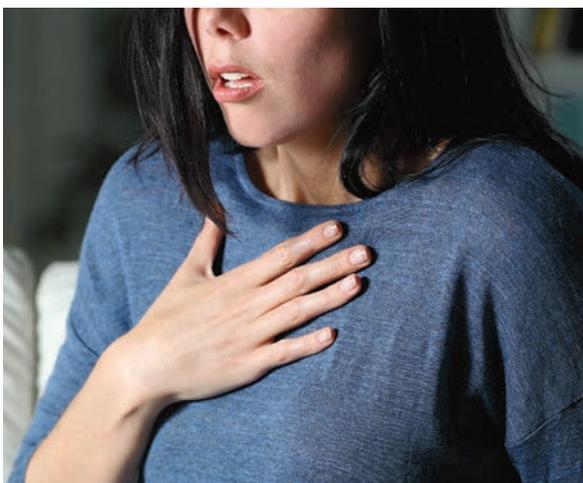
These findings come from a study of asthma severity among SGM people, with a special focus on the contribution of tobacco, reported Tugba Kaplan, MD, a resident in internal medicine at Luminis Health Anne Arundel Medical Center, Annapolis, Md.

“To the best of our knowledge, this is the first study assessing asthma severity among SGM people in a nationally representative longitudinal cohort study,” she said in an oral abstract session at the annual meeting of the American College of Chest Physicians (CHEST).

There has been only limited research on the health status and health needs of SGM people, and most of the studies conducted have focused on issues such as HIV/AIDS, sexual health, and substance use, not respiratory health, she said.

Following the PATH

Dr. Kaplan and colleagues drew on data from the Population Assessment of Tobacco and Health (PATH) Study, a nationally representative longitudinal cohort study with data on approximately 46,000 adults and adolescents in the United States.



AntoninoGuillem/Getty Images

The study uses self-reported data on tobacco use patterns; perceptions of risk and attitudes toward tobacco products; tobacco initiation, cessation, and relapse; and associated health outcomes.

The investigators combined data from three waves of the PATH Study, conducted from 2015 to 2019 on nonpregnant participants aged 18 years and older, and used mixed-effect logistic regression models to look for potential associations between sexual orientation and asthma severity.

They used standard definitions of asthma severity, based on lung function impairment measured by forced expiratory volume in 1 second and forced vital capacity, nighttime

awakenings, use of a short-acting beta2-agonist for symptoms, interference with normal activity, and exacerbations requiring oral systemic corticosteroids.

The study also includes a sexual orientation question, asking participants, “do you consider yourself to be ...” with the options “straight, lesbian or gay, bisexual, something else, don’t know, or refused.”

Based on these responses, Dr. Kaplan and colleagues studied a total sample of 1,815 people who identify as SGM and 12,879 who identify as non-SGM.

Risks increased

In an analysis adjusted for age, sex, race/ethnicity, tobacco use, body mass index, physical activity, and asthma medication use, the authors found that, compared with non-SGM people, SGM respondents were significantly more likely to have had asthma attacks requiring steroid use in the past years (odds ratio, 1.47; 95% confidence interval, 1.01-2.15), asthma interfering with daily activities in the past month (OR, 1.33; 95% CI, 1.10-1.61), and shortness of breath in any week over the 30 days (OR, 1.82; 95% CI, 1.32-2.51). There was no significant difference between the groups in inhaler use over the past month, however.

They also found two interactions in the logistic regression models, one between urgent care visits and respondents who reported using both regular

ASTHMA continued on following page

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Learn More and Apply

Intense exercise may lead to colds?

BY COURTNEY SOUTHWICK

Can too much of a healthy habit become bad?

Lots of evidence shows that regular exercise wards off respiratory infections such as colds, flu, and COVID-19. However, very vigorous exercise may lead to these infections by triggering immune changes that increase risk, according to a new study.

The findings come as we enter another possible tripledemic this winter, with an increase in COVID, flu, and respiratory syncytial virus (RSV). Public health officials are on alert for a potentially severe flu season, following high flu activity this year in Australia (which can help predict how bad the U.S. flu season will be).

Studies show that the risk for acute respiratory infections is lower in people who exercise regularly. Physically active people are also less likely to suffer severe outcomes from COVID.

But while inactivity has emerged as a potential risk factor for respiratory infections, scientists have long proposed that too much activity, particularly of a prolonged and highly intense nature, may also increase susceptibility.

“The theory suggests that a short-term suppression of the immune system following intense exercise leads to an increase in susceptibility to infection, especially upper respiratory illness,” said Choukri Ben Mamoun, PhD, professor of medicine (infectious diseases) and microbial pathogenesis at the Yale Institute for Global Health, New Haven, Conn. Researchers have documented a greater incidence of upper respiratory illness “among both highly trained and healthy untrained individuals following



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increased activity during competition or heaving training blocks.”

That’s important if you treat athletes or patients with physically demanding jobs that push them to their physical limits, such as firefighters, police officers, or military personnel.

The new study was small but sheds light on a possible mechanism. Researchers tested blood, saliva, and urine samples from 11 firefighters before and 10 minutes after intense exercise designed to mimic wildfire fighting. The firefighters hiked over hilly terrain for 45 minutes in humid weather wearing up to 44 pounds of wildland gear.

After the workout, subjects had fewer proinflammatory cytokines and ceramides, and more antimicrobial peptides, changes that indicate a greater susceptibility to infection, researchers said. A systematic review adds weight to their findings, revealing a handful of studies in marathon runners, firefighters, soldiers, and soccer players that found an increase in respiratory symptoms after strenuous workouts.

“The relationship between

exercise and the immune system is complex and varies from person to person,” said Dr. Mamoun, who was not part of the study. “Physicians can use this study’s findings to provide individualized exercise recommendations.”

An adaptive mechanism gone awry

During intense exercise, the body may reduce airway inflammation to help you breathe, say the authors. The boost in antimicrobial peptides found in the saliva samples could be the body’s way of compensating for the diminished immune function.

Antimicrobial peptides are part of the immune response but they’re “usually not very effective for viral infections,” said lead author Ernesto Nakayasu, PhD, senior research scientist at the Pacific Northwest National Laboratory, a U.S. Department of Energy lab in Richland, Wash. “That’s why we think it may make you more exposed to respiratory infections.”

The drop in proinflammatory molecules had an inverse relationship with opiorphin, a peripheral

tissue vasodilator thought to increase blood flow and improve oxygen delivery to the muscles during exercise. This may be an adaptive mechanism to improve gas exchange in response to greater oxygen demand.

But as with many adaptive mechanisms, this one may have an unintended consequence. Fewer proinflammatory molecules on patrol may leave you more vulnerable to infection. Plus, during intense exercise, people tend to breathe through their mouths, bypassing the nasal barriers and allowing more microbes – including viruses – to penetrate and deposit in the distal airways of the lungs.

