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Surgeon General



Critical care response to COVID-19: Don't wait, get ready now

outbreak at the annual meeting of the Society of Critical Care Medicine.

BY ANDREW D. BOWSER

MDedge News

ORLANDO - For critical care specialists, preparation may make the difference between a crisis situation and a well-managed response to a coronavirus event at a medical center.

The Centers for Disease Control and Prevention has now declared that community spread of COVID-19 in the United States is not a question of if, but of when. Critical care professionals need to know what to do to be prepared in the face of this dynamic and rapidly evolving outbreak, speakers said at the Critical Care Congress sponsored by the Society of Critical Care Medicine.

"Priorities for us in our hospitals are early detection, infection prevention, staff safety, and obviously, taking care of sick people," said Ryan C. Maves, MD, FCCP, of the Naval Medical Center, San Diego, in a special session on the 2019 novel coronavirus outbreak.

At press time, over 80,000 cases of coronavirus disease 2019 (COVID-19) had been reported, according to statistics from Johns Hopkins Center for Science and Engineering in Baltimore. Nearly 3,000 deaths had been recorded, nearly all of which were in Hubei Province, China, the central point of the outbreak. In the United States, the number of cases stood at 14, with 39 cases repatriated to the U.S. and no deaths reported. The

CORONAVIRUS // continued on page 10

calls for renewed focus on smoking cessation

BY ALICIA AULT

Medscape.com

he U.S. Surgeon General is calling on all physicians to help patients stop smoking, noting that two-thirds of adult smokers say they want to quit, but only 40% report that their doctor has advised them to stop.

"I've got to own this as the nation's doctor, and our health providers in this room and in this country need to own this stat," said Surgeon General Jerome Adams, MD, at a press briefing releasing a new report on smoking cessation.

"Smoking is the No. 1 preventable cause of death, disease, and disability in the United States," he said. "So why are 40% of our health providers out there not advising smokers to quit when they come in?"

In the first U.S. Surgeon General report on smoking cessation in 30 years, the 700-page report suggests smoking cessation-related quality measures that include physician reimbursement would increase treatment.

The evidence also suggests that using electronic health records to prompt clinicians to inquire

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NSIDE HIGHLIGHT



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CHEST Board Review 2020



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Vaping marijuana gaining traction among U.S. teens

BY HEIDI SPLETE

MDedge News

aping has expanded as a popular method of drug delivery for U.S. teenagers, and one in five students in grades 10 and 12 reported vaping marijuana in the past year, according to results of the 2019 Monitoring the Future survey conducted by the National Institute on Drug Abuse.

The 2019 findings, announced Dec. 18, 2019, continue to illustrate "a clear shift in the pattern of drug taking among teenagers," said NIDA Director Nora D. Volkow, MD, in a teleconference held to review the results.

Use of alcohol and drugs – including opioids and stimulants – continues to decline among teens, but vaping continues its significant rise, with a surge in marijuana vaping this year.



The increase in past-month marijuana vaping among 12th graders, from 7.5% in 2018 to 14% in 2019, represents the second-largest 1-year jump tracked for any substance in the survey's history, Dr. Volkow said. The largest jump was the increase in past-month nicotine vaping among 12th graders from 2017 to 2018.

Past-year marijuana vaping has more than doubled in the past 2 years, with rates this year of 20.8% among 12th graders, 19.4% among 10th graders, and 7.0% among 8th graders.

"It is very unfortunate that we are seeing the steep rise in the use of vaping devices" because the devices deliver drugs in very high concentration, Dr. Volkow said. The growing popularity of vaping "threatens to undo years of progress protecting the health of adolescents in the U.S.," Dr. Volkow said in a statement. The Monitoring the Future survey began including vaping questions in 2017.

Monitoring the Future is a national tool to assess drug and alcohol use

and related attitudes among adolescent students across the United States. This year's self-reported survey included 42,531 in grades 8, 10, and 12 from 396 public and private schools.

Nicotine vaping increased from 2018 to 2019 across all three grades; past-month nicotine use equated to 1 in 4, 1 in 5, and 1 in 10 (26%, 20%, and 10%) among 12th, 10th, and 8th graders, respectively, according to the survey. Daily nicotine vaping, measured for the first time last year because of public health concerns, was approximately 12% for 12th graders, 7% for 10th graders, and 2% for 8th graders.



Dr. Volkow

Daily marijuana vaping, also measured for the first time last year, was approximately 4%, 3%, and 1% among 12th, 10th, and 8th graders, respectively. Additional find-

ings on the rise of vaping by U.S. teenagers were released Dec. 17, 2019, in a research letter published online in JAMA (doi: 10.1001/jama.2019.20185).

Meanwhile, positive trends in this year's survey included a reduction in the misuse of prescription drugs, including OxyContin, Vicodin, and Adderall, and in the use of traditional cigarettes and other tobacco products, as well as alcohol, noted Richard A. Miech, PhD, MPH, of the University of Michigan, Ann Arbor, principal investigator for Monitoring the Future. However, the challenge of preventing and reducing vaping in teens remains "a whole new uncharted territory," in part because the design of the vaping devices facilitates discreet use at home and at school, he said

Physicians and parents have important roles to play in screening for vaping among teens, Dr. Volkow said in a question-and-answer session.

Health care clinicians, including pediatricians and family physicians, "are in a unique position to communicate with their young patients" by educating them about the dangers of vaping, encouraging them to stop if they have started using these devices, and referring them for further treatment if they are showing signs of addiction, she said.

Monitoring the Future was funded by NIDA. The researchers had no disclosures.

chestphysiciannews@chestnet.org



14% of Americans smoke // continued from page 1

about smoking would increase cessation treatment.

EHRs could be used to "empower and enable" physicians to advise people to quit, said Dr. Adams. Physicians also need "the education and the confidence to be able to have that conversation, because too many of them look at someone and say: 'Nope, too hard, too much effort, no, that's not what they're here for today," he said.

However, "simply asking, advising, and referring can be enough to get someone on the pathway to quitting," Dr. Adams said.

34 million still smoke

The new report is the first on the topic released since 1990, and the 34th on tobacco control since the first one was issued in 1964, said Dr. Adams. Since that first report, adult smoking has declined 70%, but some 34 million Americans (14%) still smoke, he said.

In addition, Dr. Adams said that

VIEW ON THE NEWS

Daniel Ouellette, MD, FCCP, comments: I have been treating patients with disease related to smoking since entering medical school 40 years ago. COPD, lung cancer, cardiovascular disease,

and many other conditions that we as physicians encounter every day are either caused by or are otherwise epidemiologi-



cally associated with smoking. Too many people in our population still smoke. The most important factor in getting patients to stop smoking is their physician advising them to quit. If we as physicians truly believe that our role is to help our patients improve their health, then we fall short if we do not query every patient we see about his or her smoking habits, and tell all patients who smoke to quit. Health care systems are failing if the tools are not provided to patients and providers to promote smoking cessation. The Surgeon General is right: Tell your patients to quit smoking!

many subpopulations have been left behind, noting: "Cigarette smoking remains highest among LGBTQ adults, people with disabilities or limitations, American Indians and Alaska Natives, and people with mental health conditions or substance use disorders."

He also noted that 40% of cigarettes are consumed by those with a mental illness or a substance use disorder.

Quitting is beneficial at any age and can add as much as a decade to life expectancy, the report notes. Quitting also reduces the risk of 12 cancers, cuts the risk of chronic obstructive pulmonary disease, and reduces cardiovascular and stroke morbidity and mortality.

Pregnant women who quit also reduce their own morbidity and mortality risk and that of unborn children and infants, the report says.

"We know more about the science of quitting than ever before. We can, and must, do more to ensure that evidence-based cessation treatments are reaching the people that need them," said Dr. Adams.

Less than one-third of those who have quit have used Food and Drug Administration-approved cessation medications or behavioral counseling, Dr. Adams said.

Barriers to care

Despite the existence of five nicotine replacement therapies and two nonnicotine oral medications, and more widespread availability of proven counseling methods - including web- or text-based programs - barriers to access remain.

These include a lack of insurance coverage for comprehensive, evidence-based smoking cessation treatment, which, when offered, increases availability and use.

"These are cost-effective interventions," said Dr. Adams. "It's penny wise and pound foolish to not give someone access to what we know works," he said.

Because of the diversity of e-cigarette products and the variety of ways they are used, coupled with little research, it's not currently possible to determine whether they are, or are not, useful smoking cessation tools, the report notes.

"People want to quit," he said. "We know what works. Not enough of them are getting it, and there are terrible disparities in who is and who is not getting access to effective and evidence-based treatment that's the story here."

A version of this story originally appeared on Medscape.com.

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Burnout: Generational differences in coping

BY GREGORY TWATCHMAN

MDedge News

urnout among physicians appears to have decreased slightly in the past few years, but remains a significant problem for the medical profession, according to the Medscape National Physician Burnout & Suicide Report 2020: The Generational Divide.

A survey of more than 15,000 physicians revealed that 42% reported being burned out, down from 46% who responded to the survey 5 years ago. However, there are variations in the rates based on certain demographic factors such as specialty, age, and gender.

Urology sits at the top of the list as the specialty that is experiencing the highest rate of burnout, with 54% of urologists responding to the survey reporting burnout. Neurology and nephrology followed with burnout rates of 50% and 49%, respectively. The next five specialties on the list all reported burnout rates of 46%: diabetes and endocrinology, family medicine, radiology, ob.gyn., and rheumatology.

The survey divided participants into three age categories – Millennial (ages 25-39 years), Generation X (ages 40-54 years), and Baby Boomer (ages 55-73 years). Both Millennials and Baby Boomers reported similar rates of burnout (38% and 39%, respectively) and those in Generation X reported a higher rate of burnout (48%).

This higher rate is not unexpected. The survey results cite Carol Bernstein, MD, of the Albert Einstein College of Medicine, New

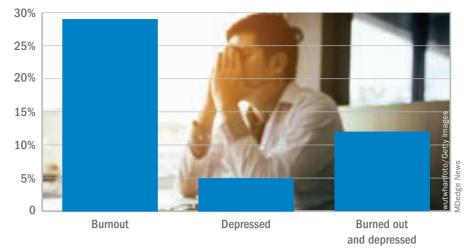
York, as noting that midcareer "is typically the time of highest burnout, which is where Gen Xers are in their career trajectory, suggesting a number of factors outside of work such as caring for children and elderly parents, planning for retirement, can play a role in contributing to burnout."

Women also reported a higher rate of burnout, although the rate has dropped from the survey conducted 5 years ago. The rate of burnout among women reported for the 2020 survey was 48%, down from 51% reported 5 years ago. By comparison, the rate of burnout for men was 37% in 2020, down from 43% in 2015.

In terms of what is causing burnout, the biggest contributor is the bureaucratic tasks (charting and paperwork, for example) that physicians must complete, which 55% of respondents to the survey said was the leading cause of burnout. Next was spending too many hours at work (33%); lack of respect from administrators, employers, colleagues, and staff (32%); and the increased computerization of the practice, including the use of electronic health records (30%).

When broken down by age category, the bureaucratic tasks was tops in all three groups (57% for Millennials, 56% for Generation X, and 54% for Baby Boomers), but what ranks next differs slightly by age group. For Millennials, the next two factors were too many hours at work (38%) and lack of respect (35%). Generation X respondents cited the same two factors, both at 33%. Baby Boomers cited comput-

Over 40% of pulmonologists feel burned out and/or depressed



Note: Online survey was conducted June 25 to Sept. 19, 2019, and involved 15,181 physicians. Source: Medscape

erization as their second-highest factor (41%) and spending too many hours at work as the third-highest factor (31%).

The generations had different approaches to coping with burnout. Millennials (56%) reported sleep as their top-ranked coping strategy, while Gen Xers and Baby Boomers ranked exercise and personal isolation as their top choice. For these two older groups, sleep was ranked last, after other activities such as talking with family and friends.

The survey also asked about depression, and respondents reported a similar rate across all age groups (15%, 18%, and 16%, respectively). Among those who said they were depressed, the three age groups had similar rates of suicidal thoughts (21%, 24%, and 22%).

Perhaps the most striking finding of the survey is the number of physicians who would take a pay cut to achieve a better work-life balance. Among Millennials, 52% would accept a pay cut, compared with 48% of Generation X and 49% of Baby Boomers. A surprising number (36%, 34%, and 31%, respectively, reported that they would accept a \$10,000-\$20,000 pay cut to have a 20% reduction in work hours.

Burnout among pulmonologists

Only 26% of pulmonologists report that they are happy at work, with about twice as many happy outside of work, according to the report. Dermatologists are the happiest at work, at 41%, and neurologists are the least happy, at 18%.

