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CHEST® Physician

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Photo courtesy the Truth Initiative

Dr. Elizabeth C. Hair (right) speaks to study lead author Dr. Lauren Czaplicki in the Truth Initiative office in front of the "monster wall." The mural conveys a message with words supplied by teens about what this generation can do to end tobacco use.

Vaping marketers take aim at youth through social media

BY THERESE BORDEN
MDedge News

JUUL and JUUL-like products, popular vaping devices, are being promoted with a large volume of social media posts directed at young people with targeted messages and images, a study of e-cigarette promotion has found.

In 2018, the JUUL company declared a commitment to support efforts to raise the age of legal purchase of tobacco to age 21 years in all U.S. states. In addition, JUUL deleted its official Facebook and Instagram accounts in November 2018, but the promotion of these products has continued through affiliated marketing campaigns from other online vendors.

Vaping among teens has shot up in popularity in recent years. The prevalence of vaping among young people aged 16-19 years has been estimated at 16% in 2018, up from 11% in 2017 (BMJ. 2019 Jun 19. doi: 10.1136/bmj.12219). A study published in JAMA Pediatrics (2019;173[7]:690-92) found that an estimated 81% of users following a popular Twitter account (@JUULvapor) were aged 13-20 years, with 45% in the 13- to 17-year age range.

Elizabeth C. Hair, PhD, senior vice president of the Truth Initiative Schroeder Institute, and a team of investigators conducted a study of the "proliferation of JUUL-related content across

VAPING // *continued on page 7*

Most patients hospitalized with pneumonia receive excessive antibiotics

BY ANDREW D. BOWSER
MDedge News

Two-thirds of patients hospitalized with pneumonia received an excess duration of antibiotics, according to a recent study of more than 6,000 patients.

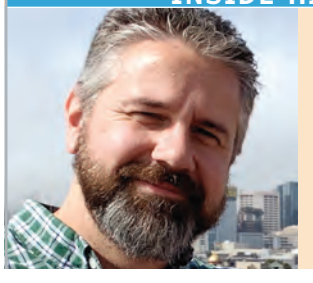
Longer antibiotic courses did not increase the survival rate or prevent any subsequent health care utilization, authors said; instead, they increased the risk of patient-reported adverse events.

The findings bolster a growing body of evidence showing that short-course therapy for pneumonia is safe and that longer durations are not only unnecessary, but "potentially harmful," said Valerie M. Vaughn, MD, assistant professor of medicine at the University of Michigan, Ann Arbor, and coinvestigators.

"Reducing excess treatment durations should be a top priority for antibiotic stewardship nationally," the investigators wrote in their report,

ANTIBIOTICS // *continued on page 8*

INSIDE HIGHLIGHT



NEWS FROM CHEST

Pulmonary Perspectives®

Vaping in 2019: Risk vs reward

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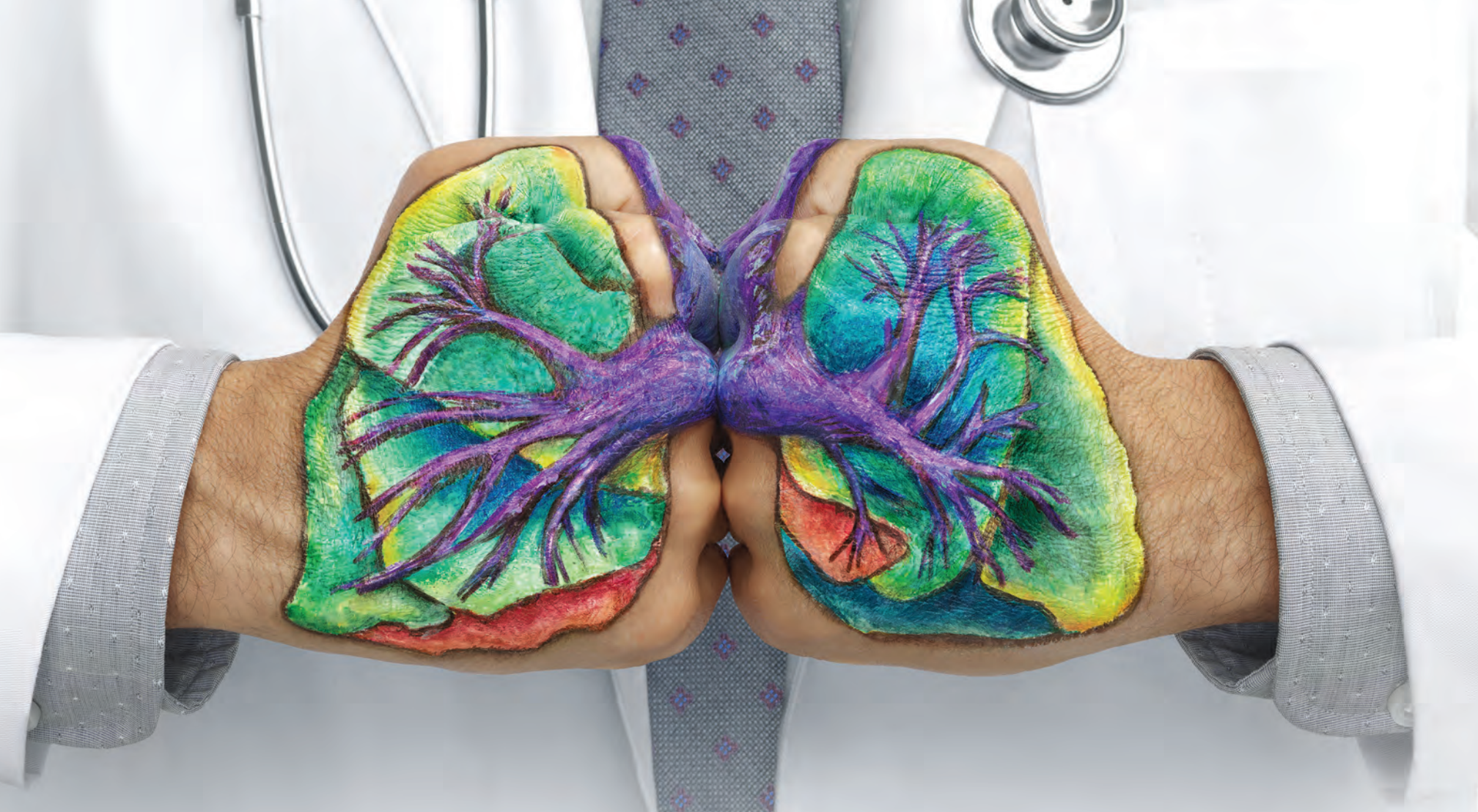

Indication

Esbriet® (pirfenidone) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

Select Important Safety Information

Elevated liver enzymes: Patients treated with Esbriet had a higher incidence of ALT and/or AST elevations of ≥3× ULN (3.7%) compared with placebo patients (0.8%). In some cases, these have been associated with concomitant elevations in bilirubin. No Esbriet-related cases of liver transplant or death due to liver failure have been reported. However, combined elevations of transaminases and bilirubin without evidence of obstruction is considered an important predictor of severe liver injury that could lead to death or the need for a transplant.

Measure ALT, AST, and bilirubin levels prior to initiating Esbriet, then monthly for the first 6 months, and every 3 months thereafter. Dosage modifications or interruption may be necessary.

Photosensitivity reaction or rash: Patients treated with Esbriet had a higher incidence of photosensitivity reactions (9%) compared with placebo patients (1%). Patients should avoid or minimize exposure to sunlight and sunlamps, regularly use sunscreen (SPF 50 or higher), wear clothing that protects against sun exposure, and avoid concomitant medications that cause photosensitivity. Dosage reduction or discontinuation may be necessary.

Gastrointestinal (GI) disorders: Patients treated with Esbriet had a higher incidence of nausea, diarrhea, dyspepsia, vomiting, gastroesophageal reflux disease (GERD), and abdominal pain. GI events required dose reduction or interruption in 18.5% of 2403 mg/day Esbriet-treated patients, compared with 5.8% of placebo patients; 2.2% of 2403 mg/day Esbriet-treated patients discontinued treatment due to a GI event, compared with 1.0% of placebo patients. The most common (>2%) GI events leading to dosage reduction or interruption were nausea, diarrhea, vomiting, and dyspepsia. Dosage modifications may be necessary.

