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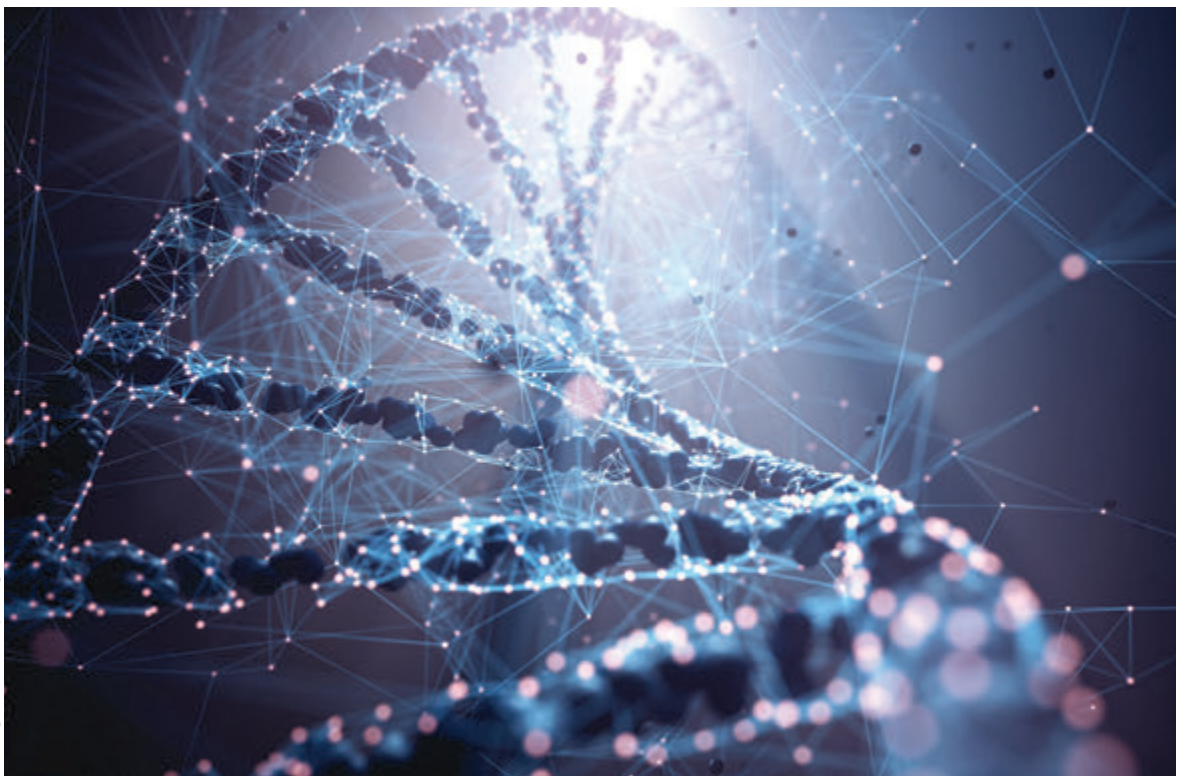

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The potential role of epigenetics in OSA

BY RICHARD MARK KIRKNER

In 2018, when the study of potentially modifiable genetic markers for obstructive sleep apnea (OSA) was emerging, researchers from Mexico published a study titled, "Dad's snoring may have left molecular scars in your DNA: The emerging role of epigenetics in sleep disorders." That title seems to summarize succinctly the role epigenetics may play in sleep disorders, most notably OSA.

Epigenetics is the study of heritable phenotypic changes that do not alter the DNA sequence, which means that these changes may also be reversible. These changes can include histone modifications, non-coding RNAs, and DNA methylation. As the researchers in Mexico reported in 2018, epigenetics involves the relationship between environmental factors and gene expression. "Environmental factors play an integral role in the way genes can be expressed," said Emily Cheung, a PhD candidate in biomedical engineering and researcher in epigenetics and pediatric sleep apnea at George Washington University in Washington, DC. "Epigenetics is a mechanism that can regulate gene expression without changes to DNA base pair sequences."

"This is an area of growing interest, with work being done across the globe to better understand the interplay between epigenetics and [OSA]," Anita Shelgikar, MD, a professor of neurology

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Monitor asthma on biologics for remission, EGPA symptoms during steroid tapering

BY MANUELA CALLARI

VIENNA — Physicians are called to record clinical details of patients with asthma undergoing biologic therapy to monitor clinical remission and keep an eye on eosinophilic granulomatosis with polyangiitis (EGPA) symptoms as patients come off the medications, according to pulmonary experts presenting at the European Respiratory Society (ERS) 2024 International Congress.

Biologics have revolutionized the treatment of severe asthma, significantly improving patient outcomes. However, the focus has recently shifted toward achieving more comprehensive disease control.

Remission, already a well-established goal in conditions like rheumatoid arthritis and inflammatory bowel disease, is now being explored in patients with asthma receiving biologics.

Peter Howarth, medical director at Global

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BIOLOGICS

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Medical, Specialty Medicine, GSK, in Brentford, England, said that new clinical remission criteria in asthma may be overly rigid and of little use. He said that more attainable limits must be created. Meanwhile, clinicians should collect clinical data more thoroughly.

In parallel, studies have also raised questions about the role of biologics in the emergence of EGPA.

Defining clinical remission in asthma

Last year, a working group, including members from the American Thoracic Society and the American College and Academy of Allergy, Asthma, and Immunology, proposed new guidelines to define clinical remission in asthma.

These guidelines extended beyond the typical outcomes of no severe exacerbation, no maintenance oral corticosteroid use, good asthma control, and stable lung function.The additional recommendations included no missed work or school due to asthma, limited use of rescue medication (no more than once a month), and reduced inhaled corticosteroid use to low or medium doses.

To explore the feasibility of achieving these clinical remission outcomes, GSK partnered with the Mayo Clinic for a retrospective analysis of the medical records of 700 patients with asthma undergoing various biologic therapies.

The study revealed that essential data for determining clinical remission, such as asthma control and exacerbation records, were inconsistently documented.

While some data were recorded, such as maintenance corticosteroid use in 50%-60% of cases, other key measures, like asthma control, were recorded in less than a quarter of the patients. GSK researchers analyzed available data and found that around 30% of patients on any biologic therapy met three components of remission. Mepolizumab performed better than other corticosteroids, with over 40% of those receiving the drug meeting these criteria.

However, when stricter definitions were applied, such as requiring four or more remission components, fewer patients achieved remission — less than 10% for four components, with no patients meeting the full seven-point criteria proposed by the working group.

An ongoing ERS Task Force is now exploring what clinical remission outcomes are practical to achieve, as the current definitions may be too aspirational, said Mr. Howarth.

"It's a matter of defying what is practical to achieve because if you can't achieve it, then it won't be valuable."

He also pointed out that biologics are often used for the most severe cases of asthma after other treatments have failed. Evidence suggests that introducing biologics earlier in the disease, before chronic damage occurs, may result in better patient outcomes.

Biologics and EGPA

In a retrospective study, clinical details of 27 patients with adult-onset asthma from 28 countries, all on biologic therapy, were analyzed. The study, a multicounty collaboration, was led by ERS Severe Heterogeneous Asthma Research Collaboration, Patient-centred (SHARP), and aimed to understand the role of biologics in the emergence of EGPA.

Importantly, the rate at which steroids were tapered did not influence the onset of EGPA.

The most significant finding presented at the ERS 2024 International Congress was that EGPA was not associated with maintenance corticosteroids; instead, it often emerged when corticosteroid doses were reduced or tapered off.

"This might suggest that steroid withdrawal may unmask the underlying disease," said Hitasha Rupani, MD, a consultant respiratory physician at the University Hospital Southampton, in Southampton, England.

Importantly, the rate at which steroids were tapered did not influence the onset of EGPA, indicating that the tapering process, rather than its speed, may be the critical factor. However, because of the small sample size, this remains a hypothesis, Dr. Rupani explained. The study also found that when clinicians had a clinical suspicion of EGPA before starting biologic therapy, the diagnosis was made earlier than in cases without such suspicion. Dr. Rupani concluded that this underscores the importance of clinical vigilance and the need to monitor patients closely for EGPA symptoms, especially during corticosteroid tapering.

The study was funded by GSK. Mr. Howarth is an employee at GSK. Dr. Rupani reports no relevant financial relationships. ■

Blood eosinophil counts might predict childhood asthma, treatment response

BY MANUELA CALLARI

VIENNA — Simply relying on clinical symptoms is insufficient to predict which children with wheezing will develop asthma and respond to treatments. More objective tests like blood eosinophil counts are needed for early diagnosis and to avoid unnecessary medication use in children unlikely to develop asthma.

Sejal Saglani, MD, PhD, a professor of pediatric respiratory medicine at the National Heart and Lung Institute, Imperial College, London, England, said that preschool wheezing has long-term adverse consequences through to adulthood. "We need to prevent that downward trajectory of low lung function," she said, presenting the latest research in the field at the annual European Respiratory Society International Congress.

Wheezing affects up to one third of all infants and preschool children, with one third developing asthma later in life. "It's important to identify those kids because then we can treat them with the right medication," said Mariëlle W.H. Pijnenburg, MD, PhD, a pulmonary specialist at Erasmus University Rotterdam in the Netherlands. "We cannot just use clinical phenotype to decide what treatment a child should get. We need to run tests to identify the endotype of preschool wheeze and intervene appropriately," Dr. Saglani added.

Eosinophilia as biomarker for predicting exacerbations, steroid responsiveness

In a cluster analysis (J Allergy Clin Immunol. 2022 Feb;149[2]:480-487), Dr. Saglani and colleagues classified preschool children with wheezing into two main subgroups: those who experience frequent exacerbations and those who experience sporadic attacks. Frequent exacerbators were more likely to develop asthma, use asthma medications, and show signs of reduced lung function and airway inflammation, such as higher fractional exhaled nitric oxide and allergic sensitization. "Severe and frequent exacerbators are the kids that get in trouble," she said. "They're the ones we must identify at preschool age and really try to minimize their exacerbations."

Research has shown that eosinophilia is a valuable biomarker in predicting both asthma exacerbations and responsiveness to inhaled corticosteroids (J Allergy Clin Immunol Pract. 2023 Jun;11[6]:1984-1985). Children with elevated blood eosinophils are more likely to experience frequent and severe exacerbations. These children often demonstrate an inflammatory profile more responsive to corticosteroids, making eosinophilia a predictor of treatment success (J Allergy Clin Immunol Pract. 2019 Mar;7[3]:915.e7-924.e7). Children with eosinophilia are also more

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EPIGENETICS // *continued from page 1*

at the University of Michigan Medical School in Ann Arbor and a spokesperson for the American Academy of Sleep Medicine, said of epigenetics. "The emerging evidence holds promise that one day we may adapt our clinical practice to incorporate our understanding of the relationship between epigenetics and [OSA]." Research into the role of epigenetics in OSA has focused on four areas, Dr. Shelgikar said: how epigenetic factors may influence adverse outcomes in OSA; how untreated OSA may influence epigenetic factors; if treatment of OSA can alter epigenetic factors; and if modification of epigenetic factors can affect OSA severity and treatment response, or both.

Dr. Shelgikar

Dr. Cortese

Search for new OSA biomarkers

The emphasis on epigenetics has given rise to research into biomarkers of OSA and sleep disorders. At his laboratory at the University of Missouri in Columbia, Rene Cortese, PhD, an assistant professor of pediatrics and obstetrics, gynecology and women's health, is researching how intermittent hypoxia and sleep fragmentation from OSA accelerates the aging process of blood vessel cells. That process, known as epigenetic age acceleration, is a marker of biological aging and has been linked to OSA and related comorbidities, Dr. Cortese said.

The need for new biomarkers that can help identify OSA early in the disease process is pressing because earlier intervention can prevent the onset of OSA and the multiple comorbidities, such as cardiovascular disease (CVD), Dr. Cortese said. "Probably the most we know about all these metrics is the apnea-hypopnea index (AHI)," Dr. Cortese said. "We need to have something more."

The role of hypoxia-mediated epigenetic regulation in cancer, pulmonary hypertension, adaptation to high altitude, and cardiorenal disease has drawn much attention, he added. Dr. Cortese recently received a $3 million National Institutes of Health grant to investigate the impact OSA has on cells in the vascular lining and potential treatments. The work will use mice to evaluate how epigenetic age acceleration causes the vascular cells to stop replicating. The thinking is that these cells can continue to release chemicals that trigger inflammation and vascular dysregulation, leading to cardiovascular disease.

His work is targeting the p16 protein, which slows cell division. "Through the selective elimination of these cells, we believe we can tackle not just the negative impacts of OSA, but maybe other aging-associated diseases," Dr. Cortese said.