Advice for patients

More research is needed to know exactly how long and how strenuously one needs to exercise to trigger these immune changes, Dr. Nakayasu said.

As shown by their lactate accumulation (an indicator of anaerobic metabolism), the firefighters in the study outpaced the average person’s aerobic respiratory capacity, meaning the average person doing moderate exercise likely wouldn’t trigger these changes.

“Regular moderate exercise is generally associated with better health outcomes [and] improved immune function,” said Dr. Mamoun. For those who exercise to the extreme, proper rest and recovery are “essential for maintaining a robust immune system,” Dr. Mamoun said.

And of course, you can encourage patients to get vaccinated. Young, healthy patients may assume they don’t need COVID-19 or flu shots, as indicated by a recent survey that found one-third of Americans feel they don’t need these vaccinations if they’re not high risk. ■

ASTHMA continued from previous page

tobacco and e-cigarettes (dual users), and between exclusive e-cigarette use and waking up at night.

Among dual users, SGM respondents had a nearly fourfold greater risk for asthma attacks requiring urgent care visits, compared with non-SGM respondents (OR, 3.89; 95% CI, 1.99-7.63). In contrast, among those who never used tobacco, there were no significant differences between the sexual orientation groups in regard to asthma attacks requiring urgent care visits.

Among those who reported using e-cigarettes exclusively, SGM respondents were nearly eight times more likely to report night awakening, compared with non-SGM users (OR, 7.81; 95% CI, 2.93-20.8).

Among never users, in contrast, there was no significant difference in nighttime disturbances.

Possible confounders

The data suggest that “in the context of chronic illnesses like asthma, it is crucial to offer patients the knowledge and tools required to proficiently handle their conditions,” Dr. Kaplan said, adding that the differences seen between SGM and non-SGM respondents may be caused by health care disparities among SGM people that result in non-adherence to regular follow-ups.

In an interview, Jean Bourbeau, MD, MSc, who was a moderator for the session but was not involved in the study, commented that “we have to be very careful before making any conclusions,

because this population could be at high risk for different reasons, and especially, do they get the same attention in terms of the care that is provided to the general population, and do they get access to the same medication?”

Nonetheless, Dr. Bourbeau continued, “I think this study is very important, because it shows us how much awareness we need to determine differences in populations, and [sexual orientation] is probably one thing that nobody had considered before, and for the first time we are now considering these potential differences in our population.”

The authors did not report a study funding source. Dr. Kaplan and Dr. Bourbeau reported having no relevant financial relationships. ■

Smartphone app detects voice quality changes indicating worsening heart failure

BY WALTER ALEXANDER

Worsening heart failure is accompanied by a build-up of fluid in the lungs. An artificial intelligence (AI) smartphone app that picks up changes in a heart failure patient's voice quality caused by this fluid accumulation and then alerts the physician about them – nearly 3 weeks before that ongoing decompensation would necessitate hospitalization and/or lead the physician to urgently introduce intravenous diuretics – is getting experts to sit up and take notice.

“In this incredibly prevalent waxing and waning condition, finding ways to identify worsening heart failure to prevent hospitalization and progressive disease is incredibly important,” observed American Heart Association (AHA)-appointed discussant David Ouyang, MD, assistant professor, Smidt Heart Institute, Division of Artificial Intelligence in Medicine, Cedars Sinai, Los Angeles. “Heart failure remains among the most common causes of hospitalization for older adults in the United States.

“The other standout feature is that we all use our cell phones on a daily basis,” Dr. Ouyang said at a late-breaking trial press briefing at the AHA 2023 annual meeting where results of the HearO Community Study were presented. “The ability to capture data from routine speech (patients speak five sentences into their phones every morning) is remarkable. ... The HearO technology was able to detect a substantial proportion of worsening heart failure events, with an average per individual of only three false positives over the course of a year. And, adherence to the study protocol was 81%. That's higher than in many other kinds of routine patient monitoring studies,” he added.

Accumulating fluid changes speech

Increased hydration may affect speech parameters such as pitch, volume, and dynamics through swelling of soft tissues in the vocal tract (e.g., pharynx, velum, tongue, and vocal folds). In the Israeli study, investigators enrolled 416 adults (75% were male, average age was 68 years) whose New York Heart Association (NYHA) 2-3 heart failure with either reduced or preserved ejection

fraction was stable but placed them at-risk for heart failure events. The study goal was to analyze their speech data using the HearO® system to refine and test its ability to detect impending heart failure deterioration. Patients recorded five sentences in their native language (Hebrew, Russian, Arabic, or English) into the smartphone app daily. In a training phase of the study, distinct speech measures from 263 participants were used to develop the AI algorithm. Then, the algorithm was used in the remaining 153 participants to validate the tool's effectiveness. In its ultimate form, once a deviation from the patient's predefined baseline is detected, the app will generate a notice and send it to the health care practitioners.

Lead study author William T. Abraham, MD, FAHA, professor of medicine, physiology, and cell biology; and a College of Medicine Distinguished Professor in the division of cardiovascular medicine at The Ohio State University in Columbus, reported that between Mar. 27, 2018, and Nov. 30, 2021, subjects in the training phase made recordings on 83% of days. They were followed for up to 44 months. The test group made recordings on 81% of days between Feb. 1, 2020, and Apr. 30, 2023, and were followed for up to 31 months. Heart failure events were defined as hospitalization or outpatient intravenous diuretic treatment for worsening heart failure.

In the training phase, the app accurately predicted 44 of 58 heart failure events (76%) and 81% of first events (n = 35) on average 24 days before hospitalization or need for intravenous fluids. In the validation phase, the app was 71% accurate in detecting 10 of 14 heart failure events and 77%

Jonathan Ludmir, MD, comments: Managing heart failure symptoms and keeping patients out of the hospital is a huge challenge. Novel therapies and therapeutics are necessary to help these patients mitigate symptoms and prevent deterioration. The AI smartphone app is intriguing, but seems to still be on the newer side. I don't think it should replace the importance of checking daily weights and monitoring daily symptoms. That being said, we know that just daily weights/symptom checks are often not sufficient. The Cardiomeas is an invasive monitor that provides real time pulmonary artery pressure readings that also helps guide diuretic treatment. However, that is invasive. If the AI app continues to show promise, it will hopefully help to prevent admissions.



Dr. Ludmir is a member of the CHEST Physician Editorial Board.

of first events (n = 10) on average 26 days in advance of events. In both periods, the app generated about 3 unnecessary alerts per patient year.

Dr. Abraham concluded, “This technology has the potential to improve patient outcomes, keeping patients well and out of the hospital, through the implementation of proactive, outpatient care in response to voice changes.”

The HearO technology is being evaluated in an ongoing pivotal trial in the United States, Dr. Abraham said. The study is limited, he added, by the small number of patients and heart failure events, particularly in the test group.

