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Depression, suicidal ideation continue to plague physicians

BY STEPH WEBER

Research suggests that physicians have suicidal thoughts at about twice the rate of the general population (7.2% vs. 4%). Now, as they bear the weight of a multiyear pandemic alongside the perpetual struggle to maintain some semblance of work-life balance, their resiliency has been stretched to the brink.

In 2022, the Medscape Physician Suicide Report surveyed more than 13,000 physicians in 29 specialties who were candid about their experiences with suicidal thoughts, how they support their besieged colleagues, and their go-to coping strategies.

Overall, 21% of physicians reported having

feelings of depression. Of those, 24% had clinical depression, and 64% had colloquial depression. The number of physicians who felt sad or blue decreased slightly, compared with the 2021 report, but the number of physicians experiencing severe depression rose 4%.

One in 10 physicians said they have thought about or attempted suicide. However, the number of physicians with suicidal thoughts dropped to 9%, down substantially from the 22% who reported similar feelings in 2020.

Still, there was a slight uptick in women physicians contemplating suicide, likely linked to their larger share of childcare and family responsibilities.

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Air trapping common in patients with long COVID

BY WALTER ALEXANDER

Small airway disease with air trapping appears to be a long-lasting sequela of SARS-CoV-2 infection, according to a prospective study that compared 100 COVID-19 survivors who had persistent symptoms and 106 healthy control persons.

“Something is going on in the distal airways related to either inflammation or fibrosis that is giving us a signal of air trapping,” noted senior author Alejandro P. Comellas, MD, in a press release. The study was stimulated by reports from University of Iowa clinicians noting that many patients with initial SARS-CoV-2 infection who were either hospitalized or were treated in the ambulatory setting later reported shortness of breath and other respiratory symptoms indicative of chronic lung disease.

Study results

Investigators classified patients (mean age, 48 years; 66 women) with post-acute sequelae of COVID-19 according to whether they were ambulatory (67%), hospitalized (17%), or

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INSIDE HIGHLIGHT



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Dr. Steven Q. Simpson on the importance of Sep-1

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AIR TRAPPING AND LONG COVID // continued from page 1

required treatment in the intensive care unit (16%). They then compared CT findings of patients who had COVID-19 and persistent symptoms with those of a healthy control group.

COVID-19 severity did not affect the percentage of cases of lungs with air trapping among these patients. Air trapping occurred at rates of 25.4% among ambulatory patients, 34.6% in hospitalized patients, and in 27.3% of those requiring intensive care ($P = .10$). The percentage of lungs affected by air trapping in ambulatory participants was sharply and significantly higher than in healthy controls (25.4% vs. 7.2%; $P < .001$). Also, air trapping persisted; it was still present in 8 of 9 participants who underwent imaging more than 200 days post diagnosis.

Qualitative analysis of chest CT images showed that the most common imaging abnormality was air trapping (58%); ground-glass opacities (GGOs) were found in 51% (46/91), note Dr. Comellas and coauthors. This suggests ongoing lung inflammation, edema, or fibrosis. These symptoms are often observed during acute COVID-19, frequently in an organizing pneumonia pattern, and have been shown to persist for months after infection in survivors of severe disease. The mean percentage of total lung classified as having regional GGOs on chest CT scans was 13.2% and 28.7%, respectively, in the hospitalized and ICU groups, both very much higher than in the ambulatory group, at 3.7% ($P < .001$ for both). Among healthy controls, the GGO rate on chest CT was only 0.06% ($P < .001$).

In addition, air trapping correlated with the ratio of residual volume to total lung capacity ($r = 0.6$; $P < .001$) but not with spirometry results. In fact, the investigators did not observe airflow obstruction by spirometry in any group, suggesting that air trapping in these patients involves only small rather than large airways and that these small airways contribute little to total airway resistance. Only when a large percentage, perhaps 75% or more, of all small airways are obstructed will spirometry pick up small airways disease, the authors observe.

Continuing disease

The findings taken together suggest that functional small airways disease and air trapping are a consequence of SARS-CoV-2 infection, according to Dr. Comellas. "If a portion of patients continues to have small

airways disease, then we need to think about the mechanisms behind it," he said. "It could be something related to inflammation that's reversible, or it may be something related to a scar that is irreversible, and then we need to look at ways to prevent further progression of the disease." Furthermore, "studies aimed at determining the natural history of functional small airways disease in patients with post-acute sequelae of COVID-19 and the biological mechanisms that underlie these findings are urgently needed to identify therapeutic and preventative interventions," Dr. Comellas, professor of internal medicine at Carver College of Medicine, University of Iowa, Iowa City, concluded.

The study limitations, the authors state, include the fact that theirs was a single-center study that enrolled participants infected early during the COVID-19 pandemic and did not include patients with Delta or Omicron variants, thus limiting the generalizability of the findings.

The study was published in *Radiology* (2022 Mar 15. doi: 10.1148/radiol.212170).

The reported findings "indicate a long-term impact on bronchiolar obstruction," states Brett M. Elicker, MD, professor of clinical radiology, University of California, San Francisco, in an accompanying editorial (2022 Mar 15. doi: 10.1148/radiol.220449). Because collagen may be absorbed for months after an acute insult, it is not entirely clear whether the abnormalities seen in the current study will be permanent. He said further, "the presence of ground glass opacity and/or fibrosis on CT were most common in the patients admitted to the ICU and likely correspond to post-organizing pneumonia and/or post-diffuse alveolar damage fibrosis."

Dr. Elicker also pointed out that organizing pneumonia is especially common among patients with COVID-19 and is usually highly steroid-responsive. The opacities improve or resolve with treatment, but sometimes residual fibrosis occurs. "Longer-term studies assessing the clinical and imaging manifestations 1-2 years after the initial infection are needed to fully ascertain the permanent manifestations of post-COVID fibrosis."

The study was supported by grants from the National Institutes of Health. The authors and Dr. Elicker have disclosed no relevant financial relationships. ■

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FDA approves generic Symbicort for asthma, COPD

BY MARK S. LESNEY, PHD

The U.S. Food and Drug Administration approved the first generic of Symbicort (budesonide and formoterol fumarate dihydrate) inhalation aerosol for the treatment of asthma in patients 6 years of age and older and for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

The approval was given for a complex generic drug-device combination product – a metered-dose inhaler that contains both budesonide (a corticosteroid that reduces inflammation) and formoterol (a long-acting bronchodilator that relaxes muscles in the airways to improve breathing). It is intended to be used as two inhalations,

two times a day (usually morning and night, about 12 hours apart), to treat both diseases by preventing symptoms, such as wheezing for those with asthma, and for improved breathing for patients with COPD.



The inhaler is approved at two strengths (160/4.5 mcg/actuation and 80/4.5 mcg/actuation), according to the March 15 FDA announcement. The device is not intended for the treatment of acute asthma.

“Today’s approval of the first generic for one of the most commonly prescribed complex drug-device combination products to treat asthma and COPD is another step forward in our commitment to bring generic copies of

complex drugs to the market, which can improve quality of life and help reduce the cost of treatment,” said Sally Choe, PhD, director of the Office of Generic Drugs in the FDA’s Center for Drug Evaluation and Research.

The most common side effects associated with budesonide and formoterol fumarate dihydrate oral inhalation aerosol for those with asthma are nasopharyngitis pain, sinusitis, influenza, back pain, nasal congestion, stomach discomfort, vomiting, and oral candidiasis (thrush). For those with COPD, the most common side effects are nasopharyngitis, oral candidiasis, bronchitis, sinusitis, and upper respiratory tract infection, the FDA reported.

The approval of this generic drug-device combination was granted to Mylan Pharmaceuticals. ■

SUICIDE SURVEY // continued from page 1

“They have needed to pull double duty even more than usual, and that may have increased their sense of burnout and vulnerability to suicidal thoughts,” according to Andrea Giedinghagen, MD, assistant professor in the department of psychiatry at Washington University in St. Louis, and coauthor of “Physician Suicide: A Call to Action” (Mo Med. 2019 May-Jun;116[3]:211-6).

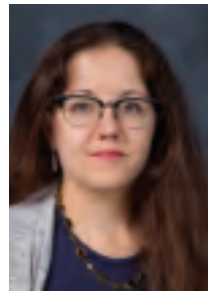
Fighting the stigma of seeking mental health help

Although the number of physicians attempting, but not completing, suicide has remained steady at 1% for several years, the recent passage of the Dr. Lorna Breen Health Care Provider Protection Act by Congress aims to drive that figure even lower. Dr. Breen, an ED physician at New York-Presbyterian Hospital, died by suicide in April 2020. Overwhelmed by the onslaught of COVID patients, Dr. Breen was reluctant to seek mental health services for fear of being ostracized.

“Many physicians don’t seek mental health care due to fear of negative consequences in the workplace, including retribution, exclusion, loss of license, or even their job,” Gary Price, MD, president of The Physicians Foundation, told this news organization. “This was the experience of Dr. Lorna Breen. She was convinced that if she talked to a professional, she would lose her medical license. Perhaps if Dr. Breen was equipped with the accurate information – there is no mental health reporting requirement in her state’s medical license application – it might have saved her life.”

This same stigma was reflected in

the survey, with one physician saying: “I’m afraid that if I spoke to a therapist, I’d have to report receiving psychiatric treatment to credentialing or licensing boards.” Roughly



Dr. Giedinghagen

40% of survey respondents, regardless of age, chose not to disclose their suicidal thoughts to anyone, not even a family member or suicide hotline. And just a tiny portion of physicians (10% of men and 13% of women) said that a colleague had discussed their suicidal thoughts with them.

“There is a longstanding culture of silence around physician mental health in the medical community,” said Dr. Price. “The strategies within the Act are critical to fixing this culture and making it acceptable and normalized for physicians to seek mental health care,” and for it to “become a fundamental and ongoing element of being a practicing physician.”

As part of the legislation, the Department of Health & Human Services must award grants to hospitals, medical associations, and other entities to facilitate mental health programs for providers. They must also establish policy recommendations and conduct campaigns to improve providers’ mental and behavioral health, encourage

providers to seek mental health support and assistance, remove barriers to such treatment, and identify best practices to prevent suicide and promote resiliency.

“[Women physicians] have needed to pull double duty even more than usual, and that may have increased their sense of burnout and vulnerability to suicidal thoughts.”

Addressing barriers to mental health

The new bill is a step in the right direction, but Dr. Price said health organizations must do more to address the six key structural barriers that are “discouraging physicians from seeking [mental health] help,” such as the inclusion of “intrusive mental health questions on medical board, hospital credentialing, and malpractice insurance applications.”

In addition, employers should allow physicians to seek out-of-network mental health services, if necessary, and not cause further humiliation by requiring them to be treated by colleagues within their hospital system. A similar proposal has recently been introduced and is gaining traction in Utah, following the suicide of ED physician Scott

Jolley, MD, in 2021 after he was admitted for psychiatric care where he worked.

Diminishing the stigma surrounding physicians’ mental health encourages a more open dialogue, so if a colleague reaches out – listen. “Start by thanking the colleague for sharing the information: ‘I’m sure that wasn’t easy but I appreciate that you respect me enough to share this. Let’s talk more,’” said Michael F. Myers, MD, professor of clinical psychiatry at State University of New York, Brooklyn. “Then ask what you can do to help, which cuts down on the sense of isolation that colleague may feel.”

According to the survey, many physicians have developed strategies to support their happiness and mental health. Although fewer than

10% said reducing work hours or transitioning to a part-time schedule was most effective, the majority of physicians relied on spending time with family and friends (68%) – a choice

that has considerable benefits.

“Close and intimate relationships are the single most protective factor for our mental health,” said Peter Yellowlees, MBBS, MD, chief wellness officer for UC Davis Health and professor of psychiatry at the University of California, Davis. “Isolation and loneliness are very important stressors, and we know that about 25% of the population reports being lonely.” ■



Dr. Myers



Dr. Yellowlees

Pan-coronavirus vaccines may be key to fighting future pandemics

BY RICKI LEWIS, PHD

As the COVID-19 pandemic winds down – for the time being at least – efforts are ramping up to develop next-generation vaccines that can protect against future novel coronaviruses and variants. Several projects are presenting clever combinations of viral parts to the immune system that evoke a robust and hopefully lasting response.

The coming generation of “pan” vaccines aims to tamp down SARS-CoV-2, its closest relatives, and whatever may come into tamer respiratory viruses like the common cold. Whatever the eventual components of this new generation of vaccines, experts agree on the goal: preventing severe disease and death. And a broader approach is critical.

“All the vaccines have been amazing. But we’re playing a whack-a-mole game with the variants. We need to take a step back and ask if a pan-variant vaccine is possible. That’s important because Omicron isn’t the last variant,” said Jacob Lemieux, MD, PhD, instructor in medicine and infectious disease specialist at Massachusetts General Hospital, Boston.

A broad-spectrum vaccine

The drive to create a vaccine that would deter multiple coronaviruses arose early, among many researchers. An article published in *Nature* in May 2020 (doi: 10.1038/s41541-020-0198-1) by National Institute of Allergy and Infectious Diseases researcher Luca T. Giurgea, MD, and colleagues said it all in the title: “Universal coronavirus vaccines: The time to start is now.”

Their concerns? The diversity of bat coronaviruses poised to jump into humans; the high mutability of the spike gene that the immune response recognizes; and the persistence of mutations in an RNA virus, which can’t repair errors.

Work on broader vaccines began in several labs as SARS-CoV-2 spawned variant after variant.

On Sept. 28, NIAID announced funding for developing “pan-coronavirus” vaccines – the quotation marks theirs to indicate that a magic bullet against any new coronavirus is unrealistic. “These new awards are designed to look ahead



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and prepare for the next generation of coronaviruses with pandemic potential,” said NIAID director Anthony S. Fauci, MD. An initial three awards went to groups at the University of Wisconsin, Brigham and Women’s Hospital, and Duke University.

President Biden mentioned the NIAID funding in his State of the Union Address. He also talked about how the Biomedical Advanced Research and Development Authority, founded in 2006 to prepare for public health emergencies, is spearheading development of new vaccine platforms and vaccines that target a broader swath of pathogen parts.

Meanwhile, individual researchers from eclectic fields are finding new ways to prevent future pandemics.

Artem Babaian, PhD, a computational biologist at the University of Cambridge (England), had the idea to probe National Institutes of Health genome databases, going back more than a decade, for overlooked novel coronaviruses. He started the project while he was between jobs as the pandemic was unfurling, using a telltale enzyme unique to the RNA viruses to fish out COVID cousins. The work is published in *Nature* (2022 Jan 26. doi: 10.1038/s41586-021-04332-2) and the data freely available at serratus.io.

Among the nearly 132,000 novel RNA viruses Dr. Babaian’s team found, 9 were from previously unrecognized coronaviruses. The

novel nine came from “ecologically diverse sources”: a seahorse, an axolotl, an eel, and several fishes. Deciphering the topographies of these coronaviruses may provide clues to developing vaccines that stay ahead of future pandemics.

But optics are important in keeping expectations reasonable. “‘Universal vaccine’ is a misnomer. I think about it as ‘broad-spectrum vaccines.’ It’s critical to be up front that these vaccines can never guarantee immunity against all coronaviruses. There are no absolutes in biology, but they hopefully will work against the dangers that we do know exist. A vaccine that mimics exposure to many coronaviruses could protect against a currently unknown coronavirus, especially if slower-evolving antigens are included,” Dr. Babaian said in an interview.

Nikolai Petrovsky, MD, PhD, of Flinders University, Adelaide, and the biotechnology company Vaccine Pty, agrees, calling a literal pan-coronavirus vaccine a “pipe dream. What I do think is achievable is a broadly protective, pan-CoV-19 vaccine – I can say that because we have already developed and tested it, combining antigens rather than trying just one that can do everything.”

Immunity lures

The broader vaccines in development display viral antigens, such as spike proteins, to the immune system on diverse frameworks. Here

are a few approaches.