Ms. Cheung and her colleagues at George Washington University also have studied epigenetics in OSA in children. "Pediatric OSA increases the risk of cardiovascular, metabolic, and endothelial disease susceptibility in adulthood, specifically diseases such as obesity, hypertension, diabetes, and heart failure," Ms. Cheung said. Their research has focused on modifications to the epigenome and identified a micro-RNA, miR-92a, as a potential biomarker for childhood OSA. Researchers at the University of San Diego also reported on elevated miR-92a levels in children and adults with OSA.

In a preclinical study published last year, Ms. Cheung and her colleagues demonstrated that neonatal chronic intermittent hypoxia (CIH) exposure, a hallmark of OSA, resulted in an upregulation of genes in males, which they linked to inhibition of growth and nutrient utilization pathways, and a downregulation of genes in females, which they associated with increased cardiac inflammation. Research has also focused on micro-RNA in OSA related to CVD. Researchers in China in 2023 reported that endothelial dysfunction is an early biomarker of CVD in adults and pediatric patients, and studies have shown that endothelial dysfunction in chronic intermittent hypoxia is related to nitric oxide impairment, oxidative stress, and inflammation.

Ms. Cheung

But research into the relationship between epigenetics and OSA has a lot of gaps to fill, Ms. Cheung noted. "One of the first steps toward better understanding the long-term effects of epigenetic regulation in pediatric OSA is to perform prospective cohort studies, both clinical and preclinical, that track epigenetic changes from childhood into adulthood," Ms. Cheung said. Such research will provide insights into potentially modifiable epigenetic signatures and allow researchers to refine the list of epigenetic biomarkers that persist into adulthood, she said.

"Epigenetic signatures have the potential to be used as biomarkers to diagnose OSA and may become instrumental in future diagnostic panels that will assess a child's predisposition of OSA, for early detection and treatment," Ms. Cheung said.

"It is a very new field," Dr. Cortese said. "People are starting to recognize the potential of epigenetics, but it is a lot of work and we are at the very beginning."

Ms. Cheung, Dr. Shelgikar, and Dr. Cortese have no relevant disclosures. ■

Poor inhaler technique may lead to hospitalizations

BY HEIDI SPLETE

Approximately two thirds of hospitalized adults with chronic obstructive pulmonary disorder (COPD) received suboptimal treatment with inhalers, mainly resulting from errors, based on data from 96 individuals. "Numerous studies have highlighted the significant issue of improper inhaler use in outpatient settings, but the extent of this problem within hospital settings remains poorly documented," said lead author Gaël Grandmaison, MD, of the University of Fribourg in Switzerland. "This gap in knowledge is concerning, especially considering that several factors associated with suboptimal inhaler use, such as improper inhalation techniques, insufficient inspiratory flow, or the use of inhalers that are not suited to the patient's specific characteristics, are associated with poorer disease control, more frequent exacerbations, and increased costs," Dr. Grandmaison said.

The researchers reviewed data from consecutive patients with COPD who were hospitalized in the general internal medicine department of a single institution between August 2022 and April 2023 (Chronic Obstr Pulm Dis. 2024 Jul 25;11[4]:406-415). Patients were assessed for peak inspiratory flow (PIF) and inhaler technique.

The primary outcome was the proportion of misused inhalers, which was defined as any inhaler used with either insufficient PIF and/or a critical error. The mean age of the patients was 71.6 years, 63% were men, and 67% were hospitalized for COPD exacerbations. Patients used 3.0 inhalers on average. The study included 96 patients and 160 inhalers that were assessed at hospital admission. Overall, 111 were misused. Of those misused, 105 were associated with a critical error in the inhalation technique, and 22 were used with an insufficient PIF. After an episode of misuse, patients received teaching on correct use that was repeated until they performed the technique without errors. The percentage of inhaler misuse decreased over the course of the teaching sessions. The proportion of inhaler misuse decreased to 20.6%, 9.4%, and 5.6% after one, two, and three sessions, respectively. Factors associated with inhaler misuse included cognitive disorders, fine motor disorders, poor coordination between inhaler activation and aspiration, and the inability to hold one's breath. In an analysis at the patient level, 79 patients used at least one misused inhaler, 78 used at least one inhaler with a critical error, and 21 used inhalers with insufficient PIF. "This study is particularly timely because reasons for hospitalization, such as COPD exacerbations or confusional states, could exacerbate the problem, leading to a potentially higher prevalence of suboptimal inhaler use compared to outpatient settings," Dr. Grandmaison said.

> *"In the majority of cases, poor inhalation technique is the primary cause..."*
> *– Dr. Grandmaison*

The researchers also examined secondary outcomes including the prevalence of inhalers that were not suited to them and the number of patients using at least one misused inhaler. The study findings confirm that suboptimal inhaler use is a significant problem in the hospital setting and provide new insights into the specific reasons behind this suboptimal usage, Dr. Grandmaison said. "In the majority of cases, poor inhalation technique is the primary cause, which can generally be corrected through targeted therapeutic education," she said. However, the study also revealed that 20% of patients are unable to use at least one of their inhalers correctly because of insufficient inspiratory force. Another 10% struggle despite receiving proper instruction, often because of cognitive impairments or difficulty with fine motor skills. The results underscore the need for a comprehensive approach to inhaler use in hospitalized patients that combines continuous therapeutic education with personalized assessment in order to improve technique and subsequently enhance patient outcomes, she said.

The findings were limited by the possible underreporting of misuse caused by inadequate PIF, a lack of consensus on what constitutes a critical error, and a small sample of patients. However, the study adds to the understanding of improper inhaler use in the hospital setting, Dr. Grandmaison said. "Our subsequent research demonstrated that a systematic evaluation of inhalers, with therapeutic education and an algorithm to select an inhaler suited to the patient's characteristics, significantly reduces the number of improperly used inhalers at hospital discharge." However, several areas require further investigation, Dr. Grandmaison said, including the most effective methods and frequency for teaching inhalation techniques, and better understanding of the factors influencing PIF and its progression.

"Poor inhaler technique can lead to ineffective inhaler use and suboptimal treatment of COPD," said Arianne K. Baldomero, MD, a pulmonologist and assistant professor of medicine at the University of Minnesota, Minneapolis. "The results from this study are consistent with prior studies showing a high prevalence of suboptimal inhaler use," said Dr. Baldomero, who was not involved in the study. "The investigators also found that therapeutic education led to a significant reduction in the number of critical errors," she said. "What is surprising is that it can take up to three lessons to reduce this critical error down to 3.8%," Dr. Baldomero said. "In most real-world clinic settings, many patients are not taught how to properly use inhalers, and many patients who receive inhaler technique education only receive instructions once."

Dr. Baldomero's takeaway is that inhaler education may need to be repeated multiple times and that some inhalers are not suited for patients who cannot generate adequate respiratory flow. Looking ahead, Dr. Baldomero said a larger sample size is needed to better identify which patients need further teaching and "the characteristics of patients in outpatient settings who would benefit from additional inhaler teaching."

The study was supported by a grant from the Hospital of Fribourg. The researchers and Dr. Baldomero had no financial conflicts to disclose. ■

ASTHMA *continued from previous page*

likely to have underlying allergic sensitizations, which further supports the use of corticosteroids as part of their management strategy.

Dr. Saglani said a simple blood test can provide a window into the child's inflammatory status, allowing physicians to make more targeted and personalized treatment plans.

Traditionally, identifying eosinophilia required venipuncture and laboratory analysis, which can be time consuming and impractical in a busy clinical setting. Dr. Saglani's research group is developing a point-of-care test designed to quickly and efficiently measure blood eosinophil levels in children with asthma or wheezing symptoms from a finger-prick test. Preliminary data presented at the congress show that children with higher eosinophil counts in the clinic were more likely to experience an asthma attack within 3 months.

"The problem is the majority of the children we see are either not atopic or do not have high blood eosinophils. What are we going to do with those?"

How to treat those who don't have eosinophilia

Most children with wheezing are not atopic and do not exhibit eosinophilic inflammation, and these children may not respond as effectively to corticosteroids. How to treat them remains the "1-billion-dollar question," Dr. Saglani said.

Respiratory syncytial virus and rhinovirus play a crucial role in triggering wheezing episodes in these children. Research has shown that viral-induced wheezing is a common feature in this phenotype, and repeated viral infections can lead to an increased severity and frequency of exacerbations (J Allergy Clin Immunol Pract. 2022 Mar;10[3]:673-681). However, there are currently no effective antiviral therapies or vaccines for rhinovirus, which limits the ability to address the viral component of the disease directly.

Up to 50% of children with severe, recurrent wheezing also have bacterial pathogens like *Moraxella catarrhalis* and *Haemophilus influenzae* in their lower airways. For these children, addressing the bacterial infection is the best treatment option to mitigate the wheezing. "We now have something that we can target with antibiotics for those who don't respond to corticosteroids," Dr. Saglani said.

Dr. Pijnenburg said this body of research is helping pulmonary specialists and general pediatricians navigate the complexity of childhood wheezing beyond phenotyping and symptoms. "We need to dive more deeply into those kids with preschool wheezing to see what's happening in their lungs."

Dr. Pijnenburg and Dr. Saglani reported no relevant financial relationships. ■

Genetic testing, novel biomarkers aid in cystic fibrosis diagnosis and monitoring

BY MANUELA CALLARI

VIENNA — Advances in genetic testing and newly discovered biomarkers can help screen newborns and monitor inflammation and pulmonary exacerbations in patients diagnosed with cystic fibrosis. At the European Respiratory Society (ERS) 2024 International Congress, clinical researchers presented results.

Cystic fibrosis is the most common genetic disorder among Caucasians and rates vary significantly based on geographic area. In the central Anatolia region, one study found the incidence of cystic fibrosis is 1 in 3400 live births.

Çigdem Korkmaz, a researcher at the Department of Pediatric Pulmonology at the Istanbul University-Cerrahpasa in Istanbul, Turkey, said that diagnosis in Turkey is especially challenging because of the genetic diversity of cystic fibrosis within the population. She said genetic testing might be necessary to catch missed cases by traditional screening methods.

Genetic testing picks up missed cases

In 2022, 30 European countries ran newborn bloodspot screening for cystic fibrosis, with 26 national programs. Screening protocols vary between countries but generally involve screening using an immunoreactive trypsinogen (IRT) blood test. Follow-up testing may include a second IRT test, DNA analysis for common cystic fibrosis transmembrane conductance regulator mutations, and sweat chloride test (SCT).

Turkey introduced newborn screening for cystic fibrosis in 2015. Newborns with an elevated IRT and confirmatory SCT undergo genetic testing. However, in a retrospective study, researchers found that IRT tests turn many false-positive results, and some patients who turn a normal SCT are diagnosed with the disease through genetic testing.

The study included 205 infants referred to a tertiary care center in Istanbul between January 2015 and January 2023 following an elevated IRT result. The researchers analyzed the clinical and sociodemographic data, IRT and SCT values, and genetic analysis results. They found that cystic fibrosis was confirmed in only 30% of newborns, while genetic testing could identify nine cases otherwise missed by SCT. "The high false-positive rate of the current screening strategy suggests that the IRT thresholds used in Turkey may be too low," said Ms. Korkmaz, who presented the study at the ERS Congress. She added that genetic testing might be important, especially in patients with normal SCT results. "Early diagnosis means these patients avoid missing or delaying treatments."

Biomarkers for monitoring cystic fibrosis exacerbations

C-reactive protein (CRP) blood testing is typically used in monitoring inflammation and pulmonary exacerbations in patients who have already been diagnosed with cystic fibrosis. CRP is an inflammatory biomarker that increases in patients with cystic fibrosis during pulmonary exacerbations and settles with treatment.

Researchers at Gazi University in Ankara, Turkey, found other biomarkers to identify inflammation and pulmonary exacerbations with great sensitivity and specificity in patients with cystic fibrosis. Over 3 years, from 2021 to 2024, the researchers analyzed blood samples from 54 children aged 1-18 years during exacerbation and non-exacerbation periods. Besides CRP, they tested CRP/albumin (ALB) ratio, neutrophil-to-lymphocyte ratio (NLR), delivered NLR (dNLR), and systemic immune inflammation (SII).

All biomarkers increased during exacerbation episodes. All showed high specificity and sensitivity:

- CPR/ALB had a specificity of 81% and a sensitivity of 90% at a cutoff of 1.7 mg/dL.
- SII had a specificity of 86% and a sensitivity of 67% at a cutoff of 426 mg/dL.
- NLR had a specificity of 62% and a sensitivity of 79% at a cutoff of 2.2 mg/dL.
- SII had a specificity of 86% and a sensitivity of 67% at a cutoff of 426 mg/dL.
- dNLR had a specificity of 71% and a sensitivity of 66% at a cutoff of 1.15 mg/dL.
- In comparison, CPR had a specificity of 85% and a sensitivity of 84% at a cutoff of 6.2 mg/dL.