“We continue to struggle with the burden of heart failure morbidity,” observed AHA press briefing moderator (and past AHA president) Clyde Yancy, MD, Magerstadt Professor at Northwestern University, Chicago. “So any tool that we can utilize and further refine that helps us address the need for hospitalization becomes very important. The

idea that speech evaluation might give us sufficient early warning to forestall any admissions – and consider the cost savings attributable to that – is a very credible goal that we should continue to follow.” He pointed out that the technology enables assessments in the home environment for older patients who are less mobile.

In response to a press briefing question about the potential for physicians to be trained to hear early subtle voice changes on their own, Dr. Abraham stated, “I guess that is unknown, but the important difference is the system's ability to take data in every day from patients and then process it automatically with AI.”

Joining in, Dr. Yancy said, “You know, this is interesting because even if you saw a patient once a month, which is an incredible frequency for any practice, there's still 353 days that you haven't seen the patient.” He noted that the AHA had just announced a multi-million dollar program to more deeply understand telemanagement. “So I think this is here to stay,” Dr. Yancy said.

Dr. Ouyang posed a further question. “Like with most AI recognition tools, we can now identify individuals at risk. How do we get from that step of identifying those at risk to improving their outcomes? This has been a critical question about heart failure, remote management, and remote monitoring, and I think it is a critical question for many of our AI tools.”

Dr. Abraham disclosed that he has received personal fees from Cordio Medical. Dr. Ouyang said that he had no disclosures relevant to this presentation. ■



ArtemisDiana/iStock/Getty Images

Chest pain with long COVID common but undertreated

BY MEG BARBOR, MPH

As many as 87% of patients experience symptoms after COVID-19 infection that last 2 months or more, one of the most common being chest pain. Chronic chest discomfort may persist in some individuals for years after COVID, warranting future studies of reliable treatments and pain management.

“Recent studies have shown chest pain occurs in as many as 89% of patients who qualify as having long COVID,” said Ansley Poole, an undergraduate student at the University of South Florida, Tampa, who conducted the research under the supervision of Christine Hunt, DO, and her colleagues at Mayo Clinic, Jacksonville, Fla. The preliminary findings shed light on the prevalence, current treatments, and ongoing challenges in managing symptoms of long COVID, said Ms. Poole.

Long COVID, which affects an estimated 18 million Americans, manifests approximately 12 weeks after the initial infection and can persist for 2 months or more. Ms.

Poole and her team set out to identify risk factors, treatment options, and outcomes for patients dealing with post-COVID chest discomfort. The study involved a retrospective chart review of 520 patients from the Mayo Clinic network, narrowed to a final sample of 104. To be included, patients had to report chest discomfort 3-6 months post COVID that continued for 3-6 months after presentation, and no history of prior chronic chest pain. The researchers identified no standardized method for the treatment or management of chest pain linked to long COVID. “Patients were prescribed multiple different treatments, including opioids, post-COVID treatment programs, anticoagulants, steroids, and even psychological programs,” Ms. Poole said.

The median age of the patients was around 50 years; more than 65% were female and more than 90% were White. More than half (55%) had received one or more vaccine doses at the time of infection. The majority were classified as overweight or obese at the time of their SARS-CoV-2 infection. Of the 104

patients analyzed, 30 were referred to one or more subspecialties within the pain medicine department, 23 were hospitalized, and 9 were admitted to the intensive care unit or critical care.

Overall, chest pain was described as intermittent instead of constant, which may have been a barrier to providing adequate and timely treatment. The inconsistent presence of pain contributed to the prolonged suffering some patients experienced, Ms. Poole noted.

The study identified several comorbidities, potentially complicating the treatment and etiology of chest pain. These comorbidities – when combined with COVID-related chest pain – contributed to the wide array of prescribed treatments, including steroids, anticoagulants, beta blockers, and physical therapy. Chest pain also seldom stood alone; it was often accompanied by other long COVID-related symptoms, such as shortness of breath. “Our current analysis indicates chest pain continues on for years in many individuals, suggesting COVID-related chest pain may be resistant to treatment,” Ms. Poole reported.

The observed heterogeneity in treatments and outcomes in patients experiencing long-term chest discomfort after COVID infection underscores the need for future studies to establish reliable treatment and management protocols for this population, said Dalia Elmofty, MD, an associate professor of anesthesia and critical care at the University of Chicago, who was not involved in the study. “There are things about COVID we don’t fully understand. As we’re seeing its consequences and trying to understand its etiology, we recognize the need for further research,” Dr. Elmofty said.

“So many different disease pathologies came out of COVID, whether it’s organ pathology, myofascial pathology, or autoimmune pathology, and all of that is obviously linked to pain,” Dr. Elmofty said. “It’s an area of research we are going to have to devote a lot of time to in order to understand, but I think we’re still in the very early phases, trying to fit the pieces of the puzzle together.”

Ms. Poole and Dr. Elmofty report no relevant financial relationships. ■

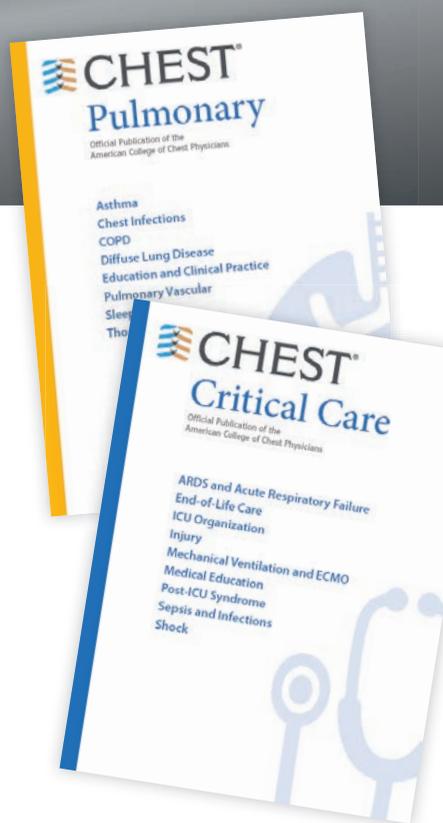
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START APPLYING TODAY

Breast implants used to maintain heart position before double lung transplant

BY HEIDI SPLETE

An innovative surgical procedure combining breast implants and an artificial lung may help more patients with severe lung disease survive to receive transplants. The case was described in a press conference sponsored by Northwestern University, Evanston, Ill.

In May 2023, a surgical team at Northwestern removed both infected lungs from David “Davey” Bauer, aged 34 years, and temporarily used double D breast implants to hold his heart in place until new lungs were available.

In April 2023, Mr. Bauer, a longtime smoker and vaper, experienced shortness of breath. His girlfriend, Susan Gore, took him to an urgent care center, and he returned home, but “the next morning he couldn’t walk,” Ms. Gore said in the press conference. A trip to the ED yielded a diagnosis of influenza A, followed rapidly by a bacterial lung infection that proved resistant to antibiotics. Mr. Bauer had no prior medical history of serious illness, but he was soon in an intensive care unit. His condition continued to decline, and a double lung transplant was his only option.