Ferritin nanoparticles: A candidate vaccine from the emerging infectious diseases branch of Walter Reed National Military Medical Center began phase 1 human trials in April 2021. Called SpFN, the vaccine consists of arrays of ferritin nanoparticles linked to spike proteins from various variants and species. Ferritin is a protein that binds and stores iron in the body.

“The repetitive and ordered display of the coronavirus spike protein on a multifaceted nanoparticle may stimulate immunity in such a way as to translate into significantly broader protection,” said Walter Reed’s branch director and vaccine coinventor Kayvon Modjarrad, MD, PhD.

A second vaccine targets only the “bullseye” part of the spike that the virus uses to attach and gain access to human cells, called the receptor-binding domain (RBD), of SARS-CoV-2 variants and of the virus behind the original SARS. The preclinical data appeared in *Science Translational Medicine* (2022 Feb 16. doi: 10.1126/scitranslmed.abi5735).

Barton Haynes, MD and colleagues at the Duke Human Vaccine Institute are also using ferritin to design and develop a “pan-betacoronavirus vaccine,” referring to the genus to which SARS-CoV-2 belongs. They say their results in macaques, published in *Nature* (2021 Jun 24. doi: 10.1038/s41586-021-03594-0), “demonstrate that current mRNA-based vaccines may provide some protection from future outbreaks of zoonotic betacoronaviruses.”

Mosaic nanoparticles: Graduate student Alexander Cohen is leading an effort at CalTech, in the lab of Pamela Björkman, PhD, that uses nanoparticles consisting of proteins from a bacterium (*Strep. pyogenes*) to which RBDs from spike proteins of four or eight different betacoronaviruses are attached. The strategy demonstrates that the whole is greater than the sum of the parts.

“Alex’s results show that it is possible to raise diverse neutralizing antibody responses, even against coronavirus strains that were not represented on the injected nanoparticle. We are hopeful that this technology could be used to protect against future animal

coronaviruses that cross into humans,” said Dr. Björkman. The work appeared in *Science* (2021 Feb 12;371[6530]:735-41).

Candidate vaccines from Inovio Pharmaceuticals also use a mosaic spike strategy, but with DNA rings (plasmids) rather than nanoparticles. One version works against pre-Omicron variants and is being tested against Omicron, and another with “pan-COVID-19” coverage has tested well in animal models. Inovio’s vaccines are delivered into the skin using a special device that applies an electric pulse that increases the cells’ permeability.

Chimeric spikes: Yet another approach is to fashion vaccines from various parts of the betacoronaviruses that are most closely related to SARS-CoV-2 – the pathogens behind Middle East respiratory syndrome and severe acute respiratory syndrome as well as several bat viruses and a few pangolin ones. The abundance and ubiquity of these viruses provide a toolbox of sorts, with instructions written in the language of RNA, from which to select, dissect, recombine, and customize vaccines.

“SARS-like viruses can recombine and exhibit great genetic diversity in several parts of the genome. We designed chimeric spikes to improve coverage of a multiplexed vaccine,” said David Martinez, PhD.

His team at the University of North Carolina at Chapel Hill has developed mRNA vaccines that deliver “scrambled coronavirus spikes” representing various parts, not just the RBD, as described in *Science* (2021 Aug 27;373[6558]:991-8).

In mice, the chimeric vaccines elicit robust T- and B-cell immune responses, which stimulate antibody production and control other facets of building immunity.

Beyond the spike bullseye

The challenge of developing pan-coronavirus vaccines is dual. “The very best vaccines are highly specific to each strain, and the universal vaccines have to sacrifice effectiveness to get broad coverage. Life is a trade-off.” Dr. Petrovsky told this news organization.

Efforts to broaden vaccine efficacy venture beyond targeting the RBD bullseyes of the spike triplets that festoon the virus. Some projects are focusing on less changeable spike parts that are more alike among less closely related coronaviruses than is the mutation-prone RBD. For example, the peptides that twist into the “stem-helix” portion of the part of

the spike that adheres to host cells are the basis of some candidate vaccines now in preclinical studies.

Still other vaccines aren’t spike based at all. French company Osivax, for example, is working on a vaccine that targets the nucleocapsid protein that shields the viral RNA. The hope is that presenting various

faces of the pathogen may spark immunity beyond an initial antibody rush and evoke more diverse and lasting T-cell responses.

With the myriad efforts to back up the first generation of COVID-19 vaccines with new ones offering broader protection, it appears that science may have finally learned

something from history.

“After the SARS outbreak, we lost interest and failed to complete development of a vaccine for use in case of a recurrent outbreak. We must not make the same mistake again,” Dr. Giurgea and colleagues wrote in their *Nature* article about universal coronavirus vaccines. ■



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

Digital monitors can relieve asthma burden by boosting medication adherence and inhaler technique

BY ESTHER LANDHUIS

PHOENIX – Before considering oral steroids or biologic therapies, many people with difficult-to-control asthma can reduce symptoms by addressing medication adherence and inhaler technique – and digital monitoring devices can play a key role.

Often physicians “will approach a patient about a biologic if they’re not responding to standard therapy. But we need to sometimes go back to those basic building blocks; like, are you taking the standard therapy?” William C. Anderson, MD, codirector of the multidisciplinary asthma clinic at Children’s Hospital Colorado, Aurora, said in an interview.

At the annual meeting of the American Academy of Allergy, Asthma, and Immunology, he and others presented data highlighting the diagnostic and therapeutic potential of digital monitoring devices for difficult-to-control asthma, the theme of the 2022s meeting.

The Global Initiative for Asthma (GINA) defines asthma as “difficult to control” if it remains uncontrolled despite medium- or high-dose inhaled corticosteroids with a second controller or with maintenance oral steroids, or if the asthma requires high-dose treatment to curb symptoms and exacerbations. About 17% of adult asthma patients have difficult-to-control asthma, according to the 2021 GINA report.

However, correcting for inhaling technique and adherence cuts the 17% down to just 3.7%, Giselle Mosnaim, MD, an allergist at NorthShore University HealthSystem outside Chicago and AAAAI immediate past president, told attendees at a Feb. 25 session on digital technologies for asthma management.

The CRITIKAL study (*J Allergy Clin Immunol Pract.* Jul-Aug 2017;5[4]:1071-81.e9), which reviewed data from more than 5,000 asthma patients, “showed that, if you have critical errors in inhaler technique, this leads to worse asthma outcomes and increased asthma exacerbations,” Dr. Mosnaim said. Sadly, it also shows that, from 1975 to 2014, despite new devices and new technologies, “we still have poor inhaler technique.”

As for ways to measure adherence, physician judgments tend to be inaccurate, patient self-reporting has proved unreliable, and prescription refill data don’t indicate whether patients actually used the medications. “The ideal measure of adherence should be objective, accurate and unobtrusive to minimize impact on patient behavior and allow reliable data collection in real-world settings,” Dr. Mosnaim said. “So electronic medication monitors are the gold standard.”

Tracking adherence

A closing afternoon session featured three presentations on research tracking adherence and outcomes in difficult-to-treat asthma patients – two pediatric cohorts and one across all ages. All studies used the Propeller Health sensor, a Food and Drug Administration–cleared device that

attaches to the patient’s inhaler and automatically collects information on where, when, and how often they use their medication. The sensor then sends that information to a data cloud accessible to the patient and their health care professional.

Dr. Anderson’s team scoured a nationwide Propeller Health database for 8,000 patients using the digital monitors with controller therapies for asthma or chronic obstructive pulmonary disease (COPD). The study explored whether adherence differed for once-daily versus twice-daily medications, and if adherence differed based on patient age (4-60+ years).

For both asthma and COPD patients, those on once-daily regimens had higher medication adherence, compared with those who were prescribed twice-daily therapies. Plus, a greater proportion of once-daily patients met the pre-specified 80% adherence threshold.

Looking across ages, medication use in the youngest group (aged 4-11 years) looked comparable with 30-somethings, “probably because parents are the ones giving the drug,” Dr. Anderson said. Mirroring patterns from other studies, adherence levels dipped in adolescents and young adults, relative to other age subsets.

Since this population-level analysis didn’t include individualized data on exacerbations or asthma control, “we can’t relate this to outcomes,” Dr. Anderson noted. But he said the data correlating medication use with adherence suggest that once-daily formulations may be the better option.

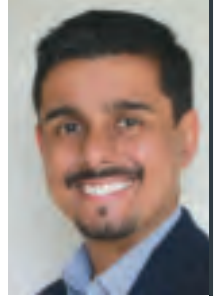
In one of the two pediatric studies, Matt McCulloch, MD, an allergy and immunology fellow working with Dr. Anderson, and colleagues reviewed charts of 40 children who received care at the Colorado Children’s multidisciplinary asthma clinic between 2018 and 2021. Half of these patients used Propeller Health sensors with their daily inhaled controller; the other patients were matched for age, ethnicity, sex, medication level, and disease control and severity – but had no electronic monitoring device.

On the whole, children who used digital monitoring for 12 months did not fare much better than matched controls on lung function (judged by forced expiratory volume) or asthma control (measured by Asthma Control Test scores).

However, within the digital monitoring group, patients who stayed on the Propeller system for 12 months did have better asthma control, fewer exacerbations, and improved asthma severity scores (measured by the Composite Asthma Severity Index), compared with when they first began digital monitoring. These children had all received care at the clinic for a while before their families opted for the electronic sensor, so “the effect wouldn’t have just been from starting in the clinic,” Dr. McCulloch said in an interview.

The gains came despite waning medication adherence. Similar to other digital monitoring studies, use of daily controller therapies in this retrospective analysis began at 50%-80% but dropped considerably during the first 4-5 months before settling into the 20%-30% range by 1 year.

Sachin Gupta, MD, FCCP, comments: The data presented in this article from studies of digital inhaler monitoring provide an inside story to factors that make populations of asthmatics difficult to control. Inhaler adherence and technique, in my experience, are often tied hand-in-hand. The high-touch experience that poorly controlled asthmatics benefit from may often be supported by digital health platforms. That digital monitoring is not just about diagnosing the gap, but also potentially addressing it, may prove to both improve patient outcomes and clinician experience.



Rachelle Ramsey, PhD, a pediatric research psychologist at Cincinnati Children’s Hospital Medical Center, presented data from 20 children with difficult-to-treat asthma who received 8 weeks of a digital adherence intervention during a 12-month treatment period. They analyzed three subsets – each with interventions based on how well the patients were managing daily controller therapy at baseline.

One patient with high (>80%) baseline adherence just received digital monitoring. The seven patients who began the study with intermediate (50%-80%) adherence received digital monitoring plus prescriptive text messaging. And the 12 children with poorest (<50%) baseline adherence received digital monitoring and a telehealth session in which a behavioral health specialist helped them set goals and create strategies to overcome barriers – for example, keeping the inhaler near their toothbrush in order to pair medication use with a daily habit.

“Overall, we found that matching Propeller with a behavioral intervention really improved adherence,” Dr. Ramsey said in an interview. While patients were receiving the intervention, adherence averaged across all groups increased from 39% to 76%. However, once the intervention period ended, the group’s adherence regressed toward baseline (36%).

Although adherence did not associate with clinical gains in this small study, the use of digital monitoring to improve medication adherence has translated to better outcomes in other recent efforts.

Remote monitoring

In a quality improvement project in the United Kingdom, nurses asked difficult-to-control asthma patients if they understood how to use their corticosteroid/long-acting beta₂-agonist (LABA) inhalers and if they were adhering to treatment guidelines.

Those who answered yes to these questions were

DIGITAL continued on following page

Legionnaires disease shows steady increase in U.S.

BY LORRAINE L. JANECKO, MPH

Legionnaires disease (LD) in the United States appears to be on an upswing that started in 2003, according to a study from the Centers for Disease Control and Prevention. The reasons for this increased incidence are unclear, the researchers write in *Emerging Infectious Diseases* (2022 Mar. doi: 10.3201/eid2803.211435).

“The findings revealed a rising national trend in cases, widening racial disparities between Black or African American persons and White persons, and an increasing geographic focus in the Middle Atlantic, the East North Central, and New England,” lead author

Albert E. Barskey, MPH, an epidemiologist in CDC’s Division of Bacterial Diseases, Atlanta, said in an email.

“Legionnaires disease cannot be diagnosed based on clinical features alone, and studies estimate that it is underdiagnosed, perhaps by 50%,” he added. “Our findings may serve to heighten clinicians’ awareness of this severe pneumonia’s etiology, so with an earlier correct diagnosis, appropriate treatment can be rendered sooner.”

Mr. Barskey and his coauthors at CDC – mathematical statistician Gordana Derado, PhD, and epidemiologist Chris Edens, PhD – used surveillance data to investigate the incidence of LD in the U.S. over time. They compared LD incidence

Sachin Gupta, MD, FCCP, comments: As EMR adoption in healthcare systems has increased over the past 20 years, at many of the hospitals I have worked at the “Community Acquired Pneumonia” order-set has more frequently included *Legionella* urine antigen testing as a check-box along with blood and sputum cultures. Given the method of transmission of *Legionella* and evolving population demographics, these data confirm that we should be vigilant to check this box when working up cases, and be mindful to report positive cases. Of note, tetracycline based antibiotics are considered second-line and may not be effective against all strains.

in 2018 with average incidence between 1992 and 2002. The incidence data, from over 80,000 LD cases, were age-standardized using the 2005 U.S. standard population as the reference.

The researchers analyzed LD data

reported to CDC by the 50 states, New York City, and Washington, D.C., through the National Notifiable Diseases Surveillance System. They performed regression analysis to identify the optimal year when

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invited to a 28-day study that involved swapping their steroid/LABA inhalers for a different controller/bronchodilator (fluticasone/salmeterol) with INCA (Inhaler Compliance Assessment), a device that not only tracks adherence but also uses acoustics to gauge inhaler technique.

Among the 23 patients who participated, many had better clinical outcomes after 28 days of INCA monitoring (*J Allergy Clin Immunol Pract.* 2021 Apr;9[4]:1529-38.e2). As Dr. Mosnaim told attendees, “what was amazing is so many of the patients that had been these difficult-to-control asthmatics who would have gone on to oral steroids or perhaps a biologic – lo and behold, you put them on a digital inhaler, and what do you see?” In two-thirds of the patients, “you see FeNo [a test that measures airway inflammation by detecting nitric oxide in exhalations] goes down. You see spirometry improve. You see the asthma control questionnaire improve. You see blood eosinophils go down.”

And in a 2020 randomized trial, Dr. Mosnaim and colleagues recruited 100 adults with uncontrolled asthma who had prescriptions for a daily inhaled corticosteroid and a short-acting beta-agonist (SABA) inhaler (*J Allergy Clin Immunol Pract.* 2021 Apr;9[4]:1586-94). Participants received Propeller sensors for their steroid and SABA inhalers. After a 2-week run-in period to calculate baseline corticosteroid adherence and SABA use for all participants, half the participants were randomly assigned to the control group, which had the app and sensor in silent mode, merely to collect data on medication use – whereas the treatment group received reminders, alerts, and monthly phone calls from providers who gave feedback on adherence and technique.

After 3 months of digital monitoring, patients didn’t use their rescue medication quite as often – as judged by a rise in the percentage of SABA-free days, compared with when they began the study. But the change in SABA-free days relative to baseline was more pronounced in the treatment group

(19%) than in the control group (6%).

As seen in the other digital monitoring studies, adherence to daily corticosteroids fell with time, but the drop was milder in treated participants (2%) versus the control group (17%). So in this study, digital monitoring plus mobile app reminders and clinician feedback “prevented against fall in adherence to inhaled steroids over time,” Dr. Mosnaim said.