Ayse Tana Aslan, a professor at the Department of Pediatric Pulmonology, Faculty of Medicine, at Gazi University in Ankara, who presented the results at the ERS Congress, said that these biomarkers can be easily and quickly identified with a blood test while waiting on phlegm culture results, which can take days.

Ms. Korkmaz and Ms. Aslan reported no relevant financial relationships. ■

It's never too late to convince patients to quit smoking

BY KENNETH W. LIN, MD, MPH

An estimated 450,000 US deaths are expected this year from conditions attributed to cigarette smoking. Although the percentage of adults who smoke declined from 21% in 2005 to 11% in 2022, the annual death toll has been stable since 2005 and isn't expected to decline until 2030, owing to an aging population of current and former smokers.

In 2022, based on a national survey, two thirds of the 28.8 million US adult smokers wanted to quit, and more than half tried quitting on their own or with the help of clinicians, but less than 9% succeeded in kicking the habit. The health benefits of quitting, summarized in a patient education handout from the American Cancer Society, include a lower risk for cancer, diabetes, and cardiovascular disease. Furthermore, the handout states, "quitting smoking can add as much as 10 years to your life, compared to if you continued to smoke."

For my patients older than age 50 who are lifelong smokers, the qualifier "as much as" can be a sticking point. Although most recognize that continuing to smoke exposes them to greater health risks and are willing to undergo lung cancer screening and receive pneumococcal vaccines, a kind of fatalism frequently sets in. I've heard more times than I can recall some version of the declaration, "It's too late for quitting to make much difference for me." Many smokers think that once they reach middle age, gains in life expectancy will be too small to be worth the intense effort and multiple failed attempts that are typically required to quit permanently. Until recently, there were few data I could call on to persuade them they were wrong.

In February 2024, Eo Rin Cho, PhD, and colleagues pooled data from four national cohort studies (United States, United Kingdom, Norway, and Canada) to calculate mortality differences among current, former, and never smokers aged 20-79 years. Compared with never smokers, lifelong smokers died an average of 12-13 years earlier. However, quitting before age 50 nearly eliminated the excess mortality associated with smoking, and in the 50- to 59-year-old age group, cessation eventually reduced excess mortality by 92%-95%. Better yet, more than half of the benefits occurred within the first 3 years after cessation.

At first glance, these estimates may seem too good to be true. A few months later, though, a different research group, using data from a large cancer prevention study and 2018 US population census and mortality rates, largely confirmed their findings. Thuy Le, MD, and colleagues found that quitting at age 35, 45, 55, 65, or 75 years resulted in average life gains of 8, 5.6, 3.5, 1.7, and 0.7 years, respectively, relative to continuing to smoke. Because no patient is average, the analysis also presented some helpful probabilities. For example, a smoker who quits at age 65 has about a one in four chance of gaining at least 1 full year of life and a one in six chance of gaining at least 4 years. In other words, from a life expectancy perspective alone, it's almost never too late to quit smoking. ■

Dr. Lin is a family physician and associate director, Family Medicine Residency Program, Lancaster General Hospital, Lancaster, Pennsylvania. He blogs at Common Sense Family Doctor. *He has disclosed no relevant financial relationships.*

Comparable survival in bilateral or heart-lung

BY MANUELA CALLARI

VIENNA — Survival rates at 1 and 5 years for patients with pulmonary arterial hypertension (PAH) who receive bilateral lung and heart-lung transplants are similar, said researchers presenting at the European Respiratory Society (ERS) 2024 International Congress.

Transplant for end-stage PAH remains an important treatment option. Heart-lung transplantation plummeted from 91.7% to 21.4% between 1991 and 2014. Yet in the United States and Europe, PAH is the second most common reason to perform a heart-lung transplant, said Baharan Zarrabian, DO, a pulmonologist at the Mayo Clinic in Rochester, Minnesota.

"...the most affected part of the heart in [PAH] has a huge ability to readapt to the new situation..." – Dr. Bos

Over the past decades, physicians have debated whether to opt for a bilateral lung or a heart-lung transplant. However, there is currently a lack of definitive cardiac indicators to guide the decision between the two procedures in patients with PAH. While the lung condition has cardiac ramifications, some experts suggest the heart can repair itself over time after a bilateral lung transplant.

Researchers compared the outcomes of bilateral lung transplantation with those of combined heart-lung transplantation in patients with PAH. They used data from the Organ Procurement and Transplantation Network, focusing on adult patients with PAH without congenital or structural cardiac abnormalities who underwent transplantation between June 2004 and September 2022. The study included 918 patients, with the majority (84.6%) receiving bilateral lung transplants and 15.4% receiving heart-lung transplants. Pretransplant mean pulmonary arterial pressure and pulmonary vascular resistance were similar between the two groups.

However, those who received bilateral lung transplants had higher cardiac output and lower pulmonary capillary wedge pressure than those who received heart-lung transplants. A higher percentage of heart-lung transplant recipients required extracorporeal membrane oxygenation (ECMO) before transplantation, while bilateral lung transplant recipients had longer median ischemic times. Despite these differences in pretransplant characteristics and surgical factors, researchers found no significant difference in survival outcomes between the two groups at the 1-year and 5-year marks. Similarly, graft survival rates at 1 and 5 years post transplant did not differ significantly between the two groups. A higher proportion of patients who received bilateral lung transplant were on ECMO and remained intubated at 72 hours. "That did not translate into a worse outcome later on," Dr. Zarrabian said.

Cardiac recovery trends

Saskia Bos, MD, PhD, a respiratory consultant, lung transplant physician, and transplant pulmonologist at University Hospitals Leuven, Belgium, who was not involved in the study, said doctors have historically preferred combined heart-lung transplantation. The decision was motivated by a lack of understanding regarding whether the heart could remodel.

"Now we know that the right ventricle, which is the most affected part of the heart in [PAH], has a huge ability to readapt to the new situation after just bilateral lung transplantation," she said.

Dr. Bos suggested, in cases where a patient has PAH without any structural heart defects and where the left side of the heart is functioning normally, doctors can opt for a bilateral lung transplant. The right ventricle, typically the only part of the heart affected by the condition, can recover once the PAH is addressed through lung transplantation, she explained. The advantage of bilateral lung transplantation over a heart-lung transplant is that the donor's heart remains available for someone else.

"The recommendation is that physicians opt for a bilateral lung transplant," Dr. Zarrabian concluded. "But we need to make that decision on a case-by-case basis because we still don't know the cardiac parameters that we need to look for before the transplant to decide whether or not they should receive a bilateral lung or a heart-lung."

Dr. Zarrabian and Dr. Bos reported no relevant financial relationships. ■

Controversy surrounds optimal treatment for high-risk pulmonary embolism

BY MANUELA CALLARI

VIENNA — The optimal course of treatment when managing acute, high-risk pulmonary embolism (PE) remains a contentious topic among respiratory specialists.

Systemic thrombolysis, specifically using recombinant tissue plasminogen activator (rtPA), is the current gold standard treatment for high-risk PE. However, the real-world application is less straightforward because of patient complexities.

Some clinicians believe that advances in mechanical and surgical techniques have made rtPA a thing of the past. Others think there is still insufficient evidence to support alternatives as the standard of care.

Here at the European Respiratory Society (ERS) 2024 Congress, respiratory specialists presented contrasting viewpoints and the latest evidence on each side of the issue to provide a comprehensive framework for navigating the complex decision-making process required for effective treatment.

"High-risk PE is a mechanical problem and thus needs a mechanical solution," said Parth M. Rali, MD, an associate professor in thoracic medicine and surgery at the Lewis Katz School of Medicine at Temple University, Philadelphia.

"The marketing on some of the mechanical techniques is very impressive," said Olivier Sanchez, MD, a pulmonologist in the Department of Pneumology and Intensive Care at the Georges Pompidou European Hospital in France. "But what is the evidence of such treatment in the setting of pulmonary embolism?"

The case against rtPA as the standard of care

High-risk PE typically involves hemodynamically unstable patients presenting with conditions such as low blood pressure, cardiac arrest, or the need for mechanical circulatory support. There is a spectrum of severity within high-risk PE, making it a complex condition to manage, especially since many patients have comorbidities like anemia or active cancer, complicating treatment. "It's a very dynamic and fluid condition, and we can't take for granted that rtPA is a standard of care," Dr. Rali said.

Alternative treatments such as catheter-directed therapies, extracorporeal membrane oxygenation (ECMO), and surgical embolectomy are emerging as promising options, especially for patients who do not respond to or cannot receive rtPA. Mechanical treatments offer benefits in reducing clot burden and stabilizing patients, but they come with their own challenges.

ECMO can stabilize patients who are in shock or cardiac arrest, buying time for the clot to resolve or for further interventions like surgery or catheter-based treatments, Dr. Rali said. However, it is an invasive procedure requiring cannulation of large blood vessels, often involving significant resources and expertise.

Catheter-directed thrombolysis is a minimally invasive technique where a catheter is inserted directly into the pulmonary artery to deliver thrombolytic drugs at lower doses. This method allows for more targeted treatment of the clot, reducing the risk for systemic bleeding that comes with higher doses of thrombolytic agents used in systemic therapy, Dr. Rali explained.

Dr. Rali reported results from the FLAME study, which investigated the effectiveness of FlowTriever mechanical thrombectomy compared with conventional therapies for high-risk PE. This prospective, multicenter observational study enrolled 53 patients in the FlowTriever arm and 61 in the context arm, which included patients treated with systemic thrombolysis or anticoagulation. The primary endpoint, a composite of adverse

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The wellness industry: Financially toxic, ethicist says

BY ARTHUR L. CAPLAN, PHD

I'm Art Caplan. I'm at the Division of Medical Ethics at the NYU Grossman School of Medicine in New York City.

We have many debates and arguments that are swirling around about the out-of-control costs of Medicare. Many people are arguing we've got to trim it and cut back, and many people note that we can't just go on and on with that kind of expenditure.

People look around for savings. Rightly, we can't go on with the prices that we're paying. No system could. We'll bankrupt ourselves if we don't drive prices down.

There's another area that is driving up cost where, despite the fact that Medicare doesn't pay for it, we could capture resources and hopefully shift them back to things like Medicare coverage or the insurance of other efficacious procedures. That area is the wellness industry.

I looked up a number recently, and I was shocked to see that worldwide, $1.8 trillion is being spent on wellness, including billions in the US. Again, Medicare doesn't pay for that. That's money coming out of people's pockets that we could hopefully aim at the payment of things that we know work, not seeing the money drain out to cover bunk, nonsense, and charlatanism.

Does any or most of this stuff work? Do anything? Help anybody? No. We are spending money on charlatans and quacks. The US Food and Drug Administration (FDA), which you might think is the agency that could step in and start to get rid of some of this nonsense, is just too overwhelmed trying to track drugs, devices, and vaccines to give much attention to the wellness industry.

What am I talking about specifically? I'm talking about everything from gut probiotics that are sold in sodas to probiotic facial creams and the Goop industry of Gwyneth Paltrow, where you have people buying things like wellness mats or vaginal eggs that are supposed to maintain gynecologic health.

We're talking about things like PEMF, or pulse electronic magnetic fields, where you buy a machine and expose yourself to mild magnetic pulses. I went online to look them up, and the machines cost $5000-$50,000. There's no evidence that it works. By the way, the machines are not only out there as being sold for pain relief and many other things to humans, but also they're being sold for your pets.

That industry is completely out of control. Wellness interventions, whether it's transcranial magnetism or all manner of supplements that are sold in health food stores, over and over again, we see a world in which wellness is promoted but no data are introduced to show that any of it helps, works, or does anybody any good.

It may not be all that harmful, but it's certainly financially toxic to many people who end up spending good amounts of money using these things. I think doctors need to ask patients if they are using any of these things, particularly if they have chronic conditions. They're likely, many of them, to be seduced by online advertisement to get involved with this stuff because it's preventive or it'll help treat some condition that they have.

The industry is out of control. We're trying to figure out how to spend money on things we know work in medicine, and yet we continue to tolerate bunk, nonsense, quackery, and charlatanism, just letting it grow and grow and grow in terms of cost.

That's money that could go elsewhere. That is money that is being taken out of the pockets of patients.

They're doing things that may even delay medical treatment, which won't really help them, and they are doing things that perhaps might even interfere with medical care that really is known to be beneficial.

I think it's time to push for more money for the FDA to regulate the wellness side. I think it's time for the Federal Trade Commission to go after ads that promise health benefits.

I think it's time to have some honest conversations with patients: What are you using? What are you doing? Tell me about it, and here's why I think you could probably spend your money in a better way. ■

Dr. Caplan, director, Division of Medical Ethics, New York University Langone Medical Center, New York, disclosed ties with Johnson & Johnson's Panel for Compassionate Drug Use (unpaid position). He serves as a contributing author and adviser for Medscape.