According to the report, 29% of pulmonologists report feeling

burned out, with 5% reporting feeling depressed and 12% both depressed and burned out. An overabundance of bureaucratic tasks is the lead contributor to burnout (52%), according to pulmonologists, followed by lack of respect from administrators, employers, colleagues, and staff (38%) and spending too many hours at work (35%).

Pulmonologists report that exercise is the biggest way they cope with burnout (47%), compared with neurologists, for example, who ranked it third at 40%. Other ways they deal with burnout include isolating themselves from others (43%) and playing or listening to music (38%).

Among depressed or burned-out pulmonologists, 70% reported not planning to seek professional help or seeking it in the past, while 12% reported currently seeking professional help. Furthermore, almost half of pulmonologists (48%) say they're unlikely to participate in workplace programs.

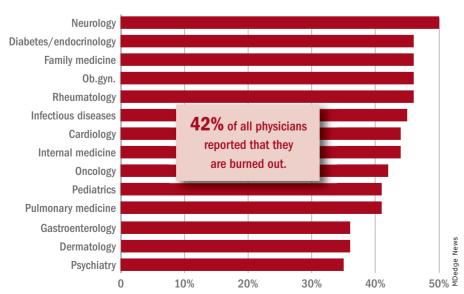
When asked for reasons they wouldn't seek professional help, 60% said they deal with it without professional help and 49% didn't think their symptoms were severe enough, while 31% were simply too busy.

The slideshow of the full report is available on Medscape.com. Christopher Palmer contributed to this story.

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SOURCE: Kane L et al. Medscape National Physician Burnout & Suicide Report 2020: The Generational Divide. Medscape. 2020 Jan 15. https://www.medscape.com/slideshow/2020-life-style-burnout-6012460.

Physicians in selected specialties who reported burnout



Note: Based on a survey of 15,181 physicians conducted from June 25 to Sept. 19, 2019. Source: Medscape

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INNOVATIVE MEDICINE Best Practices

Treatment of Unresectable Stage III Non-small Cell Lung Cancer

Introduction

With a recent renaissance in cancer diagnostics and treatment, there is renewed promise for many who previously held little hope. Lung cancer represents the second most frequently diagnosed cancer, a close second to breast cancer, at 12.9% of expected new cancer cases in 2019.1 However, the 23.5% death rate predicted for lung cancer outranks breast, prostate, colorectal, and skin melanomas combined.1 Five-vear lung cancer survival rates have increased from 11% in 1975 to more than 20% in 2016.1 This relatively low rate of survival can probably be explained by the fact that the majority of patients are diagnosed with locally advanced disease (Stage III, disease metastatic to mediastinal or supraclavicular nodes) or advanced disease (Stage IV. disease metastatic to other organs).2-4 Recent advancements in treatment are proving effective in improving patient outcomes^{5,6}; combined with adherence to screening recommendations and immediate referral to appropriate specialists, earlier diagnosis and staging can help lead to improved outcomes.⁷⁻⁹

Non-small cell lung cancer (NSCLC) constitutes 80% to 85% of lung cancer diagnoses, including histological identification of adenocarcinoma, squamous cell, large cell, and undifferentiated carcinomas. 10-12 Approximately 25% to 30% of patients with NSCLC are diagnosed with locally advanced or Stage III disease. 12 A proportion of these patients may experience the curative benefits of combined chemotherapy and surgery or concurrent chemotherapy and radiation therapy.^{5,13} About 40% of patients with NSCLC are diagnosed with Stage IV disease, and the treatment goal in these patients is to manage symptoms, improve quality of life, and extend survival. 13,14 Treatment options include systemic chemotherapy, targeted mutation therapies, radiation, immunotherapy, and on occasion surgery.7 It is vital that we increase early diagnosis, accurate staging, and referral to the appropriate specialists in lung cancer to ensure that treatment is optimized and more lives are potentially saved.7

Screening and Diagnosis

Unlike with breast, prostate, and colorectal cancers, systematic screening for lung cancer is not a well-established population-based practice, and its role is not fully grasped by primary caregivers. 15 Risk factors such as history of tobacco use and exposure to second-hand smoke are common knowledge, but other environmental exposures (diesel smoke, pollution,

and other cancer-causing agents) are difficult to quantify. 16,17 Populations with lifestyles with higher exposure to these factors are generally more reticent to intervention and skeptical of the benefits of treatment, while others may be concerned that radiation-based screening techniques contribute to the risk. 15 In addition to patient perceptions that defer intervention, presenting symptoms of cough and dyspnea are frequently confounded with other respiratory conditions, creating a delay in early detection and staging.9 Even further delays have been seen when patients present with more generalized symptoms like fatigue or bone or joint pain.9

Based on the National Lung Screening Trial (NLST),18 the American College of Chest Physicians (ACCP) has published recommendations that low-dose computerized tomography (LDCT) scans be performed annually on patients meeting the following criteria: (1) 30 pack-year current smoker or former smoker between the ages of 55 and 74 years, (2) former smokers who have guit within the past 15 years. and (3) no comorbidities that potentially preclude curative treatment benefit.¹⁵ The National Comprehensive Cancer Network® (NCCN®) also encourages patients to seek yearly screening if they are 50 years or older, have a 20 or more pack-year smoking history, and have other known risk factors besides second-hand smoke exposure, such as radon exposure. 19 Screening with LDCT, in select patients at high risk for lung cancer, decreased the relative risk of death from lung cancer by 20% when compared with chest radiography. 18 As such, efforts are being made to educate general practitioners and the public about this tremendous benefit. 15,19,20

The goal of screening is to identify a lung cancer in the earliest possible stage, which, as Table 1 demonstrates, directly improves survivability.19 However, imaging alone does not provide accurate staging, and once lung cancer is suspected, time is of the essence in ensuring no further progression. Various target time recommendations have been published advocating for improved wait times across the care spectrum, ranging from 30 to 52 days of median wait time from diagnosis to first treatment.^{23,24} Yet one Canadian study showed that despite the recommended time of 2 weeks between symptom onset and diagnosis, the actual median time to diagnosis was 4.5 months.9 It has been estimated that every 4 weeks between scans represents the potential for a 13% progression.²⁵ Kasymjanova et al describe 2 studies

and a meta-analysis demonstrating that increased wait times impart a negative effect on recurrence and survival.²³ In their own study, it was noted that reduced wait times particularly benefited Stage III NSCLC survival.23

Because pulmonologists may be the first specialist a patient sees, they are relied upon to diagnose, stage, and coordinate care for many patients with lung cancer.²⁶ Because Stage III NSCLC is a curative intent setting, 13,27 it is of particular importance to coordinate more complicated surgical, radiation, and chemotherapy care for these patients as soon as the diagnosis and stage have been ascertained.7 While initial chest computed tomography or positron emission tomography (PET) scans often determine tumor size(s) and location(s), and presence of hilar or mediastinal nodes and extrathoracic lesions (excluding the brain), these studies cannot be the sole factors used in staging, and they falsely overstage 19% of the time and understage 13% of the time.²⁸ The ACCP guidelines recommend magnetic resonance imaging (MRI) of the brain for patients with clinical Stage III or IV disease with or without symptoms of intracranial disease,²⁹ whereas NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®) recommend staging brain MRI in patients with clinical Stage IB (optional), IIA/B, IIIA/B/C and IV.30

Diagnostic procedures to obtain accurate histological diagnosis and staging and adequate tissue samples for molecular testing must be considered, ideally with input from a multidisciplinary team (MDT) composed of pulmonologists, thoracic surgeons, and radiology specialists who are board certified and have expertise in thoracic oncology whenever any stage of NSCLC is suspected.30 PET imaging can be used to identify the optimal biopsy site that produces the highest yield, is minimally invasive, and is most likely to confer the highest staging.30 Whenever possible, procedures should be combined (bronchoscopy and endobronchial ultrasound with needle aspiration of lymph nodes) to improve time to diagnosis and clinical staging.30 Invasive mediastinal staging is recommended before surgical resection.³⁰ The organization of lung cancer care requires development of a multidisciplinary program committed but not limited to the expeditious coordination of the patient's care among various disciplines to avoid unnecessary tests and procedures, delay in care, costly care, and patient frustration and anxiety.31 Multidisciplinary care has been shown to decrease time to diagnosis and improve referral for appropriate treatment.32 In particular, patients with Stage III NSCLC are more

TABLE 1. Summary of NSCLC Staging & Prognosis^{3,21,22}

Stage	TNM Classification ²¹ (Tumor, Node, Metastases)		Nodal Zones & Stations ^{3,22}	Treatment/Goal ²²	5-Year Survival ²¹
IA ₁	T1a or T1a(mi), N0, M0			Surgery or radiation	92%
IA ₂	T1b, N0, M0			Surgery ± radiation, OR	83%
IA ₃	T1c, N0, M0			Radiation	77%
IB	T2a, N0, M0				68%
IIA	T2b, N0, M0			Surgery ± Chemotherapy± Radiation	60%
IIB	T1a-c, N1, M0 <or> T2a-b, N1, M0 <or> T3, N0, M0</or></or>	N1 generally resectable N2 = heterogenous resectability N2 heterogenous resectability N3 generally non-resectable	N1 = Hilar Zone if ipsilateral		53%
IIIA	T1a-c, N2, M0 <or> T2a-b, N2, M0 <or> T3-4, N1, M0 <or> T4, N1, M0</or></or></or>			Surgery ± Chemotherapy ± Radiation	36%
IIIB	T3, N2, M0 <or> T4, N2, M0</or>		N2 = Lower Zone if ipsilateral		26%
IIIA	T1a-c, N2, M0 <or> T2a-b, N2, M0 <or></or></or>			Radiation ± Chemotherapy ± Immunotherapy	36-41% [†]
IIIB	T1a-c, N3, M0 <or> T2a-b, N3, M0 <or> T3, N2, M0 <or> T4, N2, M0</or></or></or>		N3 = Supraclavicular Zone • Station 1 (Low cervical, supraclavicular, sternal notch nodes • contralateral mediastinal, contralateral hilar, ipsilateral/contralateral scalene, superclavicular nodes	Radiation ± Chemotherapy ± Immunotherapy	24-26% [†]
IIIC	T3-4, N3, M0				12-13% [†]
IVA	Any T, Any N, M1a-b			Palliative Care with	0%
IVB	Any T, Any N, M1c			Systemic Therapy	0%

Abbreviations: M1a, separate tumor contralateral lobe or primary tumor with pleural/pericardial nodules or malignant effusions; M1b, single extrathoracic mass; M1c, multiple extrathoracic masses; mi, minimally invasive adenocarcinoma.

likely to receive appropriate treatment when referred to oncology specialists.⁷ Still, data suggest that up to 20% of patients diagnosed with Stage III NSCLC are never evaluated by an oncologist.³³

The tumor, node, metastasis (TNM) system for staging has been used since 1944.8 Now governed by the International Association for the Study of Lung Cancer (IASLC), the eighth edition took effect in 2017.²¹ Several changes from the seventh edition, including new TNM definitions and addition of categories, have caused shifts in staging, with a greater emphasis on tumor size and invasion of surrounding tissues.3 As a result, Stage III now includes subtype C (T3-T4, N3, M0), which is still treated in a curative intent setting.21 Additionally, nodal zones were further broken down into more specific stations that clearly define anatomic landmarks within each zone, as this too proved to be associated with prognosis.3 Differentiating Stage IIIC from Stage IVA has provided more patients the opportunity to be treated in a curative intent setting, as further data collection and new research are expanding within each subtype and allowing for individualized treatment approaches.3,21

Clinically, the distinction between resectable and unresectable Stage III

disease is of significance because unresectable Stage III does not afford a treatment path as well-established as resectable disease (surgery).³⁴ Unresectable generally includes Stage IIIA tumors (T1-T2 tumors with multiple positive ipsilateral mediastinal notes), often described as bulky or extensive; Stage IIIB (T1-T2 tumors with positive contralateral mediastinal or supraclavicular nodes or T3-T4 tumors with positive ipsilateral mediastinal nodes); and Stage IIIC (T3-T4 tumors with positive contralateral mediastinal or supraclavicular nodes).¹¹

Treatment of Stage III NSCLC

Patients clinically determined to have resectable Stage III NSCLC are candidates for a variety of treatment options. none of which have proven to be superior.¹¹ The 2019 NCCN Guidelines® suggest the following course for resectable Stage III NSCLC: (1) Preoperative chemotherapy (CT) and radiation (CTR), or preoperative CT followed by postoperative RT (split-panel decision); and (2) surgery, using minimally invasive techniques where possible.30 The panel acknowledges that controversy remains regarding the sequencing of surgery, chemotherapy, and radiation techniques.