These results are “very encouraging” and offer “proof of concept that this type of remote monitoring could work,” Thanai Pongdee, MD, an allergist-immunologist with the Mayo Clinic in Rochester, Minn., said in an interview. One limitation was that the study was too short to

“The ideal measure of adherence should be objective, accurate, and unobtrusive to minimize impact on patient behavior and allow reliable data collection in real-world settings.”

measure exacerbation rates. A yearlong analysis would be “really fascinating because you’d catch all the seasons of the year – all the pollen seasons, all these things that could exacerbate you. Some people’s asthma can be quite seasonal.”

More important, the clinical utility of digital sensors will depend on how physicians choose to use them. If the doctor puts out a “blanket recommendation for using it but doesn’t ask you about it or doesn’t use the data to inform your care, then I think people just lose engagement and lose excitement over it,” Dr. Ramsey said. But if the health care team “asks you about the data or looks at the data with you or shows you how valuable this can be to your care, then I think that changes things.”

Building these analyses and interactions into the clinic workflow isn’t trivial. “If you have this wealth of data coming in, how are you going to look at it? Are you going to have an individual person assigned to this role? How are you going

to respond to alerts?” Dr. Anderson asked.

In addition, because some digital monitors issue alerts when a patient’s asthma is not well controlled, some providers worry about liability if “something bad were to happen if you had that data but didn’t act upon it,” he said. Yet he noted that remote data monitoring is already used routinely in other areas of medicine, such as managing diabetes and heart conditions, “and it’s not like people are getting dinged for that stuff.”

Another issue is cost. Insurance covers digital monitors only in select cases, but it’s a bit of a catch-22. Insurers “don’t want to cover it until they get the data, but you can’t get the data until insurance covers it,” said Dr. Anderson, who added that “this year we finally got CPT reimbursement codes for monitoring devices.”

On the whole, studies of digital medication monitors suggest that better outcomes require “a good partnership between the health care provider and the patient,” Dr. Pongdee said. “It wasn’t like you could just put these things on and expect them to help. You still need that personal relationship to get the optimal results. We can have all this technology, but you still can’t take the people out of it.”

Dr. Mosnaim reported receiving current research grant support from GlaxoSmithKline, Novartis, Sanofi-Regeneron, and Teva; and past research grant support from AstraZeneca, Alk-Abello, and Genentech. She is immediate past president of the AAAAI, and directs the board of directors for the American Board of Allergy and Immunology. Dr. Anderson has served as a consultant for Regeneron, GlaxoSmithKline, and AstraZeneca, and has received research support from Colorado Medicaid. Dr. McCulloch and Dr. Ramsey disclosed no relevant financial relationships. Dr. Pongdee serves as an at-large director on the American Academy of Allergy, Asthma and Immunology board of directors. He receives grant funding from GlaxoSmithKline, and the Mayo Clinic is a trial site for GlaxoSmithKline and AstraZeneca. ■

population parameters changed, and for most analyses, they compared 1992-2002 data with 2003-2018 data.

- The overall age-standardized average incidence grew from 0.48 per 100,000 people during 1992-2002 to 2.71 per 100,000 in 2018 (incidence risk ratio, 5.67; 95% confidence interval, 5.52-5.83).
- LD incidence more than quintupled for people over 34 years of age, with the largest relative increase in those over 85 (RR, 6.50; 95% CI, 5.82-7.27).
- Incidence in men increased slightly more (RR, 5.86; 95% CI, 5.67-6.05) than in women (RR, 5.29; 95% CI, 5.06-5.53).
- Over the years, the racial disparity in incidence grew markedly. Incidence in Black persons increased from 0.47 to 5.21 per 100,000 (RR, 11.04; 95% CI, 10.39-11.73), compared with an increase from 0.37 to 1.99 per 100,000 in White persons (RR, 5.30; 95% CI, 5.12-5.49).
- The relative increase in incidence was highest in the Northeast (RR, 7.04; 95% CI, 6.70-7.40), followed by the Midwest (RR, 6.13; 95% CI, 5.85-6.42), the South (RR, 5.97; 95% CI, 5.67-6.29), and the West (RR, 3.39; 95% CI, 3.11-3.68). Most LD cases occurred in

summer or fall, and the seasonal pattern became more pronounced over time. The average of 57.8% of cases between June and November during 1992-2002 grew to 68.9% in 2003-2018.

Although the study “was hindered by incomplete race and ethnicity data,” Mr. Barskey said, “its breadth was a strength.”

“Legionella needs antibiotics that differ a bit from traditional antibiotics used to treat bacterial pneumonia, so a correct diagnosis can inform a more directed therapy.”

In an interview, Paul G. Auwaerter, MD, a professor of medicine and the clinical director of the Division of Infectious Diseases at Johns Hopkins University School of Medicine, Baltimore, said he was not surprised by the results. “CDC has been reporting increased incidence of Legionnaires disease from water source outbreaks over the years. As a clinician, I very much

depend on epidemiologic trends to help me understand the patient in front of me.

“The key point is that there’s more of it around, so consider it in your diagnosis,” he advised.

“Physicians are increasingly beginning to consider Legionella. Because LD is difficult to diagnose by traditional methods such as culture, they may use a PCR test,” said Dr. Auwaerter, who was not involved in the study. “Legionella needs antibiotics that differ a bit from traditional antibiotics used to treat bacterial pneumonia, so a correct diagnosis can inform a more directed therapy.”

“Why the incidence is increasing is the big question, and the authors nicely outline a litany of things,” he said.

The authors and Dr. Auwaerter proposed a number of possible contributing factors to the increased incidence:

- An aging population
- Aging municipal and residential water sources that may harbor more organisms
- Racial disparities and poverty
- underlying conditions, including diabetes, end-stage renal disease, and some cancers
- occupations in transportation,



Courtesy CDC

repair, cleaning services, and construction

- Weather patterns
- Improved surveillance and reporting

“Why Legionella appears in some locations more than others has not been explained,” Dr. Auwaerter added. “For example, Pittsburgh always seemed to have much more Legionella than Baltimore.”

Mr. Barskey and his team are planning further research into racial disparities and links between weather and climate and Legionnaires disease.

The authors are employees of CDC. Dr. Auwaerter has disclosed no relevant financial relationships. ■

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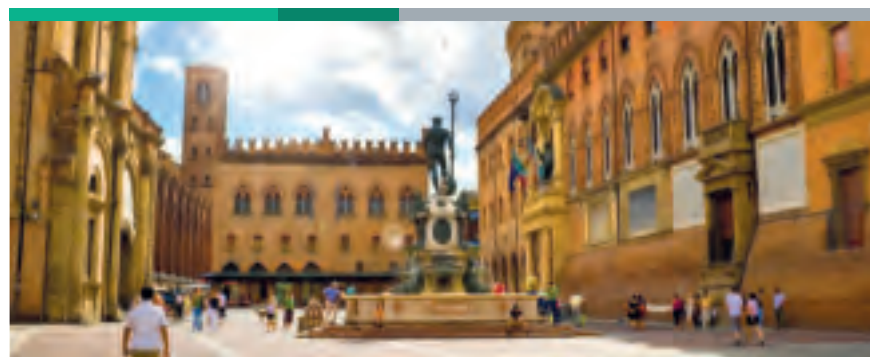
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CMS screening criteria now more aligned with USPSTF

BY ROXANNE NELSON, RN

The Centers for Medicare & Medicaid Services (CMS) will expand eligibility guidelines for lung cancer screening with low-dose computed tomography for Medicare recipients.

According to the final decision, announced Feb. 10, CMS will lower the age for screening from 55 to 50 years up to 77 years and reduce criteria for tobacco smoking history from at least 30 pack-years to 20 pack-years. The expanded Medicare recommendation will address racial disparities associated with lung cancer, given evidence that one-third of Black patients are diagnosed with lung cancer before age 55.

The updated CMS guidelines align closely with recommendations made by the U.S. Preventive Services Task Force (USPSTF) in March 2021. The USPSTF expanded its guidelines for screening to include individuals ages 50 to 80 years, as well as those who have a 20-pack-year smoking history and who currently smoke or have quit within the past 15 years.

Overall, the expanded guidelines will nearly double the number of individuals who are eligible for screening and have the potential to save significantly more lives by identifying cancers at an

earlier, more treatable stage.

“Expanding coverage broadens access for lung cancer screening to at-risk populations,” said Lee Felisher, MD, CMS chief medical officer and director of the Center for Clinical Standards and Quality, in a statement. “Today’s decision not

“[The] announcement from CMS will give more people enrolled in Medicare access to lifesaving lung cancer screening ... the only tool to catch this disease early when it is more curable.”

only expands access to quality care but is also critical to improving health outcomes for people by helping to detect lung cancer earlier.”

CMS’s decision also simplifies requirements for counseling and shared decision-making visits and removes an initial requirement for the reading radiologist to document participation in continuing medical education, which will reduce administrative burden. CMS also added a requirement back to the National Coverage Determination criteria that requires radiology imaging facilities to use a standardized lung nodule identification,

classification, and reporting system.

The American Lung Association applauds the decision to update eligibility.

“[The] announcement from CMS will give more people enrolled in Medicare access to lifesaving lung cancer screening. Screening for individuals at high risk is the only tool to catch this disease early when it is more curable,” Harold Wimmer, president and CEO of the American Lung Association, said in a statement. “Unfortunately, only 5.7% of people who are eligible have been screened, so it’s important that we talk with our friends and family who are at high risk about getting screened.”

While access to screening will significantly increase, the American Lung Association recommends CMS go a step further and expand eligibility to individuals up to 80 years of age, as the USPSTF recommendations do, as well as remove the recommendation that individuals cease screening once they have stopped smoking for 15 years.

Given the new guidelines, most private insurance plans will need to update screening coverage policies to reflect the updated guidelines for plan years beginning after March 31.

To read the final decision, visit the CMS website. ■

Patients with lung cancer and ILD tend to fare poorly after thoracic radiotherapy

BY HEIDI SPLETE

MDedge News

Most lung cancer patients with interstitial lung disease will not benefit from thoracic radiotherapy, based on data from a systematic review of 24 studies.

Thoracic radiotherapy remains a key part of lung cancer treatment for early and metastatic disease. However, patients with both small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC) associated with interstitial lung disease (ILD) fare worse than do those without ILD, often because of acute exacerbation of ILD and severe or fatal pneumonitis, wrote Animesh Saha, MD, of Apollo Multi-Specialty Hospitals, Kolkata, India, and colleagues. Consequently, clinicians may hesitate to offer radiotherapy to these patients.

In a review published in *Clinical Oncology* (2022 Feb 12. doi: 10.1016/j.clon.2022.01.043), the researchers identified 24 studies, including phase II and phase III randomized or nonrandomized trials, as well as prospective, observational studies and retrospective real-world studies. The goal of the

review was to report the incidence and predictors of radiation pneumonitis associated with different types of thoracic radiotherapy for lung cancer patients with ILD, the researchers said. Treatment types included curative-intent fractionated radiotherapy or chemoradiotherapy or moderately hypofractionated (nonstereotactic ablative radiotherapy [SABR]) and hyperfractionated radiotherapy as well as particle-beam therapies.

The studies included patients with SCLC or NSCLC and any form of ILD, including subclinical, radiologically diagnosed, or symptomatic, the researchers said.

Overall, the median incidence of grade 3 or higher radiation pneumonitis was 19.7%; the median incidence in patients treated with conventional radical radiotherapy, SABR, and particle-beam therapy was 31.8%, 11.9%, and 20.25%, respectively.

Eighteen studies reported grade 5 radiation pneumonitis; the overall median incidence was 6%, but as high as 60% in some studies. When separated by treatment type, the median incidence was 2.7%, 6.25%, and 6.25%, respectively, in patients

treated with radical radiotherapy (non-SABR), SABR, and particle-beam therapy.

Independent predictors of severe radiation pneumonitis (grade 2 or higher and grade 3 or higher)

“There is always concern about using thoracic radiotherapy in lung cancer patients with coexisting ILD in view of the risks involved.”

included subclinical or radiological ILD, the researchers said. Among ILD subtypes, studies have shown increased risk for severe radiation pneumonitis among those with non-IPF or non-UIP pattern fibrosis.

In addition, patient-related factors of low forced vital capacity (FVC) and low forced expiratory volume in 1 second (FEV₁), have been associated with severe radiation pneumonitis, the researchers said. They also found increased risk for patients with lower lobe tumor location compared to other lobes.

As for treatment-related factors, a

history of gemcitabine chemotherapy was associated with an increased risk of grade 3 or higher radiation pneumonitis.

“There is always concern about using thoracic radiotherapy in lung cancer patients with coexisting ILD in view of the risks involved,” the researchers wrote in their discussion of the findings. “Although thoracic radiotherapy is expected to produce similar local control, overall survival is worse in lung cancer patients with ILD than without, probably due to the poor prognosis associated with ILD and associated treatment-related mortality,” they said.

The findings were limited by several factors including the heterogeneity of the studies and study population and the retrospective design of most of the studies, the researchers noted.

However, the results highlight the increased risk of severe and fatal radiation pneumonitis in lung cancer patients with ILD and the need for careful patient selection and counseling if thoracic radiotherapy is to be considered, they concluded.

The study received no outside funding. The researchers had no financial conflicts to disclose. ■

Should all women be routinely screened?

BY AMY REYES

MDedge News

The U.S. Preventive Services Task Force (USPSTF) criteria for lung cancer screening should be expanded to include more women, especially those with a history of breast cancer, according to a new study published in *BJS Open*.

The 2021 screening guidelines include adults aged between 50 and 80 years who have a 20-pack-year smoking history and currently smoke or have quit within the past 15 years, but the guidelines do not include nonsmokers or patients with a history of previous malignancies, such as breast cancer.

Led by Daniela Molena, MD, a thoracic surgeon and director of esophageal surgery at Memorial Sloan Kettering Cancer Center, New York, researchers conducted an analysis of 2,192 women with first-time lung cancer who underwent lung resections at Memorial Sloan Kettering between January 2000 and December 2017 (*BJS Open*. 2021 Nov 9. doi: 10.1093/bjsopen/zrab11). The study's objective was to determine stage at diagnosis, survival, and eligibility for lung cancer screening among patients with lung cancer who had a previous breast cancer diagnosis and those who did not have a history of breast cancer.

Only 331 (15.1%) patients were previously diagnosed with breast cancer, which was not statistically significant. "Overall, there were no statistically significant differences in genomic or oncogenic pathway alterations between the two groups, which suggests that lung cancer in patients who previously had breast cancer may not be affected at the genomic level by the previous breast cancer," the authors wrote.

However, at 58.4%, more than half of patients in the study (1,281 patients) were prior smokers and only 33.3% met the USPSTF criteria for lung cancer screening, which the authors said was concerning.

"The most important finding of the study was that a high percentage of women with lung cancer, regardless of breast cancer history, did not meet the current USPSTF criteria for lung cancer screening. This is very important given the observation that nearly half of the women included in the study did not have a history of smoking. As such, the role of imaging for other causes, such as cancer surveillance, becomes especially important for early cancer diagnosis," Dr. Molena and colleagues wrote. "To reduce late-stage cancer diagnoses, further assessment of guidelines for lung cancer screening for all women may be needed."

Instead, for almost half of women in the study group with a history of breast cancer, the lung cancer was detected on a routine follow-up imaging scan.

USPSTF guidelines for lung cancer screening do not include previous malignancy as a high-risk feature requiring evaluation, which may explain why so few women in this study were screened for lung cancer, even though lung cancer is more common in breast cancer survivors than the general population. Approximately 10% of women who have had breast cancer will develop a second malignancy within 10 years and in most cases, it will be lung cancer. Plus, according to the National Cancer Institute, breast, lung, and colorectal cancers are the three most common cancers in women and account for approximately 50% of all new cancer diagnoses in women in 2020.

A 2018 analysis published in *Frontiers in*

Oncology (doi: 10.3389/fonc.2018.00427) found that, of more than 6,000 women with secondary primary lung cancer after having had breast cancer, 42% had distant-stage disease at the time of diagnosis which, Dr. Molena and colleagues said, suggests an ongoing need to update screening recommendations.