FTC report on pharmacy middlemen is first step to address drug costs, access

BY KERRY DOOLEY YOUNG

Rising consolidation among pharmacy benefit managers (PBMs) allows the companies to profit at the expense of patients and independent pharmacists concludes a Federal Trade Commission (FTC) report on interim findings from the agency's ongoing investigation of PBMs.

Lawmakers are increasingly scrutinizing the industry amid growing concern among physicians and consumers about how PBMs exploit their market dominance.

The top six PBMs managed 94% of US drug claims in 2023, with the majority handled by the industry's three giants: CVS Caremark, Cigna's Express Scripts, and United Healthcare's OptumRx. PBMs manage prescription drug benefits for health insurers, Medicare Part D drug plans, and large employers.

They act as middlemen between health insurers and pharmacies, developing formularies of covered drugs and promising savings from the discounts and rebates they negotiate with drugmakers.

The FTC's interim report found that the giant PBMs often exercise significant control over what drugs are available, at what price, and which pharmacies patients can use to access their prescribed medications.

Madelaine A. Feldman, MD, vice president for advocacy and government affairs for the Coalition of State Rheumatology Organizations, shared her perspective on the FTC report in an email Q&A.

Dr. Feldman has long tracked the PBM industry and appeared as a witness before influential government panels, including the House Energy and Commerce Committee. She has highlighted for lawmakers the challenges physicians face in helping patients get needed medicines.

Dr. Feldman

What would you want federal and state policymakers to do in response to the FTC's report?

I think Congress needs to clearly delineate the differences between anticompetitive pharmacy issues, drug pricing issues, and their effect on formulary construction issues.

Lawmakers should demand more transparency and consider legislation that would remove incentives that prompt PBMs to choose higher priced drugs for their formularies.

That may require other regulatory or legislative actions to ensure lower prices (not higher kickbacks) are incentivized. Ultimately, in order to gain true competition within the health insurance business, these oligopolies need to be broken up.

You've followed PBM practices closely for many years. Was there anything in this interim FTC report that surprised you?

Though not surprised, I am glad that it was released because it had been a year in investigation and there were many requests for some type of substantive report.

Two things that are missing that I feel are paramount are investigating how the three big PBMs are causing physical harm to patients as a result of the profit component in formulary construction and the financial impact of hidden PBM profit centers in self-insured employer health plans.

What we have seen over the years is the result of the incentives for the PBMs to prefer the most profitable medications on their formularies.

They use utilization management tools such as step therapy, nonmedical switching, and exclusions to maintain their formularies' profitability.

These tools have been shown to delay and deny the proper care of patients, resulting in not just monetary but physical harm.

In terms of the FTC's mission to not "unduly burden" legitimate business, I would like to see the sector of self-insured employers addressed.

The report details how PBMs steer prescriptions to their affiliated pharmacies. The FTC says that can push smaller pharmacies out of the market, ultimately leading to higher costs and lower quality services for people. What's your perspective?

Having more community pharmacies is better than having fewer. We are seeing more "pharmacy deserts" in rural areas as a result of many community pharmacies having to close. ■

EMBOLISM *continued from previous page*

in-hospital outcomes, was reached in 17% of FlowTriever patients, significantly lower than the 32% performance goal and the 63.9% rate in the context arm. In-hospital mortality was dramatically lower in the FlowTriever arm (1.9%) compared to the context arm (29.5%).

When catheter-based treatment fails, surgical pulmonary embolectomy is a last-resort option. "Only a minority of the high-risk PE [patients] would qualify for rtPA without harmful side effects," Dr. Rali concluded. "So think wise before you pull your trigger."

rtPA not a matter of the past

In high-risk PE, the therapeutic priority is rapid hemodynamic stabilization and restoration of pulmonary blood flow to prevent cardiovascular collapse. Systemic thrombolysis acts quickly, reducing pulmonary vascular resistance and obstruction within hours, Dr. Sanchez said.

Presenting at the ERS Congress, he reported numerous studies, including 15 randomized controlled trials that demonstrated its effectiveness in high-risk PE. The PEITHO trial, in particular, demonstrated the ability of systemic thrombolysis to reduce all-cause mortality and hemodynamic collapse within 7 days.

However, this benefit comes at the cost of increased bleeding risk, including a 10% rate of major bleeding and a 2% risk for intracranial hemorrhage. "These data come from old studies using invasive diagnostic procedures, and with current diagnostic procedures, the rate of bleeding is probably lower," Dr. Sanchez said. The risk of bleeding is also related to the type of thrombolytic agent, with tenecteplase being strongly associated with a higher risk of bleeding, while alteplase shows no increase in the risk of major bleeding, he added. New strategies like reduced-dose thrombolysis offer comparable efficacy and improved safety, as demonstrated in ongoing trials like PEITHO-3, which aim to optimize the balance between efficacy and bleeding risk. Dr. Sanchez is the lead investigator of the PEITHO-3 study.

While rtPA might not be optimal for all patients, Dr. Sanchez thinks there is not enough evidence to replace it as a first-line treatment.

Existing studies on catheter-directed therapies often focus on surrogate endpoints, such as right-to-left ventricular ratio changes, rather than clinical outcomes like mortality, he said. Retrospective data suggest that catheter-directed therapies may reduce in-hospital mortality compared with systemic therapies, but they also increase the risk of intracranial bleeding, post-procedure complications, and device-related events.

Dr. Sanchez mentioned the same FLAME study described by Dr. Rali, which reported a 23% rate of device-related complications and 11% major bleeding in patients treated with catheter-directed therapies.

"Systemic thrombolysis remains the first treatment of choice," Dr. Sanchez concluded. "The use of catheter-directed treatment should be discussed as an alternative in case of contraindications."

The debate continues

Numerous ongoing clinical studies, such as the FLARE trial, will address gaps in evidence and refine treatment protocols, potentially reshaping the standard of care in high-risk PE in the near future by providing new data on the efficacy and safety of existing and emerging therapies.

"The coming data will make it clearer what the best option is," said Thamer Al Khouzaie, MD, a pulmonary medicine consultant at Johns Hopkins Aramco Healthcare in Dhahran, Saudi Arabia.

For now, he said, systemic thrombolysis remains the best option for most patients because it is widely available, is easily administered with intravenous infusion, and has a limited cost.

Catheter-directed treatment and surgical options are available only in specialized centers, require expertise and training, and are also very expensive.

Dr. Rali, Dr. Sanchez, and Dr. Khouzaie report no relevant financial relationships. ■

More than the paycheck: Top non-salary perks

BY DONAVYN COFFEY

Holly Wyatt, MD, had spent 20 years in UCHealth with no plans to leave. Her home, support system, and lifestyle were all rooted in Denver. But in 2020, The University of Alabama at Birmingham (UAB) made the physician an offer she couldn't resist.

The pay increase and a bump to full professorship weren't enough to lure her across the country. But then UAB sweetened the deal with fewer clinic hours and paid time to create.

"I didn't have to fit into the typical 'see patients 5 days a week; bill this many dollars,'" she said.

With no minimum billable hours, she could spend her time on clinical trials, designing programs, and recording podcasts. "When they offered that, I said, 'Ooh, that's enticing.'"

After a couple of visits to the campus, she began the job transition.

Doctors are looking for more than base pay. For many physicians, like Dr. Wyatt, non-salary incentives carry a lot of weight in the recruitment and job-hunting process.

"Some of the usual suspects are CME [continuing medical education] budget, signing bonuses, relocation assistance, loan repayment programs, and housing allowances," said Jake Jorgovan, partner at Alpha Apex Group, a physician recruiting firm in Denver.

Post pandemic, doctors are vying for other benefits, perks that support their interests, work-life balance, and financial stability. "We've come across offers like sabbatical opportunities, paid time for research or personal projects, and even concierge services that handle things like grocery shopping or pet care," said Mr. Jorgovan.

Amid physician shortages, doctors have more bargaining power than ever.

Money still talks

Financial perks are still the premiere portion of a benefits package, according to Marc Adam, physician recruiter at MASC Medical, a medical recruitment firm in Fort Lauderdale, Florida.

New data from the medical staffing company AMN Healthcare reported that the average signing bonus for physicians is $31,103. The average relocation allowance is $11,000, and the average CME allowance is $4000.

"CME budget and loan repayment programs are big because they directly impact career advancement and financial well-being," Mr. Jorgovan said. He said that given the high cost of medical training, loan repayment help, especially, has become a huge deciding factor for clinicians. Employers have historically been hesitant to offer these kinds of long-term benefits because of the financial commitment and planning involved, but that's changing.

> *"Physicians were always in the driver's seat, and their bargaining power has only increased."*
> *– Mr. Adam*

Mr. Adam said that short-term financial perks, like relocation assistance and signing bonuses, tend to be more important for younger doctors. They're not yet financially established, so the relocation support and bonus funds have more impact as they take on a new role, he said.

Mid- and late-career doctors, on the other hand, are less beholden to these types of bonuses. Mr. Adam has recruited established doctors from across the country to Florida, and he said that the relocation allowance and singing bonus didn't even rank in their top five priorities. Similarly, in Birmingham,

Dr. Wyatt recently reread her offer letter from UAB and was surprised to find a relocation stipend that she never used. "I had no idea," she said.

Vying for time

Mid- and late-career doctors who have a better financial safety net tend to seek benefits that boost their quality of life.

One of Mr. Adam's recent job-searching clients was unwilling to compromise on priorities like specific location and a 4-day workweek.

Four-day workweeks, flexible scheduling, and options for remote work are increasingly popular, especially since the pandemic. Some physicians, like those in primary care, are looking for dedicated charting hours — paid days or half-days set aside for updating the electronic medical records.

Other doctors are negotiating multistate telehealth licensing paid by their employer and work-from-home telehealth hours.

"Work life has been slowly increasing over the 14 years I've been doing this. And post COVID, the employer's willingness to be flexible with those types of accommodations increased," said Mr. Adam.

Priya Jaisinghani, MD, an obesity medicine specialist in her second year of practice, NYU Langone Health, New York City, said work-life balance can be a priority for young doctors, too.

After training in New York during the pandemic, Dr. Jaisinghani was all too aware of the risk for burnout. So she negotiated a 4-day workweek when she took her first job out of fellowship in 2022. "I was able to prioritize work-life balance from the start," she said.

Support for the career you want

When Dr. Jaisinghani signed her first contract in 2022 with NYU, her move from New Jersey to New York wasn't far enough to warrant a relocation allowance. "There was a signing bonus, sure," she said. But what really grabbed her attention were perks like mentorship, access to trainees, and autonomy.

Perks that support long-term growth — like CME allowance, teaching opportunities, or access to leadership tracks — are especially important to young doctors.

"After dedicating so many years to medical training, you want to look for some degree of autonomy in building your practice," she said. NYU offered her that kind of freedom and support.

On top of personal growth, young physicians are looking for perks that will allow them to build the practice they want for their patients, Dr. Jaisinghani said.

A lot of young doctors don't know that they can negotiate for schedule preferences, office space, their own exam room, and dedicated support staff. However, they can and should because these factors influence their daily work life and patient experience.

Experienced doctors are also looking for perks that support the career they want. Recruitment experts say that doctors tend to look for opportunities that accommodate their interests. One of Mr. Jorgovan's recent clients took a position because it offered a generous CME budget and dedicated research hours. Similarly, Dr. Wyatt at UAB moved because her contract included paid time to create.

"It really comes down to the need for balance — being able to keep learning while also having time for personal life and family," Mr. Jorgovan said.

Making and meeting demand

Thanks to the rising demand, doctors have more power than ever to negotiate the perks they want and need.

The existing physician shortage — driven by retiring doctors and an aging patient population — was only exacerbated by the pandemic. Now, a number of new market entries are further increasing competition for talent, according to AMN Healthcare's report. Retail clinics, urgent care, telehealth companies, and private equity firms compete for the same doctors, driving up salaries and doctor bargaining power.

"Physicians were always in the driver's seat, and their bargaining power has only increased," Mr. Adam said. Health care systems, once reticent about flexible working arrangements or loan repayment, are reconsidering.

Even young doctors have more negotiating power than they realize, but they might need help.

"It's underrated to get a contracts lawyer as a young doctor, but I think it's smart," Dr. Jaisinghani said. They're often more familiar with salaries in the area, flexibility options, and potential benefits, none of which doctors are taught in training, she said.

Mr. Adam said that the pandemic opened employers' eyes to the fact that doctors have the bargaining power. There's a stark need for their talent and a lot of public support for their service. So hiring managers are listening and are ready to offer "creative benefits to accommodate the market demand," he said.

In her new position at UAB, Dr. Wyatt said that money will always matter. "When your salary is low, bumping that salary will make you happier." But after a certain point, she said, other things become more important — like your time, the work you do, and the people you work with.

Her perks at UAB offer more than money can. "I get up in the morning, and I'm excited — [the work] excites me," she said. ■

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FDA 'recalls' often leave medical devices in use

BY DAVID HILZENRATH

In 2016, medical device giant Abbott issued a recall for its MitraClip cardiac device — "a Class I recall, the most serious type," the Food and Drug Administration (FDA) said.