The Northwestern Medicine Canning Thoracic Institute specializes in challenging cases, and Mr. Bauer was transferred there.

Back from the brink

Mr. Bauer made the transfer to Chicago despite being critically ill. He was in dire need of a lung transplant, and the only way to resolve his infection was to remove the lungs, said Ankit Bharat, MD, chief of thoracic surgery and director of Northwestern Medicine Canning Thoracic Institute, in the press conference.

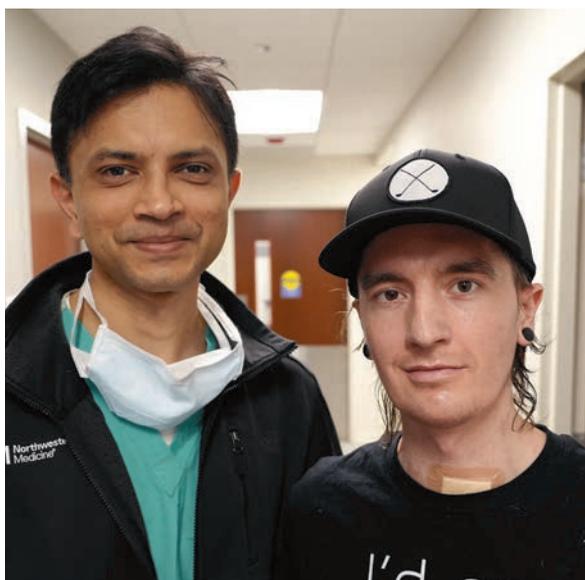
“Something needed to be done right away,” Dr. Bharat said. Mr. Bauer’s lungs were removed and the chest cavity was extensively debrided to remove the infection.

Then it was time for outside-the-box thinking. “With the lungs taken out, we needed something to support the heart,” he said. Breast implants came to mind, and double Ds were the largest available.

In addition, the surgeons created an artificial lung system of conduits to keep Mr. Bauer’s blood pumping. “We wanted to maintain the natural blood flow in the body that would be present if the lungs were there,” Dr. Bharat explained.

Plastic surgeons at Northwestern gave Mr. Bauer’s surgical team “a crash course” in managing the breast implants, Dr. Bharat said. The team anticipated that their novel surgical solution would need to last for weeks, but Mr. Bauer’s condition improved immediately once the infected lungs were removed. He was placed on a double-lung transplant list, and the team received an offer of new lungs within 24 hours.

The breast implants were removed, the new lungs were implanted, and Mr. Bauer spent several months in the ICU before his discharge to rehabilitation therapy at the end of September,



David Bauer (right) shown post transplant with Dr. Ankit Bharat.

according to a Northwestern press release.

This type of procedure could help patients with infections who need transplants but are too sick to undergo them, Dr. Bharat said in the press conference. In Mr. Bauer’s case, “a lot of stars aligned,” including Mr. Bauer’s rapid improvement and the quick availability of a perfect lung match, Dr. Bharat said. Many patients don’t survive to the point of transplant.

“We were surprised how quickly he recovered once we removed the infected lungs,” Dr. Bharat noted. The quick recovery may be in part because of Mr. Bauer’s youth and relative good health, but “this was uncharted territory.”

Mr. Bauer’s case is the first use of this particular surgical technique, although the team drew on lessons learned in other surgical settings, such as removal of both lungs to prevent cross-contamination in patients with cancer, he added.

Causes and effects

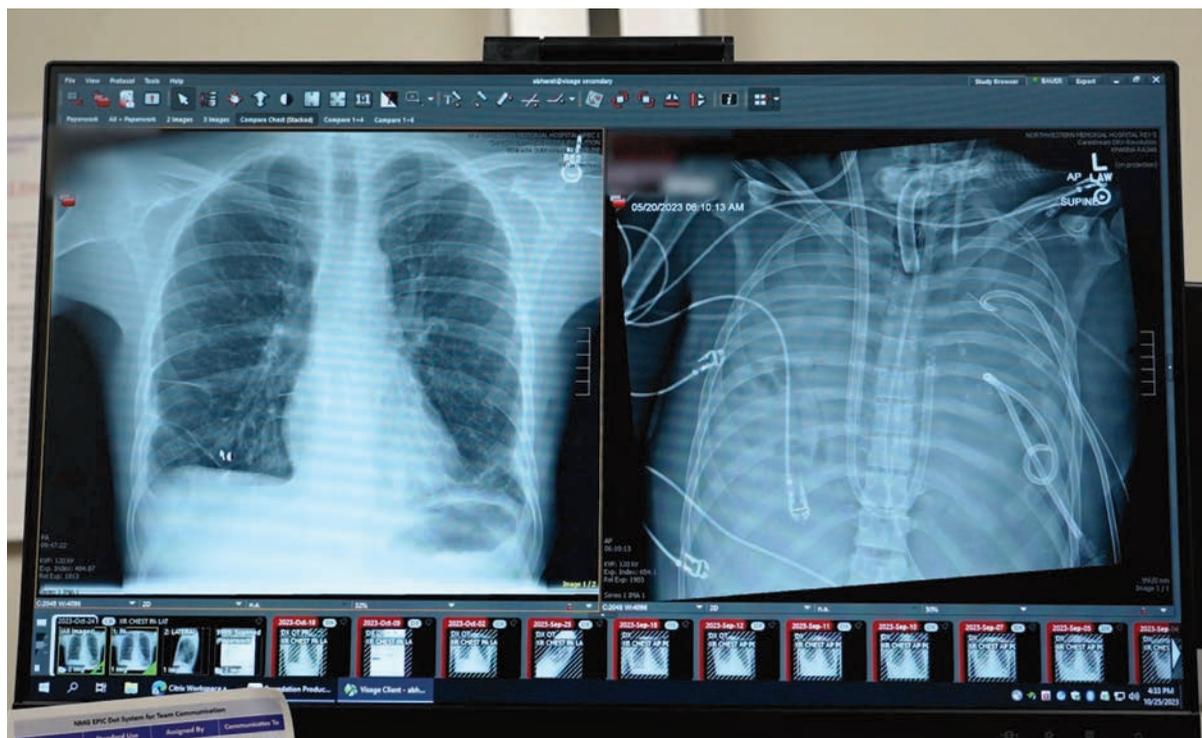
As for the factors that contributed to Mr. Bauer’s initial infection, “there is a lot we don’t know, but we can try to put things together,” said Dr. Bharat. Just as many factors lined up to promote Mr. Bauer’s recovery, many factors lined up to cause the problem, including long-standing smoking and vaping. Although some still view vaping as a safer alternative to smoking, patient data and experiences do not support this claim. “We know for a fact that both of them cause harm,” he added.

Mr. Bauer started smoking cigarettes at age 21 and typically smoked a pack of cigarettes each day before switching to vaping in 2014. In addition, Mr. Bauer had not been vaccinated against the flu, and his flu infection was followed by a bacterial infection.