Adverse reactions: The most common adverse reactions (≥10%) were nausea, rash, abdominal pain, upper respiratory tract infection, diarrhea, fatigue, headache, dyspepsia, dizziness, vomiting, anorexia, GERD, sinusitis, insomnia, weight decreased, and arthralgia.

Drug Interactions:

CYP1A2 inhibitors: Concomitant use of Esbriet and strong CYP1A2 inhibitors (e.g., fluvoxamine) is not recommended, as CYP1A2 inhibitors increase systemic exposure of Esbriet. If discontinuation of the CYP1A2 inhibitor prior to starting Esbriet is not possible, dosage reductions of Esbriet are recommended. Monitor for adverse reactions and consider discontinuation of Esbriet.

Concomitant use of ciprofloxacin (a moderate CYP1A2 inhibitor) at the dosage of 750 mg BID and Esbriet are not recommended. If this dose of ciprofloxacin cannot be avoided, dosage reductions of Esbriet are recommended, and patients should be monitored.

Moderate or strong inhibitors of both CYP1A2 and other CYP isoenzymes involved in the metabolism of Esbriet should be avoided during treatment.

CYP1A2 inducers: Concomitant use of Esbriet and strong CYP1A2 inducers should be avoided, as CYP1A2 inducers may decrease the exposure and efficacy of Esbriet.

Specific Populations:

Mild to moderate hepatic impairment: Esbriet should be used with caution in patients with Child Pugh Class A and B. Monitor for adverse reactions and consider dosage modification or discontinuation of Esbriet as needed.

Severe hepatic impairment: Esbriet is not recommended for patients with Child Pugh Class C. Esbriet has not been studied in this patient population.

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Help preserve more lung function. Reduce lung function decline.[1–3]

STUDIED IN A RANGE OF PATIENTS

Clinical trials included patients with IPF with a range of clinical characteristics, select comorbidities, and concomitant medications[4]

DEMONSTRATED EFFICACY

In clinical trials, Esbriet preserved more lung function by delaying disease progression for patients with IPF[1–4]*

ESTABLISHED SAFETY AND TOLERABILITY

The safety and tolerability of Esbriet were evaluated based on 1247 patients in 3 randomized, controlled trials[1†]

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Genentech offers a breadth of patient support and assistance services to help your patients with IPF[‡]

WORLDWIDE PATIENT EXPERIENCE

More than 37,000 patients have taken pirfenidone worldwide[4§]

Mild (CL_{cr} 50-80 mL/min), moderate (CL_{cr} 30-50 mL/min), or severe (CL_{cr} <30 mL/min) renal impairment: Esbriet should be used with caution. Monitor for adverse reactions and consider dosage modification or discontinuation of Esbriet as needed.

End-stage renal disease requiring dialysis: Esbriet is not recommended. Esbriet has not been studied in this patient population.

Smokers: Smoking causes decreased exposure to Esbriet which may affect efficacy. Instruct patients to stop smoking prior to treatment and to avoid smoking when using Esbriet.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch or to Genentech at 1-888-835-2555.

Please see Brief Summary of Prescribing Information on adjacent pages for additional Important Safety Information.

References: 1. Esbriet Prescribing Information. Genentech, Inc. October 2017. **2.** King TE Jr, Bradford WZ, Castro-Bernardini S, et al; for the ASCEND Study Group. A phase 3 trial of pirfenidone in patients with idiopathic pulmonary fibrosis [published correction appears in *N Engl J Med.* 2014;371(12):1172]. *N Engl J Med.* 2014;370(22):2083–2092. **3.** Noble PW, Albera C, Bradford WZ, et al; for the CAPACITY Study Group. Pirfenidone in patients with idiopathic pulmonary fibrosis (CAPACITY): two randomised trials. *Lancet.* 2011;377(9779):1760–1769. **4.** Data on file. Genentech, Inc. 2016.

Learn more about Esbriet and how to access medication at EsbrietHCP.com

IPF=idiopathic pulmonary fibrosis.

*The safety and efficacy of Esbriet were evaluated in three phase 3, randomized, double-blind, placebo-controlled, multicenter trials in which 1247 patients were randomized to receive Esbriet (n=623) or placebo (n=624).[1] In ASCEND, 555 patients with IPF were randomized to receive Esbriet 2403 mg/day or placebo for 52 weeks. Eligible patients had percent predicted forced vital capacity (%FVC) between 50%–90% and percent predicted diffusing capacity of lung for carbon monoxide ($\%DL_{co}$) between 30%–90%. The primary endpoint was change in %FVC from baseline at 52 weeks.[2] In CAPACITY 004, 348 patients with IPF were randomized to receive Esbriet 2403 mg/day or placebo. Eligible patients had %FVC ≥50% and $\%DL_{co}$ ≥35%. In CAPACITY 006, 344 patients with IPF were randomized to receive Esbriet 2403 mg/day or placebo. Eligible patients had %FVC ≥50% and $\%DL_{co}$ ≥35%. For both CAPACITY trials, the primary endpoint was change in %FVC from baseline at 72 weeks.[3] Esbriet had a significant impact on lung function decline and delayed progression of IPF vs placebo in ASCEND.[1,2] Esbriet demonstrated a significant effect on lung function for up to 72 weeks in CAPACITY 004, as measured by %FVC and mean change in FVC (mL).[1,3,4] **No statistically significant difference vs placebo in change in %FVC or decline in FVC volume from baseline to 72 weeks was observed in CAPACITY 006.[1,3]**

†In clinical trials, serious adverse reactions, including elevated liver enzymes, photosensitivity reactions, and gastrointestinal disorders, have been reported with Esbriet. Some adverse reactions with Esbriet occurred early and/or decreased over time (ie, photosensitivity reactions and gastrointestinal events).[1]

‡Esbriet Access Solutions offers a range of access and reimbursement support for your patients and practice. Clinical Coordinators are available to educate patients with IPF. The Esbriet® Inspiration Program™ motivates patients to stay on treatment.

§The safety of pirfenidone has been evaluated in more than 1400 subjects, with over 170 subjects exposed to pirfenidone for more than 5 years in clinical trials.[1]

Esbriet®
(pirfenidone) tablets 267 mg 801 mg

Malpractice cases often based on diagnostic errors

BY ALICIA GALLEGOS
MDedge News

A third of medical malpractice cases associated with patient death or permanent disability result from diagnostic errors by health providers, an analysis finds.

Lead investigator David E. Newman-Toker, MD, PhD, of Johns Hopkins University, Baltimore, and colleagues reviewed malpractice claims during 2006-2015 from medical liability insurer CRICO's Comparative Benchmarking System database, which represents 30% of all malpractice claims in the United States.

Investigators sought to identify diseases accounting for the majority of serious diagnosis-related harms associated with the claims. Of 55,377 closed claims, researchers identified 11,592 diagnostic error

cases, of which 7,379 resulted in high-severity harm.

Of the high-severity claims, 34% stemmed from inaccurate or delayed diagnosis (Diagnosis. 2019 Jul 11. doi: org/10.1515/dx-2019-0019).

The majority of diagnostic mistakes (74%) causing the most severe harm were attributable to cancer (38%), vascular events (23%), and infection (14%). These cases resulted in nearly $2 billion in malpractice payouts over a 10-year period, investigators found.

Clinical judgment factors were the primary reason behind the alleged errors, specifically: failure or delay in ordering a diagnostic test, narrow diagnostic focus with failure to establish a differential diagnosis, failure to appreciate and reconcile relevant symptoms or test results, and failure or delay in obtaining consultation or referral and misinterpretation of diagnostic studies.

"Diagnostic errors are the most common, the most catastrophic, and the most costly of medical errors," Dr. Newman-Toker said at a press conference July 11. "We know that this is a major problem, at an individual, personal level, but also at a societal level and something we really have to take action toward fixing."