"Use of this device may cause serious injuries or death," an FDA notice about the recall said.

But neither the manufacturer nor the FDA actually recalled the device or suspended its use. They allowed doctors to continue implanting the clips in leaky heart valves in what has become a common procedure.

In a notice, the manufacturer explained, "Abbott is not removing product from commercial distribution." Rather, Abbott revised instructions for use and required doctors who implant the clips to undergo training.

When it comes to medical devices, recalls can include not only "removals," in which the device is removed from where it is used or sold, but also "corrections," which address the problem in the field — for instance, by repairing, adjusting, relabeling, or inspecting a device.

"It's very oxymoronic," said Rita Redberg, MD, a cardiologist at the University of California, San Francisco, and former editor-in-chief of the journal *JAMA Internal Medicine*. "A recall makes it sound like it's recalled. But that is not actually what it means."

Though the FDA and federal regulations call these actions recalls, they might be described more appropriately as "non-recalls." And they have happened repeatedly in recent years. For instance, in addition to other Abbott devices, products made by Medtronic, Abiomed, and Getinge have had recalls that left them in use.

Safeguarding the public

Recalls that leave what the FDA identifies as potentially dangerous products in the marketplace can raise the question: Do they do enough to protect the public?

There are other ways to handle recalls. In announcements about products as varied as crib bumpers, pool drain covers, bicycle helmets, and coffee mugs, the Consumer Product Safety Commission routinely alerts consumers to stop using recalled products and contact the manufacturers for refunds, repairs, or replacements. The National Highway Traffic Safety Administration regularly advises consumers to bring recalled cars back to the dealer to have them fixed. When the US Department of Agriculture and the FDA announce food recalls, they routinely tell consumers to return or discard the food.

In some cases, a medical device that is the subject of a recall can be kept on the market safely because there is a simple fix, said Sanket Dhruva, MD, MHS, a cardiologist and an associate professor at UCSF who has studied FDA oversight of devices. In other cases, recalls that don't remove devices from the market can provide unwarranted reassurance and leave the public at risk, Dr. Dhruva said.

bankrx/iStock/Getty Images

From 2019 through 2023, there were 338 Class I medical device recalls, 164 of which were corrections and 174 of which were removals, FDA spokesperson Amanda Hils said.

Some products undergo recall after recall while they remain on the market. Products in the MitraClip line have been the subject of three rounds of recalls, none of which removed devices from use.

"When deciding whether a recall warrants device removal from the field, the FDA considers the frequency and severity of adverse events, effectiveness of the corrective actions that have been executed, and the benefits and risks of preserving patient access to the device," FDA spokesperson Audra Harrison said.

Where recalled devices have already been implanted, "removal" doesn't necessarily mean removing them from patients' bodies. "When an implanted device has the potential to fail unexpectedly, companies often tell doctors to contact their patients to discuss the risk of removing the device compared to the risk of leaving it in place," the FDA website says.

The FDA allowed the recalled MitraClip devices to remain in use "because the agency believed that the overall benefits of the device continued to outweigh the risks and the firm's recall strategy was appropriate and adequate," Ms. Harrison said.

The FDA reviews the recall strategies that manufacturers propose and often provides input to ensure the public will be protected, Hils said. The agency also monitors the effectiveness of recalls and, before terminating them, makes sure the strategy was carried out, Ms. Hils said.

Abbott, the maker of MitraClip, said the device has been proven safe and effective "based on more than 20 years of clinical evidence and has profoundly improved the lives of people living with mitral regurgitation [MR]," a condition in which blood flows backward through the heart's mitral valve. The condition can lead to heart failure and death.

"With MitraClip, we're addressing the needs of people with MR who often have no other options," company spokesperson Brent Tippen said.

Speaking of the MitraClip recalls, Dr. Redberg said, "So hard to imagine these are effective actions in protecting patients."

In 2021, for Medtronic's StealthStation S7 cranial software, the company and the FDA sent a different message.

StealthStation is an elaborate system of screens and other equipment that guides neurosurgeons using instruments in the brain — for instance, to biopsy or cut out tumors. Drawing from CT scans, MRIs, and other imaging, it's meant to show the location of the surgical instruments.

In connection with a Class I November 2021 recall, the FDA website said potential inaccuracies in a biopsy depth gauge could result in "life-threatening injury (such as hemorrhage, unintended tissue damage, or permanent neurological injury), which could lead to death."

The FDA website explained what Medtronic was doing about it.

"The recalling firm will provide a warning and instructional placard to be applied to impacted systems," the website said. "Until a software update is available, ensure you are following the instructions below to prevent the issue from occurring," it advised doctors.

In a statement to KFF Health News, Medtronic spokesperson Erika Winkels said the safety and well-being of patients is the company's primary concern, and certain issues "can be safely and effectively remedied with a correction on site."

Richard Everson, MD, a neurosurgeon and an assistant professor at UCLA, noted that the 2021 recall allowed doctors to continue using unaffected StealthStation features, a benefit for patients and facilities depending on them.

"But, I mean, then you could ask, 'Well, why don't they just disable the view [of the brain] that's bugged?' " Dr. Everson said. "Why would they give you the option of looking at an inaccurate one?"

"That's kind of a strange solution," he said.

The FDA lists the 2021 recall as still open, explaining "not all products have been corrected or removed."

That recall was not the last word on problems with StealthStation. Since then, the manufacturer has submitted adverse event reports to the FDA describing trouble in cases involving various versions of StealthStation.

In a September 2022 case, guidance provided by a StealthStation device was allegedly off the mark, a procedure was aborted, and, when the patient awoke, they "had almost no speech for two days," according to a Medtronic report. In the report, Medtronic said there was "insufficient information to determine the relationship of the software to the reported issue."

In a February 2024 case, after brain surgery, an MRI found that the operation "missed the tumor" and that other tissue was removed instead, according to a report Medtronic submitted to the FDA. In the report, Medtronic said that when a company representative tested the system, it performed as intended.

In March 2024, Medtronic recalled versions of StealthStation S8 without

removing them from hospitals. The company said at the time that it would provide a software update.

"Software updates are available to correct the anomalies identified in the 2021 S7 and 2024 S8 recalls and are actively being deployed," Medtronic's Ms. Winkels told KFF Health News in a July email. "While the software updates for the 2021 S7 recall are complete in the US, they remain ongoing in some international regions."

In June 2023, Abiomed issued an urgent medical device correction for its Impella 2.5 intravascular micro axial blood pump, which supports the heart. In patients with a certain type of replacement heart valve, there was a risk of "destruction of the impeller blades," which could cause "low flow" and "embolization of the fractured impeller material," an entry on the FDA website said.

"Clinicians are cautioned to position the Impella system carefully in patients," the FDA website said, among other instructions.

The updated instructions "provide technical guidance to mitigate the risk of rare complications," Abiomed spokesperson Ryan Carbain said. There were no product removals and no reports of adverse events "related to product design or manufacturing," Mr. Carbain said.

Another set of medical devices, Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps made by Getinge of Sweden, have failed persistently, according to FDA records.

The devices — which are placed in the aorta, a major artery, to assist the heart — were the subject of eight Class I recalls from December 2022 to July 2023. All were corrections rather than removals, a KFF Health News analysis found.

In a May 2024 letter to health care providers, the FDA said that, in the previous 12 months, it had received almost 3000 adverse event reports related to the balloon pumps. It was referring to reports of malfunctions and cases in which the products might have caused or contributed to a death or injury. Of those, 15 reportedly involved serious injury or death, the FDA said.

During the summer of 2023, the FDA noted that "alternative treatments are limited" and said the devices could continue to be used.

But, in May, the FDA changed its stance. The agency advised health care facilities to "transition away from these devices and seek alternatives, if possible."

"These recommendations are based on our continued concerns" that the manufacturer "has not sufficiently addressed the problems and risks with these recalled devices."

Getinge sent KFF Health News written answers from Elin Frostehav, the company's president of Acute Care Therapies.

"There is no question that we would have liked to have solved these issues in full much earlier," she said.

As with the two earlier recalls, the third advised doctors to follow the device's instructions.

As a result of the FDA's May action, the company "immediately paused proactive marketing" of the balloon pumps in the United States, and it is selling them only to customers who have no alternatives, Ms. Frostehav said.

"We are working with the agency to finalize remediation and product update solutions," Ms. Frostehav said.

'Known possible complications'

Abbott's MitraClip system includes tiny clips implanted in the heart's mitral valve and the equipment used to implant them. The apparatus features a steering mechanism with hand controls and a catheter that is threaded through a major vein, typically from an incision in the groin, to place one or more clips in the heart.

Worldwide, more than 200,000 people have been treated with MitraClip, according to an Abbott website.

The 2016 MitraClip recall described cases in which "the user was unable to separate the implantable Clip from the delivery system."

In a news release at the time, Abbott said it had "received a small number of reports" in which that happened.

Those cases "resulted in surgical interventions to remove the delivery system or replace the mitral valve, and it is expected that any future similar incidents would also require surgery to correct the problem," the FDA said in a 2016 notice. "There was one patient death in these cases as a result of severe comorbidities following surgery."

Years later, something similar happened.

In February 2021, a clip was implanted in an 81-year-old patient but the doctor couldn't separate the clip from the delivery system, according to a report Abbott filed with the FDA. The patient was transferred to surgery, where the delivery system "had to be cut down in order to detach the clip."

The patient then underwent an operation to replace the mitral valve, and, hours later, the patient was brought back to surgery to address bleeding, the report said.

The patient "coded" the next day and died from an aortic bleed, the report said.

In the report to the FDA, the manufacturer blamed "case-specific circumstances."

"Cardiac arrest, hemorrhage and death are listed" in the device instructions "as known possible complications associated with mitraclip procedures," the company said. "There is no indication of a product issue with respect to manufacture, design or labeling."

The third MitraClip recall, initiated in September 2022, cited an "increase in clip locking malfunctions."

Most of the reported malfunctions were not associated with adverse outcomes, the FDA said then. Treatment with MitraClip "remains within the anticipated risk levels," the company told customers.

As with the two earlier recalls, the third advised doctors to follow the device's instructions. But the 2022 recall identified a contributing factor: the way the device was made.

"Abbott has identified a contributing cause ... as a change in the material properties of one of the Clip locking components," the company said in a 2022 letter to customers.

"Abbott is working on producing new lots with updated manufacturing processing and raw material," the company wrote. In the same letter, Abbott told doctors that, in the meantime, they could use the devices they had in stock.

Six days later, a clip opened while locked and a patient died, according to a report the manufacturer submitted to the FDA.

"There is no evidence that death was related to the device but it was likely related to the procedure," Abbott wrote.

Now, almost 2 years later, the 2022 recall remains open, according to the FDA website, and "not all products have been corrected or removed."

KFF Health News data editor Holly K. Hacker contributed to this report. ■

KFF Health News is a national newsroom that produces in-depth journalism about health issues and is one of the core operating programs at KFF — the independent source for health policy research, polling, and journalism.

NETWORKS

Impact of gas stoves, using lung ultrasound, sleep and athletic performance, and more

SLEEP MEDICINE NETWORK
Respiratory-Related Sleep Disorders Section
Sleep and athletic performance

Considering the recent Olympics, it is timely to review the importance of sleep for optimal athletic performance. When surveyed, 20% to 50% of athletes report poor or insufficient sleep, with consequences across four categories.


Dr. Mullen


Dr. Tobias

Athletic performance: Objective measures of athletic performance, such as oxygen-carrying capacity during cardiopulmonary exercise and even sport-specific accuracy measures, like shooting percentage in basketball, have been shown to worsen with decreased sleep.

Decision-making: Insufficient sleep can impact split-second decisions in competition. In a study of male soccer players, sleep restriction negatively impacted perceptual abilities and reaction time. Traveling across time zones also appears to degrade performance; NBA players' free-throw shooting worsens when they are jet-lagged.

Recovery and injury prevention: Getting less than eight hours of sleep may increase one's chances of injury during performance. Sleepiness and insomnia are both independent risk factors for developing a concussion in college athletes and outperform more intuitive risk factors such as a history of prior concussion or participating in a high-risk sport. Impaired sleep directly alters secretion of growth hormone, cortisol, and proinflammatory cytokines—all of which can hinder recovery.

Mental health: Over a third of elite athletes are estimated to experience a mental health problem. A clear bidirectional relationship exists between mental health and sleep health, with important implications not only for optimal competitive mindset but also longevity and success over one's career.

Although much of clinical sleep medicine focuses on pathology, we can also help our patients reach their athletic goals by strategizing ways to prioritize and improve sleep.

All references are available online at chestphysician.org.

– Cassandra Mullen, MD
Clinical Fellow
– Lauren A. Tobias, MD, FCCP
Section Chair

DIFFUSE LUNG DISEASE AND LUNG TRANSPLANT NETWORK
Occupational and Environmental Health Section
The gas stove: Friend or foe?