Bacterial infections followed by hospitalizations are not new as an effect of vaping; a series of articles described the ongoing epidemic of e-cigarette or vaping product use–associated lung injury (EVALI). Patients with EVALI often present at urgent care centers, as Mr. Bauer did, with symptoms of flu or pneumonia, and they are often given medication and sent home.

Looking ahead, “We expect that Davey will fully recover and live a normal life,” although he will remain in Chicago for another year for monitoring, said Rade Tomic, MD, pulmonologist and medical director of the Northwestern Medicine Canning Thoracic Institute lung transplant program, in the press conference.

Mr. Bauer expressed his thanks to the surgical team, who also presented him with another gift: a T-shirt with his newly chosen nickname, “DD Davey.” “I feel so blessed I got a second chance at life,” Mr. Bauer said in the press conference. “You should not inhale anything into your lungs except oxygen.” ■



David Bauer’s new (left) and old lungs are shown.

PAH: Investigational agents and catheter-based denervation

BY WALTER ALEXANDER

PHILADELPHIA – Promise that the unmet need for more effective pulmonary artery hypertension (PAH) treatments may soon be met was in strong evidence in research into three strategies presented at the recent American Heart Association scientific sessions. One was based on an ancient Chinese herb *epimedium* (*yin yang huo* or horny goat weed) commonly used for treating sexual dysfunction and directly related to the phosphodiesterase inhibitors sildenafil, vardenafil, and tadalafil (sold as Viagra, Levitra, and Cialis). A second studied sotatercept, an investigational, potential first-in-class activin signaling inhibitor biologic, and a third evaluated physically ablating the baroreceptor nerves that stimulate vasoconstriction of the pulmonary artery via catheter-based techniques.

Until as recently as the late 1970s, a PAH diagnosis was a uniformly fatal one.¹ While targeted therapies have since improved prognosis, PAH remains a chronic and progressive disorder of the pulmonary vasculature with significant morbidity and mortality associated with pulmonary and right ventricle remodeling, and leads toward heart failure and death. The complex underlying pathogenesis was divided into six groups by the 6th World Symposium on Pulmonary Hypertension (WSPH) in 2018, and includes as its most common features pulmonary artery endothelial cell dysfunction, pulmonary artery smooth muscle cell proliferation and migration, and dysregulated fibroblast activity leading to dysregulated vasoconstriction, micro and in situ vascular thrombosis, vascular fibrosis, and pathogenic remodeling of pulmonary vessels.¹ The threshold mean pulmonary arterial pressure (mPAP) for PAH was defined by the 6th [WSPH] at mPAP \geq 20 mm Hg, twice the upper limit of a normal mPAP of 14.0 ± 3.3 mm Hg as reported by Kovacs et al. in 2018.²

Pathways for current therapies

Current drugs for PAH focus on three signaling pathways, including the endothelin receptor, prostacyclin, and nitric oxide pathways, stated Zhi-Cheng Jing, MD, professor of medicine, head of the cardiology department at Peking Union Medical College Hospital, Peking, China. While the phosphodiesterase 5 inhibitors sildenafil and tadalafil, which target the nitric oxide pathway, came into wide use after Food and Drug Administration approval, the need for higher PDE5-selectivity remains, Dr. Jing said. Structurally modified from the active ingredient in *epimedium*, TPN171H is an investigational PDE5 inhibitor which has shown several favorable features: a greater PDE5 selectivity than both sildenafil and tadalafil in vitro, an ability to decrease right ventricular systolic pressure and alleviate arterial remodeling in animal studies, and safety and tolerability in healthy human subjects.

The current randomized, double-blind, placebo-and active-controlled phase IIa study

assessed the hemodynamic impact of a single oral dose of TPN171H in 60 patients with PAH (mean age \sim 34 years, 83.3% female), all with negative vasodilation test results and in World Health Organization class 2 or 3. Only patients aged 18-75 years with group 1 PAH of idiopathic, connective tissue disorder, or repaired congenital heart defects etiology were included. Patients were divided into six groups: placebo, TPN171H at 2.5, 5, and 10 milligrams, and tadalafil at 20 and 40 milligrams.

PAH remains a chronic and progressive disorder of the pulmonary vasculature with significant morbidity and mortality associated with pulmonary and right ventricle remodeling.

For the primary endpoint of maximum decrease in pulmonary vascular resistance (PVR), significant reductions vs. placebo were found only for the TPN171H 5-mg group (-41.2% vs. -24.4% ; $P = .008$) and for the 20-mg (-39.8%) and 40-mg (-37.6%) tadalafil groups (both $P < .05$). What was not seen in the tadalafil groups, but was evident in the TPN171H 5-mg group, was a significant reduction in the secondary endpoint of PVR/SVR (systolic vascular resistance) at 2, 3, and 5 hours (all $P < .05$). “As we know,” Dr. Jing said in an interview, “the PDE5 inhibitor functions as a vasodilator, having an impact on both pulmonary circulation and systemic circulation. So, to evaluate the selectivity for pulmonary circulation is crucial when exploring a novel drug for PAH. The change of PVR/SVR ratio from baseline is an indicator for selectivity for pulmonary circulation and implies that TPN171H has good PDE5 selectivity in the pulmonary vasculature,” Dr. Jing said. TPN171H was well tolerated with no serious adverse effects (vomiting 10% and headache 10% were most common with no discontinuations).

TGF-signaling pathway

A meta-analysis of randomized controlled trials of sotatercept, an investigational fusion protein under priority FDA review that modulates the TGF-beta superfamily signaling pathway, looked at PVR, pulmonary arterial pressure (PAP), right arterial pressure (RAP), and N-terminal pro-brain natriuretic peptide (NT-proBNP). A literature search by corresponding author Vamsikalyan Borra, MD, Knapp Medical Center, Weslaco, Texas, and colleagues identified two trials (STELLAR and PULSAR) comprising 429 patients with PAH. The experimental arms (sotatercept) had 237 patients (mean age \sim 49 years, \sim 82% female) and the placebo arm had 192 patients (mean age \sim 47 years, \sim 80% female).

A pooled analysis showed significant reductions with sotatercept in PVR (standardization mean difference [SMD], -1.00 ; 95% confidence

interval, -1.2 to -0.79 ; $P < .001$), PAP (SMD, -1.34 ; 95% CI, 1.6 to -1.08 , $P < .001$), RAP (SMD, -0.66 ; 95% CI = -0.93 to -0.39 , $P < .001$), and the levels of NT-proBNP (SMD, -0.64 ; 95% CI, -1.01 to -0.27 , $P < .001$) at 24 weeks from baseline. The sotatercept safety profile was favorable, with lower overall incidence of adverse events (84.8% vs. 87.5%) and fewer adverse events leading to death (0.4% vs. 3.1%) compared with placebo. Further investigation is needed, however, according to Dr. Borra, into the higher frequency of reported thrombocytopenia (71.7% vs. 20.8%) with sotatercept. “Our findings,” Dr. Borra said in a poster session, “suggest that sotatercept is an effective treatment option for pulmonary arterial hypertension, with the potential to improve both pulmonary and cardiac function.”