"Given that lung cancer has a 5-year overall survival rate of less than 20% (highlighting the benefits of early-stage diagnosis), a better understanding of lung cancer in women with a history of breast cancer could have important implications for screening and surveillance," the authors wrote.

Estrogen is known to play a role in the development of lung cancer by activating the epidermal growth factor receptor (EGFR). Previous research has shown an increased risk of lung cancer in patients with estrogen receptor-negative, progesterone receptor-negative, HER2-negative, or triple-negative breast cancer.

"Anti-estrogen treatment has been demonstrated to decrease the incidence of lung cancer and has been associated with improved long-term survival in patients with lung cancer after breast cancer. Future studies should seek to identify high-risk populations on the basis of hormone receptor status and anti-estrogen therapy use," the authors wrote.

The authors noted a number of limitations to the study, including the single hospital as the sole source of data; plus, the analysis did not account for the length of time since patients quit smoking and a lung cancer diagnosis. Nor did it consider other risk factors, such as radiation, chemotherapy, or anti-estrogen therapies.

The authors did not disclose any study-related conflicts of interests. ■

CRITICAL CARE

Dealing with life-threatening asthma attacks

BY PAM HARRISON

FROM THE JOURNAL CHEST® ■ In assessing and managing patients presenting with acute, life-threatening asthma, if the exacerbation does not resolve relatively quickly, clinicians need to start looking for other causes of the patient's respiratory distress, a review of the literature suggests.

"I think one of the most important points of this review is that, asthma is a self-limiting disease, and it's important to understand that with appropriate treatment and immediate response to it, exacerbations will get better with time," Orlando Garner, MD, Baylor College of Medicine, Houston, said in an interview.

"So I think one of the key points is, if these exacerbations do not resolve within 24-48 hours, clinicians need to start thinking: 'This could be

something else,' and not get stuck in the diagnosis that this is an asthmatic patient who is having an exacerbation. If the distress doesn't resolve within 48 hours, it's time to look for other clues," he stressed.

The study was published online Feb. 23, 2022, in *Chest* (doi: 10.1016/j.chest.2022.02.029).

Appropriate triage is key in the management of acute asthma, Dr. Garner and colleagues pointed out. A simplified severity score for the evaluation of asthma in the ED can help in this regard. Depending on the presence or absence of a number of key signs and symptoms, patients can be readily categorized as having mild, moderate, or severe asthma. "Static assessments and dynamic assessments of acute asthma exacerbation in the ED can also help triage patients," the authors added.

Static assessment involves

assessing the severity at presentation, which in turn determines the aggressiveness of initial treatment. Objective static assessments include the measurement of peak expiratory flow (PEF) or forced expiratory volume in 1 second (FEV₁). A severe exacerbation is usually defined as a PEF or an FEV₁ of less than 50%-60% of predicted normal values, the authors noted.

Dynamic assessment is more helpful than static assessment because it gauges response to treatment. "A lack of improvement in expiratory flow rates after initial bronchodilator therapy with continuous or worsening symptoms suggests need for hospitalization," Dr. Garner and colleagues observed. The main treatment goals for patients with acute asthma are reversal of bronchospasm and correction of hypoxemia.

These are achieved at least initially with conventional agents, such as repeated doses of inhaled short-acting beta₂-agonists, inhaled short-acting anticholinergics, systemic corticosteroids, and occasionally intravenous magnesium sulfate. If there is concomitant hypoxemia, oxygen therapy should be initiated as well. Patients who have evidence of hypercapnic respiratory failure or diaphragmatic fatigue need to be admitted to the intensive care unit, the authors indicated.

For these patients, clinicians need to remember that there are therapies other than inhalers, such as epinephrine and systemic terbutaline. During a life-threatening asthma episode, airflow in the medium and small airways often becomes turbulent, increasing the work of breathing, the researchers pointed out.

ASTHMA continued on following page

Commentary: The best crystalloid for the critically ill

BY AARON B. HOLLEY, MD, FCCP

Hemodynamic instability is rewarded with a sojourn in the intensive care unit (ICU). When the intensivists see it, they're going to throw fluids at it. Most likely a crystalloid of some type. This has been true for decades, centuries even. When I was a medical student, which was decades but not centuries ago, I used crystalloids every day on the surgical wards, in the operating room, in the emergency department, or on the medicine wards. Medicine docs preferred normal saline (NS) and surgeons used lactated Ringer's solution (LR). I never gave this a second thought.

During medical school, I was drawn to internal medicine by the heavy emphasis on evidence-based medicine in the field. Prior to 2015 though, there were not much data to support using one crystalloid formulation over another. Pre-2010, we had an American Thoracic Society (ATS) consensus statement on using crystalloid vs. colloid, making recommendations largely drawn from the SAFE trial (N Engl J Med. 2004 May 27. doi: 10.1056/NEJMoa040232). The ATS statement also suggested starches may be harmful, a view that was confirmed in a series of articles published in 2012 and 2013. There was less discussion about what type of crystalloid was best.

In 2014, I finally read a paper that compared

crystalloid formulations (Ann Intern Med 2014 Sep 2. doi: 10.7326/M14-0178). It was a network meta-analysis, which is "statistician speak" for combining disparate trials to make indirect comparisons. In the absence of large, randomized trials, this approach was a welcome addition to the data we had at the time. The authors concluded that "balanced" (typically LR or Plasma-Lyte) are superior to "unbalanced" (another term for NS) crystalloids. Balanced fluids typically have acetate or lactate and have a higher pH and lower chloride than NS. I found the signal for balanced fluids interesting at the time but promptly forgot about it.

Since 2015, the critical care community has rallied to produce a bevy of large trials comparing balanced vs. unbalanced crystalloids. The first was the SPLIT trial (JAMA. 2015;314[16]:1701-10), which showed equivalence. Then came the SMART trial in 2018 (N Engl J Med. 378:829-39), which showed balanced fluids were better. Of note, another trial with an identical design (SALT-ED) was published in the same issue of the New England Journal of Medicine as SMART (2018;378:819-28). SALT-ED enrolled patients in the emergency department, not the ICU, but also found benefit to using balanced fluids, albeit not for their primary outcome. I admit, after SMART and SALT-ED were published, I made the switch to LR. A secondary analysis of patients with

David L. Bowton, MD, FCCP, comments: I really like Dr. Holley's article. It is a concise summary of the available evidence, and I agree completely with his conclusions including which patient populations should NOT receive balanced salt solutions. Each of the studies suffers from methodologic issues that include relatively modest volumes of fluid administered, often with prerandomization receipt of crystalloids other than the one to which a patient was randomized, consequently with generally small increments in serum chloride, and, likely, a reduction in any signal of injury consequent to large-volume normal saline resuscitation.

sepsis (Am J Respir Crit Care Med. 2019 Dec 15;200[12]:1487-95) pushed me further toward LR, while others withheld judgment (N Engl J Med. 2018;378:862-3).

Then we saw publication of the BaSICs trial (JAMA. 2021;326[9]:818-29), another large, randomized study evaluating crystalloid composition. I was hoping this one might put the issue to rest. That nephrologist who perseverated

CRYSTALLOID *continued on following page*

ASTHMA *continued from previous page*

Heliox, a combination of helium and oxygen, reduces turbulent flow, they noted, although FiO₂ requirements need to be less than 30% in order for it to work. "Heliox can be used in patients with severe bronchospasm who do not respond to the conventional therapies," the authors noted, "[but] therapy should be abandoned if there is no clinical improvement after 15 minutes of use."

Although none of the biologics such as dupilumab (Dupixent) has yet been approved for the treatment of acute exacerbations, Dr. Garner predicts they will become the "future of medicine" for patients with severe asthma as well.

Rapid sequence intubation is generally recommended for patients who require mechanical ventilation, but as an alternative, "we are advocating a slower approach, where we get patients to slow down their breathing and relax them with something like ketamine infusions and wait before we given them a paralytic to see if the work of breathing improves," Dr. Garner said. Bag-mask ventilation should be avoided because it can worsen dynamic hyperinflation or cause barotrauma.

Salvage therapies such as the use

of bronchoscopy with N-acetylcysteine instilled directly into the airway is another option in cases in which mucus plugging is considered to be the main driver of airflow limitation.

Asked to comment, Brit Long, MD, an emergency medicine

physician at the Brooke Army Medical Center in San Antonio, felt the review was extremely useful and well done.

"We see these patients very frequently, and being able to assess them right away and get an accurate picture of what's going on is very

important," he said in an interview. The one thing that is often more difficult, at least in the ED, is obtaining a PEF or the FEV₁ – "both very helpful if the patient can do them, but if the patient is critically ill, it's more likely you will not be able to get those assessments, and if patients are speaking in one-word sentences and are working really hard to breathe, that's a severe exacerbation, and they need immediate intervention." Dr. Long also liked all the essential treatments the authors recommended that patients be given immediately, although he noted that Heliox is not going to be available in most EDs.

On the other hand, he agreed with the authors' recommendation to take a slower approach to mechanical ventilation, if it is needed at all. "I try my best to absolutely avoid intubating these patients – you are not fixing the issue with mechanical ventilation; you are just creating further problems.

"And while I see the entire spectrum of asthma patients from very mild to severe patients, these authors did a good job in explaining what the goals of treatment are and what to do with the severe ones," he said.

Dr. Garner and Dr. Long disclosed no relevant financial relationships. ■

David L. Bowton, MD, FCCP, comments: The recommendation to explore alternative disease processes in those patients who fail to improve after 48 hours is an important one, reinforcing the concept that "all that wheezes is not asthma." As is pointed out by Dr. Long, Heliox may not be rapidly available in many EDs and it has not been demonstrated to reduce the need for either invasive mechanical ventilation or hospitalization. I have two areas of disagreement with this excellent review. First, while bag-valve-mask ventilation has the potential to increase dynamic hyperinflation and the risk of pneumothorax, I would argue that BVM preoxygenation with attention to the rate and depth of ventilation (slower rate, small tidal volumes) will minimize peri-intubation hypoxemia with its well-recognized adverse outcomes. Further, I am unaware of evidence that appropriate BVM technique results in an increased risk of pneumothorax in asthmatic patients. Second is the uncritical statement regarding the use of bronchoscopy with N-acetylcysteine. This has never been demonstrated to be effective in controlled trials. It is difficult to separate out the effects of the bronchial cast removal simply by bronchoscopic irrigation without mucolytic and ignores the potential deleterious effects of dynamic hyperinflation during bronchoscopy and the worsening of bronchospasm due to N-acetylcysteine.



Among critically ill adults, LMW heparin reduces DVT

BY WALTER ALEXANDER

FROM THE JOURNAL CHEST®

Compared with control treatment among critically ill adults, low-molecular-weight heparin (LMWH) reduces the incidence of deep vein thrombosis (DVT), according to a systematic review and network meta-analysis of randomized clinical trials (RCTs) published in CHEST (2022 Feb 1;161[2]:418-28). The analysis showed also that risk of DVT may be reduced by unfractionated heparin (UFH) and by mechanical compressive devices, although LMWH should be considered the primary pharmacologic agent for thromboprophylaxis.

Risk of venous thromboembolism (VTE), including DVT and pulmonary embolism (PE), is heightened in critically ill patients. VTE incidence is highest in major surgery and trauma patients, and mortality estimates from PE among intensive care unit patients are as high as 12%. Clinical practice guidelines recommend prophylaxis with pharmacologic agents over no

prophylaxis in critically ill adults. Shannon M. Fernando, MD, of the University of Ottawa and colleagues examined the comparative efficacy and safety of various agents for VTE prophylaxis in critically ill patients through a review of 13 RCTs (9,619 patients) in six databases (Medline, PubMed, EMBASE, Scopus, Web of Science, and the Cochrane Database of Systematic Reviews). The ICU patients received a variety of therapies including pharmacologic, mechanical, or their combination for thromboprophylaxis. The control population consisted of a composite of no prophylaxis, placebo, or compression stockings only.

Analysis showed LMWH to reduce the incidence of DVT (odds ratio, 0.59; high certainty), while UFH may reduce the incidence of DVT (OR, 0.82; low certainty). Compared with UFH, LMWH probably reduces DVT (OR, 0.72; moderate certainty). Compressive devices, based on low-certainty evidence, may reduce risk of DVT, compared with control treatments (OR, 0.85).

The effect of combination therapy on DVT, compared with either

therapy alone was unclear (very low certainty). The large-scale (2,000 patients) PREVENT trial in 2019, Dr. Fernando noted in an interview, found that adding compression therapy to pharmacologic therapy produced no reduction in

proximal lower-limb DVT.

“Ultimately, I think that, even if multiple RCTs and subsequent meta-analyses were performed, at best we would find that the incremental benefit of combination therapy is very

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David L. Bowton, MD, FCCP, comments: This is an excellent analysis of the evidence of the comparative efficacy of methods of DVT prophylaxis. LMWHs appears to be the consistently preferable agents based on protection against DVT, cost, frequency of dosing, and adverse effects (predominantly HIT). As the authors point out, the exceptions may be patients with renal failure and those patients potentially requiring rapid reversal of drug effects. I do wish that more definitive guidance and conclusions were possible. What is striking is the consistent absence of impact on the incidence of pulmonary embolism (PTE) or on mortality. This is likely multifactorial and related, at least in part, to the relatively low incidence of PTE in these large studies without enrichment for very high-risk patient populations.

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on every patient's chloride during morning report would be vindicated. NS would prove to be too unbalanced and would finally be retired. No such luck. This is critical care medicine, where the initial signal is rarely confirmed in the follow-up trials. BaSICs found no difference between crystalloids for most important outcomes. The study did find balanced fluids may worsen outcomes for patients with head injuries.

Finally, there's the PLUS trial, a large, multicenter randomized controlled trial comparing Plasma-Lyte vs. NS in the ICU (N Engl J Med. 2022 Jan 18. doi: 10.1056/NEJMoa2114464). I could make the argument that this trial was the best of the bunch, and it was negative. The researchers did an excellent job of showing that serum pH and chloride levels did vary by fluid composition, but despite this, mortality and renal outcomes did not differ. Case closed? Crystalloid composition doesn't matter, right?

An editorial that accompanies the BaSICs trial does an outstanding job of reviewing SPLIT, SMART, and BaSICs (JAMA. 2021;326[9]:813-15). The authors discuss design and population differences that may have led to differing results, and there are many. They conclude for most patients in the ICU, there's no compelling reason to choose one crystalloid over another. Perhaps they're right.

An updated meta-analysis (NEJM Evid. 2022 Jan 18. doi: 10.1056/

EVIDo2100010) that included all the studies I've mentioned concluded there was an 89% probability that balanced fluid reduces mortality for ICU patients. How could the meta-analysis authors reach this conclusion given all the negative trials? It has to do with their statistical methods – they performed both standard, frequentist (if statistical significance isn't reached, the study is considered negative) and Bayesian analyses (posterior probability of benefit is calculated, regardless of P value). The frequentist approach was negative, but the posterior probability for benefit remained high.

Personally, I see no reason not to favor LR when resuscitating ICU patients without head injuries. In particular, it seems that medical patients (who made up almost 80% of those in the SMART trial) and those with sepsis may benefit. The critical care community has again outdone itself by performing large, well-designed trials to address important questions. Despite not having a definitive answer on crystalloid resuscitation, we know a lot more than we did when I was a medical student. ■

Dr. Holley is associate professor of medicine at Uniformed Services University and program director of pulmonary and critical care medicine at Walter Reed National Military Medical Center. He reported receiving research funding from Fisher-Paykel and income from the American College of Chest Physicians.



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Experts recommend permanent standard time

BY CAROLYN CRIST

Sleep experts tend to agree with U.S. lawmakers about getting rid of the twice-per-year time shift, with one exception: They typically call for standard time rather than daylight saving time.

After the Senate voted unanimously on March 15 to make daylight saving time permanent, the American Academy of Sleep Medicine issued a statement that urged caution about adopting a fixed, year-round time with potential health risks.