The majority of patients with Stage III NSCLC have unresectable disease. ³⁵ Platinum-based CT has been preferred over other chemotherapeutic modalities for over 3 decades. ³⁶ Evidence supports its use as part of definitive CRT along with a minimum of 60 Gy in escalated doses; concurrent treatment is currently preferred over sequential in all histological findings. ³⁰ Accelerated RT alone imparts some benefit to those who refuse CT. ¹¹

Severe immune-mediated adverse reactions are associated with all immune checkpoint inhibitors, including pneumonitis, causing discontinuation.37 A recent retrospective single-center study suggests that patients who are on corticosteroids for cancer-unrelated indications have similar outcomes on immunotherapy as patients who are receiving 0 to < 10 mg of prednisone.³⁷ However, additional mechanistic studies as well as prospective clinical trials are needed to identify whether the use of corticosteroids affects specific aspects of the immune system necessary for immunotherapy activity. Optimal treatment duration for immune checkpoint inhibitors requires further study, and their use in patients with autoimmune disorders and a past organ transplantation should be avoided.38

Conclusion

Locally advanced and metastatic NSCLC patients have benefitted from intensive research into immunologic approaches to treatment. Accurate diagnosis and staging are critical, particularly in the differentiation between Stage III, which is treated with curative intent, and Stage IV, which is metastatic. CRT is the current standard of care for unresectable Stage III disease and has shown improvement in overall survival, while the introduction of immunotherapy following CRT treatment can be discussed as a treatment option. To reap the benefits of these advances in treatment, patients with suspected or confirmed lung cancer should be managed by an MDT that includes a pulmonologist, thoracic surgeon, and medical and radiation oncologists, and referral for appropriate treatment of Stage III and IV NSCLC is crucial to improving patient outcomes.

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EBUS-TBNA had highest diagnostic yield of lung lesions

BY HEIDI SPLETE

MDedge News

ndobronchial ultrasound with transbronchial needle aspiration (EBUS-TBNA) had the highest diagnostic yield of lung lesions, compared with other bronchoscopic approaches, according to a multisite study of current and former smokers with suspected lung cancer.

Bronchoscopy has long played a role in the identification of lung lesions, but the yield varies according to many factors associated with the lesion and the type of bronchoscopy, and recent studies suggest that the yield may be lower than previously thought, wrote Gerard A. Silvestri, MD, of Medical University of South Carolina, Charleston, and colleagues.

In a study published in Chest, the researchers sought to assess the yield of bronchoscopy based on procedure and characteristics, as well as the physician-calculated pretest probability of cancer.

They conducted a secondary analysis of 687 patients from the AEGIS trial, a prospective 28-site study of current and former smokers who underwent bronchoscopy for suspected lung cancer. Patients under 21, those without a history of smoking, and those with a concurrent cancer or history of lung cancer were excluded. The average age of the participants was 63 years, and two-thirds were male. Of these, 474 had diagnostic bronchoscopies and 213 had nondiagnostic bronchoscopies.

The overall diagnostic yield was 69%. However, the diagnostic yield significantly higher (80%) with the use of EBUS-TBNA, compared with 55% for standard bronchoscopy with biopsy +/- fluoroscopy, 57% for electromagnetic navigation, and 74% for combination procedures.

Patients with diagnostic bronchoscopies were significantly more likely than were those who had

nondiagnostic bronchoscopies to have lesions greater than 3 cm (67% vs. 45%), to have central locations (75% vs. 50%), and to have lymphadenopathy (57% vs. 55%).

In addition, yields were significantly higher (77%) for patients whose preprocedure physician-assessed probability of cancer was at least 60%, compared with yields in those whose preprocedure physi

VIEW ON THE NEWS

Mangala Narasimhan, DO, FCCP, comments: A very interesting study

by Dr. Silvestri and colleagues tells us that in patients with a high pretest probability of cancer, bronchoscopy with EBUS gives us superior yield to bronchoscopy alone. This is the largest study to assess diagnostic yields and is strengthened by



the multisite nature of the study and by the use of multiple modalities. A possible reason for this increased yield is direct visualization of the needle entering the lymph node in EBUS. This study suggests that patients at high pre-test risk of cancer, smokers, those with lesions greater than 3 cm, lesions that are centrally located, and with significant lymphadenopathy should have EBUS with TBNA rather than bronchoscopy alone or navigational bronchoscopy. The decision to start with the highest yield test may save the patient from extra procedures and long diagnostic wait times.

cian-assessed probability of cancer was less than 10% or 10%-60% (44% and 42%, respectively).

The study findings were limited by several factors including the high prevalence of cancer in the study population, a 1-year follow-up that may have missed slow-growing cancers, and lack of data on the presence or absence of a bronchus sign, the researchers noted. However, the results were strengthened by the large size, mixture of sites, and use of multiple technologies and presentations, they said.

The study is the largest to assess diagnostic yields and various bronchoscopy techniques and supports EBUS-TBNA as the most reliable, but patient selection and improved procedural training can help improve diagnostic yields, the researchers emphasized.

"While the overall yield of bronchoscopy is reasonable, EBUS-TBNA is the only technique that reliably provides a diagnosis in those suspected of having lung cancer, likely because the biopsy is targeting a central lymph node and there is direct visualization of the needle passing into the target," they said. However, "better bronchoscopic technology is needed and there are devices in the development pipeline that promise improved diagnostic yield, though these products will require evaluation through prospective comparative effectiveness trials prior to widespread adoption," they noted. Clinicians should be prepared to pursue alternatives to bronchoscopy if a diagnosis is unlikely, they concluded.

Dr. Silvestri disclosed research grant awards to his university from Olympus America, Auris robotics, Veracyte, and Veran Medical, as well as consulting fees from Olympus and Auris robotics. chestphysiciannews@chestnet.org

SOURCE: Silvestri GA et al. CHEST. 2020 Jan 21. doi: 10.1016/j.chest.2019.12.024.

The persistence of the coronavirus on surfaces is unknown // continued from page 1

CDC has acknowledged that more cases are likely to occur.

While much remains unknown, the estimated range of spread for droplet transmission is 2 meters, according to Dr. Maves. The duration of environmental persistence is not yet known, but he said that other coronaviruses persist in low-humidity conditions for up to 4 days.

The number of secondary cases that arise from a primary infection, or R0, is estimated to be between 1.5 and 3, though it can change as exposure evolves; by comparison, the R0 for H1N1 influenza has been reported as 1.5, while measles is 12-18, indicating that it is "very contagious," said Dr. Maves. Severe acute respiratory syndrome had an initial R0 of about 3.5, which he said declined rapidly to 0.7 as environmental and policy controls were put into place.

Critical care professionals need to know how to identify patients at

risk for COVID-19 and determine whether they need further work-up, according to Dr. Maves, who highlighted recent criteria released by the CDC.

The highest-risk category, he said, are individuals exposed to a laboratory-confirmed coronavirus case, which along with fever or signs and symptoms of a lower respiratory illness would be sufficient to classify them as a "person of interest" requiring further evaluation for disease. A history of travel from Hubei Province plus fever and signs/symptoms of lower respiratory illness would also meet criteria for evaluation, according to the CDC. Travel anywhere to mainland China would also meet the threshold.

The CDC also published a stepwise flowchart to evaluate patients who may have been exposed to the 2019 novel coronavirus. According to that flowchart, if an individual has traveled to China or had close contact with someone infected with the 2019 novel coronavirus within 14 days of symptoms, and has fever or symptoms of lower respiratory illness such as cough or shortness of breath, then providers should isolate that individual and assess clinical status, in addition to contacting the local health department.

Laura E. Evans, MD, MS, FCCM, University of Washington, Seattle, said she might recommend providers "flip the script" on that CDC algorithm when it comes to identifying patients who may have been exposed.

"I think perhaps what we should be doing at sites of entry is not talking about travel as the first question, but rather fever or symptoms of lower respiratory illnesses as the first question, and use that as the opportunity to implement risk mitigation at that stage," Dr. Evans said in a presentation on preparing for COVID-19.

Even with "substantial uncertainty" about the potential impact of the 2019 novel coronavirus, a significant influx of seriously ill patients would put strain the U.S. health care delivery system, she added.

"None of us have tons of extra capacity in our emergency departments, inpatient units, or ICUs, and I think we need to be prepared for that," she added. "We need to know what our process is to 'identify, isolate, and inform,' and we need to be testing that now."

Dr. Maves and Dr. Evans reported no financial conflicts of interest to report. Dr. Maves noted that the views expressed in his presentation did not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the U.S. government.

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FDA approves novel pandemic influenza vaccine

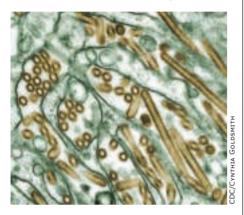
BY MEGAN BROOKS

Medscape.com

he Food and Drug Administration has approved the first and only adjuvanted, cell-based pandemic vaccine to provide active immunization against the influenza A virus H5N1 strain.

Influenza A (H5N1) monovalent vaccine, adjuvanted (Audenz, Seqirus) is for use in individuals aged 6 months and older.

The new vaccine is designed to



be rapidly deployed to help protect the U.S. population and can be stockpiled for first responders in the event of a pandemic.

The vaccine and formulated prefilled syringes used in the vaccine are produced in a state-of-the-art production facility built and supported through a multiyear public-private partnership between Seqirus and the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health & Human Services.

"Pandemic influenza viruses can be deadly and spread rapidly, making production of safe, effective vaccines essential in saving lives," BARDA Director Rick Bright, PhD, said in a company news release.

"With this licensure – the latest FDA-approved vaccine to prevent H5N1 influenza — we celebrate a decade-long partnership to achieve health security goals set by the National Strategy for Pandemic Influenza and the 2019 Executive Order to speed the availability of influenza vaccine Ultimately, this latest licensure means we can protect more people in an influenza pandemic," said Dr. Bright.

The approval of Audenz represents a key advance in influenza prevention and pandemic preparedness, combining leading-edge, cell-based manufacturing and adjuvant

technologies," Russell Basser, MD, chief scientist and senior vice president of research and development at Seqirus, said in the news release. "This pandemic influenza vaccine exemplifies our commitment to

developing innovative technologies that can help provide rapid response during a pandemic emergency." Audenz had FDA fast-track designation, a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need

A version of this article first appeared on Medscape.com.



RCT confirms CT scan screens catch lung cancer early

BY M. ALEXANDER OTTO

MDedge News

T scan screening of people with a history of heavy smoking – using lesion volume, not diameter, as a trigger for further work-up – reduced lung cancer deaths by about 24% in a randomized trial from the Netherlands and Belgium with almost 16,000 current and former smokers, investigators reported in the New England Journal of Medicine.

The Dutch-Belgian lung cancer screening trial (Nederlands-Leuvens Longkanker Screenings Onderzoek [NELSON]) is "arguably the only adequately powered trial other than the" National Lung Screening Trial (NLST) in the United States to assess the role of CT screening among smokers, wrote University of London cancer epidemiologist Stephen Duffy, MSc, and University of Liverpool (England) molecular oncology professor John Field, PhD, in an accompanying editorial.

The NLST, which used lesion diameter, found an approximately 20% lower lung cancer mortality than screening with chest x-rays among 53,454 heavy smokers after a median follow-up of 6.5 years. The trial ultimately led the U.S. Preventive Services Task Force to recommend annual screening for individuals aged 55-80 years with a smoking history of at least 30 pack-years.

European countries have considered similar programs but have hesitated "partly due to doubts fostered by the early publication of inconclusive results of a number of smaller trials in Europe. These doubts should be laid to rest," Mr. Duffy and Dr. Field wrote.

"With the NELSON results, the efficacy of low-dose CT screening for lung cancer is confirmed. Our job is no longer to assess whether low-dose CT screening for lung cancer works; it does. Our job is to identify

"Our job is no longer to assess whether low-dose CT screening for lung cancer works; it does. Our job is to identify the target population in which it will be acceptable and cost effective."

the target population in which it will be acceptable and cost effective," they added.

The 15,789 NELSON participants (84% men, with a median age of 58 years and 38 pack-year history) were randomized about 1:1 to either low-dose CT screening at baseline and 1, 2, and 2.5 years, or to no screening.

At 10 years follow-up, there were 5.58 lung cancer cases and 2.5 deaths per 1,000 person-years in the screened group versus 4.91 cases and 3.3 deaths per 1,000 person-years among controls. Lung cancer mortality was 24% lower among screened subjects overall, and 33% lower among the small number of women screened. The team estimated that screening prevented about 60 lung cancer deaths.

Using volume instead of diameter

"resulted in low[er] referral rates" – 2.1% with a positive predictive value of 43.5% versus 24% with a positive predictive value of 3.8% in NLST – for additional work-up, explained investigators led by H.J. de Koning, MD, PhD, of the department of public health at Erasmus University Medical Center in Rotterdam, the Netherlands.

The upper limit of overdiagnosis risk – a major concern with any screening program – was 18.5% with NLST versus 8.9% with NELSON, they wrote.