This study breaks new ground by drilling into the major diseases most commonly associated with diagnostic errors, Dr. Newman-Toker said. In the cancer category, the most common cancers linked to severe harm were lung, breast, colorectal, prostate, and melanoma. In the vascular category, the most common conditions were stroke; myocardial infarction; venous thromboembolism; aortic aneurysm and dissection; and arterial thromboembolism. In the area of infection, sepsis, meningitis and encephalitis, spinal abscess, pneumonia, and endocarditis were the most common infections identified.

Dr. Newman-Toker

The findings provide a starting point to make improvements in the area of medical errors, said Dr. Newman-Toker, president of the Society to Improve Diagnosis in Medicine, an organization that aims to improve diagnosis and eliminate harm from diagnostic error.

"Although diagnostic errors happen everywhere, across all of medicine in every discipline with every disease, we might be able to take a big chunk out of this problem if we save a lot of lives and prevent a lot of disability and if we focus some energy on tackling these problems," he said. "It at least gives us a starting place and a road map for how to move the ball forward in this regard."

The Society to Improve Diagnosis in Medicine has called on Congress to invest more funding into research to address diagnostic errors. Society CEO and cofounder Paul L. Epner noted that the 2019 House appropriations bill proposes not less than $4 million for diagnostic safety and quality research, which is up from $2 million last year.

"It's a small step, but in the right direction," Mr. Epner said. "[However,] the federal investment in research remains trivially small in relation to the public burden. That's why we urge Congress to commit to research funding levels proportionate to the societal cost, in both human lives and in dollars."

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Value-based metrics gain ground in physician employment contracts

BY GREGORY TWACHTMAN
MDedge News

Physician employment contracts increasingly include value- and quality-based metrics as bases for production bonuses, according to an analysis of recruitment searches from April 1, 2018, to March 31, 2019.

Metrics such as physician satisfaction rates, proper use of EHRs, following treatment protocols, and others that don't directly measure volume are becoming more commonplace in employment contracts, though volume measures still are included, according to Phil Miller, vice president of communications at health care recruiting firm Merritt Hawkins and author of the company's 2019 report on physician and advanced practitioner recruiting incentives, released July 8.

Pulmonology searches ranked 16th in the top 20 most requested searches in the 2018-2019 review period. The specialty logged 56 search requests in the most recent review period.

Of 70% of searches that offered a production bonus, 56% featured a bonus based at least in part on quality metrics, up from 43% in 2018. The finding represents the highest percent of contracts offering a quality-based bonus that the company has tracked, according to the report.

Pulmonology searches ranked 16th in the top 20 most requested searches in the 2018-2019 review period. The specialty logged 56 search requests in the most recent review period, up from 40 in the previous period, but down from the six-review period high of 62 in the 2016-2017 review period.

Despite searches increasing, average salary before benefits and bonuses dipped in 2018-2019 to $399,000 from $418,000 in the previous review period, which was also the high over the last six review periods.

Merritt Hawkins' review is based on a sample of the 3,131 permanent physician and advanced practitioner search assignments that Merritt Hawkins and its sister physician staffing companies at AMN Healthcare have ongoing or were engaged to conduct from April 1, 2018, to March 31, 2019.

Other common value-based metrics include reduction in hospital readmissions, cost containment, and proper coding.

While value-based incentives are on the rise, "facilities that employ physicians want to ensure they stay productive, and 'productivity' still is measured in part by what are essentially fee-for-service metrics, including relative value units [RVUs], net collections, and number of patients seen."

RVUs were used in 70% of production formulas tracked in the 2019 review, up from 50% in the previous year and also a record high.

Mr. Miller noted that employers are seeking the "Goldilocks zone," a balance point between traditional productivity measures and value-based metrics, very much a work in progress right now.

A possible corollary to the increase in production bonuses is a flattening of signing bonuses. During the current review period, 71% of contracts came with a signing bonus, up slightly from 70% in the previous year's report and down from 76% 2 years ago.

Signing bonuses in the review period for the 2019 report averaged $32,692, down from $33,707 during the 2018 report's review period.

Overall, family practice physicians remain the highest in demand for job searches, but specialty practice is gaining ground.

The Baby Boomers also is having an effect – as they age and are experiencing more health issues, more specialists are needed.

"[Older patients] visit the doctor twice or three times the rate of a younger person and they also generate a much higher percentage of inpatient procedures and tests and diagnoses," he said.

However, "younger people are less likely to have a primary care doctor who coordinates their care," Mr. Miller said. "What they typically do is go to an urgent care center, a retail clinic, maybe even [use] telemedicine so they are not accessing the system in the same way or necessarily through the same provider."

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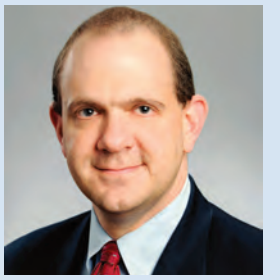

David A. Schulman, MD, FCCP, is Medical Editor in Chief of *CHEST Physician*.

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Vaping messages included giveaways and incentivized friend tagging

// continued from page 1

four themes over a 3-month period: overt promotional content, nicotine- and addiction-related content, lifestyle content, and content related to youth culture." The study appeared online in Tobacco Control (2019 Jul 2. doi: 10.1136/tobaccocontrol-2018-054824).

The investigators did a content analysis of social media posts on Instagram related to JUUL and JUUL-like products from March 1 to May 15, 2018. Hashtag keyword queries of JUUL-related posts on Instagram were collected from the Instagram application programming interface through NUVI, a licensed syndicator of the Instagram firehose.

"The results of this study demonstrate the reach of organic posts that contain JUUL-related content, and posts by third-party vendors of vaping products, who continue to push explicitly youth-targeted advertisements for JUUL and similar e-cigarette products."

The researchers used 50 hashtags to capture and enumerate individual posts. Examples of the hashtags used are #juul, #juuling, #juulvapor, #juulpod, #switchtojuul, and #juulgang.

All posts were included from the official JUUL account and JUUL-related accounts with the highest number of followers at the time of data collection (e.g., @juulcentral, @juulnation, @juul_university, @juul.girls).

The search identified 14,838 posts by 5,201 unique users that featured content relating to product promotion, nicotine and addiction messages, youth culture, and lifestyle themes. Posts were rated as promotional if they included branded content, URLs linking to commercial websites, and hashtags indicating affiliations with commercial sites. Nicotine/addiction posts contained "references to nicotine, including compatible pod-related brand names and nicotine content, as well as any references to addiction or nicotine dependence (e.g., daily use, being an addict, junkie, "nichead," fiend, maniac), or effects of nicotine use (e.g., "buzz"). Youth-themed posts included stylistic features such as jargon or slang, acronyms common among youth (e.g., di4j, doit4juul), youth-oriented cartoons, JUUL wrap imagery, youth entertainment, and music. Posts with references to school, the classroom, and other places frequented by youth and youth social networks, family, and peers were included in the youth-themed category. Lifestyle content referenced "social norms and acceptability-related messages contained any mentions of online or offline communities and peer groups (e.g., collegelife, juulgirls, juulgang, vapeusa, collegedaily, vapelyfe hashtags) as well as JUUL use during social activities, events, social acceptance of JUULing and any mentions of JUULing as a characteristic of cultural or social identity."

Content analysis of the posts found that 34.3% were promotional, 11% referenced nicotine and addiction themes, 55.4% featured youth-oriented cultural themes, and 57% featured lifestyle themes. There was overlap among the categories, for example, the 71.9% of the promotional posts had lifestyle messages included and 86.3% of the nicotine/addiction posts contained lifestyle elements. The promotional posts also contained some hashtags referencing cannabis (#420, #710).

An additional feature of the promotional posts is the incentivizing messages. "More than a third of JUUL-related posts containing overt promotional content that highlights ways to obtain products at reduced cost, such as giveaways and incentivized friend-tagging. This finding is consistent with previous research which found that Twitter users employed person-tagging (e.g., @username) when purchasing JUUL, suggesting friend-tagging plays an important role in motivating product use," the researchers wrote.