Denervation technique

Catheter-based ablation techniques, most commonly using thermal energy, target the afferent and efferent fibers of the baroreceptor reflex in the main pulmonary artery trunk and bifurcation involved in elevated PAP. Mounica Vorla, MD, Carle Foundation Hospital, Urbana, Illinois, and colleagues conducted an updated systematic review and meta-analysis of the safety and efficacy of pulmonary artery denervation (PADN) for PAH in seven clinical trials with 506 patients with moderate-severe PAH conducted from 2013 to 2022.

Compared with placebo, PADN treatment was associated with a significant reduction in mean PAP (weighted mean difference, -6.9 mm Hg; 95% CI, -9.7 to -4.1 ; $P < .01$; $I^2 = 61$) and pulmonary vascular resistance (WMD, -3.2 ; 95% CI, -5.4 to -0.9 ; $P = .005$). PADN improvements in cardiac output were also statistically significant (WMD, 0.3 ; 95% CI, 0.07 to 0.6 ; $P = .012$), with numerical improvement in 6-minute walking distance (WMD, 67.7 ; 95% CI, -3.73 to 139.2 ; $P = .06$) in the PADN group. Side effects were less common in the PADN group as compared with the placebo group, Dr. Vorla reported. She concluded, “This updated meta-analysis supports PADN as a safe and efficacious therapy for severe pulmonary arterial hypertension.” The authors noted limitations imposed by the small sample size, large data heterogeneity, and medium-quality literature. Larger randomized, controlled trials with clinical endpoints comparing PADN with optimal medical therapy are needed, they stated. ■

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Eight wealth tips just for doctors

BY NICOLE PAJER

The average physician makes \$352,000, and some earn well into the \$500,000s. So, doctors don't have to worry about money, right?

You know the answer to that.

One thing all physicians have in common about money, says James M. Dahle, MD, FACEP, founder of The White Coat Investor, is that they don't receive any training in business, personal finance, or investing throughout their schooling or careers unless they seek it out. This leaves many unprepared to make the best investing and money-saving decisions, while others get too frustrated about their lack of knowledge to even dip their toe into the investing pool.

Exhibit A: Four out of 10 physicians have a net worth below \$1 million, according to the Medscape Physician Wealth & Debt Report 2023. Elizabeth Chiang, MD, PhD, an oculoplastic surgeon and a physician money coach at Grow Your Wealthy Mindset, notes that many of those doctors are over age 65, "which means they essentially can't retire."

And that's just one pain point.

Physicians have money concerns specific to their profession and background. Luckily, some fellow doctors also serve as financial and wealth advisers just for other doctors. We sought out a few to get their advice – and fixes – for common physician blind spots.

Blind spot #1

The early lean years skew doctors' money outlook. "We have an extended training period, which commonly consists of taking on a large amount of debt, followed by 3-8 years of being paid a modest salary, and then finally a large boost in income," explains Dr. Chiang. This can lay a shaky foundation for the earning years to come, and as a result, a lot of doctors just don't think about money in healthy ways. Once their incomes increase, physicians may be surprised, for example, that making a multiple six-figure salary means paying six figures in taxes.

The fix

Treat financial health like physical health. That means money cannot be a taboo subject. "The misguided mindset is that we didn't become

physicians to make money, we did it to help people," explains Jordan Frey, MD, creator of the blog, The Prudent Plastic Surgeon.

Dr. Frey acknowledges that the desire to help is certainly true. But the result is a false idea that "to think about our personal finances makes us a worse doctor."

Blind spot #2

Because doctors know a lot about one thing (medicine), they might assume they know a lot about everything (such as investing). "Totally different fields with a different language and different way to think about it," Dr. Dahle explains. This overconfidence could lead to some negligent or risky financial decisions.

The fix

Educate yourself. There are several books on personal finance and investing written by physicians for physicians. Dr. Chiang recommends "The Physician Philosopher's Guide to Personal Finance," by James Turner, MD; "Financial Freedom Rx," by Chirag Shah, MD, and Jayanth Sridhar, MD; and "The Physician's Guide to Finance," by Nicholas Christian and Amanda Christian, MD. There are also podcasts, blogs, and courses to help educate doctors on finance, such as the Fire Your Financial Advisor course by The White Coat Investor.

Blind spot #3

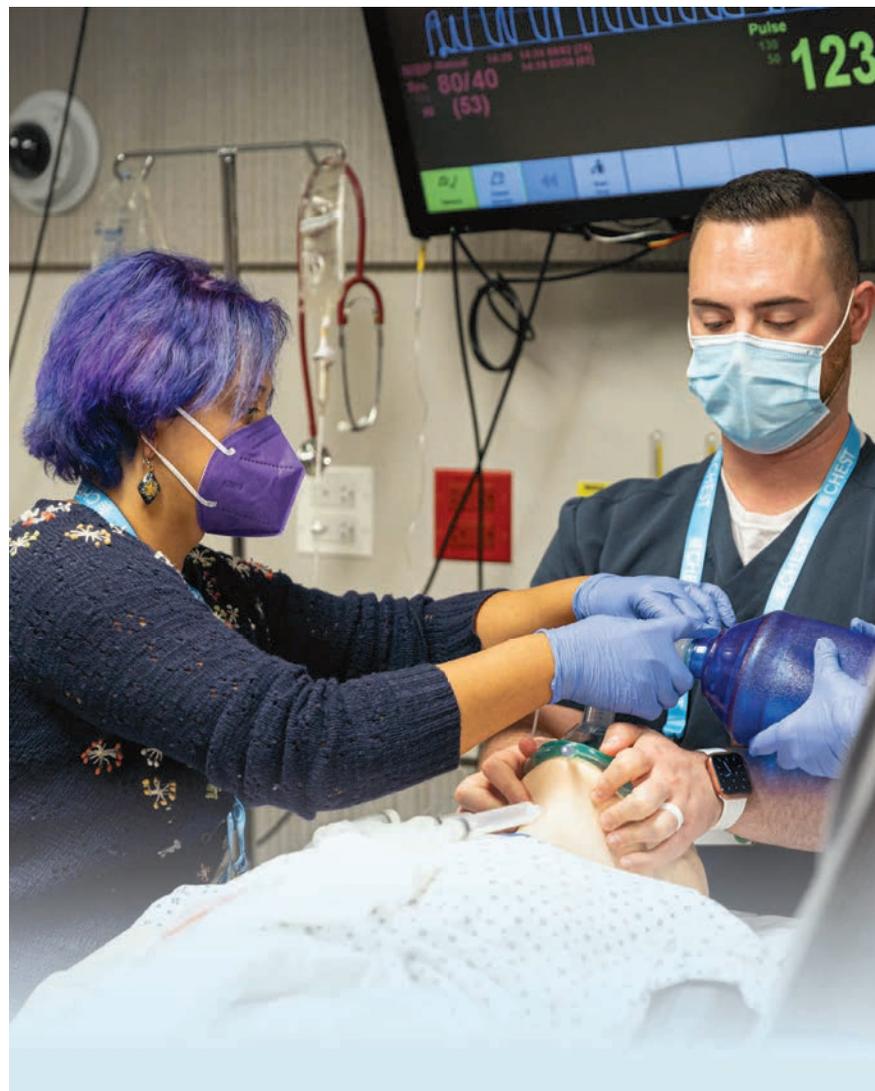
Undersaving. Retirement saving is one thing, but 24% of doctors say they don't even put money away in a taxable savings account, according to the Wealth & Debt Report.