In short: "Volume CT screening enabled a significant reduction of harms (e.g., false positive tests and unnecessary work-up procedures) without jeopardizing favorable outcomes," the investigators wrote. Indeed, an ad hoc analysis suggested "more-favorable effects on lung-cancer mortality than in the NLST, despite lower referral rates for suspicious lesions" and the fact that NLST used annual screening.

"Recently," Mr. Duffy and Dr. Field explained in their editorial, "the NELSON investigators evaluated both diameter and volume measurement to estimate lung-nodule size as an imaging biomarker for nodule management; this provided evidence that using mean or maximum axial diameter to assess nodule volume led to a substantial overestimation of nodule volume." Direct measurement of volume "resulted in a substantial number of early-stage cancers identified at the time of diagnosis and avoided false positives from the overestimation

incurred by management based on diameter."

"The lung-nodule management system used in the NELSON trial has been advocated in the European position statement on lung-cancer screening. This will improve the acceptability of the intervention, because the rate of further investigation has been a major concern in lung cancer screening," they wrote.

Baseline characteristics did not differ significantly between the screened and unscreened in NEL-

Direct measurement of volume "resulted in a substantial number of early-stage cancers identified at the time of diagnosis and avoided false positives from the overestimation incurred by management based on diameter."

SON, except for a slightly longer duration of smoking in the screened group.

The work was funded by the Netherlands Organization of Health Research and Development, among others. Mr. Duffy and Dr. de Koning didn't report any disclosures. Dr. Field is an adviser for AstraZeneca, Epigenomics, and Nucleix, and has a research grant to his university from Janssen.

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SOURCE: de Koning HJ et al. N Engl J Med. 2020 Jan 29. doi: 10.1056/NEJ-Moa1911793.

VIEW ON THE NEWS

M. Patricia Rivera, MD, FCCP, comments: The much-awaited results of the Dutch-Belgian Randomized Lung Cancer Screening Trial (NELSON trial) are finally published and they reaffirm that lung cancer screening (LCS) with low-dose CT (LDCT) could significantly reduce lung cancer mortality rates.

Heavy current and former smokers (mostly men), underwent LDCT at 1, 2- and 2.5-year intervals vs usual care (no screening) and were followed for a minimum of 10 years. Although the eligibility criteria (age range and smoking history) of the NELSON trial was broader than that of the NLST, the individuals enrolled in both trials were healthy (no moderate or severe comorbidities) and younger (majority in both trials were under the age of 65). Prior to the publication trial results, many questioned why so few women were enrolled. The NEL-

SON investigators explained this was not for lack of trying but rather because "during the time of initiation of the study (2000 to 2004), smoking was less prevalent and much less intense in women than men."

After analysis, individuals in the LDCT screening arm showed a higher incidence of lung cancer, higher rates of early-stage cancers, and importantly, had a significant reduction in the risk of lung cancer death, reinforcing the value of LCS.

An important finding in the NELSON trial is the very low rate of "false-positive" exams (2.1%) compared with the 24% rate reported in the NLST – one of the major concerns raised by those unconvinced of the benefits of LCS. Similar to the NLST, adherence to screening was very high, a factor which is critically important but has not been realized in the real world. The NLST and the NELSON are believed to underestimate the true benefit of screening

due to only a few additional rounds of screening in both trials, thus adherence to annual screening is pivotal.

The results of the NEL-SON trial should eliminate doubts about the benefits of LCS, but the work is not complete. We must continue our efforts to promote and



support smoking prevention and cessation, define how best to select individuals particularly minorities and women who are at increased risk for lung cancer but may not meet current screening guidelines, and those with comorbidities in whom the risks of competing diseases outweigh the benefits of screening. Furthermore, we have to continue our fight against health-care disparities and help all eligible patients, particularly vulnerable groups, gain access to high-quality screening programs.

Walk test may predict complications after lung cancer surgery

BY ANDREW D. BOWSER MDedge News

FROM CHEST • For lung cancer patients with moderately decreased lung function, the 6-minute walk test may be a useful tool to help predict postoperative cardiopulmonary complications, researchers have found. This is believed to be the first large study evaluating the utility of the 6-minute walk test to predict postoperative cardiopulmo-



The option of curative resection should be considered in those lung cancer patients with moderately decreased lung function but a longer 6-minute walk distance.

nary complications in this surgical setting, according to researchers led by Hyun Lee, MD, of Hanyang University in Seoul, South Korea.

Exercise testing is currently recommended to further stratify risk of postoperative complications among patients with moderately decreased lung function, according to the researchers. The 6-minute walk test might be a good tool to evaluate feasibility for moderate-risk patients, according to one recent review. However, studies so far have been limited by small numbers of patients, and larger studies have not specifically looked at predicted postoperative lung function status, they said.

The researchers evaluated data

from patients expected to undergo curative lung cancer surgery who were enrolled in a prospective cohort study in Korea. They were classified as low or moderate risk based on pulmonary function tests, and further classified into short-distance (less than 400 m) and long-distance (400 m or more) groups based on their performance on the 6-minute walk test.

Postoperative cardiopulmonary complications were seen in 42.9% of the moderate-risk, short-distance group, versus 14.4% of patients in the moderate-risk, long-distance group. In the low-risk patients, those complications were seen in 9.5% and 8.3% of those in the long-and short-distance groups.

Odds for postoperative cardio-pulmonary complications were significantly increased in the moderate-risk, short-distance group, compared with the low-risk, long-distance group (adjusted odds ratio, 7.84; 95% confidence interval, 2.24-27.46). By contrast, odds for complications were not significantly increased in the moderate-risk, long-distance group, nor in the low-risk, short-distance groups, investigators said.

Risk of cardiopulmonary complications increased nearly eightfold in patients with moderate lung function decreases who failed to walk 400 m or more, according to the study, which included data on 416 patients with non-small cell lung cancer who underwent lobectomy.

"Our findings suggest that 6-minute walk distance would provide additional information in lung cancer patients with moderately decreased lung function who plan to undergo surgical resection," said Dr. Lee and coauthors of the study report, which appears in CHEST.

More specifically, the option of curative resection should be considered in those lung cancer patients with moderately decreased lung function but a longer 6-minute walk distance, they added.

Dr. Lee and coauthors said they had no conflicts of interest to disclose.

chestphysiciannews@chestnet.org

SOURCE: Lee H et al. CHEST. 2020. doi: 10.1016/j.chest.2019.12.039.

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Cannabis for sleep: Potential for long-term tolerance

BY MICHAEL VLESSIDES

Medscape.com

atients suffering from chronic pain who take medicinal cannabis to initiate and maintain sleep appear to experience short-term benefit, but long-term use may ultimately disrupt slumber, new research shows.

Investigators found whole-plant medical cannabis use was associated with fewer problems with respect to waking up at night, but they also found that frequent medical cannabis use was associated with more problems initiating and maintaining sleep.

"Cannabis may improve overall sleep in the short term," study investigator Sharon Sznitman, PhD, University of Haifa (Israel) Faculty of Social Welfare and Health Sciences, said in an interview. "But it's also very interesting that when we looked at frequency of use in the group that used medical cannabis, individuals who had more frequent use also had poorer sleep in the long term.

"This suggests that while cannabis may improve overall sleep, it's also possible that there is a tolerance that develops with either very frequent or long-term use," she added.

The study was published online in BMJ Supportive and Palliative Care.

A common problem

Estimates suggest chronic pain affects up to 37% of adults in the developed world. Individuals who suffer chronic pain often experience comorbid insomnia, which includes difficulty initiating sleep, sleep disruption, and early-morning wakening.

For its part, medical cannabis to treat chronic pain symptoms and manage sleep problems has been widely reported as a prime motivation for medical cannabis use. Indeed, previous studies have concluded that the endocannabinoid system plays a role in sleep regulation, including sleep promotion and maintenance.

In recent years, investigators have reported the beneficial effects of medical cannabis for sleep. Nevertheless, some preclinical research has also concluded that chronic administration of tetrahydrocannabinol may result in tolerance to the sleep-enhancing effects of cannabis.

With that in mind, the researchers set out to examine the potential impact of whole-plant medicinal cannabis on sleep problems experienced by middle-aged patients suffering from chronic pain.

"People are self-reporting that they're using cannabis for sleep and that it helps, but as we know, just because people are reporting that it works doesn't mean that it will hold up in research," Dr. Sznitman said.

The study included 128 individuals (mean age, 61±6 years; 51% females) with chronic neuropathic pain: 66 were medical cannabis users and 62 were not.

Three indicators of insomnia were measured using the 7-point Likert scale to assess issues with sleep initiation and maintenance.

In addition, investigators collected sociodemographic information, as well as data on daily consumption of tobacco, frequency of alcohol use, and pain severity. Finally, they collected patient data on the use of sleep-aid medications during the past month as well as tricyclic anti-depressant use.

Frequent use, more sleep problems?

On average, medical cannabis users were 3 years younger than their nonusing counterparts (mean age, 60 ± 6 vs. 63 ± 6 years, respectively, P=.003) and more likely to be male (58% vs 40%, respectively, P=.038). Otherwise, the two groups were comparable.

Medical cannabis users reported taking the drug for an average of 4 years, at an average



Sleep problems associated with frequent medical cannabis use may signal the development of tolerance to the agent.

However, frequent users of medical cannabis also may suffer pain or other comorbidities, which, in turn, may be linked to more sleep problems.

quantity of 31 g per month. The primary mode of administration was smoking (68.6%), followed by oil extracts (21.4%) and vaporization (20%).

Results showed that, of the total sample, 24.1% reported always waking up early and not falling back to sleep, 20.2% reported always having difficulty falling asleep, and 27.2% reported always waking up during the night.

After adjusting for patient age, sex, pain level, and use of sleep medications and antidepressants, medical cannabis use was associated with fewer problems with waking up at night, compared with nonmedical cannabis use.

No differences were found between groups with respect to problems falling asleep or waking up early without being able to fall back to sleep, Dr. Sznitman and associates reported.

The final analysis of a subsample of patients that only included medical cannabis users showed frequency of medical cannabis use was associated with sleep problems, they said.

Specifically, more frequent cannabis use was associated with more problems related to waking up at night, as well as problems falling asleep.

Sleep problems associated with frequent medical cannabis use may signal the development of tolerance to the agent. However, frequent users of medical cannabis also may suffer pain or other comorbidities, which, in turn, may be linked to more sleep problems.

Either way, Dr. Sznitman said the study might open the door to another treatment option for patients suffering from chronic pain who struggle with sleep.

"If future research shows that the effect of medical cannabis on sleep is a consistent one, then we may be adding a new therapy for sleep problems, which are huge in society and especially in chronic pain patients," she said.

Early days

Commenting on the findings in an interview, Ryan G. Vandrey, PhD, who was not involved in the study, said the findings are in line with previous research.

"I think the results make sense with respect to the data I've collected and from what I've seen," said Dr. Vandrey, associate professor of psychiatry and behavioral sciences at Johns Hopkins Medicine in Baltimore.

"We typically only want to use sleep medications for short periods of time," he continued. "When you think about recommended prescribing practices for any hypnotic medication, it's usually short term, 2 weeks or less. Longer-term use often leads to tolerance, dependence, and withdrawal symptoms when the medication is stopped, which leads to an exacerbation of disordered sleep," Dr. Vandrey said.

Nevertheless, he urged caution when interpreting the results.

"I think the study warrants caution about longterm daily use of cannabinoids with respect to sleep," he said. "But we need more detailed evaluations, as the trial wasn't testing a defined product, specific dose, or dose regimen.

"In addition, this was all done in the context of people with chronic pain and not treating disordered sleep or insomnia, but the study highlights the importance of recognizing that long-term chronic use of cannabis is not likely to fully resolve sleep problems."

Dr. Sznitman agreed that the research is still in its very early stages.

"We're still far from saying we have the evidence to support the use of medical cannabis for sleep," she said. "For in the end it was just a cross-sectional, observational study, so we cannot say anything about cause and effect. But if these results pan out, they could be far-reaching and exciting."

The study was funded by the University of Haifa and Rambam Hospital in Israel, and by the Evelyn Lipper Foundation. Dr. Sznitman and Dr. Vandrey have disclosed no relevant financial relationships.

A version of this article first appeared on Medscape.com.

Journal editors seek more complete author disclosure

BY CHRISTINE KILGORE

MDedge News

group of leading medical journal editors is seeking to improve the completeness and transparency of financial disclosure reporting with a proposed new disclosure form that puts more onus on readers to decide whether relationships and activities should influence how they view published papers.

The proposed changes are described in an editorial published simultaneously in the Annals of Internal Medicine, British Medical Journal, Journal of the American Medical Association, The Lancet, New England Journal of Medicine, and several other journals whose editors are members of the International Committee of Medical Journal Editors (ICMJE).