The study was limited by the short time frame, the analysis of Instagram postings only, and the limitation of only 50 hashtags. These limitations may result in underreporting of the amount of JUUL-related social media messaging that targets youth. In addition, the investigators did not analyze the origin of accounts or the identity of the individuals creating the content.

"The results of this study demonstrate the reach of organic posts that contain JUUL-related content, and posts by third-party vendors of vaping products, who continue to push explicitly youth-targeted advertisements for JUUL and similar e-cigarette products under JUUL-related hashtags," Dr. Hair wrote. "Our research and studies done by others in the field are one way to build the evidence base to advocate for stricter social media marketing restrictions on tobacco products that are applicable to all players in the field."

She added that the Food and Drug Administration should use its power to restrict e-cigarette manufacturers from using social media to market to young people. "We also think that social media platforms should do more to adopt and enforce strong and well-enforced policies against the promotion of any tobacco products to young adults," she concluded.

The study was sponsored by the Truth Initiative. The Truth Initiative was created as a part of the Master Settlement Agreement (MSA) that was negotiated between the tobacco industry and 46 states and the District of Columbia in 1998. The MSA created the American Legacy Foundation (now known as the Truth Initiative), a nonprofit research and educational organization that focuses its efforts on preventing teen smoking and encouraging smokers to quit.

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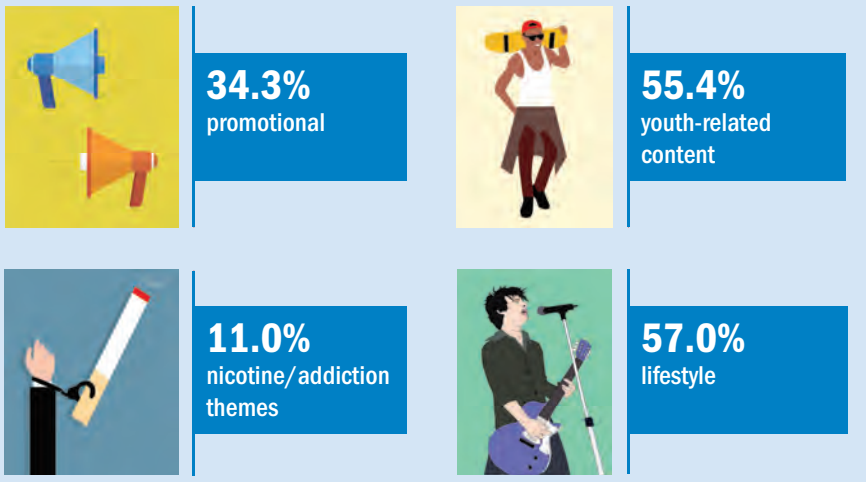
SOURCE: Czaplicki L et al. Tob Control. 2019 Jul 2. doi: 10.1136/tobaccocontrol-2018-054824.

JUUL-related posts on Instagram



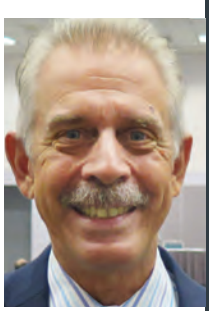
Note: Posts were retrieved from March 1, 2018, to May 15, 2018. Content of 14,858 relevant posts was classified based on four categories that were not mutually exclusive.

Source: Tob Control. 2019 Jul 2. doi: 10.1136/tobaccocontrol-2018-054824

MDEDGE NEWS

VIEW ON THE NEWS

Daniel Ouellette, MD, FCCP, comments: My son is home from college for the summer. I was reminiscing about my days in college: long hair, bell bottoms, government protests. "What's big on campus these days?" I asked my son. "E-cigarettes" he said. "Everyone is using them. I think they're stupid." I was glad that my son was not following the crowd. I wondered if a new generation of nicotine addicts was being created.



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Watch for World Lung Day 2019 news on CHEST social media outlets, and access information and activities at https://bit.ly/2Of7SjI.

Most excess antibiotics were prescribed at discharge // *continued from page 1*

which appears in the Annals of Internal Medicine.

The primary analysis of their retrospective cohort study included 6,481 individuals with pneumonia treated at 43 hospitals participating in a statewide quality initiative designed to improve care for hospitalized medical patients at risk of adverse events. About half of the patients were women, and the median age was 70 years. Nearly 60% had severe pneumonia.

The primary outcome of the study was the rate of excess antibiotic therapy duration beyond the shortest expected treatment duration consistent with guidelines. Patients with community-acquired pneumonia (CAP), representing about three-quarters of the study cohort, were expected to have a treatment duration of at least 5 days, while patients with health care–acquired pneumonia (HCAP) were expected to have at least 7 days of treatment.

Dr. Vaughn

Overall, 4,391 patients (67.8%) had antibiotic courses longer than the shortest effective duration, with a median duration of 8 days, and a median excess duration of 2 days, the researchers noted.

The great majority of excess days (93.2%) were due to antibiotic prescribed at discharge, according to Dr. Vaughn and colleagues.

Excess treatment duration was not linked to any improvement in 30-day mortality, readmission rates, or subsequent emergency department visits, they found.

In a telephone call at 30 days, 38% of patients treated to excess said they had gone to the doctor for an antibiotic-associated adverse event, compared with 31% who received appropriate-length courses ($P = .003$).

Odds of a patient-reported adverse event were increased by 5% for every excess treatment day, the investigators wrote.

Taken together, these findings have implications for patient care, research efforts, and future guidelines, according to Dr. Vaughn and coinvestigators.

"The next iteration of CAP and HCAP guidelines should explicitly recommend (rather than imply) that providers prescribe the shortest effective duration," they said in a discussion of their study results.

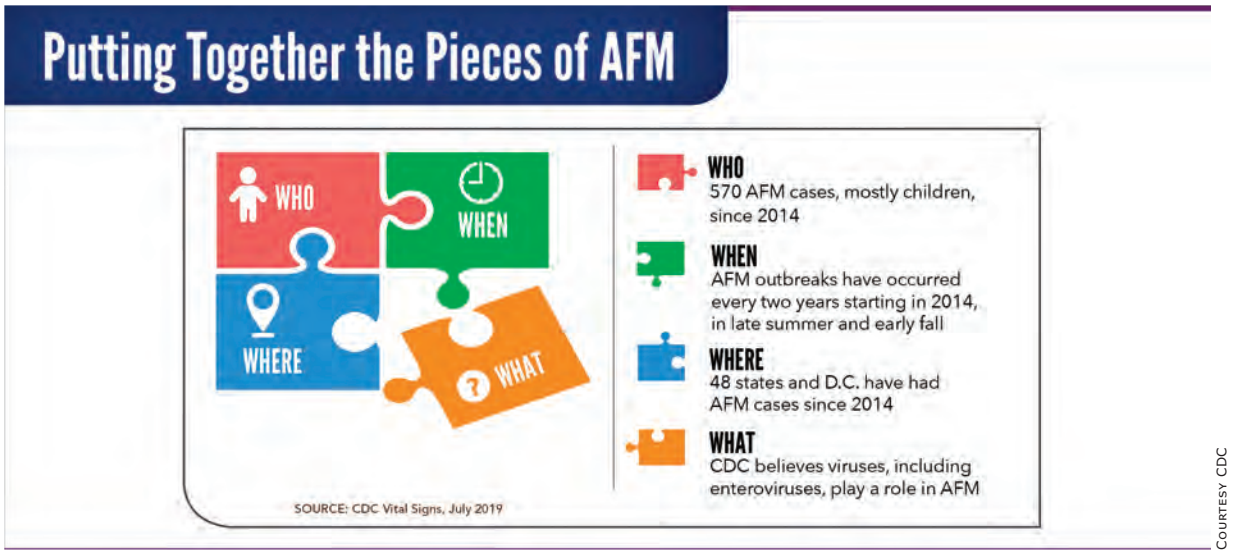
Dr. Vaughn reported no disclosures related to the study. Coauthors reported grants from Blue Cross Blue Shield of Michigan and the Agency for Healthcare Research and Quality, personal fees from Wiley Publishing, and royalties from Wolters Kluwer Publishing and Oxford University Press, among other disclosures.

chestphysiciannews@chestnet.org

SOURCE: Vaughn VM et al. Ann Intern Med. 2019;171:153-63. doi: 10.7326/M18-3640.