Cobin Soelberg, MD, JD, a board-certified anesthesiologist and founder and principal adviser with Greeley Wealth Management, is the treasurer of his anesthesiology group. "I get to see every month how much people are saving, and even on an anesthesiologist salary, where everyone's making about \$400,000 a year, a lot of people are not saving anything, which is crazy."

Undersaving can be both a time issue and a mindset one.

Time: Doctors often start investing in their retirement accounts later than the average professional, says Dr. Chiang. "A lot of physicians will max out their 401k or 403b,"

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Prescriptions for physician burnout

BY RACHEL REIFF ELLIS

Physician burnout persists even as the height of the COVID-19 crisis fades farther into the rear-view mirror. The causes for the sadness, stress, and frustration among doctors vary, but the effects are universal and often debilitating: exhaustion, emotional detachment, lethargy, feeling useless, and lacking purpose.

When surveyed, physicians pointed to many systemic solutions for burnout in Medscape's Physician Burnout & Depression Report 2023, such as a need for greater compensation, more manageable workloads and schedules, and

more support staff. But for many doctors, these fixes may be years if not decades away. Equally important are strategies for relieving burnout symptoms now, especially as we head into a busy holiday season.

Because not every stress-relief practice works for everyone, it's crucial to try various methods until you find something that makes a difference for you, said Christine Gibson, MD, a family physician and trauma therapist in Calgary, Alta., and author of *The Modern Trauma Toolkit*.

"Every person should have a toolkit of the things that bring them out of the psychological and physical distress that dysregulates their

nervous system," said Dr. Gibson.

Once you learn the personal ways to alleviate your specific brand of burnout, you can start working on systemic changes that might help the culture of medicine overall.

One or even more of these more unusual burnout prescriptions may be key to your personal emotional regulation and mental wellness.

Symptoms speak louder than words

It seems obvious, but if you aren't aware that what you're feeling is burnout, you probably aren't going to find effective steps to relieve it.

BURNOUT *continued on following page*

WEALTH *continued from previous page*

she explains. "But if you're putting in \$20,000 a year and only starting when you're in your early 30s, that's not enough to get you to retirement."

Mindset: Doctors also see people of all ages who are sick, dying, and injured. "They all know someone who worked hard and saved and then dropped dead at 55," explains Dr. Dahle. This, he says, can lead to a bit of a "you only live once" attitude that prioritizes spending over saving.

The fix

Shoot for 20%. If you can't save 20% of your gross now, strive to get to that point. Think of it as telling a patient they have to change their behavior or trouble will come – not if, but when. "Develop a written investing plan and then stick with it through thick and thin," says Dr. Dahle. "Once you have a reasonable plan, all you have to do is fund it adequately by saving 20% of your gross income, and a doctor will easily retire as a multimillionaire."

Blind spot #4

Bad investment strategies. Thirty-six percent of doctors experience their largest financial losses from lousy investments, according to the Wealth & Debt Report. Meanwhile, 17% of primary care physicians and 12% of specialists say *they haven't made any investments at all*. That's a terrible mix of doing the wrong thing and doing a worse thing.

The fix

Don't overthink investing, but don't underthink it either. "As high-income earners, doctors just don't need to take this high level of risk to reach their financial goals," Dr. Frey says. A good investment plan doesn't require you to time the stock market or predict individual stock winners. Consider what Vanguard founder Jack Bogle once said about investing:

"Be bored by the process but elated by the outcome."

Dr. Frey suggests going super-simple: index funds. Ignore investing strategies with actively managed mutual funds or individual stocks, as well as risky alternative investments such as cryptocurrency and angel investments. Everyone assumes doctors have money to burn, and they will push sketchy investment ideas at them. Avoid.

Blind spot #5

Not taking debt seriously enough. The average medical student debt is \$250,000 and can exceed \$500,000, says Dr. Soelberg. Many doctors spend the first 10-20 years of their careers paying this off. Today's graduates are paying more than 7% on their loans.

And it's not just student debt: 39% of physicians carry five or more credit cards, and 34% have mortgages larger than \$300,000 (with half of those are more than \$500K), per the Wealth & Debt Report.

The fix

Treat debt like cancer. It's a lethal enemy you can't get rid of right away, but a steady, aggressive, long-term attack will have the best results. Dr. Soelberg suggests allocating the most you can afford per month, whether that's \$1,000 or \$5,000, toward debt. Raise the amount as your income grows. Do the same with your 401k or retirement plan. Whatever is left, you can spend. Five to 10 years later, you will realize, "Wow. I'm debt free."

Blind spot #6

Not putting in the work to improve your situation. Seventy-one percent of doctors admit they haven't done anything to reduce major expenses, according to the Wealth & Debt Report. Are you leaving major money on the table?

The fix

Audit yourself in major areas like housing and taxes. While the average professional may need to put 10%-20% down on a home, physicians can qualify for physician mortgage loans and can often put down 3% or less, says Dr. Chiang. If you can afford the higher mortgage payment, excess savings earmarked for a larger down payment can be put toward debt or invested.

Another trick, if you're able, is to seek an area that is less in demand at a higher salary. "Physicians in places like New York City or San Francisco tend to make less than physicians in the Midwest or the South," Dr. Chiang explains. A colleague of hers moved to rural Pennsylvania, where he made a high salary and had a low cost of living for 3½ years, paid off his student debt, and then relocated to an area where he wanted to live long term.

As for taxes, become familiar with tax law. Research things like, "What is considered a business expense for doctors?" says Brett Mollard, MD, a diagnostic radiologist who provides financial advice to younger physicians. "What will your estimated total tax burden be at the end of the year? Will you need to make extra payments to prevent owing a large sum of money from underpaying or to avoid tax penalties?"

Blind spot #7

Living like a rock star on a doctor's income. Getting caught up in trying to live the same lifestyle as your colleagues is a classic bear trap. "Sitting in the doctor's lounge, it's so crazy," Dr. Soelberg says. He describes conversations like, "Where did you go on your trip?" "What new toys are you buying?" There's pressure to live up to an image of what a doctor's life is supposed to look like before you've sorted the basic things like paying off debt.