"While no approach to disclosure will be perfect or foolproof, we hope the changes we propose will help promote transparency and trust," the editorial stated (Ann Intern Med. 2020 Jan 27. doi: 10.7326/M19-3933).

The ICMJE adopted its currently used electronic form – the "ICMJE Form for the Disclosure of Potential Conflicts of Interest" – 10 years ago in an effort to create some uniformity amidst a patchwork of differing disclosure requirements for authors.

It's not known how many journals outside of the ICMJE's member journals routinely use the disclosure form, but the organization's website houses an extensive list of journals whose editors or publishers have requested to be listed as following the ICMJE's recommendations for editing, reporting, and publishing, including those concerning disclosures. The ICMJE does not "certify" journals. The full set of recommendations was updated in December 2019

Most authors are committed to transparent reporting, but "opinions differ over which relationships or activities to report," the editorial stated.

An author might choose to omit an item that others deem important because of a difference in opinion regarding "relevance," confusion over definitions, or a simple oversight. Some authors may be "concerned that readers will interpret the listing of any item as a 'potential conflict of interest' as indicative of problematic influence and wrongdoing," the editorial stated. The revised form, like the current one, asks authors to disclose relationships and activities that are directly related to the reported work, as well as those that are topically related (within the broadly defined field addressed in the work). But unlike the current form, the new version provides a checklist of relationships and activities and asks authors to check 'yes' or 'no' for each one (and to name them when the answer is 'yes').

Items in the checklist include grants, payments/honoraria for lectures, patents issued or planned, stock/stock options, and leadership or fiduciary roles in committees, boards, or societies.

The proposed new form makes no mention of "potential conflicts of

sures where authors aren't asked to judge "relevancy" and where readers can make decisions on their own. The American Society of Clinical Oncology, which produces the Journal of Clinical Oncology (JCO) as well as practice guidelines and continuing medical education programs, moved about 5 years ago to a system of general disclosure that asks physicians and others to disclose all financial interests and industry relationships, with no qualifiers.

In January 2020, the Accreditation Council for Continuing Medical Education issued proposed revisions to its Standards for Integrity and Independence in Accredited Continuing Education.

"We're trying to move away from calling everything a [potential] 'conflict'.... We want to remove for authors the concern or stigma, if you will, that anything listed on a form implies that there is something wrong, because that's just not true. ... We want readers to decide what relationships are important as they interpret the work."

interest" or "relevancy," per say. Authors aren't asked to determine what might be interpreted as a potential conflict of interest, but instead are asked for a "complete listing" of what readers may find "pertinent" to their work.

"We're trying to move away from calling everything a [potential] 'conflict,' Darren B. Taichman, MD, PhD, secretary of ICMJE and executive editor of the Annals of Internal Medicine, said in an interview. "We want to remove for authors the concern or stigma, if you will, that anything listed on a form implies that there is something wrong, because that's just not true. ... We want readers to decide what relationships are important as they interpret the work."

Dr. Taichman said in the interview that the ICMJE's updating of the form was more a function of "good housekeeping" and continuous appreciation of disclosure as an important issue, rather than any one specific issue, such as concern over a "relevancy" approach to disclosures.

The ICMJE is seeking feedback about its proposed form, which is available with a link for providing comments, at www.icmje.org.

Broader national efforts

Editors and others have been increasingly moving, however, toward asking for more complete disclo-

These revisions, which are open for comment, require CME providers to collect disclosure information about all financial relationships of speakers and presenters. It's up to the CME provider to then determine which relationships are relevant, according to the proposed document.

More change is on the way, as disclosure issues are being deliberated nationally in the wake of a highly publicized disclosure failure at Memorial Sloan Kettering Cancer Center in 2018. Chief medical officer José Baselga, MD, PhD, failed to report millions of dollars of industry payments and ownership interests in journal articles he wrote or cowrote over several years.

In February 2019, leaders from journals, academia, medical societies, and other institutions gathered in Washington for a closed-door meeting to hash out various disclosure related issues.

Hosted by the Association of American Medical Colleges and cosponsored by Memorial Sloan Kettering Cancer Center, ASCO, JAMA, and the Council of Medical Specialty Societies, the meeting led to a series of working groups that are creating additional recommendations "due out soon in 2020," Heather Pierce, senior director of science policy and regulatory counsel for the AAMC, said in an interview.

Among the questions being discussed: What disclosures should be verified and who should do so? How can disclosures be made more complete and easier for researchers? And, "most importantly," said Ms. Pierce, how can policy requirements across each of these sectors be aligned so that there's more coordination and oversight – and with it, public trust?

Some critics of current disclosure policies have called for more reporting of compensation amounts, and Ms. Pierce said that this has been part of cross-sector discussions.

The ICMJE's proposed form invites, but does not require, authors to indicate what payments were made to them or their institutions. "Part of this is due to the fact that it's hard to define, let alone agree on, what's an important amount," Dr. Taichman said.

A push for registries

The ICMJE is also aiming to make the disclosure process more efficient for authors – and to eliminate inconsistent and incomplete disclosures – by accepting disclosures from web-based repositories, according to the editorial. Repositories allow authors to maintain an inventory of their relationships and activities and then create electronic disclosures that are tailored to the requirements of the ICMJE, medical societies, and other entities.

The AAMC-run repository, called Convey, is consistent with ICMJE reporting requirements and other criteria (e.g., there are no fees for individuals to enter, store, or export their data), but the development of other repositories may be helpful "for meeting regional, linguistic, and regulatory needs" of authors across the world, the editorial stated.

The Annals of Internal Medicine and the New England Journal of Medicine are both currently collecting disclosures through Convey. The platform was born from discussions that followed a 2009 Institute of Medicine report on conflicts of interest.

Signers of the ICMJE editorial include representatives of the National Library of Medicine and the World Association of Medical Editors, in addition to editors in chief and other leaders of the ICMJE member journals.

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Cognitive screening of older physicians: What's fair?

BY M. ALEXANDER OTTO MDedge News

ognitive screening of 141 clinicians 70 years or older at Yale New Haven (Conn.) Hospital identified 18 with cognitive deficits likely to impair their ability to practice medicine. Six retired and 12 agreed to limit their practice to closely proctored environments, according to a report in JAMA.

It was part of a program to screen all practitioners 70 years or older who apply for reappointment to the medical staff, and every 2 years thereafter, due to "concerns about the potentially compromised ability of older clinicians," said the authors, Yale rheumatologist and

geriatrician Leo M. Cooney Jr., MD, and Thomas Balcezak, MD, Yale New Haven's chief medical officer (JAMA. 2020 Jan 14;323[2]:179-80).



Dr. Saver

Yale is not alone. Intermountain Healthcare, Stanford Hospitals and Clinics, Scripps Health Care, Penn Medicine, and the University of California, San Diego, are among the institutions with similar programs.

The move is being driven by the aging of the medical community. About 15% of U.S. physicians are over 65 years old, a tripling from 23,000 in 1980 to 73,000 in 2012-2016, and the number is growing, according to an editorial by Jeffrey L. Saver, MD, professor of neurology and senior associate vice president of neurology at the University of California, Los Angeles (JAMA. 2020 Jan 14;323[2]:127-9).

Given the trend, "it is not surprising that the issue of screening aging physicians for cognitive deficits has gained attention over the last decade," Katrina Armstrong, MD, chair of the department of medicine at Massachusetts General Hospital, Boston, and Eileen E. Reynolds, MD, associate professor of medicine at Beth Israel Deaconess Medical Center, Boston, noted in a second editorial (JAMA. 2020 Jan 14;323[2]:125-6).

"Cognitive decline often accompanies aging, and the prevalence of dementia increases rapidly after age 70 years," they said.

The data on whether older clini-

cians pose a risk to patients is limited and somewhat mixed. An analysis of 736,537 Medicare hospitalizations found no association between physician age and 30-day patient mortality among physicians 60 years or older with more than 201 admissions per year, but higher mortality among older physicians with lower volumes (BMJ. 2017 May 16;357:j1797. doi: 10.1136/bmj.j1797).

A meta-analysis of 62 studies showed that "older physicians have less factual knowledge, are less likely to adhere to appropriate standards of care, and may also have poorer patient outcomes" (Ann Intern Med. 2005 Feb 15;142[4]:260-73.)

The new Yale data, meanwhile, suggest that "approximately 13% [18



Dr. Caselli

of 141] of physicians and other clinicians older than 70 years should not be practicing independently," Dr. Armstrong and Dr. Reynolds said in their editorial.

There is support for screen-

ing efforts. "As a profession that deals with human life, medical practitioners must obviously have the cognitive capacity to safely practice medicine. I applaud the approach taken by Yale New Haven Hospital in that cognitive abilities themselves, and not simply funds of knowledge, are assessed," said Richard J. Caselli, MD, professor of neurology at the Mayo Clinic Arizona, Scottsdale, and a leader of the Alzheimer's disease program there.

However, it's not hard to imagine highly competent but older physicians taking umbrage at cognitive screening, and there's been pushback. Stanford was considering a Yale-like approach but opted instead for peer review after opposition. Objections from the Utah Medical Association led Utah to enact a law banning age-based physician screening. In 2015, the American Medical Association issued a report calling for the development of guidelines and standards for assessing competency in aging physicians, but the AMA House of Delegates shelved it pending further study.

There are concerns about age discrimination, discounting the accumulated wisdom of long-practicing physicians, and misclassifying competent physicians, particularly those who provide quality care in rural and

other underserved areas. Indeed, 8 of 14 clinicians who screened positive at Yale and underwent more extensive testing were allowed to recredential, "suggesting that the false-positive screening rate could be as high as 57%," they noted.

The consensus seems to be that there probably is a need for some sort of screening, but it must be both sound and fair. Rather than a piecemeal institutional approach, perhaps there is "an important opportunity for other groups, including specialty boards and state licensing boards" to standardize the process, they said.

Among other things, assessments could focus less on test scores and more on the practice of medicine. For instance, fine motor skill/motor planning assessments for surgeons, and intermediate results could trigger a more extensive assessment of actual clinical performance, perhaps even direct observation, Dr. Saver said in his editorial.

As far as clinical performance goes, none of the 18 clinicians at Yale had previous performance problems. "Was this a failure of the system to report impaired physicians or were these physicians compensating sufficiently to avoid



Dr. Cohen

detection?" In either case, "cognitive testing should be a red flag that triggers other clinical assessments," said Carl I. Cohen, MD, professor and director of the division of geriatric psychi-

atry at the State University of New York, Brooklyn.

The original plan at Yale was for neurologic and ophthalmologic examinations beginning at age 70, but ultimately it was decided to go with a battery of 16 tests to assess visual scanning and psychomotor efficiency, processing speed under pressure, concentration, and working memory, among other things. Testing takes about 50-90 minutes, and is graded by single neuropsychologist to ensure consistency. Results were compared with normative scores from both older and younger clinicians.

To prevent clinicians from preparing for it, Yale isn't releasing its test battery. Suboptimal performance triggered additional evaluations, including in-depth assessment of intellectual, memory, and executive function. Final reviews and recommendations were made by a committee that included a geriatrician, the clinician's section or department chair, and current and past chief medical officers.

The authors had no relevant disclosures.

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SOURCE: Cooney L et al. JAMA. 2020 Jan 14;323(2):179-80.

VIEW ON THE NEWS

Mike Nelson, MD, FCCP, comments: According to one source, almost half (46%) of physicians in the

United States were age 56 years or older in 2018 (https://www.statista.com/statistics/415961/share-of-age-among-us-physicians/).



The question of the ability of a physician to continue to maintain competency and provide care becomes more appropriate with increasing age. Some professions mandate retirement by a certain age including air traffic controllers at age 56 and airline pilots at age 65. Reasons for a mandated retirement include working in a stressful environment, long hours and responsibility for human safety ... like physicians. Mandating a retirement age for health-care providers is unfair not only to the individual, but also to the patients who count on them for their care. I applaud the medical executive committee at Yale for developing a very comprehensive method of identifying healthcare providers who are no longer able to safely practice in their specialty area. Hopefully, they will share this expertise and it becomes a nationwide program to fairly and accurately assess the competency of the aging healthcare provider. Better this be the method than an age mandate, or worse yet, governmental agencies deciding upon how it should be done.

Silent ischemia isn't what it used to be

BY BRUCE JANCIN

MDedge News

SNOWMASS, COLO. – The concept that silent myocardial ischemia is clinically detrimental has fallen by the wayside, and routine screening for this phenomenon can no longer be recommended, Patrick T. O'Gara, MD, said at the annual Cardiovascular Conference at Snowmass sponsored by the American College of Cardiology.

What a difference a decade or two can make.

"Think about where we were 25 years ago, when we worried about people who had transient ST-segment depression without angina on Holter monitoring. We would wig out, chase them down the street, try to tackle them and load them up with medications and think about balloon [percutaneous transluminal coronary angioplasty]. And now we're at the point where it doesn't seem to help with respect to quality of life, let alone death or myocardial infarction," observed Dr. O'Gara, director of clinical cardiology at Brigham and Women's Hospital and professor of medicine at Harvard Medical School, both in Boston.