“We do applaud stopping the switching during the course of the year and settling on a permanent time,” Jocelyn Cheng, MD, a member of the association’s public safety committee, told *The Washington Post*.

But “standard time, for so many scientific and circadian rationales and public health safety reasons, should really be what the permanent time is set to,” she said.

Now it’s up to the House of Representatives to decide what to do next. The legislation, which would take effect in 2023, must be passed by the House and signed by President Biden before becoming a law.

Legislators and health experts have debated the shift in recent years. In 2020, the American Academy of Sleep Medicine released a position statement in the *Journal of Clinical Sleep Medicine* (2020 Oct 15. doi: 10.5664/jcsm.8780) that recommended that the United States move to year-round standard time. Standard time is more aligned with humans’ circadian rhythms and natural light/dark cycles, the group wrote, and disrupting that rhythm has been linked to higher risks of heart disease, obesity, and depression.

At the same time, few studies have focused on the long-term effects of adopting daylight saving time. Most research has focused on the short-term risks of the seasonal shift, such as reduced sleep and increased car

crashes, or circadian misalignment caused by other things. Some health experts have called for more research before deciding on a permanent time, the newspaper reported.

Still, the March 15 statement from sleep experts received support from more than 20 groups, including the National Safety Council, National Parent Teacher Association, and the World Sleep Society.

“We have all enjoyed those summer evenings with seemingly endless dusks,” David Neubauer, MD, an associate professor of psychiatry and behavioral sciences at Johns Hopkins University, Baltimore, told *The Post*.

But daylight saving time “does not ‘save’ evening light at all, it simply steals it from the morning, when it is necessary to maintain our healthy biological rhythms,” he said.

Permanent daylight saving time would lead to more dark mornings, which opponents have said could be dangerous for kids going to school, adults driving to work, and overall sleep cycles.

“With daylight saving time, we are perpetually out of synchronization

with our internal clocks, and we often achieve less nighttime sleep, both circumstances having negative health impacts,” Dr. Neubauer said. “Extra evening light suppresses the melatonin that should be preparing us for falling asleep. The later dawn during daylight saving time deprives our biological clocks of the critical light signal.”

The pros and cons of daylight saving time and standard time were debated during a hearing held by a House Energy and Commerce subcommittee recently. Sleep experts argued in favor of standard time, while other industry experts argued for daylight saving time to reduce crime, save energy, and help businesses that benefit from more daylight in the evenings.

“Everybody advocates a permanent time, but this difference between 1 hour back or 1 hour forward is not so clear in everybody’s mind,” Dr. Cheng said. “I would like to see further debate and some due diligence done on these health consequences and public safety measures before anything else goes forward.” ■

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minimal,” Dr. Fernando stated.

The findings provide evidence supporting LMWH and UFH use as compared with no pharmacologic prophylaxis for prevention of DVT, according to the researchers. While a similar certainty of effect in reducing PE was not found, evidence with moderate certainty suggested that LMWH and UFH probably reduce the incidence of any VTE, compared with no pharmacologic prophylaxis. Cost-effectiveness modeling that takes into account VTE incidence supports the practice. “If you’re reducing the incidence of DVT, it’s likely you’re similarly reducing incidence of PE, though I will agree that currently the data do not support this,” he said in an interview.

Noting that, while support in existing literature for any specific agent is controversial, the authors cite that American Society of Hematology guidelines suggest considering LMWH over UFH in critically ill patients, and that their findings lend support to that position. Regarding safety, pair-wise meta-analysis did not reveal clear major bleeding incidence differences between UFH and LMWH.

Concordant with studies outside the ICU finding that heparin-induced thrombocytopenia (HIT) incidence is lower among patients receiving LMWH rather than UFH

for VTE prophylaxis, the meta-analysis revealed a lower incidence of HIT among the critically ill receiving LMWH, but with evidence that was of low certainty.

Uncertainty around the optimal approach to VTE prophylaxis in the ICU along with wide variations in clinical practice persist despite recognition of the issue’s importance, note Major Michael J. McMahon, MD, of Honolulu and Colonel Aaron B. Holley, MD, of Bethesda, Md., authors of an accompanying editorial, “To generalize or not to generalize? The approach to VTE prophylaxis.” They acknowledge also that the Fernando et al. analysis yields important insights into VTE prevention in the ICU. Rhetorically raising the question, “Can we now say without doubt that LMWH is the preferred agent for all patients in the ICU?” – they responded, “probably.” Not entirely eliminated, they observe, is the possibility that a specific patient subgroup may benefit from one agent compared with another. They add, “We came away more confident that LMWH should be the default choice for VTE prevention in the ICU.”

Dr. Fernando and coauthors listed multiple disclosures, but declared they received no financial support. Dr. McMahon had no disclosures. Dr. Holley reported funding from Fisher-Paykel and the American College of Chest Physicians. ■

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CPAP has only small effect on metabolic syndrome

BY NEIL OSTERWEIL

FROM THE JOURNAL CHEST®

Continuous positive airway pressure (CPAP) may be only modestly effective for ameliorating metabolic syndrome in patients with moderate to severe obstructive sleep apnea (OSA).

That conclusion comes from investigators in a randomized controlled trial, who found that, among 100 patients with OSA and a recent diagnosis of metabolic syndrome (MS), 18% of those assigned to use CPAP at night had a reversal of MS at 6 months of follow-up, compared with 4% of controls who were assigned to use nasal strips at night ($P = .04$).

The majority of patients assigned to CPAP still retained their MS diagnoses at 6 months, and CPAP did not significantly reduce individual components of the syndrome. Use of CPAP was, however, associated with small reductions in visceral fat and improvement in endothelial function, reported Sara Q.C. Giampa, PhD, from the University of São Paulo, and colleagues.

“Despite a significant rate of MS reversibility after CPAP therapy,

most of the patients maintained the MS diagnosis. The modest effects of CPAP on MS reversibility underscore the need for combined therapy with CPAP, aiming to maximize metabolic syndrome recovery in parallel with improvements in OSA severity and related symptoms,” according to their study, reported in the journal CHEST (2022 Jan 18. doi: 10.1016/j.chest.2021.12.669).

Asked whether he still recommends CPAP to patients with OSA and the metabolic syndrome, given the findings, corresponding author Luciano F. Drager, MD, PhD, replied “yes, definitely.”

“Despite the modest rate in reversing metabolic syndrome after CPAP, the rate was five-fold higher than non-effective treatment (18% vs. 4%),” he said in an interview.

Dr. Drager noted that studies of other single interventions such as physical exercise to reverse MS in patients with OSA also had modest results.

A researcher who studies the relationship between sleep, circadian rhythms, and metabolism commented that, although the patients in the CPAP group were compliant



Larry & Teddy/CC BY 2.0

with the assigned equipment and had both reductions in apneic events and improvement in oxygen saturation, the effect of CPAP on the metabolic syndrome was rather small.

“The CPAP was doing what we thought it was supposed to do, but it didn’t have the magnitude of effect on the metabolic syndrome as I expected or I think as the authors expected,” said Deanna Arble, PhD, assistant professor of biological science at Marquette University, Milwaukee.

She noted that the study also failed to detect a significant improvement in the blood pressure component of metabolic syndrome.

“In my experience and my review of the literature, blood pressure tends to be the one that’s improved most dramatically with CPAP,” she said.

Dr. Arble was not involved in the study.

Study details

In the trial, titled TREATOSA-MS, the investigators enrolled 100 patients with a recent diagnosis of metabolic syndrome and moderate to severe OSA, defined as 15 or more apnea-hypopnea index events per hour. The patients were stratified by body mass index and then randomized to undergo therapeutic CPAP or to use nasal strips for 6 months.

At baseline and at the end of each intervention, investigators measured anthropometric variables, blood pressure, glucose, and lipid profiles. They also assessed leptin and adiponectin, body composition, food intake, physical activity, subcutaneous and abdominal fat (visceral and hepatic), and endothelial function to control for potential confounders.

As noted previously, they found that after 6 months “most patients

with OSA randomized to CPAP retained the MS diagnosis, but the rate of MS reversibility was higher than observed in the placebo group.” The difference in metabolic syndrome reversal, 18% with CPAP versus 4% with nasal strips, translated into a hazard ratio favoring CPAP of 5.27 ($P = .04$).

“This could potentially be a very good, carefully controlled first insight into how obstructive sleep apnea is related to the metabolic syndrome.”

Also as noted, in analyses adjusted for baseline values, CPAP did not significantly improve either weight, liver fat, lip profiles, or the adiposity biomarkers leptin and adiponectin, but did have “very modest” influence on reducing visceral fat and improving endothelial function.

Rigorous study

Dr. Arble said that most studies of the association between OSA and metabolic syndrome have focused on only one or two of the parameters that were included in the TREATOSA-MS study, giving the findings additional weight.

“This could potentially be a very good, carefully controlled first insight into how obstructive sleep apnea is related to the metabolic syndrome,” she said.

The study was funded by grants Fundação de Amparo Q22 à Pesquisa do Estado de São Paulo and Coordenação de Aperfeiçoamento de Pessoal de Nível Superior. The authors and Dr. Arble reported having no conflicts of interest to disclose. ■



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COMMENTARY

Patients need Sep-1: Why don't some doctors like it?

BY STEVEN Q. SIMPSON, MD, FCCP

Since its inception, the CMS Sep-1 Core Quality Measure has been unpopular in some circles. It is now under official attack by the American College of Emergency Physicians (ACEP) and the Infectious Diseases Society of America (IDSA), along with a handful of smaller professional societies. These societies appealed the National Quality Forum's (NQF) 2021 recommendation that the measure be renewed. The NQF is the multidisciplinary and broadly representative group of evaluators who evaluate proposals for Centers for Medicare & Medicaid Services (CMS)-sponsored quality improvement on behalf of the American people and of CMS. Readers of *CHEST Physician* are likely familiar with core measures, in general, and with Sep-1, in particular. CMS requires hospitals to publicly report their compliance with several Core Quality Measures, and the failure to do so results in across the board reductions in Medicare payments. As of now, no penalties are levied for the degree of compliance but only for failure to report the degree of compliance.

The measure asks, in the main, for hospitals to perform what most physicians can agree should be standard care for patients with sepsis. Depending on whether shock is present, the measure requires:

1. Blood cultures before antibiotics
2. Antibiotics within 3 hours of recognition of sepsis
3. Serum lactate measurement in the first 3 hours and, if increased, a repeat measurement by 6 hours
4. If the patient is hypotensive, 30 mL/kg IV crystalloid within 3 hours, or documentation of why that is not appropriate for the patient
5. If hypotension persists, vasopressors within 6 hours
6. Repeat cardiovascular assessment within 6 hours for patients with shock

If I evaluate these criteria as a patient who has been hospitalized for a serious infection, which I am, they do not seem particularly stringent. In fact, as a patient, I would want my doctors and nurses to act substantially faster than this if I had sepsis or septic shock. If my

doctor did not come back in less than 6 hours to check on my shock status, I would be disappointed, to say the least. Nevertheless, some physicians and professional societies see no reason why these should be standards and state that the data underlying them are of low quality. Meanwhile, according to CMS' own careful evaluation, national compliance with the measures is less than 50%, while being compliant with the measures reduces absolute overall mortality by approximately 4%, from 26.3% to 22.2% (Townsend SR et al. *Chest*. 2022;161[2]:392-406). This would translate to between 14,000 and 15,000 fewer patients dying from sepsis per year, if all patients received bundled, measure-compliant care. These are patients I don't care to ignore.

Before Sep-1 many, if not most, of the hospitals in the United States had no particular strategy in place to recognize and treat patients with sepsis, even though it was and is the most common cause of death in American hospitals.

ACEP and IDSA point specifically to the new Surviving Sepsis Campaign Guidelines (SSC) recommendations as evidence that the antibiotic measure is based on low quality evidence (Evans L et al. *Crit Care Med*. 2021;49[11]:1974-82). In this regard, they are technically correct; the system of evidence review that the SSC panel uses, Grading of Assessment, Recommendations, and Evaluation (GRADE), considers that retrospective analyses, which nearly all of these studies are, can be graded no higher than low quality. Clearly, retrospective studies will never achieve the level of certainty that we achieve with randomized controlled trials, but the NQF, itself, typically views that when a number of well-performed retrospective studies point in the same direction, the level of evidence is at least moderate. After all, just as it would be inappropriate to randomize participants to decades of smoking vs nonsmoking in order to prove that smoking causes lung cancer, it is not



Dr. Simpson is a pulmonologist and intensivist with an extensive background in sepsis and in critical care quality improvement, including by serving as a senior adviser to the Solving Sepsis initiative of the Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Department of Health and Human Services and an author of the 2016 and 2020 updates of the Surviving Sepsis Campaign Guidelines. Dr. Simpson is the senior medical adviser for Sepsis Alliance, a nationwide patient information and advocacy organization. He is the Immediate Past President of CHEST.

appropriate to randomize patients with sepsis to receive delayed antibiotics before we accept that such delays are harmful to them.

ACEP and IDSA also assert that the association of early antibiotics with survival is "stronger" for septic shock than for sepsis. In fact, the association is quite strong for both severities of illness. Until it progresses to septic shock, the expected mortality of sepsis is lower, and the percent reduction in mortality is less than for septic shock. However, the opportunity for lives preserved is quite large, because the number of patients with sepsis at presentation is approximately 10 times higher than the number with septic shock at presentation. Antibiotic delays are also associated with progression from infection or sepsis to septic shock (Whiles BB et al. *Crit Care Med*. 2017;45[4]:623-29; Bisarya R et al. *Chest*. 2022;161[1]:112-20). Importantly, SSC gave a strong recommendation for all patients with suspected sepsis to receive antibiotics within 3 hours of suspecting sepsis and within 1 hour of suspecting septic shock, a recommendation even stronger than that of Sep-1.

Critics opine that CMS should stop looking at the process measures and focus only on the outcomes of sepsis care. There is a certain attractiveness to this proposition. One could say that it does not matter so much how a hospital achieves lower mortality as long as they do achieve it. However, the question would then become – how low should the mortality rate be? I have a notion that whatever the number, the Sep-1 critics would find it unbearable.

There is a core principle embedded in the Sep-1 process measures, in SSC guidelines, and in the concept of early goal-directed therapy that preceded them: success is not dependent only on what we

do but on when we do it. All of you have experienced this. Each of you has attended a professional school, whether medical, nursing, respiratory therapy, etc. None of you showed up unannounced on opening day of the semester and was admitted to that school. All of you garnered the grades, solicited the letters of recommendation, took the entrance exams, and submitted an application. Some of you went to an interview. All of these things were done in a timely fashion; professional schools do not accept incomplete applications or late applications. Doing the right things at the wrong time would have left us all pursuing different careers.

Very early in my career as an attending physician in the ICU, I found myself exasperated by the circumstances of many patients who we received in the ICU with sepsis. I would peruse their medical records and find that they had been septic, ie, had met criteria for severe sepsis, 1 to 2 days before their deterioration to septic shock, yet they had not been diagnosed with sepsis until shock developed. In the ICU, we began resuscitative fluids, ensured appropriate antibiotics, and started vasopressors, but it was often to no avail. The treatments we gave made no difference for many patients, because they were given too late. For me, this was career altering; much of my career since that time has focused on teaching medical personnel how to recognize sepsis, how to give timely and appropriate treatments, and how to keep the data to show when they have done that and when they have not.

Before Sep-1 many, if not most, of the hospitals in the United States had no particular strategy in place to recognize and treat patients with sepsis, even though it was and is

SEP-1 continued on following page

SEP-1 continued from previous page

the most common cause of death and the costliest condition in American hospitals. Now, most hospitals do have such strategies. Assertions by professional societies that it is difficult to collect the data for Sep-1 reporting are likely true. However, keeping patients safe and alive is a hospital's primary reason for existing. As long as hospitals are tracking each antibiotic and every liter of fluid so that they can bill for them, my own ears are deaf to hearing that it is too difficult to make sure that we are doing our job. Modifying or eliminating Sep-1 for any reason except data that show we can clearly further improve the outcome for all patients with sepsis is the wrong move to make.