The fix

Live like a resident even if you haven't been one for years, at least until you're in a better financial position. "You're already used to living a life of lower means, and you're an expert when it comes to delaying gratification," says Dr. Mollard. "Do it a little longer." Live frugally and spend only on things that bring you joy. "A lot of physicians are trying to be really rich in all areas of their life instead of the ones that actually matter to them," Dr. Soelberg says. Identify what's important to you and only splurge on that.

Blind spot #8

Never asking for help. The right financial planner can provide expert help. Emphasis on *right*. "Doctors can be very trusting of other professionals, even when they should not be," says Dr. Dahle. He notes that in financial services, many people masquerade as knowledgeable advisers who are really just salespeople. While legitimate financial advisers strive to make their clients money, they are also ultimately out to line their pockets and love to work with physician salaries. Thus, doctors can end up working with financial planners that don't specifically understand their situations or end up taking too much from their clients.

The fix

Find a planner who specializes in, or at least understands, physicians. Ask them how they make money, says Dr. Chiang. If someone hesitates to tell you about their fee structure or if it sounds like a lot, shop around and ask colleagues for recommendations.

"Ultimately, the path to wealth is to create and grow the margin between what you make and what you spend," says Dr. Frey. Throw some investing into the mix and physicians can set themselves up on a path for a stress-free financial life. ■

Jessi Gold, MD, assistant professor and director of wellness, engagement, and outreach in the department of psychiatry, Washington University in St. Louis, is a psychiatrist who treats health care professionals, including frontline workers during the height of the pandemic. But even as a burnout expert, she admits that she misses the signs in herself.

“I was fighting constant fatigue, falling asleep the minute I got home from work every day, but I thought a B12 shot would solve all my problems. I didn’t realize I was having symptoms of burnout until my own therapist told me,” said Dr. Gold. “As doctors, we spend so much time focusing on other people that we don’t necessarily notice very much in ourselves – usually once it starts to impact our job.”

Practices like meditation and mindfulness can help you delve into your feelings and emotions and notice how you’re doing. But you may also need to ask spouses, partners, and friends and family – or better yet, a mental health professional – if they notice that you seem burnt out.

Practice ‘in the moment’ relief

Sometimes, walking away at the moment of stress helps like when stepping away from a heated argument. “Step out of a frustrating staff meeting to go to the bathroom and splash your face,” said Eran Magan, PhD, a psychologist at the University of Pennsylvania, Philadelphia, and founder and CEO of the suicide prevention system Early-Alert.me. “Tell a patient you need to check something in the next room, so you have time to take a breath.”

Dr. Magan recommended finding techniques that help lower acute stress while it’s actually happening. First, find a way to escape or excuse yourself from the event, and when possible, stop situations that are actively upsetting or triggering in their tracks.

Next, recharge by doing something that helps you feel better, like looking at a cute video of your child or grandchild or closing your eyes and taking a deep breath. You can also try to “catch” good feelings from someone else, said Dr. Magan. Ask someone about a trip, vacation, holiday, or pleasant event. “Ask a colleague about something that makes [them] happy,” he said. “Happiness can be infectious too.”

Burnout is also in the body

“Body psychotherapy” or somatic therapy is a treatment that focuses on how emotions appear within your body. Dr. Gibson said it’s a valuable tool for addressing trauma and a mainstay in many a medical career; it’s useful to help physicians learn to “befriend” their nervous system.

Somatic therapy exercises involve things like body scanning, scanning for physical sensations; conscious breathing, connecting to each inhale and exhale; grounding your weight by releasing tension through your feet, doing a total body stretch; or releasing shoulder and neck tension by consciously relaxing each of these muscle groups.

“We spend our whole day in sympathetic tone; our amygdala’s are firing, telling us that we’re in danger,” said Dr. Gibson. “We actually have to practice getting into and spending time in our parasympathetic nervous system to restore the



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balance in our autonomic nervous system.”

Somatic therapy includes a wide array of exercises that help reconnect you to your body through calming or activation. The movements release tension, ground you, and restore balance.

Bite-sized tools for well-being

Because of the prevalence of physician burnout, there’s been a groundswell of researchers and organizations who have turned their focus toward improving the well-being in the health care workforce.

One such effort comes from the Duke Center for the Advancement of Well-being Science, which “camouflages” well-being tools as continuing education credits to make them accessible for busy, stressed, and overworked physicians.

“They’re called bite-sized tools for well-being, and they have actual evidence behind them,” said Dr. Gold. For example, she said, one tool is a text program called Three Good Things that encourages physicians to send a text listing three positive things that happened during the day. The exercise lasts 15 days, and texters have access to others’ answers as well. After 3 months, participants’ baseline depression, gratitude, and life satisfaction had all “significantly improved [Ann Fam Med. 2023 May-Jun;21(3):220-6].”

“It feels almost ridiculous that that could work, but it does,” said Dr. Gold. “I’ve had patients push back and say: ‘Well, isn’t that toxic positivity?’ But really what it is is dialectics. It’s not saying there’s only positive; it’s just making you realize there is more than just the negative.”

These and other short interventions focus on concepts such as joy, humor, awe, engagement, and self-kindness to build resilience and help physicians recover from burnout symptoms.

Cognitive restructuring could work

Cognitive restructuring is a therapeutic process of learning new ways of interpreting and responding to people and situations. It helps you change the “filter” through which you interact with your environment. Dr. Gibson said it’s a tool

to use with care after other modes of therapy that help you understand your patterns and how they developed because of how you view and understand the world.

“The message of [cognitive-behavioral therapy] or cognitive restructuring is there’s something wrong with the way you’re thinking, and we need to change it or fix it, but in a traumatic system [like health care], you’re thinking has been an adaptive process related to the harm in the environment you’re in,” said Dr. Gibson.

“So, if you [jump straight to cognitive restructuring before other types of therapy], then we just gaslight ourselves into believing that there’s something wrong with us, that we haven’t adapted sufficiently to an environment that’s actually harmful.”

Strive for a few systemic changes

Systemic changes can be small ones within your own sphere. For example, Dr. Magan said, work toward making little tweaks to the flow of your day that will increase calm and reduce frustration.

“Make a ‘bug list,’ little, regular demands that drain your energy, and discuss them with your colleagues and supervisors to see if they can be improved,” he said. Examples include everyday frustrations like having unsolicited visitors popping into your office, scheduling complex patients too late in the day, or having a computer freeze whenever you access patient charts.

Though not always financially feasible, affecting real change and finding relief from all these insidious bugs can improve your mental health and burnout symptoms.

“Physicians tend to work extremely hard in order to keep holding together a system that is often not inherently sustainable, like the fascia of a body under tremendous strain,” said Dr. Magan. “Sometimes the brave thing to do is to refuse to continue being the lynchpin and let things break, so the system will have to start improving itself, rather than demanding more and more of the people in it.” ■



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