CDC: Look for early symptoms of acute flaccid myelitis, report suspected cases

BY JEFF CRAVEN
MDedge News



COURTESY CDC

Watch for the symptoms of acute flaccid myelitis early and report any suspected cases to your health department, the CDC said in a telebriefing.

Acute flaccid myelitis (AFM) is defined as acute, flaccid muscle weakness that occurs less than 1 week after a fever or respiratory illness. Viruses, including enterovirus, are believed to play a role in AFM, but the cause still is unknown. The disease appears mostly in children, and the average age of a patient diagnosed with AFM is 5 years.

"Doctors and other clinicians in the United States play a critical role," Anne Schuchat, MD, principal deputy director of the Centers for Disease Control and Prevention, said in the telebriefing. "We ask for your help with early recognition of patients with AFM symptoms, prompt specimen collection for testing, and immediate reporting of suspected AFM cases to health departments."

While there is no proven treatment for AFM, early diagnosis is critical to getting patients the best care possible, according to a Vital Signs report released today. This means that clinicians should not wait for the CDC's case definition before diagnosis, the CDC said.

"When specimens are collected as soon as possible after symptom onset, we have a better chance of understanding the causes of AFM, these recurrent outbreaks, and developing a diagnostic test," Dr. Schuchat said. "Rapid reporting also helps us to identify and respond to outbreaks early and alert other clinicians and the public."

AFM appears to follow a seasonal and biennial pattern, with the number of cases increasing mainly in the late summer and early fall. As the season approaches where AFM cases increase, CDC is asking clinicians to look out for patients with suspected AFM so cases can be reported as early as possible.

Since the CDC began tracking AFM, the number of cases has risen every 2 years. In 2018, there were 233 cases in 41 states, the highest number of reported cases since the CDC began tracking AFM following an outbreak in 2014, according to a Vital Signs report. Overall, there have been 570 cases of AFM reported in 48 states and the District of Columbia since 2014.

There is yet to be a confirmatory test for AFM, but clinicians should obtain cerebrospinal fluid, serum, stool and nasopharyngeal swab from patients with suspected AFM as soon as possible, followed by an MRI. AFM has unique MRI features, such as gray-matter involvement, that can help distinguish it from other diseases characterized by acute weakness.

In the Vital Signs report, which examined AFM in 2018, 92% of confirmed cases had respiratory symptoms or fever, and 42% of confirmed cases had upper-limb involvement. The median time from limb weakness to hospitalization was 1 day, and time from weakness to MRI was 2 days. Cases were reported to the CDC a median of 18 days from onset of limb weakness, but time to reporting ranged between 18 days and 36 days, said Tom Clark, MD, MPH, deputy director of the division of viral diseases at CDC.

"This delay hampers our ability to understand the causes AFM," he said. "We believe that recognizing AFM early is critical and can lead to better patient management."

In lieu of a diagnostic test for AFM, clinicians should make management decisions through review of patient symptoms, exam findings, MRI, and other test results, and in consulting with neurology experts. The Transverse Myelitis Association also has created a support portal for 24/7 physician consultation in AFM cases.

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SOURCE: Lopez A et al. MMWR Morb Mortal Wkly Rep. 2019;68:1-7.

MIPS: Nearly all eligible clinicians got a bonus for 2018

BY GREGORY TWACHTMAN
MDedge News

Nearly all clinicians who are eligible to participate in the Merit-Based Incentive Payment System (MIPS) track of the Quality Payment Program did so in 2018; most scored above the performance threshold and got a bonus.

According to the most recent data released this month by the Centers for Medicare & Medicaid Services, 98.37% of MIPS-eligible clinicians participated in the program. In the small/solo practice space, 89.20% of MIPS-eligible clinicians participated.

Participation increased from 341,220 clinicians in 2017 to 356,828 clinicians in 2018, while virtually all performed above the performance threshold.

But more importantly, the clinicians are performing better 1 year later with the program, even though fewer are participating.

In 2018, 97.63% of clinicians scored above the performance threshold, up from 93.12% in 2017. There also were fewer clinicians performing at the threshold (0.42% in 2018, down from 2.01% in the previous year) and fewer clinicians scoring below the threshold (1.95%, down from 4.87%).

Exceeding the performance threshold resulted in a bonus to fee schedule payments in 2018, although the agency did not disclose how much money was paid out in performance bonuses.

MIPS scored "improved across performance categories, with the biggest gain in the Quality performance category, which highlights the program's effectiveness in measuring outcomes for beneficiaries," CMS Administrator Seema Verma wrote in a blog post.

The total number of eligible clinicians decreased in 2018 to 916,058, down from 1,057,824 in 2017 because CMS broadened the low-volume threshold to exempt providers from participation requirements.

Participants in a MIPS program alternative payment model saw even more success in 2018.

Participation increased from 341,220 clinicians in 2017 to 356,828 clinicians in 2018, while virtually participants all performed above the performance threshold (100% in 2017 and 99.99% in 2018). The 0.01% that was not above the threshold still met it, while no clinicians in either year that participated in a MIPS alternative payment model performed below the threshold.

Participation in the advanced alternative payment model track increased as well, going from 99,026 in 2017 to 183,306 in 2018.

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C-reactive protein testing reduced antibiotic prescribing in patients with COPD exacerbation

BY ANDREW D. BOWSER
MDedge News

For primary care patients with acute exacerbations of chronic obstructive pulmonary disease (COPD), point-of-care C-reactive protein testing reduced antibiotic use with no evidence of harm, according to a recent randomized, controlled trial.

Point-of-care C-reactive protein (CRP) testing led to fewer antibiotic prescriptions at the initial consultation, according to investigators participating in the PACE study, a multicenter, open-label trial of more than 600 patients with COPD enrolled at of 86 general practices in the United Kingdom.

Patient-reported antibiotic use over the next 4 weeks was more than 20 percentage points lower for the group managed with the point-of-care strategy, compared with those who received usual care, according to the investigators, led by Christopher C. Butler, FMedSci, of the Nuffield Department of Primary Care Health Sciences at the University of Oxford (England).

Less antibiotic use and fewer prescriptions did not compromise patient-reported, disease-specific quality of life, added Dr. Butler and colleagues. Their report appears in the New England Journal of Medicine.

Dr. Christopher C. Butler

In the United States and in Europe, more than 80% of COPD patients with acute exacerbations will receive an antibiotic prescription, according to Dr. Butler and coauthors.

"Although many patients who have acute exacerbations of COPD are helped by these treatments, others are not," wrote the investigators, noting that in one hospital-based study, about one in five such exacerbations were thought to be due to noninfectious causes.

The present study included patients at least 40 years of age who presented to a primary care practice with an acute exacerbation and at least one of the three Anthonisen criteria (increased dyspnea, sputum production, and sputum purulence) intended to guide antibiotic therapy in COPD. A total of 325 were randomly assigned to the CRP testing group, and 324 to a group that received usual care.

Antibiotic use was reported by fewer patients in the CRP testing group, compared with the usual-care group (57.0% vs. 77.4%; adjusted odds ratio, 0.31; 95% confidence interval, 0.20-0.47), the investigators reported.

Only 47.7% of patients in the CRP-guided group received antibiotic prescriptions at the initial consultation, vs. 69.7% of patients in the usual-care group. Hospitalizations over 6 months of follow-up were reported for 8.6% and 9.3% of patients in the CRP-guided and usual-care groups, respectively, while diagnoses of pneumonia were recorded for 3.0% and 4.0%. There was no clinically important difference between groups in the rate of antibiotic-related adverse effects.

"The evidence from our trial suggests that CRP-guided antibiotic prescribing for COPD exacerbations in primary care clinics may reduce patient-reported use of antibiotics and the prescribing of antibiotics by clinicians," the investigators wrote.

The findings from the study are "compelling enough" to support CRP testing to guide antibiotic use in patient who have acute exacerbations of COPD, wrote the authors of an accompanying editorial.