So far, other professional societies want to remove elements of Sep-1 without evidence that it would improve our care for patients with sepsis or their outcomes. Thankfully, from the time we proposed the first criteria for diagnosing sepsis, CHEST has promoted what is best for patients, whether it is difficult or not. ■

CHEST in the news

CHEST works to provide opportunities for members to serve as expert sources for both mainstream and trade media to create a stronger voice for members in pulmonary, critical care, and sleep medicine.

Below are media coverage highlights from the past few months that work to expand awareness of CHEST and to promote the expertise of CHEST members in the media.

Improving NIV access for patients with COPD

In December, *Pulmonology Advisor* covered recommendations from the noninvasive ventilation Technical Expert Panel report published in the journal *CHEST*® by The American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society.

The article shares that, in the United States, patients with COPD are often prescribed home mechanical ventilators rather than more appropriate devices, due largely to current Centers for Medicare &

Medicaid Services (CMS) policies that do not always take into account unique complexities of patients' conditions.

In addition to the recommendations covered in "Optimal NIV Medicare Access Promotion: Patients With COPD," the Technical Expert Panel also published reports on patients with Obstructive Sleep Apnea, patients with Central Sleep Apnea, patients with Hypoventilation Syndromes, and patients with Thoracic Restrictive Disorders in the journal *CHEST*.

The full article, "Expert Panel Guidelines Promote Access to In-Home NIV for Patients With COPD," can be found on the *Pulmonology Advisor* website.

OSA and cardiovascular mortality

A journal *CHEST*® article, "A Validation Study of Four Different Cluster Analyses of OSA and the Incidence of Cardiovascular Mortality in a Hispanic Population," by Gonzalo Labarca, MD, et al was featured in a *Healio Pulmonology* article.

The research showed an

association between excessive sleepiness and increased risk for cardiovascular mortality in Hispanic adults with moderate to severe Obstructive Sleep Apnea and, in the article, Dr. Labarca says, "The Latino population is underrepresented in the scientific literature. Therefore, validation data regarding novel approaches to better identify a subtype of OSA patients at high risk of CV mortality is strongly needed."

The full article, "Risk for CV Mortality Elevated in Hispanic Adults with OSA, Excessive Sleepiness," can be found on the *Healio* website.

Member in the news

Chair of the CHEST COVID-19 Task Force, Ryan Maves, MD, joined *New York Times* podcast, "The Daily" to discuss how the omicron COVID-19 surge was different than previous surges because unvaccinated deaths are skewing younger. During the podcast, Dr. Maves said, "You know, many more [unvaccinated] people in their 40s and 50s are dying. And it's a grim feeling,

NEWS continued on following page



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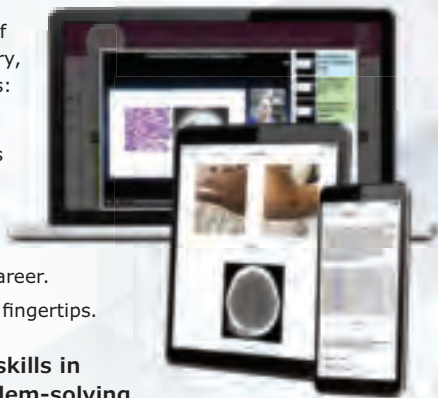
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About ABIM's Longitudinal Knowledge Assessment

BY MICHAEL E. NELSON, MD, FCCP

Member, ABIM Council

Physicians from every specialty have stepped up in extraordinary ways during the pandemic; however, ABIM recognizes that pulmonary disease and critical care physicians, along with hospitalists and infectious disease specialists, have been especially burdened. ABIM has heard from many pulmonary disease and critical care medicine physicians asking for greater flexibility and choice in how they can maintain their board certifications.

For that reason, **ABIM has extended deadlines for all Maintenance of Certification (MOC) requirements to 12/31/22 and to 2023 for Critical Care Medicine, Hospital Medicine, Infectious Disease, and Pulmonary Disease.**

What assessment options does ABIM offer?

If you haven't needed to take an MOC exam for a while, you might not be aware of ABIM's current options and how they might work for you:

- The traditional, 10-year MOC assessment (a point-in-time exam taken at a test center)
- The new Longitudinal Knowledge Assessment (LKATM) (available in 12 specialties including Internal Medicine

and Sleep Medicine now, and in Critical Care Medicine and Pulmonary Disease in 2023)

The 2-year Knowledge Check-In was retired at the end of 2021 with the introduction of the LKA.

How the new LKA works

As a longitudinal assessment, the LKA is designed to help you measure your medical knowledge over time and better melds assessment and learning. It consists of a 5-year cycle, during which you'll be offered 30 questions each quarter, and need to open at least 500 out of 600 questions to meet the LKA Participation Requirement. You can choose not to open up to 100 questions over 5 years, allowing you to take breaks when you need them.

Once enrolled, you can take questions on your laptop, desktop, or smartphone. You'll also be able to answer questions where and when it's convenient for you, such as at your home or office – with no need to

schedule an appointment or go to a test center. You can use all the same resources you use in practice – journals, apps, and your own personal notes—anything except another person. For most questions, you'll find out immediately if your answer was correct or not, and you'll receive a rationale explaining why, along with one or more references.

You'll have 4 minutes to answer each question and can add extra time if needed by drawing from an annual 30-minute time bank. For each correct answer, you'll earn 0.2 MOC points, and if you choose to participate in LKA for more than one of your certificates, you'll have even more opportunities to earn points. In addition, beginning in your second year of participation, interim score reports will give you helpful information to let you know how you're doing, so you can re-adjust your approach and focus your studies as needed. A pass/fail decision is made at the end of the 5-year cycle.

About eligibility

If you are currently certified in Critical Care Medicine or Pulmonary Disease and had an assessment due in 2020, 2021 or 2022, you don't need to take an assessment this year and will be eligible to enroll in the LKA in 2023, or you can choose to take the traditional 10-year MOC exam.

Upon enrolling, you will continue to be reported as "Certified" as long as you are meeting the LKA Participation Requirement. If your next assessment isn't due for a while, you will be able to enroll in the LKA in your assessment due year—not before then.

More information about eligibility can be found in a special section of ABIM's website.

How much does it cost?

ABIM revised its MOC fees in 2022 to provide an option to pay less over time than previously, and the LKA will be included in your annual MOC fee at no additional cost (see table at left).

In closing

Thousands of physicians have already started taking the LKA in 2022 and are reporting positive experiences with it. The ABIM is excited that physicians in additional disciplines, including Critical Care Medicine and Pulmonary Disease, will get to experience it themselves in 2023. ■

Annual MOC Fee	\$220/year	Each Additional Certificate You Maintain	+\$120/year
<ul style="list-style-type: none"> • For the first certificate you're maintaining • Paid annually • Includes LKA for that discipline • 5% discount if paid prior to year it is due • \$40 fee if paid in year after due 		<ul style="list-style-type: none"> • Paid annually and includes LKA for that discipline • 5% discount if paid prior to year it is due • \$40 fee if paid in year after due 	
		Traditional, 10-year MOC Exam	+\$700
		<ul style="list-style-type: none"> • In addition to the annual MOC fee • Taken in a test center and paid when you register • Waived if the LKA is not developed in your specialty* 	

*Transplant Hepatology, Adult Congenital Heart Disease, Advanced Heart Failure and Transplant Cardiology and Clinical Cardiac Electrophysiology

MDeedge News

NEWS continued from previous page

watching people who are your own age and maybe not that much older than you die of an entirely preventable illness." The full podcast, "This COVID Surge Feels Different," can be found on the *New York Times* website.

CHEST news

CHEST regularly issues statements and press releases on a variety of topics, including closing the synthetic nicotine loophole and requests for Congress to extend telehealth services.

For all recent CHEST News, including these statements, visit the CHEST Newsroom at chestnet.org, and follow the hashtag #CHESTNews on Twitter.

If you have been included in a recent news article and would like it to be featured, send the coverage to media@chestnet.org. ■

Belmont Stakes to support initiatives focused on improving the patient experience

There is a variety of ways to support the many impactful new programs the CHEST Foundation will launch in 2022, but one of the most anticipated options is the annual Belmont Stakes Dinner and Auction on June 11 in New York City. This fun-filled evening will include a viewing of the 154th running of "The Championship Track," a cocktail reception and plated dinner, a silent auction, a rooftop party, and much more.

This year, the dinner and auction will support the CHEST Foundation's work in patient education and CHEST initiatives to improve patient care. Two areas of focus are disparities in care delivery and improving patients' quality of life through

partnerships designed to encourage earlier diagnosis and treatment.

With these goals in mind, new initiatives include an extension of the 2020 Foundation Listening Tour designed to help clinicians increase trust, equity, and access to health care for patients in traditionally marginalized communities.

In addition, CHEST is partnering with the Three Lakes Foundation on a program dedicated to shortening the time to diagnosis for pulmonary fibrosis (PF). This initiative will bring together pulmonologists and primary care physicians to develop a strategy for identifying PF more quickly, ensuring treatment can begin earlier in the disease trajectory. Early detection of PF is associated with better

quality of life for patients, so improving clinicians' understanding of the signs and symptoms of this rare disease and formulating better guidance for diagnosing it could result in drastic improvements for those living with PF.

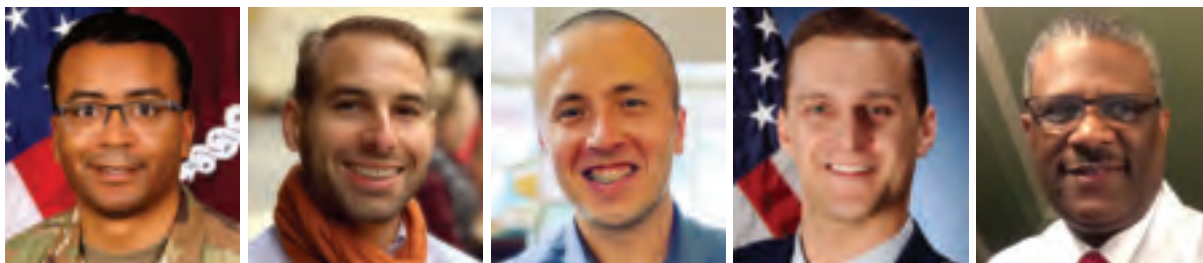
To highlight the importance of these efforts, the evening also will include speeches from two patient advocates who have turned their own experiences with living with chronic lung disease into incredible action on behalf of patients.

To learn more about the CHEST Foundation's initiatives in 2022 and how you can attend the Belmont Stakes Dinner and Auction to support these efforts, visit foundation.chestnet.org. ■

PULMONARY PERSPECTIVES®

Continuous remote patient monitoring

BY ANDREW N. SALOMON, MD; JAMES B. MULLER, MD; JOSHUA M. BOSTER, MD; KEVIN A. LOUDERMILK, DO; AND KENNETH R. KEMP, MD, FCCP



L-R: Dr. Salomon is an Internal Medicine Resident (PGY-2); Dr. Muller is an Internal Medicine Resident (PGY-2); Dr. Boster is a Pulmonary and Critical Care Fellow; Dr. Loudermilk is a Pulmonary and Critical Care Fellow; and Dr. Kemp is Pulmonary and Critical Care staff, San Antonio Military Medical Center, Fort Sam Houston, Texas.

The SARS-CoV-2 pandemic required health care systems around the world to rapidly innovate and adapt to unprecedented operational and clinical strain. Many health care systems leveraged virtual care capabilities as an innovative approach to safely and efficiently manage patients while reducing staff exposure and medical resource constraints (*Healthcare [Basel]*. 2020 Nov;8[4]:517; *JMIR Form Res*. 2021 Jan;5[1]:e23190). With Medicare insurance claims data demonstrating a 30% reduction of in-person health visits, telemedicine has become an essential means to fill the gaps in providing essential medical services (*JAMA Intern Med*. 2021 Mar;181[3]:388-91). A vast majority of virtual health care visits come via telephonic encounters, which have inherent limitations in the ability to monitor patients with complex or critical medical conditions (*Front Public Health*. 2020;8:410; *N Engl J Med*. 2020 Apr;382[18]:1679-81). Remote patient monitoring (RPM) has been established in multiple clinical models as an effective adjunct in telemedicine encounters in order to ensure treatment regimen adherence, make real-time treatment adjustments, and identify patients at risk for early decompensation.

Long-term RPM data has demonstrated cost reduction, reduced burden of in-office visits, expedited management of significant clinical events, and decreased all-cause mortality rates. Previously RPM was limited to the care of patients with chronic conditions, particularly cardiac patients with congestive heart failure and invasive devices, such as pacemakers or implantable cardioverter-defibrillators (*JMIR Form Res*. 2021 Jan;5[1]:e23190; *Front Public Health*. 2020;8:410). In response to the pandemic, the Centers for Medicare & Medicaid Services (CMS) added RPM billing codes in 2019 and then included coverage of acute conditions in 2020 that permitted a more extensive role of RPM in telemedicine. This change in financial reimbursement led to a more aggressive expansion of RPM devices to assess physiologic parameters, such as weight, blood pressure, oxygen saturation, and blood glucose levels for clinicians to review.

Currently, RPM devices fall within a low-risk FDA category that do not require clinical trials for validation prior to being cleared for CMS billing in a fee-for-service reimbursement model (*N Engl J Med*. 2021 Apr;384[15]:1384-6). A shortage of evidence-based publications to guide clinicians in this new landscape creates challenges from underuse, misuse, or abuse of RPM tools. In order to maximize the clinical benefits of RPM, standardized processes and device specifications derived from up-to-date research need to be established in professional society guidelines.

Formalized RPM protocols should play a key role in overcoming the hesitancy of health

institutions becoming early adopters of RPM technologies. Some significant challenges leading to reluctance of executing an RPM program were recently highlighted at the REPROGRAM international consortium of telemedicine. These concerns involved building a technological infrastructure, training clinical staff, ensuring remote connectivity with broadband internet, and working with patients of various technologic literacy (*Front Public Health*. 2020;8:410). We attempted to address these challenges by using a COVID-19 remote patient monitoring (CRPM) strategy within our Military Health System (MHS). By using the well-established responsible, accountable, consulted, and informed (RACI) matrix process mapping tool, we created a standardized enrollment process of high-risk patients across eight military treatment facilities (MTFs). High-risk patients included those with COVID-19 pneumonia and persistent hypoxemia, those recovering from acute exacerbations of congestive heart failure, those with cardiopulmonary instability associated with malignancy, and other conditions that required continuous monitoring outside of the hospital setting.

In our CRPM process, the hospital inpatient unit or ED refer high-risk patients to a primary designated provider at each MTF for enrollment prior to discharge. Enrolled patients are equipped with an FDA-approved home monitoring kit that contains an electronic tablet, a network hub that operates independently of and/or in conjunction with Wi-Fi, and an armband containing a coin-sized monitor. The system has the capability to pair with additional smart-enabled accessories, such as a blood pressure cuff, temperature patch, and digital spirometer. With continuous bio-physiologic and symptom-based monitoring, a team of teleworking critical-care nurses monitor patients continuously. In case of a decompensation necessitating a higher level of care, an emergency action plan (EAP) is activated to ensure patients urgently receive emergency medical services. Once released from the CRPM program, discharged patients use prepaid shipping boxes to facilitate contactless repackaging, sanitization, and pickup for redistribution of devices to the MTF.

Given the increased number of hospital admissions noted during the COVID-19 global

pandemic, the CRPM program has allowed us to address overutilization of hospital beds. Furthermore, it has allowed us to address issues of screening and resource utilization as we consider patients for safe implementation of home monitoring. While data concerning the outcome of the CRPM program are pending, we are encouraged about the ability to provide high-quality care in a remote setting. To that end, we have addressed technologic difficulties, communication between remote providers and patients in the home environment, and communication between health care providers in various settings, such as the ED, inpatient wards, and the outpatient clinic.