The kitchen is considered the heart of the home, but recent discoveries have raised concerns about whether this beloved space might also pose hidden health risks. Gas stoves, present in 38% of U.S. homes, generate multiple pollutants including nitrogen dioxide (NO_2),


Dr. Glick


Dr. Church


Dr. Balakrishnan

a known respiratory irritant. Studies have identified a correlation between NO_2 levels and respiratory conditions, with children being particularly vulnerable.

The association between domestic NO_2 exposure from gas stoves and conditions such as asthma has led to increased scrutiny of indoor air quality.

Studies have demonstrated that households using gas stoves have higher indoor NO_2 levels, with levels that far exceed the EPA national ambient air quality standards. While the predominance of studies have looked at a correlation with pediatric pulmonary processes, there is also evidence of increased lung function loss in patients who smoke and have COPD.

Switching from gas to electric stoves is one proposed solution to mitigate exposure to NO_2. Evidence suggests that electric stoves significantly reduce indoor NO_2 levels, lowering the risk of respiratory illnesses. Another proposed solution has been to utilize hoods; however, capture efficiency is variable and some recycle the air and return it indoors. While existing data indicates a connection between gas stove use and respiratory health risks, conclusive evidence examining the magnitude and mechanisms linking these factors to chronic lung diseases is still needed. Comprehensive studies will help determine whether the kitchen staple—a gas stove—is indeed a friend or a foe to our respiratory health.

All references are available online at chestphysician.org.

– Matthew Glick, MD
Fellow-in-Training
– Tyler Church, DO
Section Member
– Priya Balakrishnan, MD, MS, FCCP, Section Vice-Chair

THORACIC ONCOLOGY AND CHEST PROCEDURES NETWORK
Ultrasound and Chest Imaging Section
Lung ultrasound: An indispensable yet underutilized tool

An assessment using bedside thoracic ultrasound (TUS) improves diagnostic evaluation and therapeutic management in critically ill patients without undue risk. With changes in diagnosis occurring in 23% of cases and alterations in management in 39% of critically ill patients, TUS can improve length of stay, reduce complications, minimize delays in therapy, and lower hospitalization costs. Compared with its cardiac counterpart, attaining proficiency in lung ultrasound (LUS) is easier. Intensivists are at risk of forgoing mastering LUS in favor of developing more difficult skills. Proficiency in LUS is essential, as more than half of


Dr. Renzetti


Dr. Chichra

TUS evaluations are for respiratory complaints and most findings are pulmonary.

A quick bedside assessment outperforms chest radiographs and available clinical scores in distinguishing pneumonia from atelectasis. The presence of dynamic air bronchograms within the consolidation is 45% sensitive and 99% specific for pneumonia over atelectasis. When air bronchograms are static, the presence of flow on color Doppler is 98% sensitive and 68% specific for pneumonia over atelectasis. Similarly, a closer look at the pleural lining shows more than the presence or absence of lung sliding. The presence of fragmentation, irregularity, or thickening of pleural lines provides 100% specificity in discriminating a noncardiogenic interstitial pathology from cardiogenic pulmonary edema.

LUS is the workhorse and unsung hero of point-of-care ultrasound. In the last year, LUS has shown utility beyond evaluation for pneumothorax, pulmonary edema, and pleural effusion. Its potential impact on diagnosis and management is still growing. We just need to take a closer look.

All references are available online at chestphysician.org.

– Madelyn Renzetti, MD
Fellow-in-Training
– Astha Chichra, MBBS
Member-at-Large

CRITICAL CARE NETWORK
Sepsis/Shock Section
Prediction models in sepsis

Early recognition is the linchpin of sepsis management, as mortality from sepsis increases by 4% to 9% for every hour that diagnosis and treatment are delayed. Artificial intelligence (AI) and machine

NETWORKS *continued on following page*

Top reads from the *CHEST* journal portfolio

Explore articles on PAP adherence, plasma biomarkers in ARDS, and airways disorders hospitalizations during wildfire season

Journal *CHEST*®

Association Between Healthy Behaviors and Health Care Resource Use With Subsequent Positive Airway Pressure Therapy Adherence in OSA

By Claire Launois, MD, PhD, and colleagues

One of the pitfalls in the interpretation of the effect of treatment adherence on health outcomes is the healthy-adherer effect (HAE) bias. Healthy-adherer bias occurs when patients who are treatment-adherent tend to actively seek out preventative care and engage in other healthy behaviors. Incomplete adjustment for such behaviors can lead to spurious inferences regarding study outcomes because healthy behaviors are associated with a reduced risk of many poor health outcomes.

This study demonstrates that HAE proxies (adherence to CV active drugs, no history of smoking, or sleepiness-related car accidents) were associated with subsequent PAP adherence after adjustment for confounders. PAP-adherent patients used less health care resources before PAP initiation. Unfortunately, the study did not measure other healthy behaviors (nutrition, physical activity, psychosocial support) that could also potentially explain HAE. Until the HAE associated with PAP adherence is better understood, clinicians should use caution when interpreting the association of PAP adherence with CV health outcomes and health care resource use.

Dr. Venkateshiah

– Commentary by Sai Venkateshiah, MD, FCCP, Member of the *CHEST Physician* Editorial Board

CHEST® Critical Care

Circulating Biomarkers of Endothelial Dysfunction Associated With Ventilatory Ratio and Mortality in ARDS Resulting From SARS-CoV-2 Infection

Treated With Anti-inflammatory Therapies

By Jehan Alladina, MD, and colleagues

Practitioners in the intensive care unit have become increasingly aware that the population of patients with ARDS is highly heterogenous not only in terms of the inciting factors of their condition but also in terms of their respiratory physiology. Calfee and co-workers opened new horizons for us with their 2014 descriptions of two phenotypes of ARDS based upon biological markers that had different clinical outcome profiles. The work by Alladina et al adds to this body of knowledge by studying biomarkers from patients with COVID-ARDS who were receiving anti-inflammatory therapies. These researchers demonstrated that in such patients, endothelial biomarkers, particularly NEDD9, were associated with 60-day mortality. Increased understanding of biologic phenotypes in ARDS patients may facilitate the application of precision medicine to patients with this condition, improving outcome prediction and allowing practitioners to target specific treatments to selected patients.

Dr. Ouellette

– Commentary by Daniel R. Ouellette, MD, FCCP, Critical Care Commentary Editor of *CHEST Physician*

CHEST® Pulmonary

Association of Short-Term Increases in Ambient Fine Particulate Matter With Hospitalization for Asthma or COPD During Wildfire Season and Other Time Periods

By Benjamin Horne, PhD, MStat, MPH, and colleagues

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NETWORKS *continued from previous page*

learning (ML) are increasingly featured in discussions and publications about sepsis care. Already ML models are embedded in electronic medical records (EMR), driving best-practice advisories that are presented to users. Epic, the EMR that serves over half of patients in the US, offers its own proprietary cognitive computing model for early detection.

As ML permeates the critical care space, it is increasingly important that clinicians understand the limitations of these models. Recently Kamran et al (NEJM AI) evaluated the Epic sepsis model with disappointing results after excluding cases already recognized by clinicians. The model achieved a positive predictive value of 5%, and 80% of high-risk sepsis cases were missed.

An application study by Lilly et al (CHEST) showed that an ML model for clinically actionable events was more accurate with less alarm burden when compared to biomedical monitor alarms or telemedicine systems. The clinical utility of this model, however, remains questionable; presumably by the time a patient monitor has alarmed, the term "early recognition" can no longer be applied. In this study a significantly elevated false-positive rate required clinicians to review all cases prior to action.

Dr. Achamallah

Dr. Lee

ML models seem to offer incredible potential to clinicians. How they fit into current practice, however, deserves careful consideration. It may be that we just are not there yet.

All references are available online at chestphysician.org.

– Natalie Achamallah, MD, MA, MS
Member-at-Large
– Shu Xian Lee, MD

PULMONARY PERSPECTIVES®

Pseudomonas infection in patients with noncystic fibrosis bronchiectasis

BY O'NEIL GREEN, MBBS, FCCP

Pseudomonas aeruginosa is a clinically important organism that infects patients with noncystic fibrosis bronchiectasis (NCFB). In the United States, the estimated prevalence of NCFB is 213 per 100,000 across all age groups and 813 per 100,000 in the over 65 age group. A retrospective cohort study suggests the incidence of NCFB as ascertained from International Classification of Diseases codes may significantly underestimate its true prevalence.

As the incidence of patients with NCFB continues to increase, the impact of the *Pseudomonas* infection is expected to grow. A recent retrospective cohort study of commercial claims from IQVIA's PharMetrics Plus database for the period 2006 to 2020 showed that patients with NCFB and *Pseudomonas* infection had on average 2.58 hospital admissions per year, with a mean length of stay of 9.94 (± 11.06) days, compared with 1.18 admissions per year, with a mean length of stay of 6.5 (± 8.42) days, in patients with *Pseudomonas*-negative NCFB. The same trend applied to 30-day readmissions and ICU admissions, 1.32 (± 2.51 days) vs 0.47 (± 1.30 days) and 0.95 (± 1.62 days) vs 0.33 (± 0.76 days), respectively. The differential cost of care per patient per year between patients with NCFB with and without *Pseudomonas* infection ranged from $55,225 to $315,901.[3]

Recent data from the United States Bronchiectasis Registry showed the probability of acquiring *Pseudomonas aeruginosa* was 3% annually.[4] The prevalence of *Pseudomonas* infection in a large, geographically diverse cohort in the United States was quoted at 15%.[5] A retrospective analysis of the European Bronchiectasis Registry database showed *Pseudomonas* infection was the most commonly isolated pathogen (21.8%).[6]

Given the high incidence and prevalence of NCFB, the high prevalence of *Pseudomonas* infection in patients with NCFB, and the associated costs and morbidity from infection, identifying effective treatments has become a priority. The British, Spanish (SEPAR), South African, and European bronchiectasis guidelines outline several antibiotic regimens meant to achieve eradication. Generally, there is induction with a (1) quinolone, (2) β-lactam + aminoglycoside, or (3) quinolone with an inhaled antibiotic followed by three months of maintenance inhaled antibiotics.[7-10] SEPAR allows for retreatment for recurrence at any time during the first year with any regimen.

For chronic *Pseudomonas* infection, SEPAR recommends treatment with inhaled antibiotics for patients with more than two exacerbations or one hospitalization, while the threshold in the British and European guidelines is more than three exacerbations. Azithromycin may be used for those who are intolerant or allergic to the nebulized antibiotics. It is worth noting that in the United States, the antibiotics colistin, ciprofloxacin, aztreonam, gentamicin, and tobramycin are administered off label for this indication. A systematic review found a 10% rate of bronchospasm in the treated group compared with 2.3% in the control group, and premedication with albuterol is often needed.[11]

Unfortunately, the data supporting the listed eradication and suppressive regimens are weak. A systematic review and meta-analysis of six observational studies including 289 patients showed a 12-month eradication rate of only 40% (95% CI, 34-45; P < 0.00001; I2 = 0).[12] These results are disappointing and identify a need for further research into the manner in which *Pseudomonas* infection interacts with the host lung.

We currently know *Pseudomonas* infection evades antibiotics and host defenses by accumulating mutations and deletions. These include loss-of-function mutations in *mucA* (mucoidy), *lasR* (quorum-sensing), *mexS* (regulates the antibiotic efflux pump), and other genes related to the production of the polysaccharides Psl and Pel (which contribute to biofilm formation).[13] There may also be differences in low and high bacteria microbial networks that interact differently with host cytokines to create an unstable environment that predisposes to exacerbation.[14]

In an attempt to improve our eradication and suppression rates, investigators have begun to target specific aspects of *Pseudomonas* infection behavior. The GREAT-2 trial compares gremubamab (a bivalent, bispecific, monoclonal antibody targeting Psl exopolysaccharide and the type 3 secretion system component of PcrV) with placebo in patients with chronic *Pseudomonas* infection. A phase II trial with the phosphodiesterase inhibitor esifentrine, a phase III trial with a reversible DPP1 inhibitor called brensocatib (ASPEN), and a phase II trial with the CatC inhibitor BI 1291583 (Airleaf) are also being conducted. Each of these agents targets mediators of neutrophil inflammation.

In summary, NCFB with *Pseudomonas* infection is common and leads to an increase in costs, respiratory exacerbations, and hospitalizations. While eradication and suppression are recommended, they are difficult to achieve and require sustained durations of expensive medications that can be difficult to tolerate. Antibiotic therapies will continue to be studied (the ERASE randomized controlled trial to investigate the efficacy and safety of tobramycin to eradicate *Pseudomonas* infection is currently underway), but targeted therapies represent a promising new approach to combating this stubbornly resistant bacteria. The NCFB community will be watching closely to see whether medicines targeting molecular behavior and host interaction can achieve what antibiotic regimens thus far have not: consistent and sustainable eradication. ■

All references are available online at chestphysician.org.