The end of the line for the now-discredited notion that silent ischemia carries clinical significance approaching that of ischemia plus angina pectoris was the landmark ISCHEMIA trial, reported in November 2019 at the annual scientific sessions of the American Heart Association. This randomized trial asked the question: Is there any high-risk subgroup of patients with stable ischemic heart disease not involving the left main coronary artery for whom a strategy of

VIEW ON THE NEWS

G. Hossein Almassi, MD,

FCCP, comments: This is an interesting review on the topic of silent ischemia by an authority in the field highlighting the need for



the revision of guidelines based on the results of the latest studies and thus, a change in physicians' practice toward management of this condition. routine revascularization improves hard outcomes in the current era of highly effective, guideline-directed medical therapy?

The answer turned out to be no. At 5 years of follow-up of 5,179

randomized patients with baseline stable coronary artery disease (CAD) and rigorously determined baseline moderate or severe ischemia affecting more than 10% of the myocardium, there was no difference between patients randomized to routine revascularization plus optimal medical therapy versus those on optimal medical therapy alone in the primary combined outcome of

Continued on following page



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cardiovascular death, MI, heart failure, cardiac arrest, or hospitalization for unstable angina.

Of note, 35% of participants in the ISCHEMIA trial had moderate or severe silent ischemia. Like those who had angina, they achieved no additional benefit from a strategy of routine revascularization in terms of the primary outcome. ISCHEMIA participants with angina did show significant and durable improvements in quality of life and angina control with routine revascularization; however, those with silent ischemia showed little or no such improvement with an invasive strategy.

That being said, Dr. O'Gara added

that he supports the ISCHEMIA investigators' efforts to obtain funding from the National Institutes of Health for another 5 years or so of follow-up in order to determine whether revascularization actually does lead to improvement in the hard outcomes.

"Remember, in the STICH trial it took 10 years to show superiority of



Dr. O'Gara



CABG [coronary artery bypass surgery] versus medical therapy to treat ischemic cardiomyopathy [N Engl J Med 2016; 374:1511-20]. My own view is that it's too premature to throw the baby out with the bathwater. I think shared decision making is still very important, and I think, for many of our patients, relief of angina and improved quality of life

are legitimate reasons in a low-risk situation with a good interventionalist to proceed," he said.

Dr. O'Gara traced the history of medical thinking about silent ischemia. The notion that silent ischemia carried a clinical significance comparable with ischemia with angina gained wide credence more than 30 years ago, when investiga-

tors from the National Institutes of Health–sponsored Coronary Artery Surgery Study registry reported: "Patients with either silent or symptomatic ischemia during exercise testing have a similar risk of developing an acute myocardial infarction or sudden death – except in the three-vessel CAD subgroup, where the risk is greater in silent

ischemia" (Am J Cardiol. 1988 Dec 1;62[17]:1155-8).

"This was a very important observation and led to many, many recommendations about screening and making sure that you took the expression of ST-segment depression on exercise treadmill testing pretty seriously, even if your patient

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did not have angina," Dr. O'Gara recalled.

The prevailing wisdom that silent ischemia was detrimental took a hit in the Detection of Ischemia in Asymptomatic Diabetics (DIAC) trial. DIAC was conducted at a time when it had become clear that type 2 diabetes was a condition associ-

ated with increased cardiovascular risk, and that various methods of imaging were more accurate than treadmill exercise testing for the detection of underlying CAD. But when 1,123 DIAC participants with type 2 diabetes were randomized to screening with adenosine-stress radionuclide myocardial perfusion imaging or not and prospective-

ly followed for roughly 5 years, it turned out there was no between-group difference in cardiac death or MI (JAMA. 2009 Apr 15;301[15]:1547-55).

"This pretty much put the lid on going out of one's way to do routine screening of this nature in persons with diabetes who were considered to be at higher than average risk for the development of coronary disease," the cardiologist commented.

Another fissure in the idea that silent ischemia was worth searching for and treating came from CLAR-IFY, an observational international registry of more than 20,000 individuals with stable CAD, roughly 12% of whom had silent ischemia, a



figure in line with the prevalence reported in other studies. The 2-year rate of cardiovascular death or MI in the group with silent ischemia didn't differ from the rate in patients with neither angina nor provocable ischemia. In contrast, rates of cardiovascular death or MI were significantly higher in the groups with angina but no ischemia or angina

with ischemia (JAMA Intern Med. 2014 Oct;174[10]:1651-9).

"There's something about the expression of angina that's a very key clinical marker," Dr. O'Gara observed.

He noted that just a few months before the ISCHEMIA trial results were released, a report from the far-smaller, randomized second Medicine, Angioplasty, or Surgery Study "threw cold water" on the notion that stress-induced ischemia in patients with multivessel CAD is a bad thing. Over 10 years of follow-up, the risk of major adverse cardiovascular events or deterioration in left ventricular function was identical in patients with or without baseline ischemia on stress

testing performed after percutaneous coronary intervention, CABG surgery, or initiation of medical therapy (JAMA Intern Med. 2019 Jul 22. doi: 10.1001/jamaint-ernmed.2019.2227).

What the guidelines say

The 6-year-old U.S. guidelines on

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the diagnosis and management of patients with stable ischemic heart disease are clearly out of date on the topic of silent ischemia (Circulation. 2014 Nov 4;130[19]:1749-67). The recommendations are based on expert opinion formed prior to the massive amount of new evidence that has since become

available. For example, the current guidelines state as a class IIa, level of evidence C recommendation that exercise or pharmacologic stress can be useful for follow-up assessment at 2-year or greater intervals in patients with stable ischemic heart disease with prior evidence of silent ischemia.

"This is a very weak recommen-

dation. The class of recommendation says it would be reasonable, but in the absence of an evidence base and in light of newer information, I'm not sure that it approaches even a class IIa level of recommendation," according to Dr. O'Gara.

Dr. O'Gara reported receiving funding from the National Heart, Lung, and Blood Institute; from Medtronic in conjunction with the ongoing pivotal APOLLO transcatheter mitral valve replacement trial; from Edwards Lifesciences for the ongoing EARLY TAVR trial; and from Medtrace Pharma, a Danish company developing an innovative form of PET diagnostic imaging.

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STEMI patients benefit from PCI of nonculprit lesions

BY BRUCE JANCIN

MDedge News

PHILADELPHIA – Nearly half of patients with ST-elevation MI and multivessel coronary artery disease

in the landmark COMPLETE trial had an obstructive coronary lesion with vulnerable plaque morphology in a segment far from the culprit lesion, Natalia Pinilla-Echeverri, MD, reported at the American Heart Association scientific sessions.

This novel finding from an opti-

substudy of COMPLETE provides a likely mechanistic explanation for the major clinical benefits documented in the full COMPLETE trial, noted Dr. Pinilla-Echeverri, a

Dr. Pinilla-Fcheverri

cardiologist at the Population Health Research Institute at Mc-Master University, Hamilton, Ont.

COMPLETE was a multinational trial which randomized 4,041 ST-elevation MI

(STEMI) patients with multivessel disease to culprit lesion-only percutaneous coronary intervention (PCI) or additional routine angiography-guided staged PCI of nonculprit obstructive lesions with at least 70% stenosis. As previously reported, the risk of the coprimary composite endpoint comprising cardiovascular death, new MI, or ischemia-driven revascularization was reduced by 49% over 3 years of follow-up in the group with staged PCI of nonculprit lesions, with an impressive number needed to treat of just 13 (N Engl J Med. 2019 Oct 10;381[15]:1411-21).

Dr. Pinella-Echeverri reported

on the 93 patients who participated in the OCT substudy, the purpose of which was to determine the prevalence of high-risk, vulnerable plaque in obstructive and nonobstructive nonculprit lesions. For this purpose, vulnerable plaque was defined as thin-cap fibroatheroma (TCFA), a coronary lesion known to pose high risk of worsening stenosis, plaque rupture, and cardiovascular events.

Of note, these 93 patients had a total of 425 diseased segments: 150 obstructive and 275 nonobstructive.

"This is reassuring that the concept of acute coronary syndrome implies a diffuse pathophysiology of affecting not only the culprit segment but the coronary vasculature as a whole," Dr. Pinella-Echeverri observed.

The main study finding, however, was that TCFA was significantly more prevalent in obstructive, compared with nonobstructive, nonculprit lesions by a margin of 35% to 23%. The obstructive and nonobstructive TCFA lesions had a similar lipid-rich composition; however, the obstructive ones were significantly longer and had a smaller mean lumen area.

The COMPLETE OCT Substudy was supported by Abbott Vascular, the Population Health Research Institute, Hamilton Health Sciences, and the Canadian Institutes of Health Research.

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Dapagliflozin gets FDA Priority Review for treatment of HFrEF

BY LUCAS FRANKI

MDedge News

The Food and Drug Administration has accepted a supplemental New Drug Application and granted Priority Review for dapagliflozin (Farxiga) for the reduction of risk of cardiovascular death or worsening of heart failure in adult patients with heart failure with reduced ejection fraction (HFrEF).

The application was based on results from the landmark, phase 3 DAPA-HF trial, published in September 2019 in the New England Journal of Medicine. The study showed that dapagliflozin plus standard care reduced the incidence of cardiovascular death and worsening of heart failure versus placebo in pa-

tients with HFrEF.

Dapagliflozin was granted Fast Track designation for heart failure by the FDA in September 2019. In August 2019, the FDA also granted Fast Track designation to dapagliflozin for the delayed progression of renal failure and prevention of cardiovascular and renal death in patients with chronic kidney disease.

The drug is currently indicated for the improvement of glycemic control in adults with type 2 diabetes as either monotherapy or in combination. The FDA approved dapagliflozin in October 2019 for the reduction of heart failure hospitalization risk in patients with type 2 diabetes and cardiovascular risk factors.

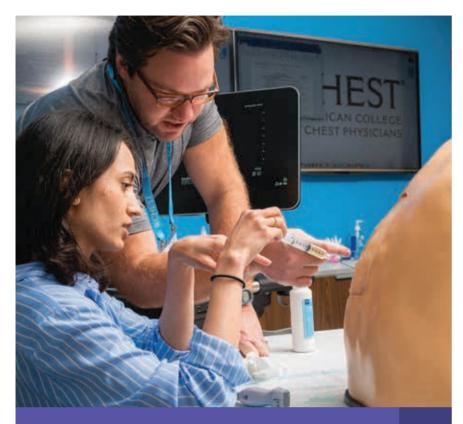
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SLEEP STRATEGIES

Stimulation to titration: An update on hypoglossal nerve stimulation for OSA

BY MICHAEL AWAD, MD; AND ROBSON CAPASSO, MD

Clinical significance

Continuous positive airway pressure remains the gold standard and firstline treatment for moderate to severe OSA. When CPAP and other medical therapies fail or are poorly adopted, surgical solutions - either standalone or in unison - can be directed to

target precision therapy.

The newest of these techniques is neuromodulation of the lingual musculature, particularly by way of selective stimulation of the hypoglossal nerve, which



Dr. Awad

first demonstrated success in human clinical trials in 1996. Upper airway stimulation (UAS) was formally FDA-approved in 2014 (Inspire Medical Systems, Inc). UAS is designed to eliminate clinically significant OSA through stimulation of the anteriorly directed branches of the hypoglossal nerve, increasing the posterior airway space in a multilevel fashion.² Since this time, over 7,500 patients have been treated with Inspire in nine countries 3 (United States, Germany, The Netherlands, Switzerland, Belgium, Spain, France, Italy, and Finland). Prospective, international multicenter trials have demonstrated 68% to 96% clinical efficacy in well selected individuals. This is defined as a \geq 50% reduction in the apnea hypopnea index (AHI) to an overall AHI of \leq 20/hour.^{4,5} Additionally, post-UAS analysis demonstrates subjective reduction in daytime sleepiness as reported by Epworth sleepiness scores, with improvements in sleep-related quality of life. Further, UAS reduces socially disruptive snoring with 85% of bedpartners reporting soft to no snoring at 48-month follow-up.⁶ The procedure has also demonstrated long-term cost benefit in the US health-care system.⁷

Background and pathophysiology Oliven and colleagues⁸ first observed the critical finding that selec-

tive intra-muscular stimulation of the genioglossus muscle lowered airway critical closing pressure (PCrit), thereby stabilizing the pharyngeal airway. Conversely, activation of the "retrusor" musculature, namely the hyoglossus and styloglossus muscles, increased Pcrit, increasing collapsibility of the pharyngeal airway.