To be sure, there are many challenges in making sure that CRPM adequately addresses the needs of patients, who may have persistent perturbations in cardiopulmonary status, tremendous anxiety about the progress or deterioration in their health status, and lack of understanding about their medical condition. Furthermore, providers face the challenge of making clinical decisions sometimes without the advantage of in-person examinations. Sometimes decisions must be made with incomplete information or when the status of the patient does not follow presupposed algorithms. Nevertheless, like many issues during the COVID-19 pandemic, patients and providers have evolved, pivoted, and made necessary adjustments to address an unprecedented time in recent history.

Ultimately, we believe that a continuous remote patient monitoring program can be designed, implemented, and maintained across a multi-facility health care system for safe, effective, and efficient health care delivery. Limitations in implementing such a program might include lack of adequate Internet services, lack of telephonic communication, inadequate home facilities, lack of adequate home support, and, perhaps, lack of available emergency services. However, if the conditions for home monitoring are optimized, CRPM holds the promise of reducing the burden on emergency and inpatient hospital services, particularly when those services are strained in circumstances such as the ongoing global pandemic due to COVID-19. With further study, standardization, and evolution, remote monitoring will likely become a more acceptable and necessary form of health care delivery in the future. ■

CRITICAL CARE COMMENTARY

What COVID-19 taught us: The challenge of maintaining contingency level care to proactively forestall crisis care

BY KELLY M. GRIFFIN, MD;
AND JEFFREY R. DICHTER,
MD, FCCP

In 2014, the Task Force for Mass Critical Care (TFMCC) published a CHEST consensus statement on disaster preparedness principles in caring for the critically ill during disasters and pandemics (Christian et al. *CHEST*. 2014;146[4_suppl]:8s-34s). This publication attempted to guide preparedness for both single-event disasters and more prolonged events, including a feared influenza pandemic.

Despite the foundation of planning and support this guidance provided, the COVID-19 pandemic response revealed substantial gaps in our understanding and preparedness for these more prolonged and widespread events.

In New York City, as the first COVID-19 wave began in March and April of 2020, area hospitals responded with surge plans that prioritized what was felt to be most important (Griffin et al. *Am J Respir Crit Care Med*. 2020;1;201[11]:1337-44). Tiered, creative staffing structures were rapidly created with intensivists supervising non-ICU physicians and APPs. Procedure teams were created for intubation, proning, and central line placement. ICU space was created with adaptations to ORs and PACUs, and rooms on med-surg floors and step-down units underwent emergency renovations to allow creation of new “pop-up” ICUs. Triage protocols were altered: patients on high levels of supplemental oxygen, who would under normal circumstances have been admitted to an ICU, were triaged to floors and stepdown units. Equipment was reused, modified, and substituted creatively to optimize care for the maximum number of patients.

In the face of all of these struggles, many around the country and the world felt the efforts, though heroic, resulted in less than standard of care. Two subsequent publications validated this concern (Kadri et al. *Ann Int Med*. 2021;174;9:1240-51;

Bravata DM et al. *JAMA Open Network*. 2021;4[1]:e2034266), demonstrating during severe surges, COVID-19 patients’ mortality increased significantly beyond that seen in non-surging or less-severe surging times, demonstrating a mortality effect of surge itself. Though these studies observed COVID-19 patients only, there is every reason to believe the findings applied to all critically ill patients cared for during these surges.

These experiences led the TFMCC to report updated strategies for remaining in contingency care levels and avoiding crisis care (Dichter JR et al. *CHEST*. 2022;161[2]:429-47). Contingency is equivalent to routine care though may require adaptations and employment of otherwise non-traditional resources. The ultimate goal of mass critical care in a public health emergency is to avoid crisis-operating conditions, crisis standards of care, and their associated challenging triage decisions regarding allocation of scarce resources.

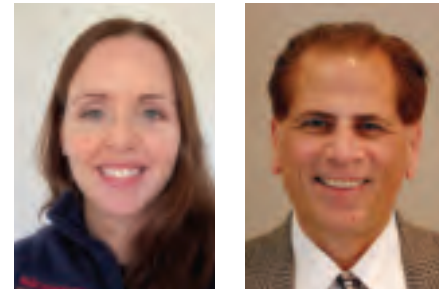
The 10 suggestions included in the most recent TFMCC publication include staffing strategies and suggestions based on COVID-19 experiences for graded staff-to-patient ratios, and support processes to preserve the existing health care work force. Strategies also include reduction of redundant documentation, limiting overtime, and most importantly, approaches for improving teamwork and supporting psychological well-being and resilience. Examples include daily unit huddles to update care and share experiences, genuine intra-team recognition and appreciation, and

embedding emotional health experts within teams to provide ongoing support.

Consistent communication between incident command and frontline clinicians was also a suggested priority, perhaps with a newly proposed position of physician clinical support supervisor. This would be a formal role within hospital incident command, a liaison between the two groups.

Surge strategies should include empowerment of bedside clinicians and leaders with both planning and real-time assessment of the clinical situation, as being at the front line of care enables the situational awareness to assess ICU strain most effectively. Further, ICU clinicians must recognize when progression deeper into contingency operations occurs and they become perilously close to crisis mode. At this point, decisions are made and scarce resources are modified beyond routine standards of care to preserve life. TFMCC designates this gray area between contingency and crisis as the Critical Clinical Prioritization level (Figure). At this point, more resources must be provided, or patients must be transferred to other resourced hospitals.

Critical Clinical Prioritization is an illustration of necessity being the mother of invention, as these are adaptations clinicians devised under duress. Some particularly poignant examples are the spreading of 24 hours of continuous renal replacement therapy (CRRT) resource between two and sometimes three patients to provide life sustainment to all; and when ventilators were in short supply, determining which



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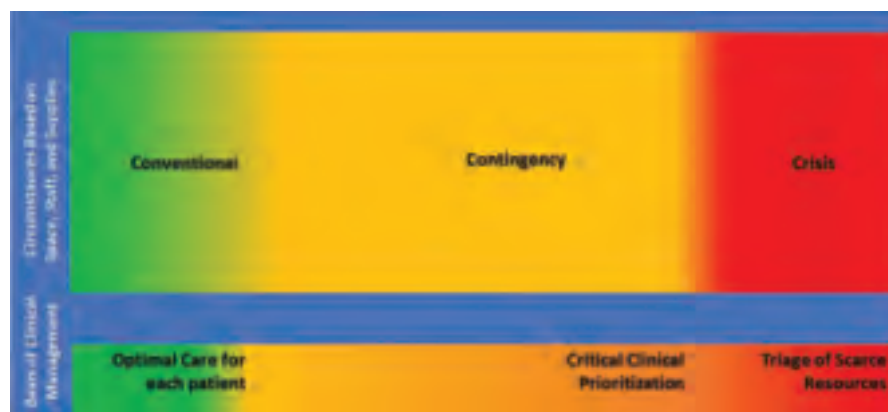
patients required full ICU ventilator support vs those who could manage with lower functioning ventilators, and trading them between patients when demands changed.

These adaptations can only be done by experienced clinicians proactively managing bedside critical care under duress, further underscoring the importance of our suggestion that Critical Clinical Prioritization and ICU strain be managed by bedside clinicians and leaders.

The response of early transfer of patients – load-balancing – should be considered as soon as any hospital enters contingency conditions. This strategy is commonly implemented within larger health systems, ideally before reaching Critical Clinical Prioritization. Formal, organized state or regional load-balancing coordination, now referred to as medical operations command centers (MOCCs), were highly effective and proved life-saving for those states that implemented them (including Arizona, Washington, California, Minnesota, and others). Support for establishment of MOCCs is crucial in prolonging contingency operations and further helps support and protect disadvantaged populations (White et al. *N Engl J Med*. 2021;385[24]:2211-4).

Establishment of MOCCs has met resistance due to challenges that include interhospital/intersystem competition, logistics of moving critically ill patients sometimes

COVID-19 continued on following page



Courtesy CHEST

Building trust together

During the fall of 2020, the CHEST Foundation launched a Listening Tour in areas of the United States that were experiencing disproportionate incidents and mortality from COVID-19. This program was initiated to gain insights in order to understand and identify solutions to combat lung health inequities among marginalized communities. The COVID-19 pandemic has exacerbated health disparities in America. Underserved communities, communities with higher rates of poverty, and communities of color have suffered disproportionate rates of illness and mortality due to COVID-19.

Even before the COVID-19 pandemic, underserved communities were impacted disproportionately by four of the most common lung diseases: asthma, chronic obstructive pulmonary disease, interstitial lung disease, and lung cancer. Inequities in care and health outcomes are well documented. Inequities are due to a multitude of factors, including socioeconomic status, environmental issues such as air pollution, and issues that impact access to care, such as individuals

being uninsured or under insured, and a lack of specialists in underserved communities.

The CHEST Foundation selected Listening Tour cities based on a number of criteria, including documented inequities in lung health and prevalence of the predominant lung diseases. Listening Tour events were held virtually in Jackson, MS; New York, NY; Chicago, IL; South Texas; and the US Southwest. In each location, the CHEST Foundation approached community leaders, clinicians, patients, and families to participate. Individual interviews focused on lung health experiences, positive and negative; needs from clinicians, patients, families, and community leaders; and help actually received (or not) based on these needs.

A theme that emerged centered on the importance trust plays in the patient/clinician relationship. Barriers to the establishment of trust as expressed by patients related to:

- Perceived dismissive attitudes among physicians
- Lack of understanding and/or appreciation about social

- determinants of health
- Overuse of highly technical/medical terminology that can be intimidating to patients
- General cultural and philosophical differences that may contribute to implicit biases

Gaining trust and building rapport among patients is not only limited to key findings from the Listening Tour but also corroborated through peer-



reviewed studies. Many studies have documented that trust is the foundation on which patient/clinician relationships are built and without it, patients are less likely to maintain adherence to treatment plans, miss appointments, minimize sharing information about their symptoms, and suffer from poorer health and overall quality of life.

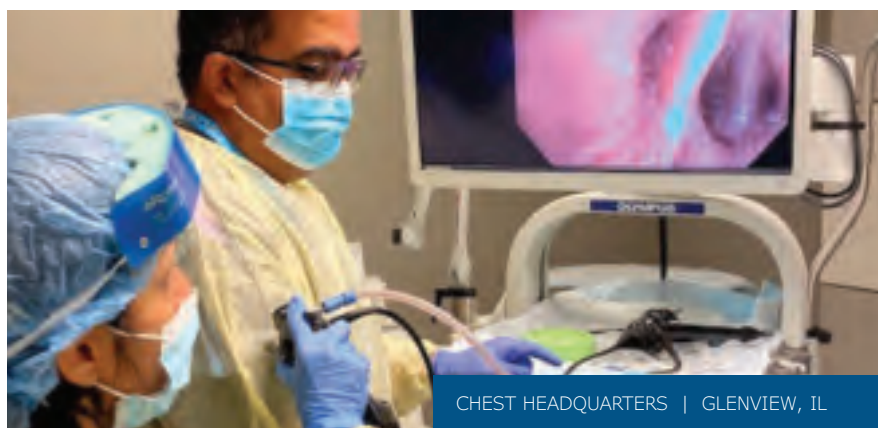
In response, the CHEST Foundation is proposing a project with the aim of broader replication based upon key findings. Building trust and developing rapport with patients are key in creating an environment where they are active participants in their care. An empathetic care training model will provide clinicians with an understanding of the barriers that exist and the tools needed to establish trust with their patients.

The major components of the

project include:

1. Development and standardization of a culturally competent toolkit for use during the first five 5 minutes of clinician/patient encounters
2. Creation of education on the tool and training clinicians that who will pilot the tool in health care clinics/medical institutions and collect data on its impact
3. Implementation of the tool during clinician/patient visits and data collection
4. Data analysis and synthesis of findings for use in refinement and scalability for broader impact

Future plans include scaling the project to additional sites and health care settings; disseminating the culturally competent tool along with education for its utilization to CHEST's membership and to a larger audience of health care providers; and sharing results and lessons learned. The CHEST Foundation is hoping to build a national, sustainable program that helps achieve health equity, but in order to achieve this, we need your help. Make a donation, and join the CHEST Foundation as we embark on a bold new initiative to build trust, identify and remove barriers, and promote health care access for all in order to help fight lung disease. Together, we will build trust and understanding within communities, specifically between patients, their families, their caregivers, and their clinicians. ■



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COVID-19 continued from previous page

and the costs of assuming care of uninsured or underinsured patients. Nevertheless, the benefits to the population as a whole necessitate working through these obstacles as successful MOCCs have done, usually with government and hospital association support.

In their final suggestion of the 2022 updated strategies, TFMCC suggests that hospitals use telemedicine technology both to expand specialists' ability to provide care and facilitate families virtually visiting their critically ill loved one when safety precludes in-person visits.

These suggestions are pivotal in planning for future public health emergencies that include mass critical care, even during events that are limited in scope and duration.

Lastly, intensivists struggled with legal and ethical concerns when mired in crisis care circumstances and decisions of allocation, and potential reallocation, of scarce resources. These issues were not

well addressed during the COVID-19 pandemic, further emphasizing the importance of maintaining contingency level care and requiring further involvement from legal and medical ethics professionals for future planning.

The guiding principle of disaster preparedness is that we must do all the planning we can to ensure that we never need crisis standards of care (National Academies of Sciences, Engineering, and Medicine. 2020 Mar 28. Rapid Expert Consultation on Crisis Standards of Care for the COVID-19 Pandemic. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25765>).

We must be prepared. Guidelines and suggestions laid out through decades of experience gained a real-world test in the COVID-19 pandemic. Now we must all reorganize and create new plans or augment old ones with the information we have gained. The time is now. The work must continue. ■

NETWORKS

Asthma, IPF, mechanical ventilation, and more...

AIRWAYS DISORDERS NETWORK
Asthma and COPD section

Betting on asthma: The over and under of diagnosis

Asthma is one of the major chronic respiratory diseases worldwide (WHO 2020), yet it is a clinical



Dr. Nahar



Dr. Blaivas

syndrome that lacks a consensus on its definition, is comprised of nonspecific respiratory symptoms, and is without a gold standard diagnostic test or a set guideline on confirmation of bronchial hyperresponsiveness (Sá-Sousa A et al. *Clin Transl Allergy*. 2014;4:24). In addition, once adequately treated, there is an absence of an algorithm to diagnose disease remission (Aaron SD et al. *Am J Respir Crit Care Med*. 2018;198[8]:1012-20). It is estimated that 20%-70% of people with asthma worldwide across the spectrum of all ages remain undiagnosed.

Spirometry and bronchoprovocation challenges with fixed cut-off values demonstrate reduced sensitivity with day-to-day, diurnal, and long-term variation in airflow obstruction, inflammation, and bronchial hyperresponsiveness (Wang R et al. *Thorax*. 2021;76[6]:624-31). Inflammatory biomarkers like fractional exhaled nitric oxide (FeNO) have higher specificity but are subject to diurnal variation and confounding diagnoses.

Overdiagnosis of asthma can result in lost opportunity to diagnose significant cardiopulmonary diseases, unnecessary escalation of the asthma treatment regimen for poorly controlled respiratory symptoms, potential for medication adverse effects, and increased cost burden to the patient and to the health care system (Aaron SD et al. *JAMA*. 2017;317:269-79; Shaw D et al. *Prim Care Respir J*. 2012;21:283-7). Among the newly physician-diagnosed asthmatics, <50% have spirometry performed within 1 year of diagnosis (Sokol KC et al. *Am J Med*. 2015;128[5]:502-8).