Dr. Green is Assistant Professor in Medicine, Medical Director, Bronchiectasis Program, UMass Chan/Baystate Health, Chest Infections Section, Member-at-Large

JOURNAL *continued from previous page*

Trigger avoidance is one the most important interventions in the control of symptoms and prevention of exacerbations in chronic airways diseases. Nevertheless, trigger avoidance is at times not possible. This is the case with wildfire smoke and other environmental irritants—an increasing global health problem. Using data from 11 hospitals along the Utah's Wasatch Front, the study by Horne and colleagues shows a clear association between a short-term increase in ambient fine particulate matter exposure resulting from wildfires and a surge in asthma exacerbations. This effect was also seen in patients with COPD but to a lesser degree. The study is limited by its observational design and because measurements of pollution levels were performed regionally and not at individual patient level. Yet this study offers valuable insights on the effects of environmental exposures in patients with chronic airways diseases and the consequences to our health care systems. Futures studies are still needed to assess the long-term consequences of sustained exposures to these irritants in patients with respiratory conditions.

– Commentary by Diego J. Maselli, MD, FCCP, Member of the *CHEST Physician* Editorial Board

Dr. Maselli

In Memoriam

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

Michael W. Kattan, MBA, PhD
Statistical Editor, *CHEST*® journal
Chair, Department of Quantitative Health Sciences, The Cleveland Clinic
Professor of Medicine, Cleveland Clinic Lerner College of Medicine

Rick L. Scacewater, MD, FCCP

Advocating for diversity in medical education

Earlier this year, Representative Greg Murphy, MD, along with several cosponsors, introduced H.R. 7725, the Embracing Anti-Discrimination, Unbiased Curricula, and Advancing Truth in Education (EDUCATE) Act.

If enacted, the EDUCATE Act would cut off federal funding to medical schools that force students or faculty to adopt specific beliefs; discriminate based on race or ethnicity; or have diversity, equity, and inclusion (DEI) offices or any functional equivalent. The bill would also require accreditation agencies to check that their standards do not push these practices, while still allowing instruction about health issues tied to race or collecting data for research.

In response to the introduction of this act, CHEST published a statement in support of DEI practices and their necessary role within the practice of health care and medical training programs.

It is our belief that health care requires a solid patient-provider therapeutic alliance to achieve successful outcomes, and decades of scientific research have shown that a lack of clinician diversity worsens health disparities. For patients from historically underserved communities, having clinicians who share similar lived experiences almost always leads to significant improvements in patient outcomes. If identity concordance is not feasible, clinicians with considerable exposure to diverse patient populations, equitable approaches to care, and inclusive perspectives on health gained through continuing, comprehensive medical education and professional training can also positively impact outcomes.

Research indicates that a diverse medical workforce improves cultural competence and can help clinicians better meet the needs of patients from diverse backgrounds and ethnicities and that the benefits of diverse learning environments enhance the educational experience of all participants. Racial and ethnic health inequities illuminate the greatest gaps and worst patient outcomes, especially when compounded by disparities related to gender identity, ability, language, immigration status, sexual orientation, age, socioeconomics, and other social drivers of health. Research also shows that nearly one-fifth of Latine Americans avoid medical care due to concern about experiencing discrimination, Black Americans have significantly lower life expectancies, and Asian Americans are the only racial group to experience cancer as a leading cause of death. It is also well documented that communities experiencing disproportionately high rates of COVID-19 infection, hospitalization, and mortality when compared with White Americans include Black, Latine, Asian, Native Hawaiian, and Native Americans.

"... CHEST is firmly committed to the necessity of diversity, equity, and inclusion in health care research, education, and delivery."
– Dr. Jack D. Buckley

"In 2023, the CHEST organization shared its organizational values: community, inclusivity, innovation, advocacy, and integrity," said CHEST President, Jack D. Buckley, MD, MPH, FCCP. "In strong accordance with these values and with our mission to champion the prevention, diagnosis, and treatment of chest diseases and advance the best patient outcomes, CHEST is firmly committed to the necessity of diversity, equity, and inclusion in health care research, education, and delivery."

Guided by our core values, CHEST is relentlessly committed to improving the professional's experience and patient outcomes equally. This commitment compels us to work toward eliminating disparities in the medical field. According to the most recent US Census projections, by 2045, White Americans will no longer be considered a racial majority, with Black, Latine, and Asian American populations continuing to grow. It is incumbent upon us to ensure that our clinician workforce reflects the diversity of its

DIVERSITY *continued on following page*

New vaccines that target KP.2 variant available

BY HEIDI SPLETE

New COVID-19 vaccines formulated for better protection against the currently circulating variants have been approved by the US Food and Drug Administration.

The COVID vaccines available this fall have been updated to better match the currently circulating COVID strains, said William Schaffner, MD, professor of medicine in the Division of Infectious Diseases at Vanderbilt University, Nashville, Tennessee.

"The Pfizer and Moderna vaccines — both mRNA vaccines — target the KP.2 variant, while the Novavax vaccine targets the JN.1 variant, which is a predecessor to KP.2," said Dr. Schaffner, who also serves as a spokesperson for the National Foundation for Infectious Diseases.

"The Novavax vaccine is a protein adjuvant vaccine made in a more traditional fashion and may appeal to those who remain hesitant about receiving an mRNA vaccine," he explained. However, all three vaccines are designed to protect against severe COVID illness and reduce the likelihood of hospitalization, he said.

Who needs it?

"The CDC's [Centers for Disease Control and Prevention] Advisory Committee on Immunization Practices continues to recommend that everyone in the United States who is age 6 months and older receive the updated COVID vaccine this fall, along with influenza vaccine," Dr. Schaffner said.

"This was not a surprise because COVID will produce a sizable winter outbreak," he predicted. Although older people and those who have chronic medical conditions such as heart or lung disease, diabetes, or other immunocompromising conditions suffer the most serious impact of COVID, he said, "The virus can strike anyone, even the young and healthy." The risk for long COVID persists as well, he added.

As with earlier versions of the COVID-19 vaccine, side effects vary from person to person. Reported side effects of the updated vaccine are similar to those seen with earlier versions and may include injection-site pain, redness and swelling, fatigue, headache, muscle pain, chills, nausea, and fever, but most of these are short-lived, according to the CDC.

Clinical guidance

The CDC's clinical guidance for COVID-19 vaccination outlines more specific guidance for vaccination based on age, vaccination history, and immunocompromised status and will be updated as needed.

A notable difference in the latest guidance is the recommendation of only one shot for adults aged 65 years and older who are NOT moderately or severely immunocompromised. For those who are moderately or severely immunocompromised, the CDC recommends two to three doses of the same brand of vaccine.

Dr. Schaffner strongly encouraged clinicians to recommend the COVID-19 vaccination for all eligible patients.

The updated COVID-19 vaccination recommendations have become much simpler for clinicians and patients, with a single messenger RNA (mRNA) vaccine required for anyone older than 5 years, said David J. Cennimo, MD, associate professor of medicine and pediatrics in the Division of Infectious Disease at Rutgers New Jersey Medical School, Newark, New Jersey.

"We need to explain to our patients that COVID-19 is still here and is still dangerous. The yearly influenza vaccination campaigns should have established and normalized the idea of an updated vaccine targeted for the season's predicated strains."
– Dr. Cennimo

"The recommendations are a bit more complex for children under 5 years old receiving their first vaccination; they require two to three doses depending on the brand," he said. "It is important to review the latest recommendations to plan the doses with the correct interval timing. Considering the doses may be 3-4 weeks apart, start early," he advised.

One-time dosing

Although the updated mRNA vaccine is currently recommended as a one-time dose, Dr. Cennimo said he can envision a scenario later in the season when a second dose is recommended for the elderly and those at high risk for severe illness. Dr. Cennimo said that he strongly agrees with the recommendations that everyone aged 6 months and older receive an updated COVID-19 vaccine. Older age remains the prime risk factor, but anyone can become infected, he said.

Best time to vaccinate

Predicting a prime time to get vaccinated is tricky because no one knows when the expected rise in winter cases will occur, Dr. Cennimo said. "We know from years of flu vaccine data that some number of people who delay the vaccine will never return and will miss protection," he said. Therefore, delaying vaccination is not recommended. Dr. Cennimo plans to follow his habit of getting vaccinated in early October. "I anticipate the maximal effectiveness of the vaccine will carry me through the winter," he said.

Data support the safety and effectiveness for both flu and COVID vaccines if they are given together, and some research on earlier versions of COVID vaccines suggested that receiving flu and COVID vaccines together might increase the antibody response against COVID, but similar studies of the updated version have not been done, Dr. Cennimo said.

Clinicians may have to overcome the barrier of COVID fatigue to encourage vaccination, Dr. Cennimo said. Many people say they "want it to be over," he said, but SARS-CoV-2, established as a viral respiratory infection, shows no signs of disappearing. In addition, new data continue to show higher mortality associated with COVID-19 than with influenza, he said.

"We need to explain to our patients that COVID-19 is still here and is still dangerous. The yearly influenza vaccination campaigns should have established and normalized the idea of an updated vaccine targeted for the season's predicated strains is expected," he emphasized.

"We now have years of safety data behind these vaccines, and we need to make a strong recommendation for this protection," he said.

COVID-19 vaccines are covered by private insurance, as well as by Medicare and Medicaid, according to the CDC. Vaccination for uninsured children is covered through the Vaccines for Children Program. ■

DIVERSITY *continued from previous page*

local and national communities.

The underrepresentation of physicians from racially diverse backgrounds is factually clear. Black physicians comprise 5% of the current physician workforce despite Black Americans representing 13% of the population. Similarly, while Native Americans comprise 3% of the United States population, Native American physicians account for less than 1% of the physician workforce, with less than 10% of medical schools reporting total enrollment of more than four Native American students. Where gender is concerned, women make up about 36% of the physician workforce, a professional disparity that is further exacerbated given the intersections of race and gender, resulting in a significant impact on the current workforce. Allowing disinformation to influence the future of medical education and patient care directly contradicts our mission as clinicians dedicated to improving the health of all people.

If physician representation and patient outcomes are linked, as research shows, the lack of diverse medical school representation has dire consequences for matriculation, job recruitment, retention, and promotion. Without supportive policies, programs, and equity-focused curriculums in medical education, we will never close the gap on professional disparities, which means we will similarly never close the gap on health disparities.

Our commitment to our members, all health care professionals, and the field of medicine means that we will stand firm in our defense of DEI today and every day until we have achieved optimal, equitable health for all people in all places. CHEST is committed to an intersectional approach to equitable health care education and delivery. We strive to design solutions that center the most impacted and radiate support outward, ensuring our interventions benefit all others experiencing discrimination.

Read more about CHEST's commitment to diversity and other advocacy work at chestnet.org/advocacy. ■

All references are available online at chestphysician.org.

Patient navigators for serious illnesses can now bill under new Medicare codes

BY KERRY DOOLEY YOUNG

In a move that acknowledges the gauntlet the US health system poses for people facing serious and fatal illnesses, Medicare will pay for a new class of workers to help patients manage treatments for conditions like cancer and heart failure.

The 2024 Medicare physician fee schedule includes new billing codes, including G0023, to pay for 60 minutes a month of care coordination by certified or trained auxiliary personnel working under the direction of a clinician.


Dr. Mullangi

A diagnosis of cancer or another serious illness takes a toll beyond the physical effects of the disease. Patients often scramble to make adjustments in family and work schedules to manage treatment, said Samyukta Mullangi, MD, MBA, medical director of oncology at Thyme Care, a Nashville, Tennessee–based firm that provides navigation and coordination services to oncology practices and insurers.

"It just really does create a bit of a pressure cooker for patients," Dr. Mullangi said.

Medicare has for many years paid for medical professionals to help patients cope with the complexities of disease, such as chronic care management (CCM) provided by physicians, nurses, and physician assistants.

The new principal illness navigation (PIN) payments are intended to pay for work that to date typically has been done by people without medical degrees, including those involved in peer support networks and community health programs. The US Centers for Medicare & Medicaid Services (CMS) expects these navigators will undergo training and work under the supervision of clinicians.

The new navigators may coordinate care transitions between medical settings, follow up with patients after emergency department (ED) visits, or communicate with skilled nursing facilities regarding the psychosocial needs and functional deficits of a patient, among other functions.

CMS expects the new navigators may:

- Conduct assessments to understand a patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.
- Provide support to accomplish the clinician's treatment plan.
- Coordinate the receipt of needed services from health care facilities, home- and community-based service providers, and caregivers.

Peers as navigators

The new navigators can be former patients who have undergone similar treatments for serious diseases, CMS said. This approach sets the new program apart from other care management services Medicare already covers, program officials wrote in the 2024 physician fee schedule.