"The trial achieved its objective, which was to show that CRP testing safely reduces antibiotic use," stated Allan S. Brett, MD, and Majdi N. Al-Hasan, MB,BS, of the department of medicine at the University of South Carolina, Columbia.

Point-of-care testing of CRP could be applied even more broadly in clinical practice, Dr. Brett and Dr. Al-Hasan wrote, since testing has been shown to reduce prescribing of antibiotics for suspected lower respiratory tract infections and other common presentations in patients with no COPD.

"Whether primary care practices in the United States would embrace point-of-care CRP testing is another matter, given the regulatory requirements for in-office laboratory testing and uncertainty about reimbursement," they noted.

Reduced antibiotic prescribing in patients with COPD likely has certain benefits, including reducing risk of *Clostridioides difficile* colitis, according to the authors.

The study was supported by the Health Technology Assessment Program of the UK National Institute for Health Research. Dr. Butler reported disclosures related to Roche Molecular Systems and Roche Molecular Diagnostics, among others.

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SOURCE: Butler CC et al. N Engl J Med. 2019 Jul 10;381:111-20. doi: 10.1056/NEJMoa1803185.

PAD risk persists long term after smoking cessation

BY HEIDI SPLETE
MDedge News

Adults who quit smoking reduced their risk for peripheral artery disease in the short term, but remained at increased risk for up to 30 years, compared with never-smokers, based on data from more than 13,000 adults in a community-based study.

Most reports on the impact of smoking cessation on cardiovascular disease have focused on coronary heart disease (CHD), and stroke, while data on the effects of smoking cessation on peripheral artery disease (PAD) are limited, wrote Ning Ding, MBBS, SCM, of the Johns Hopkins Bloomberg School of Public Health, Baltimore, and colleagues.

To compare the impact of smoking on PAD, CHD, and stroke, the researchers used data from the Atherosclerosis Risk in Communities (ARIC) study, which included 15,792 adults aged 45-64 years in four communities. The findings were published in the Journal of the American College of Cardiology.

The study population of 13,355 individuals had no baseline history of PAD, CHD, or stroke. Over a median 26 years of follow-up, the researchers identified 492 cases of PAD, 1,798 cases of CHD, and 1,106 cases of stroke.

The risk of all three conditions began to decline within 5 years of smoking cessation, which could be encouraging to smokers who wish to quit, the researchers noted. In addition, the longer the duration of smoking cessation, the lower the risk for all three conditions.

However, a significantly elevated risk remained for PAD for up to 30 years after smoking cessation and for CHD for up to 20 years after smoking cessation, compared with never-smokers.

The researchers also found a roughly four-fold increased risk for PAD for smokers who smoked for 40 or more pack-years, compared with never-smokers, which was greater than the 2.1 hazard ratio for CHD and 1.8 HR for stroke. In addition, current smokers of at least 1 pack per day had a significantly greater risk of PAD, compared with never-smokers (HR, 5.36) that was higher than the risk for CHD or stroke (HR, 2.38 and HR, 1.88, respectively).

The study findings were limited by the reliance on self-reports, potential misclassification of data, and the potential exclusion of mild PAD cases that did not require hospitalization, the researchers noted. However, the results support the value of encouraging smokers to quit and support the need to include PAD risk in public health information, they said. "The ARIC study was funded by the National Heart, Lung, and Blood Institute, National Institutes of Health. Lead author Dr. Ding had no financial conflicts to disclose; coauthors disclosed relationships with Bristol-Myers Squibb and Fukuda Denshi.

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SOURCE: Ding N et al. J Am Coll Cardiol. 2019 Jul 22;74:498-507. doi: 10.1016/j.jacc.2019.06.003.

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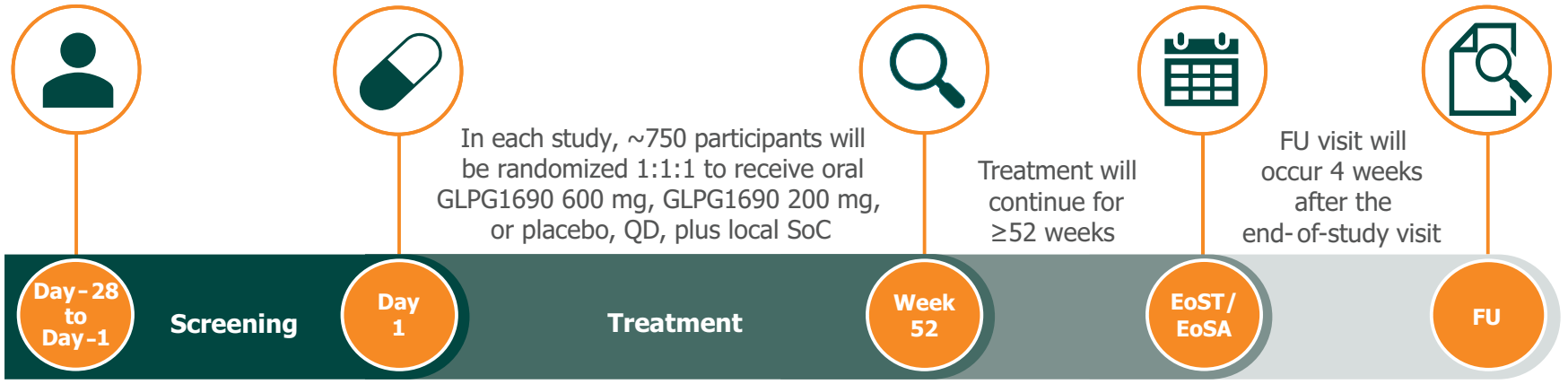
ISABELA will aim to recruit 1500 participants across over 200 sites worldwide, with nearly 80 sites in the US alone



EoSA, end-of-study assessment; EoST, end-of-study treatment; FU, follow-up; QD, once daily; SoC, standard of care

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Risk of cardiac events jumps after COPD exacerbation

BY BIANCA NOGRADY
MDedge News

Acute exacerbations in chronic obstructive pulmonary disease could also trigger a cardiac event such as MI or stroke, particularly in older individuals, new research has found.

In Respirology, researchers report the outcomes of a nationwide, register-based study involving 118,807 patients with chronic obstructive pulmonary disease (COPD) who experienced a major adverse cardiac event after an exacerbation.

They found that the risk of any major cardiac adverse event increased 270% in the 4 weeks after the onset of an exacerbation (95% confidence interval, 3.60-3.80). The strongest association was seen for cardiovascular death, for which there was a 333% increase in risk, but there was also a 257% increase in the risk of acute MI and 178% increase in the risk of stroke.

The risk of major adverse cardiac events was even higher among individuals who were hospitalized because of their COPD exacerbation (odds ratio, 5.92), compared with a 150% increase in risk among those who weren't hospitalized but were treated with oral corticosteroids and 108% increase among those treated with amoxicillin with enzyme inhibitors.

The risk of a major cardiac event after a COPD exacerbation also increased with age. Among individuals younger than 55 years, there was a 131% increase in risk, but among those aged 55-69 years there was a 234% increase, among those aged 70-79 years the risk increased 282%, and among those aged 80 years and older it increased 318%.

Mette Reilev, from the department of public health at the University of Southern Denmark, Odense, and coauthors suggested that acute exacerbations were associated with elevated levels of systemic inflammatory markers such as fibrinogen and interleukin-6, which were potently prothrombotic and could potentially trigger cardiovascular events.

"Additionally, exacerbations may trigger type II myocardial infarctions secondary to an imbalance in oxygen supply and demand," they wrote.

The authors raised the question of whether cardiovascular prevention strategies should be part of treatment recommendations for people with COPD, and suggested that prevention of COPD exacerbations could be justified even on cardiovascular grounds alone.

"Studies investigating the effect of cardiovascular treatment on the course of disease among COPD exacerbators are extremely scarce," they wrote. "Thus, it is currently unknown how to optimize treatment and mitigate the increased risk of [major adverse cardiovascular events] following the onset of exacerbations."

Six authors declared funding from the pharmaceutical industry – three of which were institutional support – unrelated to the study.