Therapeutic implantation requires three incisions directed to the neck,



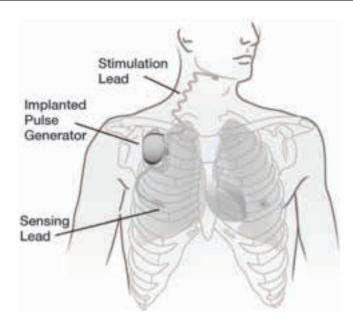
Dr. Capasso

chest, and right rib space (between the 4th and 6th intercostal spaces), with an operative time of 90 minutes or less in experienced hands. The majority of patients are discharged

on the day of the procedure. Morbidity remains low with minimal pain reported during recovery. The most common complication is that of temporary tongue weakness, which typically resolves within 2 to 3 weeks. While very infrequent, patients should be counseled on the risk of postoperative hematoma, which can precipitate infection and subsequent explant of the device. Average recovery time spans between 3 and 7 days with activation of the device 4 weeks after surgical implantation to allow for appropriate tissue healing and reduce the risk of dislodgement of the implanted components. In contrast to other surgical treatment options, UAS is also reversible with no underlying alteration to existing pharyngeal anatomy apart from external incisions created during the procedure.

Stimulation to titration

As the need for a multidisciplinary approach to salvage of patients failing first-line therapy for OSA continues to grow, UAS with its multilevel impact continues to be of key interest. In similar fashion to established medical therapies such as PAP and oral appliance therapy (OAT), close observation between sleep medicine specialists and the implanting surgeon during the adaptation period with attention paid to titration parameters such as



Schematic of Inspire UAS System, FDA Approved 2014. Implanted pulse generator receives synchronous feedback from the sensing lead, placed between 4th and 6th intercostal spaces, above the internal intercostal muscles. The sensing lead responds to pressure changes during the respiratory cycle. This triggers the pulse generator to deliver an electrical pulse to the stimulation lead in tune with inspiration, stimulating the anterior fibers of the hypoglossal nerve. Courtesy Inspire Medical Systems.

stimulation duration, pulse width, amplitude, and polarity, allow optimization of response outcome.

The stimulation electrode, which is designed in the form of a cuff to envelope the anterior (protrusor) branches of the hypoglossal nerve, receives electrical stimulation from the implanted pulse generator, implanted above the pectoralis muscle of the chest wall. This design allows for collaborative awake and overnight titration of the device as directed by a sleep medicine physician. Attention is paid not only to the voltage "strength" administered with each pulse but also the degree of synchronization between respiration and stimulation, as well as pattern of pulse administration. Our experience remains that true success and adaptation to therapy requires not just meticulous surgical technique but a diligent approach to postoperative therapeutic titration to achieve a comfortable, yet effective, voltage for maintaining airway patency. Thus, akin to initiation of CPAP, UAS requires regular follow-up and device fine-tuning with patient comfort taken into consideration to achieve optimal results, and patient expectation should be aligned with this process.

Current indications

Success in UAS relies heavily on appropriate presurgical evaluation and clinical phenotyping. The following surgical indications have been demonstrated in the Stimulation Therapy for Apnea Reduction (STAR) trial and subsequent 3-year clinical follow-up: AHI between 15 and 80 events/hour (with $\leq 25\%$ central apneas) and a BMI ≤ 32.9

As OSA often results from multi-level airway collapse, UAS targets an increase not only in the diameter of the retropalatal/oropharyngeal airway space but also the antero-posterior hypopharyngeal airway. Original criteria for implantation excluded patients with a pattern of complete circumferential collapse (CCC) noted on dynamic airway evaluation during pre-implant drug-induced sleep endoscopy (DISE). DISE aims to precisely target dynamic airway collapse patterns during simulated (propofolor midazolom-induced) sleep.

Figure 2: Indications for Upper Airway Stimulation

Moderate to Severe Obstructive Sleep Apnea Syndrome (AHI of 15 - 80)

< 25% Central Apneas Reported on Overnight Polysomnography

Body Mass Index < 32

No evidence of concentric collapse of the velum on drug-induced sleep endoscopy

Adapted from Woodson BT, Gillespie MB, et al. Three-year outcomes of cranial nerve stimulation for Obstructive Sleep Apnea: the STAR trial (Otolaryngol Head Neck Surg. 2016; 154:181-8) with permission.4

Future directions

The effects of UAS are dependent on upper-airway cross-sectional area, particularly diameter. In patients who demonstrate CCC, the anteroposterior direction of activation derived from the UAS stimulus is unable to overcome CCC. In a recent prospective study, our group demonstrated that CCC can be converted to an airway collapse pattern compatible with UAS implantation, using a modified palatopharyngoplasty prior to UAS implantation. By stabilizing the lateral walls of the oropharyngeal airway with pre-implant palatal surgery, UAS is able to successfully direct widening of the airway cross-sectional area in an antero-posterior fashion. This exciting finding potentially allows for expansion of current indications, thus opening treatment to a wider patient population.¹⁰ Still, UAS remains highly studied in a relatively uniform patient population with data in more diverse subsets requiring further directed attention to expand and better define optimal patient populations for treatment.

From the perspective of improving patient adaptation and tolerance in UAS, a well-established concept in the CPAP literature can be applied,

as explained by the Starling resistor model. The starling resistor is comprised of two rigid tubes connected by a collapsible segment in between. In parallel, the pharynx is a collapsible muscular tube connected on either end by the nose/nasal cavity and the trachea – both of which are bony/cartilaginous, noncollapsible structures. As has been shown in the use of CPAP, the same pressure required to maintain stability of the collapsible muscular pharynx via nasal breathing may lead to pharyngeal collapse when applied orally.³ This concept has also been directed towards UAS with our clinical experience demonstrating that oro or oronasal breathers tend to require a higher amplitude to maintain airway patency versus nasal breathers. This is an important area for future-directed study as medically/surgically improving nasal breathing in UAS subjects may subsequently lower amplitude requirements and improve patient tolerance.

Future direction to allow for improvement in the technology for application in a broader populational segment, external or alternative device powering mechanisms, along with MRI compatibility and

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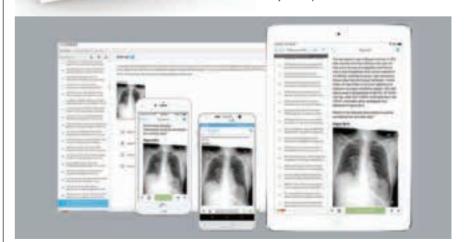
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CHEST NETWORKS

Disaster response. Medicare billing. Lung transplantation. Asthma.

Disaster response and global health

Corona virus and disaster preparedness campaign

On January 28, 2020, the US Centers for Disease Control and Prevention (CDC) issued a travel advisory recommending against all nonessential



Dr. Agapian

travel to China, in light of the 2019 novel coronavirus (2019nCoV) outbreak.

Shortly thereafter, a plane that flew out of China was directed to land on a US air force base in California on

Friday, January 31. Since then, other US government flights have evacuated patients to military bases throughout the country. The CDC issued a federal quarantine order lasting the 14-day incubation period to these repatriated US citizens. Nearby hospitals were debriefed and command centers set up in anticipation of any required intervention.

Initial diagnostic testing for 2019nCoV could only be conducted at the CDC, but testing has recently become available at a larger number of laboratories via the CDC's International Reagent Resource (IRR) network. Signs and symptoms that would warrant diagnostic testing include fever, cough, respiratory symptoms, shortness of breath, and breathing difficulties, in the context of travel to China within the prior

14 days or a high-risk contact with an ill patient. Severe cases can lead to pneumonia, kidney failure, severe acute respiratory distress, and death, with an in-hospital mortality of approximately 4% reported by clinicians in Wuhan, the epicenter of the outbreak (Wang D, et al. JAMA. Published online February 07, 2020. doi: 10.1001/jama.2020.1585).

The influenza vaccine will not protect against 2019-nCoV, and, currently, there is no available vaccine. The best prevention is to cover your mouth and nose with a tissue or your sleeve (not your hands) when coughing or sneezing. Surgical masks are not currently recommended as protection against 2019-nCoV. Hospitalized patients should be in negative-pressure rooms under respiratory and contact precautions, with gowns, gloves, eye protection, and either N95 masks or a powered air purifying respirator (PAPR) worn by clinical staff. Human-to human transmission is reported both within and outside of China (Rothe C, et al. N Engl J Med. Published online, Jan 30, 2020. doi: 10.1056/NEJMc2001468).

Clinical updates are available via the CDC at https://tinyurl.com/ wz7ojes. Clinicians are advised to check frequently, given the rapidly changing state of this epidemic.

John Agapian, MD, MS, FCCP Steering Committee Member

Practice operations

New Medicare billing rules bring welcome documentation relief At the end of 2019, the Centers for Medicare and Medicaid Services (CMS) released several changes to the Medicare Physician Fee Schedule, which will go into effect starting January 1, 2021. Though the adjustments are substantial (the document outlining the revisions

is nearly 2,500

pages!), there

are a few that

deserve high-

The most sig-

nificant modifi-

cation contained

policy involves

lighting.

within the



Dr. Dempsey



Dr. Ramachandran

revisions to E/M codes for office visits. While the changes eliminate **99201**, they preserve other graded levels for visits, with increases to the relative value units (RVUs) for most levels. The most

welcome changes for clinicians are twofold. First, billing no longer needs to be based on the maddening practice of trying to meet a minimum number of points from the history and exam. Clinicians can instead now bill based on time spent. The second refreshing modification is that time-based billing need no longer be solely face-toface but can now be based on the realities of clinical practice today,

ie, reviewing information and coordinating care with others.

Thus, these re-valued levels will allow outpatient physicians to bill based on time spent on things other than the office visit, such as time to review lab work and coordinate care with other specialties.

There will also be small changes to billing for pulmonary function testing, bronchoscopy (including the option for new indications for endobronchial valves), and for "brief communications via technology." For a recap of these and other changes coming in January 2021, CHEST and ATS have produced a free webinar that is found online at: http://www.chestnet.org/ Guidelines-and-Resources/Resources/ Clinical-Practice-Resources.

> Timothy Dempsey, MD, MPH Steering Committee Fellow-in-Training Deep Ramachandran, MD, FCCP Steering Committee Member

Transplant

Investigating clinical practice of lung transplantation in systemic sclerosis

Interstitial lung disease (ILD) as a sequela of systemic sclerosis (SSc) poses a significant health concern. Patients with SSc-ILD experience symptoms of shortness of breath, reduced exercise capacity, and limited activities of daily living. Inducing fibrotic parenchymal change and pulmonary hypertension, SSc-ILD presents as both the most common extra-cutaneous manifestation and

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reducing the number of required external incisions will continue to broaden the patient selection criteria. As we move from a "stimulation" to a precision-tailored "stimulation and titration" approach, the mid- to long- term data supporting UAS remains very promising with 5-year follow-up demonstrating sustained polysomnographic and subjective reported outcomes in well selected patients.

Dr. Awad is Assistant Professor - Department of Otolaryngology/Head & Neck Surgery, and Chief - Division of Sleep Surgery; Northwestern University, Chicago, Illinois. Dr. Capasso is Associate Professor - Department of Otolaryngology/Head & Neck Surgery, and Chief - Division of Sleep Surgery; Stanford Hospital and Clinics, Stanford, California.

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Continued from page 30

cause for mortality in this cohort (Mathai et al. *Springer*. 2014;139). Although rare, the prognosis of SSc-ILD is both difficult to understand and complex to manage.

With lung transplant being a treatment for end-stage pulmonary disease, the role for lung



Dr. Louis

transplantation in SSc-ILD is considered; however, it remains controversial. Published literature exist without consensus. According to the recommendations of ISHLT,

SSc is to be "carefully selected," however, for some institutions, SSc remains a relative contraindication for lung transplant as definitive therapy (Weill et al. *J Heart Lung Transplant*. 2014;34[1]:1). Disease-specific concerns for SSc patients following lung transplant are esophageal dysmotility, dysphagia, gastroparesis, aspiration, and reflux disease. These comorbidities are associated with worsening prognosis in transplant survival (De

Cruz, et al. *Curr Opin Rheumatol*. 2013;25[6]:714).

As clinical practices vary significantly in the management of SSc-ILD, we will survey transplant pulmonologists and surgeons from programs listed in Scientific Registry of Transplant Recipients (SRTR). We will evaluate transplant candidacy, preoperative transplant testing, postoperative transplant care, and outcomes. With this survey, we plan to determine the key practices of lung transplant programs regarding candidacy of patients with SSc-ILD perioperative management.

Clauden Louis, MD Fellow-in-Training Member

Women's lung health

Asthma and sex hormones

Overall asthma prevalence, severity, exacerbation rate, hospitalizations, and mortality are higher among women than men. Population studies show that asthma becomes more prevalent and severe in women following puberty, particularly in women with early menarche or multiple gestations. These findings suggest that sex hormones are important to the development and severity of asthma. Additional confounding variables include obesity, exposures,

atopy, and age (Zien, et al. Curr Allergy Asthma Rep. 2015;15[6]:28).