"For some conditions, patients are best able to engage with the health care system and access care if they have assistance from a single, dedicated individual who has 'lived experience,'" according to the rule.

The agency has taken a broad initial approach in defining what kinds of illnesses a patient may have to qualify for services. Patients must have a serious condition that is expected to last at least 3 months, such as cancer, heart failure, or substance use disorder.

But those without a definitive diagnosis may also qualify to receive navigator services.

In the rule, CMS cited a case in which a CT scan identified a suspicious mass in a patient's colon. A clinician might decide this person would benefit from navigation services because of the potential risks for an undiagnosed illness.

"Regardless of the definitive diagnosis of the mass, presence of a colonic mass for that patient may be a serious high-risk condition that could, for example, cause obstruction and lead the patient to present to the emergency department, as well as be potentially indicative of an underlying life-threatening illness such as colon cancer," CMS wrote in the rule.

"[The navigators] see the whole picture. They see the whole journey the patient takes, from pre-diagnosis all the way through diagnosis care out through survival."

Navigators often start their work when cancer patients are screened and guide them through initial diagnosis, potential surgery, radiation, or chemotherapy, said Sharon Gentry, MSN, RN, a former nurse navigator.

The navigators are meant to be a trusted and continual presence for patients, who otherwise might be left to start anew in finding help at each phase of care.

The navigators "see the whole picture. They see the whole journey the patient takes, from pre-diagnosis all the way through diagnosis care out through survival," Ms. Gentry said.

Gaining a special Medicare payment for these kinds of services will elevate this work, she said.

Many newer drugs can target specific mechanisms and proteins of cancer. Often, oncology treatment involves testing to find out if mutations are allowing the cancer cells to evade a patient's immune system.

Checking these biomarkers takes time, however. Patients sometimes become frustrated because they are anxious to begin treatment. Patients may receive inaccurate information from friends or family who went through treatment previously. Navigators can provide knowledge on the current state of care for a patient's disease, helping them better manage anxieties.

"You have to explain to them that things have changed since the guy you drink coffee with was diagnosed with cancer, and there may be a drug that could target that," Ms. Gentry said.

Potential challenges

Initial uptake of the new PIN codes may be slow going, however, as clinicians and health systems may already use well-established codes. These include CCM and principal care management services, which may pay higher rates, Dr. Mullangi said.

"There might be sensitivity around not wanting to cannibalize existing programs with a new program," she explained.

In addition, many patients will have a copay for the services of principal illness navigators, Dr. Mullangi said.

While many patients have additional insurance that would cover the service, not all do. People with traditional Medicare coverage can sometimes pay 20% of the cost of some medical services.

"I think that may give patients pause, particularly if they're already feeling the financial burden of a cancer treatment journey," Dr. Mullangi said.


Ms. Gentry

Pay rates for PIN services involve calculations of regional price differences, which are posted publicly by CMS, and potential added fees for services provided by hospital-affiliated organizations.

Consider payments for code G0023, covering 60 minutes of principal navigation services provided in a single month.

A set reimbursement for patients cared for in independent medical practices exists, with variation for local costs. Medicare's non-facility price for G0023 would be $102.41 in some parts of Silicon Valley in California, including San Jose.

In Arkansas, where costs are lower, reimbursement would be $73.14 for this same service.

Patients who get services covered by code G0023 in independent medical practices would have monthly copays of about $15-$20, depending on where they live.

The tab for patients tends to be higher for these same services if delivered through a medical practice owned by a hospital, as this would trigger the addition of facility fees to the payments made to cover the services. Facility fees are difficult for the public to ascertain before getting a treatment or service.

Dr. Mullangi and Ms. Gentry reported no relevant financial disclosures outside of their employers. ■

Are nurse practitioners and physician assistants 'quiet quitting'?

BY KELLY K. JAMES

While she cared deeply about her work, Melissa Adams*, a nurse practitioner (NP) in Madison, Alabama, was being frequently triple-booked, didn't feel respected by her office manager, and started to worry about becoming burned out. When she sought help, "the administration was tone-deaf," she said. "When I asked about what I could do to prevent burnout, they sent me an article about it. It was clear to me that asking for respite from triple-booking and asking to be respected by my office manager wasn't being heard ... so I thought, 'how do I fly under the radar and get by with what I can?'" That meant focusing on patient care and refusing to take on additional responsibilities, like training new hires or working with students.

"You're overworked and underpaid, and you start giving less and less of yourself," Ms. Adams said.

Quiet quitting, defined as performing only the assigned tasks of the job without making any extra effort or going the proverbial extra mile, has gained attention in the press in recent years. A Gallup poll found that about 50% of the workforce were "quiet quitters" or disengaged.

It may be even more prevalent in health care, where a recent survey found that 57% of frontline medical staff, including NPs and physician assistants (PAs), report being disengaged at work.

The causes of quiet quitting

Potential causes of quiet quitting among PAs and NPs include:

- **Unrealistic care expectations.** They ask you to give your all to patients, handle everything, and do it all in under 15 minutes since that's how much time the appointment allows, Ms. Adams said.
- **Lack of trust or respect.** Physicians don't always respect the role that PAs and NPs play in a practice.
- **Dissatisfaction with leadership or administration.** There's often a feeling that the PA or NP isn't "heard" or appreciated.
- **Dissatisfaction with pay or working conditions.**
- **Moral injury.** "There's no way to escape being morally injured when you work with an at-risk population," Ms. Adams said. "You may see someone who has 20-24 determinants of health, and you're expected to schlep them through in 8 minutes — you know you're not able to do what they need."

What quiet quitting looks like

Terri Smith*, an NP at an academic medical center outpatient clinic in rural Vermont, said that, while she feels appreciated by her patients and her team, there's poor communication from the administration, which has caused her to quietly quit.

"...at our institution, I'm not just an NP — I'm the nurse, the doctor, the secretary — I'm everybody."
– Ms. Smith

"I stopped saying 'yes' to all the normal committee work and the extra stuff that used to add a lot to my professional enjoyment," she said. "The last couple of years, my whole motto is to nod and smile when administration says to do something — to put your head down and take care of your patients."

While the term "quiet quitting" may be new, the issue is not, said Bridget Roberts, PhD, a health care executive who ran a large physician's group of 100 health care providers in Jacksonville, Florida, for a decade. "Quiet quitting is a fancy title for employees who are completely disengaged," Dr. Roberts said. "When they're on the way out, they 'check the box'. That's not a new thing."

"Typically, the first thing you see is a lot of frustration in that they aren't able to complete the tasks they have at hand," said Rebecca Day, PMNHP, a doctoral-educated NP and director of nursing practice at a Federally Qualified Health Center in Corbin, Kentucky. "Staff may be overworked and not have enough time to do what's required of them with patient care as well as the paperwork required behind the scenes. It [quiet quitting] is doing just enough to get

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Why more doctors are joining unions

BY LAMBETH HOCHWALD

With huge shifts over the past decade in the way doctors are employed — half of all doctors now work for a health system or large medical group — the idea of unionizing is not only being explored but gaining traction within the profession. In fact, 8% of the physician workforce (or 70,000 physicians) belong to a union, according to statistics gathered in 2022. Exact numbers are hard to come by, and, although the American Medical Association (AMA) "supports the right of physicians to engage in collective bargaining," the organization doesn't track union membership among physicians, according to an AMA spokesperson.

Forming a union

One challenge is that forming a union is not only time-consuming but also difficult, owing to several barriers. For starters, the laws dictating unionization differ by state, and the rules governing unionization vary if a hospital is public or private. If there's enough momentum from doctors leading unionization efforts, approval from hospital leaders is required before an official election can be requested from the National Labor Relations Board.

That said, for doctors who are in a union — the two most popular are the Union of American Physicians and Dentists and the Doctors Council branch of the Service Employees International Union (SEIU) — the benefits can be immense, allowing union members to focus on providing the best patient care possible. This year, nine medical residency programs at hospitals such as Stanford Health, Montefiore Medical Center, and the University of Pennsylvania, formed unions, reported WBUR in Boston.

Belonging matters

"When you build a relationship with your patients, it's special, and that connection isn't replaceable," said Nicholas VenOsdel, MD, a pediatrician at Allina Health Primary Care in Hastings, Minnesota, and a union member of the Doctors Council. "However, a lot of us have felt like that hasn't been respected as the climate of health care has changed so fast."

In fact, autonomy over how much time doctors spend with patients is driving a lot of interest in unionization.

"We don't necessarily have that autonomy now," said Amber Higgins, MD, an emergency physician and an obstetrician at ChristianaCare, a hospital network in Newark, Delaware, and a member of the Doctors Council. "There are so many other demands, whether it's billing, patient documentation, or other demands from the employer, and all of that takes time away from patient care."

Union members are bullish and believe that having a cohesive voice will make a difference. "We need to use our collective voices to get back to focusing on patient care instead of staring at a computer screen for 80% of the day," Dr. Higgins said. "So much of medicine involves getting to the correct diagnosis, listening to patients, observing them, and building a relationship with them. We need time to build that."

"We've lost power in every way. We have the degrees, the liability, and the knowledge — we should have more power to make our workplaces safer and better."
– Dr. Bussey

With corporate consolidation and a profit-driven mandate by health care systems, doctors are increasingly frustrated and feel that their voices haven't been heard enough when it comes to issues like workplace safety, working hours, and benefits, said Stuart Bussey, MD, JD, a family practice physician and president of the Union of American Physicians and Dentists in Sacramento, California.

However, he adds that urging doctors to join together to fight for a better working environment hasn't been easy. "Doctors are individualists, and they don't know how to work in packs like hospital administrators do," Dr. Bussey said. "They're hard to organize, but I want them to understand that unless they join hands, sign petitions, and speak as one voice, they're going to lose out on an amazing opportunity."

Overcoming misperceptions about unions

One barrier to doctors getting involved is the sentiment that unions might do the opposite of what's intended — that is, they might further reduce a doctor's autonomy and work flexibility. Or there may be a perception that the drive to join a union is predicated on making more money.

Though he's now in a union, Dr. VenOsdel, who has been in a hospital-based practice for 7 years, admits that he initially felt very differently about unions than he does today.

"Even though I have family members in health care unions, I had a neutral to even slightly negative view of unions," Dr. VenOsdel said. "It took me working directly with the Minnesota Nurses Association and the Doctors Council to learn the other side of the story."

Armed with more information, he began lobbying for stricter rules about how his state's large health care systems were closing hospitals and ending much-needed community services.

"I remember standing at the Capitol in Minnesota and telling one of the members that I once felt negatively about unions," he added. "I realized then that I only knew what employers were telling me via such things as emails about strikes — that information was all being shared from the employers' perspective."

Social justice plays a role

For Dr. VenOsdel, being part of a union has helped him return to what he calls the "art" of medicine. "Philosophically, the union gave me an option for change in what felt like a hopeless situation," he said. "It wasn't just that I was tossing the keys to someone else and saying, 'I can't fix this.' Instead, we're taking the reins back and fixing things ourselves."

Dr. Bussey argues that as the uneven balance between administrators and providers in many health care organizations grows, the time to consider forming a union is now.

"We're in a $4 trillion medical industrial revolution," he said. "Administrators and bureaucrats are multiplying 30-fold times vs providers, and most of that $4 trillion supports things that don't contribute to the doctor-patient relationship."

Furthermore, union proponents say that where a one-on-one relationship between doctor and patient once existed, that has now been "triangulated" to include administrators.

"We've lost power in every way," Dr. Bussey said. "We have the degrees, the liability, and the knowledge — we should have more power to make our workplaces safer and better." ■

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by, but shortcutting as much as they can to try to save some time."

Addressing quiet quitting

Those kinds of shortcuts may affect patients, admits Ms. Smith. "I do think it starts to seep into patient care," she said. "And that really doesn't feel good ... at our institution, I'm not just an NP — I'm the nurse, the doctor, the secretary — I'm everybody, and for the last year, almost every single day in clinic, I'm apologizing [to a patient] because we can't do something."

Watching for this frustration can help alert administrators to NPs and PAs who may be "checking out" at work. Open lines of communication can help you address the issue. "Ask questions like 'What could we do differently to make your day easier?'" Dr. Roberts said. Understanding the day-to-day issues NPs and PAs face at work can help in developing a plan to address disengagement.

When Dr. Day sees quiet quitting at her practice, she talks with the advance practice provider about what's causing the issue. "'Are you overworked? Are you understaffed? Are there problems at home? Do you feel you're receiving inadequate pay?'" she said. "The first thing to do is address that and find mutual ground on the issues ... deal with the person as a person and then go back and deal with the person as an employee. If your staff isn't happy, your clinic isn't going to be productive."

Finally, while reasons for quiet quitting may vary, cultivating a collaborative atmosphere where NPs and PAs feel appreciated and valued can help reduce the risk for quiet quitting. "Understand their strengths and what they're about.

*Names have been changed. ■

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