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SOURCE: Reilev M et al. Respirology. 2019 Jun 21. doi: 10.1111/resp.13620.

Inhaler technique not to blame for uncontrolled asthma in inner-city study

BY CHRISTINE KILGORE
MDedge News

Inhaler technique may not be the cause of chronic uncontrolled asthma in a population of low-income, inner-city adults with the condition, a study has found.

"Incorrect inhaler technique cannot explain the poor disease control in our patient population," wrote Patrick K. Gleeson, MD, of the University of Pennsylvania, Philadelphia, and coinvestigators. Their report is in the Journal of Allergy and Clinical Immunology: In Practice. "In individuals with poorly controlled asthma, other factors contributing to disease mortality must be considered."

The 586 patients in the study were observed using their inhalers, and their technique was scored by way of a checklist developed for the study. Inhaler technique – widely regarded as a risk factor for poor disease control – was "better than expected," the investigators reported, with 56% of patients using metered-dose inhalers and 64% of those using dry-powder inhalers not making any errors.

"The seeming disassociation between subjects' asthma control and inhaler technique is counterintuitive, and may be explained by important baseline characteristics in our patients," they wrote. For instance, participants had suboptimal living conditions in lower income Philadelphia neighborhoods. Almost a quarter – 23% – were current smokers, and almost half were Medicaid recipients. In addition, their mean body mass index was 35.1 kg/m^2.

The investigators hypothesized that patients with lower health literacy would have poorer technique but found instead that technique did not vary by reading comprehension or numeracy levels.

More than half of the adults in the study had uncontrolled asthma as defined by prednisone use, an emergency department visit, or a hospitalization for asthma in the past 12 months. A subset had moderate to severe disease per a physician's diagnosis, forced expiratory volume in 1 second less than 80% predicted, and improvement with a bronchodilator. All patients, however, were considered to have uncontrolled asthma.

There is "uncertainty" in the field about how to measure inhaler technique, and the technique checklist used in the study "may have omitted potentially important errors," the investigators noted. Still, "good technique predominated among our [population of vulnerable patients]."

The project was supported through awards from the National Institutes of Health/National Heart, Lung, and Blood Institute and the Patient-Centered Outcomes Research Institute.

Coinvestigator Andrea J. Apter, MD, reported that she consults for UpToDate and is an associate editor for the journal. Coinvestigator Knashawn H. Morales, ScD, reported owning stock in Altria Group, British American Tobacco, and Philip Morris International. The other authors reported having no conflicts of interest.

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SOURCE: Gleeson PK. J Allergy Clin Immunol Pract. 2019 Jun 5. doi: 10.1016/j.jaip.2019.05.048.

Tailored intervention boosts asthma self-management

BY JEFF CRAVEN
MDedge News

A needs- and barriers-based intervention that addressed psychosocial, physical, cognitive, and environmental barriers to self-management of asthma for older adults was successful in improving asthma outcomes and management, a recent trial has shown.

"This study demonstrates the value of patient centeredness and care coaching in supporting older adults with asthma and for ongoing efforts to engage patients in care delivery design and personalization," Alex D. Federman, MD, of the division of general internal medicine at Icahn School of Medicine at Mount Sinai, New York, and colleagues wrote in their study, which was published in JAMA Internal Medicine. "It also highlights the challenges of engaging vulnerable populations in self-management support, including modest retention rates and reduced impact over time despite repeated encounters designed to sustain its effects."

The researchers said older adults often have difficulty with self-management tasks like inhaler technique and use of inhaled corticosteroids, which can be caused by various psychosocial, physical, cognitive, or environmental barriers. However, an attempt at creating self-management tools around specific problems, rather than generalized training, has not been traditionally attempted, they noted.

For the SAMBA trial, Dr. Federman and colleagues enrolled 391 patients who were randomized to receive a home-based intervention, clinic-based intervention, or usual care, where an asthma care coach would identify the barriers to asthma control, train the patient in areas of improvement, and provide reinforcement when necessary. Patients were at least age 60 years (15.1% men) with uncontrolled asthma in New York City and were enrolled between February 2014 and December 2017. Researchers used the Mini Asthma Quality of Life Questionnaire, Asthma Control Test, metered-dose inhaler technique, Medication Adherence Rating Scale, and visits to the emergency room to assess outcomes between interventions and usual care, and between home and clinic care. The data were analyzed using the "difference in differences" statistical technique to compare the change differential between the groups.

They found significantly better asthma control scores between the intervention group and the control groups at 3 months (difference-in-differences, 1.2; 95% confidence interval, 0.2-2.2; P = .02), 6 months (D-in-Ds, 1.0; 95% CI, 0.0-2.1; P = .049), and 12 months (D-inDs, 0.6; 95% CI, −0.5 to 1.8; P = .28). Quality of life was significantly improved in the intervention group, compared with control patients (overall effect, chi-squared = 10.5; with 4 degrees of freedom; P = .01), as was adherence to medication (overall effect, chi-squared = 9.5, with 4 degrees of freedom; P = .049), and inhaler technique as measured by correctly completed steps at 12 months (75% vs. 58%). Visits to the emergency room were also lower in the intervention group, compared with the control group (6.2% vs. 12.7%; adjusted odds ratio, 0.8; 95% CI, 0.6-0.99; both P = .03). The researchers noted there were no significant differences between home care and clinic care.

Potential limitations in the study included a lower-than-planned statistical power, 70% retention in the intervention arms, low generalizability of the findings, and lack of blinding on the part of research assistants as well as some improvement in asthma control and outcomes in the control group.

This study was funded in part by the Patient-Centered Outcomes Research Institute. Coauthors Nandini Shroff reported grants from the Patient-Centered Outcomes Research Institute; Michael S. Wolf reported grants from Eli Lilly; and Juan P. Wisnivesky reported personal fees from Sanofi, Quintiles, and Banook, and grants from Sanofi and Quorum. The other authors reported no relevant conflicts of interest.

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SOURCE: Federman AD et al. JAMA Intern Med. 2019. doi: 10.1001/jamainternmed.2019.1201.

Smoking cessation apps share users' personal, health data

BY JEFF CRAVEN
MDedge News

When making prescribing decisions, health care professionals should assume that apps for smoking cessation and depression will share user data with third parties despite claims made in privacy policy statements, recent research shows.

"Mechanisms that potentially enable a small number of dominant online service providers to link information about the use of mental health apps, without either user consent or awareness, appear to be prevalent," Kit Huckvale, MB ChB, MSc, PhD, of Black Dog Institute at the University of New South Wales Sydney, and colleagues wrote in their study. "Mismatches between declared privacy policies and observed behavior highlight the continuing need for innovation around trust and transparency for health apps." The study was published in JAMA Network Open.

Dr. Huckvale and colleagues examined the top 36 depression and smoking cessation apps for Android and iOS in the United States accessed in January 2018; Of the apps downloaded, 15 apps were Android only, 14 apps were iOS only, and 7 apps were available on both platforms. The apps were assessed over a series of two sessions while network traffic was captured during use, which allowed researchers to determine what personal information was in each data transmission and where the information was going.

There were 25 apps with a privacy policy (69%), 22 of 25 apps (88%) described how that app primarily collected data, and only 16 of 25 apps (64%) provided information on secondary uses of data. Despite 23 of 25 apps (92%) addressing "the possibility of transmission of data to any third party," 33 of 36 apps overall (92%) transmitted data to third parties. The two most common entities that received third-party data for marketing, advertising, or analytic purposes were Google and Facebook (29 of 36 apps; 81%). However, 12 of 28 apps (43%) that sent data to Google and 6 of 12 apps (50%) that sent data to Facebook disclosed that they would share data with those companies.

The type of data sent to Google and Facebook consisted of a strong identifier to the device or a username (9 of 33 apps; 27%), or a weak identifier in the form of an advertising identifier or a pseudonymous profile that can link users to their behavior on the app and on other products and platforms (26 of 33 apps; 79%).

"As smartphones continue to gain capabilities to collect new forms of personal, biometric, and health information, it is imperative for the health care community to respond with new methods and processes to review apps and ensure they remain safe and protect personal health information," the researchers concluded.