Recent studies further define the gender disparity by detailing







Dr. Pisani

sex hormone differences in men and women with asthma. Han and colleagues recently reported on a cross-sectional study of serum-free testosterone and estradiol levels in over 7,000 adults in the National Health and Nutrition Examination Survey (NHANES, 2013-2016) (Han, et al. *Am J Respir Crit Care Med.* 2020;201[2]:158).

Elevated free testosterone levels were associated with lower odds of current asthma in women. After stratification for obesity, elevated free testosterone and estradiol levels were associated with reduced odds of current asthma in obese women, and elevated estradiol was

associated with lower odds of asthma in non-obese men. It should be noted that increased luteal phase progesterone levels have also been



Dr. Poole

implicated in increasing airway hyperresponsiveness (AHR) in asthmatics (Lipworth, et al. *Am J Respir Crit Care Med.* 2019; Oct 22, 2019). In summary, testosterone is suggested to pro-

vide a protective, anti-inflammatory effect in women with asthma (Sathish, et al. *Pharmacol Ther*. 2015;150:94). Obesity interaction with sex hormones highlights its role as an important risk factor and disease modifier (Peters, et al. *J Allergy Clin Immunol*. 2018;141:1169). Future studies should continue to expand upon the role of sex hormones in relation to multiple confounders. These insights will continue to define mechanisms that can be manipulated leading to novel pathway targeted therapies.

Candace Huebert, MD, FCCP Margaret Pisani, MD, MPH, FCCP Jill Poole, MD Steering Committee Members

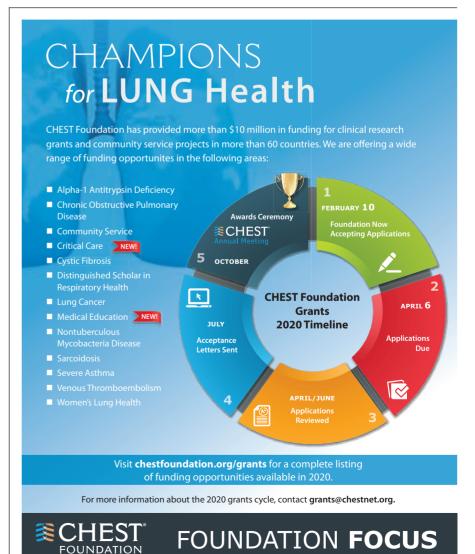




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Cultivating resilience against nurse burnout

From AACN Bold Voices

Developing resilient nurses and work environments can help organizations prevent burnout.

The Joint Commission released an advisory urging health-care organizations to promote resilience as a way to combat and prevent nurse burnout.

"Developing resilience to combat nurse burnout," in The Joint Commission's Quick Safety newsletter, notes that 15.6% of all nurses in a survey of more than 2,000 healthcare partners reported experiencing burnout "with emergency room nurses being at a higher risk," which can affect the physical and emotional health of staff, as well as patient safety, mortality, and satisfaction.

According to data presented in the article, omitting nurses from the decision-making process, security risks, a need for more autonomy, and staffing challenges are the most common factors associated with nurse burnout.

To promote resilience in nurses and in the work environment, which can help prevent and reduce burnout among nurses and other frontline staff, health-care organizations should consider a number of strategies, including the following:

- Teach nurses and nurse leaders the elements of resilience, such as empowerment and colleague support, and how to identify symptoms of burnout.
- Provide positive role models and mentors.
- "Engage nursing input in staff meetings by posting an agenda and asking for additional items the nurses would like to discuss or present."
- Measure the well-being of healthcare providers; try interventions and then assess their effectiveness.

The article also notes that "mindfulness and resilience training alone cannot effectively address burnout unless the leadership is simultaneously reducing and eliminating barriers and impediments to nursing workflow, such as staffing and workplace environment concerns"

Reference

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This month in the journal CHEST®

Editor's Picks

BY PETER J. MAZZONE, MD, MPH, FCCP

Editor in Chief

Original Research

Safety and Effectiveness of Bronchial Thermoplasty When ${\rm FEV}_1$ Is Less Than 50%.

By Dr. D. Langton, et al.

Utilization and Outcomes of Thrombolytic Therapy for Acute Pulmonary Embolism: A Nationwide Cohort Study.

By Dr. S. E. Beyer, et al.

An Individualized Prediction Model for Long-term Lung Function Trajectory and Risk of



COPD in the General Population. By Dr. W. Chen, et al.

CHEST Review

Six-Minute Walk Test: Clinical Role, Technique, Coding, and Reimbursement.

By Dr. P. Agarwala, et al.

How I Do It

An Algorithmic Approach to the Interpretation of Diffuse Lung Disease on Chest CT Imaging: A Theory of Almost Everything. By Dr. J. F. Gruden, et al.

Meet the FISH Bowl Finalists

HEST 2019 marked the inaugural FISH Bowl competition for attendees. Inspired by Shark Tank, our kinder, gentler, yet still competitive and cutting-edge FISH Bowl (Furthering Innovation and Science for Health) featured CHEST members disrupting our



Dr. Gao

beliefs about how clinical care and education are performed. As health-care providers, they presented innovative ideas pertaining to education and clinical disease

for pulmonary, critical care, and sleep medicine. Six finalists were chosen from dozens of submissions, and three emerged winners. In this new Meet the FISH Bowl Finalists series, CHEST introduces you to many of them – including Clinical Disease Category Winner Dr. Gao.

Name: Catherine Gao, MD Institutional Affiliation: Northwestern University

Position: Pulmonary & Critical Care Fellow

Title: Time to Vent: A Blended Learning Experience

Brief Summary: It is difficult for ventilated patients to communicate, and this is cited by patients as one of the most stressful parts of their ICU stays. Brain-computer interface technology allows for communication to happen directly from brain wave activity and represents a potential tool to fix this problem.

- 1. What inspired your innovation? Every clinician has had the frustrating experience of difficulty communicating with their ventilated patients, and it is even more challenging for patients and their families. I read about recent advances in communication methods from the neurology literature and thought about expanding this technology to the ICU.
- 2. What do you see as challenges to your innovation gaining widespread acceptance? How can they be overcome? This is still an early idea with technology still being developed there have been investments by the military and large tech companies, as well

as universities – it will take time for the technology to be ready for clinical use, and there will be troubleshooting needed as with all new technologies.

- 3. What impact has winning FISH Bowl 2019 had on your vision for the innovation? The judges gave great feedback and had wonderful suggestions and questions. This is just the beginning.
- 4. How do you think your success at FISH Bowl 2019 will continue to impact your career overall in the months and years to come? This was a great experience to talk about interesting ideas, and I had the opportunity to talk to many people with similar interests after the presentation. I thank CHEST for this amazing opportunity and look forward to the years to come!



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News from the CHEST Board of Regents

BY VERA A. DE PALO, MD, **FCCP**

he first quarterly meeting of your CHEST Board of Regents for the 2019-2020 CHEST year occurred from January 30 to February 1. We were welcomed to Coronado, California, by CHEST's new President Stephanie M. Levine, MD,

FCCP, who began by reviewing the success of the CHEST 2019 Annual Meeting. The meeting had both the highest attendance of medical professionals and the highest total at-

tendance in CHEST history, as well as CHEST's largest Fellow-in-Training attendance. There was also a significant increase in the number of international colleagues who attended the meeting. Dr. Levine next reported on upcoming CHEST activities including six live-learning courses scheduled to occur before

May, the CHEST Congress in collaboration with the Italian delegation in Bologna, Italy in June, ongoing planning for CHEST 2020, the next volume of SEEK Critical Care and two



Dr. De Palo

additional cough guidelines.

Both the CHEST Boards and our members benefit from an incredibly talented staff. As for any team whose members bring a variety of talents and background experiences, aligning to propel the team mission forward requires excellent understanding on individual strengths and weaknesses and strong communication. For several months, under the guidance of CHEST EVP/CEO Robert Musacchio, PhD, CHEST senior staff have participated in team-development activities. Our Presidents, along with Dr. Musacchio and the executive leadership team, wanted to further the process by including all members of the Board of Regents and the Board of Trustees in teamand Board-development activities at this meeting. Exercises focused on the recognition of organizational strengths and opportunities, as well as improving team communication. The insight gained through these activities will undoubtedly pay dividends longitudinally as we continue to move CHEST toward the goals needed to meet the needs of our membership.

Other agenda items covered during the Winter Board meeting included:

- The Governance Committee discussed continued efforts for Board orientation and mentorship of new members. A strategy of self-assessment and feedback has been planned to allow individuals to develop the skills that they need to strengthen the Boards as a whole.
- The Guidelines Task Force presented recommendations about the scope and scale of the CHEST

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Presenters:



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Susan Gregory MD, FACP, FCCP Medical Director, Critical Care Pulmonology Associates Lankenau Medical Center



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Hot Topics in the journal CHEST - February 2020

BY CHRIS CARROLL, MD, FCCP

ach month, we ask our Social Media Co-Editors of CHEST, to weigh in on the hot topics in CHEST.

There are some great articles in Feruary, and these were three of my favorites.

Estimated Ventricular Size, Asthma Severity, and Exacerbations

Asthma is the most common chronic respiratory disease; but despite the prevalence, there is still much to learn about the treatment and pathophysiology of severe asthma. The use of CT scans has become increasingly common to assess patients with pulmonary disease. In this issue of CHEST, Dr. Samuel Ash and colleagues from the Severe



Dr. Carroll

Asthma Research Program Investigators used CT scans to assess cardiac measurements (including right, left, and total epicardial cardiac ventricular volume indices) and pulmonary

arterial and ascending aortic diameter and compared these parameters with asthma severity in a cohort of 233 patients with asthma.

Dr. Ash and colleagues found that patients with severe asthma had smaller left, right, and biventricular volumes than healthy control subjects and patients with mild to moderate asthma. Additionally, in a multivariate analysis, they found that

patients with smaller ventricular volumes had increased rates of asthma exacerbations, both in the year prior to enrollment and during follow-up. Reduced ventricular size may be a useful marker for severe asthma; however, further study is needed.

Use of Imaging and Diagnostic Procedures After Low-Dose CT Screening for Lung Cancer

Translating clinical trials into the real world is challenging for all fields of medicine. In 2011, the National Lung Screening Trial (NLST) showed that annual lowdose CT screening of high-risk individuals could reduce risk of lung cancer death and set high standards for subsequent screenings and testing. In an article in this month's CHEST, Dr. Shawn Nishi and colleagues aimed to assess the rates of follow-up testing in the real world.

In a retrospective review of a national commercial insurance database, Dr. Nishi and colleagues examined the frequency of diagnostic imaging and procedures in 11,520 patients in the 12 months after screening. They found relatively low rates of diagnostic imaging after screening and lower rates than found in the NLST (13.8-17.7% vs 21.7% in the NLST). Additionally, they found HIGHER rates of invasive procedures compared with the NLST, with nearly double the rates of bronchoscopy and triple the rates of percutaneous biopsy and thoracoscopy. This important study raises significant questions about the practice of low-dose CT screening for lung cancer and how the recommendations from the NLST are being implemented in the real world.

Critically Ill Patients With HIV: 40 Years Later

Finally, comes this excellent review by Dr. Élie Azoulay and colleagues reflecting on the state of critical care for patients with HIV. As a trainee, I vividly remember taking care of patients with HIV and AIDS. As a third-year medical student, my first patient at the VA hospital had HIV and I still remembering him admonishing me not to stick myself as I drew his blood each morning.

In the early 90s, HIV was a death sentence—but so much has changed in 40 years. Now, when admitted patients with HIV (and treated with combination antiretroviral therapies) are admitted to the ICU, they are more commonly admitted for non-AIDS-related events. In this excellent comprehensive review in this month's CHEST, Dr. Azoulay and colleagues review the state of the art for the management of critically ill, HIV-infected patients.





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Guidelines program moving forward, including several options as to how CHEST could deploy available resources to meet member needs, which led to a robust discussion about quality of guidelines, quantity of guidelines, and how they could both be optimized.

The NetWorks Task Force reported on their progress toward designing a system that better allows the leaders of our 22 NetWorks opportunities to curate and create sustainable resources for NetWork members, increase their digital presence, and engage more CHEST members by creat-

ing more leadership opportunities within the current NetWork structure.

The next face-to-face meeting of the Board of Regents will occur in April at CHEST Headquarters in Glenview, Illinois; the Spring meeting is also an opportunity for our main committees (Training and Transitions, Guidelines Oversight, Membership, Council of NetWorks, among others) to meet face-to-face to develop plans for the coming year. If you want to get more involved in CHEST, please watch for the upcoming call for applications for leadership positions coming this spring.