Spirometry was further underutilized with limit on aerosol-generating procedures during COVID-19 pandemic (Kankaanranta H et al. *J Allergy Clin Immunol Pract*. 2021;9[12]:4252-3); 30%-35% obese and nonobese patients with physician-diagnosed asthma did not have current asthma when objectively assessed for airflow limitation (Aaron SD et al. *JAMA*. 2017;317:269-79; van Huisstede A, et al. *Respir Med*. 2013;107:1356-64).

Clinical remission is greater in early-onset asthma as compared with late-onset asthma (De Marco R et al. *J Allergy Clin Immunol*. 2002;110:228-35). If asthma is well controlled, a stepping down treatment regimen is suggested (Global Initiative for Asthma 2021; Usmani et al. *J Allergy Clin Immunol Pract*. 2017;5[5]:1378-87.e5; Hagan JB et al. *Allergy*. 2014;69[4]:510-6), and although a randomized trial is lacking, it may be feasible to “undiagnose” patients who don’t experience clinical worsening, airflow obstruction, or bronchial hyperresponsiveness after being tapered off all asthma medications with a low relapse rate (Aaron SD et al. *JAMA*. 2017;317:269-79; *J Fam Pract*. 2018;67(11):704-7).

Asthma over- and underdiagnosis is prevalent and has clinical and global health consequences. New standardized algorithms with improved biomarkers may help alter this oversight.

Richa Nahar, MD

Network Member-at-Large

Allen J. Blaivas, DO, FCCP

Network Steering Committee Chair

DIFFUSE LUNG DISEASE &
LUNG TRANSPLANT NETWORK
Interstitial lung disease section
Future therapies for IPF

Idiopathic pulmonary fibrosis (IPF) is a chronic lung disease characterized by progressive fibrosis, respiratory failure, and a mortality rate of 80% at 5 years. Only two drugs are currently FDA-approved for IPF treatment. The antifibrotics pirfenidone and nintedanib reduce the rate of forced vital capacity (FVC) decline and improve progression free survival (King TE et al. *N Engl J Med*. 2014;370:2083-92; King TE et al. *N Engl J Med*. 2014;370:2071-82). While considered revolutionary when introduced, these medications neither reverse disease progression nor improve

symptoms. More recently, the Galapagos ISABELA Phase III clinical trial of ziritaxestat in IPF was discontinued due to an unfavorable risk-benefit profile. Despite this, several prospects for IPF therapy exist.

Post hoc analysis of the



Dr. Shifren



Dr. Schroeder

INCREASE Trial demonstrated a positive effect of inhaled treprostinil on FVC in patients with IPF and group 3 pulmonary hypertension (Waxman A et al. *N Engl J Med*. 2021;384:325-34). Consequently, a phase 3 randomized trial investigating its safety and efficacy in patients with IPF alone is ongoing (<https://tinyurl.com/yv6tyjff>). Additional targeted therapies for IPF are also emerging. Recombinant human pentraxin-2, an inhibitor of monocyte differentiation into proinflammatory macrophages, and pamrevlumab, a recombinant human monoclonal antibody against connective tissue growth factor, both demonstrated attenuation of FVC decline compared with placebo in phase 2 trials. Both are currently in phase 3 studies (Raghu G et al. *JAMA*. 2018;319[22]:2299-307; Sgalla G et al. *Expert Opin Investig Drugs*. 2020;29[8]:771-7). Lastly, in February the Food and Drug Administration granted breakthrough therapy designation to BI 1015550 for treating IPF based on a 12-week phase 2 randomized, double-blind, placebo-controlled trial (<https://tinyurl.com/ycktvw76>). (Data will be presented at ATS). BI 1015550 is an oral, phosphodiesterase 4B (PDE4B) inhibitor with both antifibrotic and anti-inflammatory properties. These advances in drug development provide hope for a future where IPF is transformed from a fatal disease to one manageable over many years.

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Network Member-at-Large

Gabriel Schroeder, MD

Network Member-at-Large

SLEEP MEDICINE NETWORK
Home-based mechanical
ventilation and
neuromuscular section

Role of airway clearance therapies in neuromuscular disease

Individuals with neuromuscular weakness have an impaired ability to cough and clear secretions from the airway, which can result in atelectasis and pneumonia. Proximal airway clearance therapies (ACT), including manual lung volume recruitment (LVR) and mechanical in-exsufflation (MI-E), mobilize secretions, improve cough efficacy, maintain chest wall compliance, and slow progression of restrictive lung impairment (Chatwin et al. *Respir Med*. 2018;136:98-110; Sheers et al. *Respirology*. 2019;24:512-520).

ACT are recommended in international care guidelines for



Dr. Katz

respiratory management of individuals with neuromuscular disease. At a recent Home-based Mechanical Ventilation and Neuromuscular Disease Section “PEEPS Talking PAP”

rounds, participants discussed their approach to ACT. Practices varied by country and between adult/pediatric care providers. MI-E is most often used in the United States, but elsewhere in the world, LVR with a self-inflating bag and one-way valve is first-line therapy. Clinical care guidelines suggest initiation of regular ACT when cough peak flow is < 270 L/minute, forced vital capacity < 40%-60% predicted, or with subjectively weak cough (Hull et al. *Thorax*. 2012;67(7):654-655; Amin et al. *Can J Respir Crit Care Sleep Med*. 2017;1(1):7-36; McKim et al. *Can Respir J*. 2011;18(4):197-215; Birnkrant et al. *Lancet Neurol*. 2018;17(4):347-361; Sheehan et al. *Pediatrics*. 2018;142(Suppl 2):S62-s71).

Optimal timing for initiation of routine ACT, however, is not clear. A newly published randomized controlled trial of twice daily LVR in boys with Duchenne muscular dystrophy with relatively normal baseline lung function did not

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Building CHEST 2022: A look into the Scientific Program Committee meeting

BY LAURA DIMASI

A quality educational meeting starts with a great slate of programs tailored to its audience, and CHEST 2022 is on track to offer the highest tier of education for those in pulmonary, critical care, and sleep medicine.

Although planning for the meeting started after CHEST 2021 wrapped up, the real magic started to happen a few months ago when the schedule began coming together. In mid-February, members of the Scientific Planning Committee gathered both virtually and in-person at the CHEST headquarters to solidify the schedule for the upcoming CHEST 2022 meeting taking place in Nashville, TN, October 16-19.

The excitement in the room was palpable as

committee members gathered for the first time in over a year to plan what will be the first in-person meeting since CHEST 2019 in New Orleans.

Chair of CHEST 2022, Subani Chandra, MD, FCCP, has high expectations for the meeting and is excited for everyone to be together in Nashville.

“There is something special about an in-person meeting and my goal for CHEST 2022 is to not only meet the academic needs of the attendees, but also to serve as a chance to recharge after a long haul in managing COVID-19,” says Dr. Chandra. “Many first-time CHEST attendees are fellows and, with the last two meetings being virtual, there are a lot of fellows who have yet to attend a meeting in-person, so that is a big responsibility for us and opportunity for them.

We want to make sure they have a fun and

productive meeting – learn from the best, understand how to apply the latest research, get to present their work, network, participate, and have fun doing it all!”

With something for everyone in chest medicine, the CHEST 2022 meeting will feature over 200 sessions covering eight curriculum groups:

- Obstructive lung disease
- Sleep
- Chest infections
- Cardiovascular/pulmonary vascular disease
- Pulmonary procedures/lung cancer/cardi thoracic surgery
- Interstitial lung disease/radiology
- Interdisciplinary/practice operations/education
- Critical care

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demonstrate a significant slowing of decline in forced vital capacity over 2 years. In individuals with preserved lung function, the burden of regular therapy may outweigh benefit (Katz et al. *Thorax*. 2022; doi: 10.1136/thoraxjnl-2021-218196). While we are still learning about how best to apply this therapy in less advanced neuromuscular disease, ACT has demonstrated benefits during respiratory exacerbations, and routine use plays a role in preservation of lung function in more advanced disease (Katz et al. *Ann Am Thorac Soc*. 2016;13(2):217-222; McKim et al. *Arch Phys Med Rehabil*. 2012;93(7):1117-1122; O’Sullivan et al. *Arch Phys Med Rehabil*. 2021;102(5):976-983; Bach et al. *Am J Phys Med Rehabil*. 2008;87(9):720-725).

Sherri Katz, MD, FCCP
Section Steering Committee Chair

CRITICAL CARE NETWORK Mechanical ventilation and airways management section NIV following extubation: Which devices and which patients?

For those of us interested in studying mechanical ventilation, an interesting paradox exists: despite our interest and enthusiasm in studying it, our patients benefit from avoiding it! Patients who require re-intubation are at high risk of in-hospital mortality (Frutos-Vivar et al. *J Crit Care*. 2011;26:502-9).

Studies in high-risk patients receiving mechanical ventilation have demonstrated that patients

treated with immediate noninvasive ventilation (NIV) following extubation had reduced risk of re-intubation. CHEST guidelines focused on



Dr. Ouellette

ventilator liberation considered these studies in a meta-analysis which led to recommendations to employ NIV immediately after extubation in high-risk patients to reduce re-

intubation rates (Ouellette D et al. *Chest*. 2017;151:166-80).

In the years since the publication of the CHEST guidelines, more information has been forthcoming. Evidence has emerged that treatment with high-flow nasal cannula devices following extubation may mitigate against re-intubation. An interesting strategy from the High-Wean Study Group suggested that postextubation combination therapy with both a high-flow cannula and NIV leads to improved outcomes compared with high-flow alone (Thille AW et al. *JAMA*. 2019;322:1465-75).

Thille and coworkers recently broadened our concept of patients who may benefit from NIV post extubation. They examined a cohort of obese patients requiring mechanical ventilation, finding that when patients were treated with NIV and high-flow nasal cannula post extubation, that they had a reduced risk of re-intubation compared with a group receiving high flow alone (Thille AW,

et al. *Am J Respir Crit Care Med*. 2022;205:440-9).

As the incoming chair of the Mechanical Ventilation and Airways Management Section of the CHEST Critical Care Network, I look forward during the next 2 years to having interesting conversations about topics like this one and working with section members to develop exciting new projects concerning mechanical ventilation.

Daniel Ouellette, MD, MS, FCCP
Section Steering Committee Chair

THORACIC ONCOLOGY & CHEST PROCEDURES NETWORK Pleural disease section Management of recurrent transudative pleural effusions (REDUCE trial)

Nonmalignant pleural effusions contribute significantly to health care costs and mortality (Mummadi SR et al. *CHEST*. 2021;160[4]:1534-51; Walker SP et al. *CHEST*. 2017 May;151[5]:1099-105). Management of transudative effusions has traditionally been to treat the underlying etiology. However, despite maximal medical therapies, these recurrent effusions may add to patients’ symptom burden and often create a challenge for the clinician. In 2017, the FDA approved the use of indwelling pleural catheters (IPC) in patients with recurrent transudative effusions, but data are limited.

In a recent prospective multicenter randomized control trial, Walker and colleagues (*Eur Respir J*. 2022;59:2101362) aimed to compare IPCs to repeated therapeutic

thoracentesis (TT) in the management of transudative effusions. Pleural fluid etiologies included heart (68%), liver (24%), and renal failure (8%).



Dr. Faiz

The primary outcome was mean dyspnea score (daily visual analog scales) over 12 weeks, and there was no significant difference noted (39.7 vs 45.0, mean dif-

ference -2.9 mm, 95% confidence interval [CI] -16.1 to 10.3; $P = .67$). Secondary outcomes demonstrated increased overall drainage in the IPC vs TT group (17,412 mL vs 2,901 mL, difference 13,892 mL, 95% CI, 7,669-20,116 mL; $P < .001$) and fewer invasive procedures required in the IPC group. Adverse events were noted in 59% of the IPC group compared with 37% managed with TT (OR, 3.13, 95% CI, 1.07-9.13, $P = .04$).

The REDUCE trial offers valuable data, but failure to meet primary outcome, study size, and adverse events highlight limitations to a definitive change in practice. Further study with specific disease processes (eg, cardiac) may be helpful in the future. As in malignant pleural effusions, the selection of definitive pleural intervention should be tailored for each patient.

Maria Azhar, MD
Network Member-at-Large
Saadia A. Faiz, MD, FCCP
Section Steering Committee Chair

This month in the journal *CHEST*[®]

Editor's picks

BY PETER J. MAZZONE,
MD, MPH, FCCP
Editor in Chief

Barriers and Enablers to Objective Testing for Asthma and COPD in Primary Care: A Systematic Review Using the Theoretical Domains Framework.
By Dr. Janet Yamada et al.

COVID Complications: Diagnostic and Therapeutic Considerations for Critical COVID.
By Dr. David M. Maslove et al.

Interstitial Lung Abnormalities, Emphysema, and Spirometry in Smokers.
By Dr. Aravind A. Menon et al.

Sleep-Disordered Breathing in Hospitalized Patients: A Game Changer?
Dr. Sunil Sharma and Dr. Robert Stansbury.

Distribution, Risk Factors, and Temporal Trends for Lung Cancer Incidence and Mortality: A Global Analysis. *By Dr. Junjie Huang et al.*



CHEST 2022 *continued from previous page*

Covering a large breadth of information, the sessions will include the latest trends in COVID-19 care – recommended protocols, surge planning, and best practices; deeper looks into the latest CHEST guidelines – thromboprophylaxis in patients with COVID-19, antithrombotic therapy for VTE disease, and the guidelines for lung cancer screening; and sessions speaking to diversity, inclusion, and equity within medicine, including how lung disease affects populations differently.

Dr. Chandra says diversity was top of mind throughout the planning process. When submitting session ideas, it was noted that “submissions with speakers representing one gender and/or one institution will not be

considered,” and that “selection priority will be given to outstanding submissions with proposed speakers who represent diversity of race, ethnicity, and professional status.”

During February’s meeting, as the committee members confirmed each of the sessions, they took the time to ensure every single one had presenters from a variety of backgrounds, including diversity of gender, race, credentialing, and years of experience in medicine.

It was important to the committee that this not be a physician-only meeting, because CHEST, pulmonary care, critical care, and sleep medicine feature an array of team members, including physicians, advance practice providers, respiratory therapists, nurses, and other members of the care team, and the sessions will reflect that.

When asked what she hopes attendees will gain from CHEST 2022, Dr. Chandra said, “I want attendees to feel the joy that comes from not only being together, but learning together.”

She continued, “I want this meeting to remind clinicians why they fell in love with medicine and to remember why it is that we do what we do, especially after 2 grueling years. Attendees should leave feeling reinvigorated and charged with the latest literature and clinical expertise ready to be implemented into practice. Most of all, I want all of the attendees to have fun, because we are there to learn, but CHEST is also about enjoying medicine and those around you. I just cannot wait.” ■

Pulmonology’s Growing Influence in Lung Cancer Care

Scan the QR codes below to view a series of CHEST webinars that discuss the pulmonologist’s role in the analysis, diagnosis, treatment, and management of the lung cancer patient.



Role of the Pulmonologist in Multidisciplinary Approach to the Patient With Newly Diagnosed Lung Cancer

Speakers: Gerard A. Silvestri, MD, MS, FCCP; Catherine R. Sears, MD



Role of the Pulmonologist in Tissue Acquisition, Specimen Handling, and Molecular Testing of Patients With Early-Stage Lung Cancer

Speakers: Gerard A. Silvestri, MD, MS, FCCP; Lonny B. Yarmus, DO, MBA, FCCP



Role of the Pulmonologist in Tissue Acquisition, Specimen Handling, and Molecular Testing in Late-Stage NSCLC

Speakers: Gerard A. Silvestri, MD, MS, FCCP; Jennifer Brainard, MD; Michael Machuzak, MD, FCCP



Role of the Pulmonologist in the Early Detection and Management of Lung Cancer Treatment Complications

Speakers: Gerard A. Silvestri, MD, MS, FCCP; Lynn Tanoue, MD, MBA, FCCP

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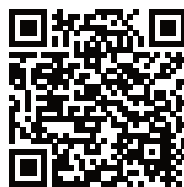


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