One of the investigators, Mark E. Larsen, DPhil, reported receiving grants from National Health and Medical Research Council. The other authors reported no conflicts.

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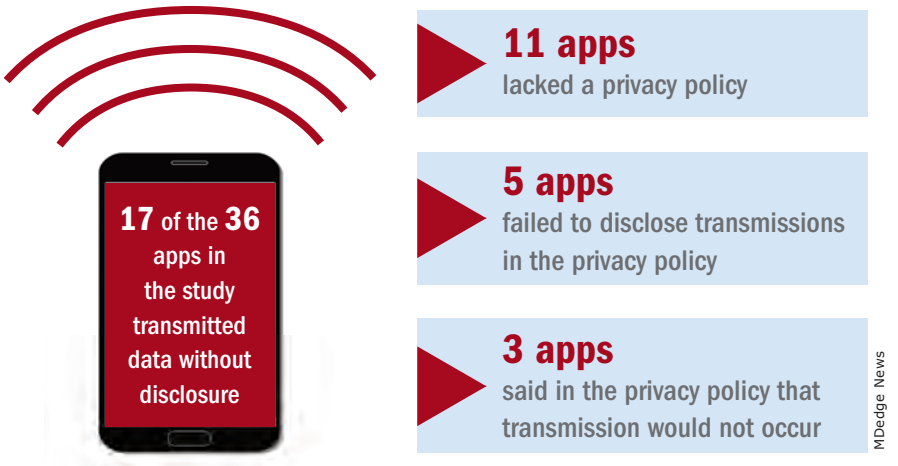
SOURCE: Huckvale K et al. JAMA Netw Open. 2019. doi: 10.1001/jamanetworkopen.2019.2542.

Third-party data sharing by smoking cessation, depression apps



Notes: Search rank on official Android and iOS app marketplaces was used as a proxy for popularity. Apps were selected on Jan. 14 (U.S.) and Jan. 15 (Australia) of 2018.

Source: JAMA Netw Open. 2019. doi: 10.1001/jamanetworkopen.2019.2542

AASM hypopnea definition best for detecting OSA

BY DOUG BRUNK
MDedge News

SAN DIEGO – The prevalence of obstructive sleep apnea (OSA) is substantially lower using the Centers for Medicare & Medicaid Services apnea-hypopnea index definition of OSA than using the one recommended by the American Academy of Sleep Medicine.

In addition, among individuals who did not have OSA using the CMS definition but met criteria using the AASM definition of OSA, an apnea-hypopnea index (AHI) of five events or greater per hour was associated with a greater likelihood of having hypertension.

The findings come from an analysis which set out to assess the relationship between OSA and hypertension using the AASM-recommended definition and the 2018 American Heart Association/American College of Cardiology blood pressure guidelines, and to determine if there is an association between hypertension and OSA among individuals who did not meet the CMS definition of OSA.

"Given the substantial morbidity associated with hypertension, these results suggest that universal adoption of the AASM AHI definition would be a reasonable step in ensuring appropriate diagnosis and

Doug Brunk/MDedge News

Dr. Stuart F. Quan

treatment of OSA," lead study author Stuart F. Quan, MD, said at the annual meeting of the Associated Professional Sleep Societies.

Dr. Quan, of Brigham and Women's Hospital, Boston, noted that a number of studies have demonstrated that OSA is a risk factor for hypertension and a variety of other conditions. "Rightly or wrongly, the most important metric for determining whether OSA is present and determining its severity, is the apnea-hypopnea index," he said. "It's the most common metric used for determining OSA severity, and most importantly, Medicare and some other insurers use this metric to determine whether a person is eligible for treatment. If a person falls above the line, they can get continuous positive airway pressure, for example. If they're below the line, that's too bad; they don't have OSA insofar as the insurance company is concerned."

There is no controversy as to what constitutes apnea, he continued, but some disagreement exists on the definition of hypopnea. The AASM recommends using a 3% oxygen desaturation or an arousal, while Medicare uses a definition of hy popnea requiring only a 4% oxygen desaturation. Hypertension definitions have changed recently as well. Before 2018, the definition of hypertension was greater than 140/90 mm Hg for people younger than age 65 years and 150/80 mm Hg for people age 65 years and older. In 2018, the AHA and ACC changed the hypertension guidelines, defining normal as less than 120/80 mm Hg.

He reported on results from an analysis of 6,307 participants in the Sleep Heart Health Study who underwent home polysomnography. Their AHI defined by a 3% oxygen desaturation or an arousal was classified into four categories of OSA severity: fewer than 5 events per hour (normal sleep), 5-14 events per hour (mild sleep apnea), 15-29 events per hour (moderate sleep apnea), and 30 or more events per hour (severe sleep apnea).

The researchers used three definitions of dichotomous BP elevation: elevated (greater than 120/80 mm Hg or use of hypertension medications [meds]), stage 1 (greater than 130/80 mm Hg or meds), or stage 2 (greater than 140/90 mm Hg or meds). They used logistic regression to assess the association between elevated BP and/or hypertension and OSA severity, controlling for demographics and body mass index. Additional analyses utilized multiple linear regression to determine the relationship between natural log AHI and systolic and diastolic BP, controlling for the same covariates.

For all definitions of elevated BP, increasing OSA severity was associated with greater likelihood of an elevated or hypertensive status in fully adjusted models.

Dr. Quan characterized the study as "a practical analysis, a way to help identify patients who might benefit from treatment. This is not the issue of whether the science of 3% AHI is better than 4%."

The Sleep Heart Health Study was supported by the National Heart, Lung, and Blood Institute. Dr. Quan reported that he helped draft the AASM AHI recommendations but had no other relevant disclosures.

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SOURCE: Quan SF et al. SLEEP 2019, Abstract 0501.

Study eyes narcolepsy's impact on patient quality of life

BY DOUG BRUNK
MDedge News

SAN ANTONIO – Narcolepsy adversely impacts one's health-related quality of life in a variety of ways, from elevated levels of depression to negative social stigma, results from a mixed methods study suggest.

"Despite established pharmacological treatments to reduce narcolepsy symptoms, health-related quality of life remains poor," the study's first author, Jason C. Ong, PhD, said at the annual meeting of the Associated Professional Sleep Societies. "The impact these symptoms have on functioning, the disease burden, and psychosocial functioning in particular is very important. Psychosocial functioning is particularly poor."

Previous research has shown that people with narcolepsy have two to four times the rate of psychiatric comorbidities and that health-related stigma is a predictor of depression and poor functioning, said Dr. Ong, a psychologist with the Center for Circadian and Sleep Medicine at the Northwestern University Feinberg School of Medicine, Chicago. In an effort to assess current practices for addressing the psychosocial needs of persons with narcolepsy and to identify potential strategies that could be used to develop a psychosocial intervention, he and his associates conducted a mixed methods study to examine how narcolepsy symptoms impact health-related quality of life and the appropriateness of different health-related quality of life measures for the disorder. "Our long-term goal is to see if we can use this information to help inform the feasibility of a psychosocial intervention to improve health-related quality of life," he said.

For the study, 29 adults with an established diagnosis of narcolepsy completed online versions of the Patient Health Questionnaire-9 (PHQ-9), the Patient Reported Outcomes Measurement Information System (PROMIS), the 36-item Short Form Survey (SF-36), and the Epworth Sleepiness Scale (ESS). They also participated in a focus group, which consisted of questions pertaining to quality of life for persons with narcolepsy, current practices for addressing psychosocial health of affected individuals, and suggestions for developing a psychosocial intervention. The researchers used thematic analysis to reduce the qualitative data to key themes.


Doug Brunk/MDedge News

Dr. Jason C. Ong

Most of the study participants (93%) were female, 90% were white, their mean age was 31, and their mean time since narcolepsy diagnosis was 4.3 years. Clinically significant elevations on the PROMIS scale, defined as a T score of greater than 60, were reported for depression (T score of 64.8), anxiety (66.3), fatigue (68.3), and sleep impairment (66.9). Elevations in depressive symptoms were reported on the PHQ-9 (a mean of 15.79),

Continued on page 16

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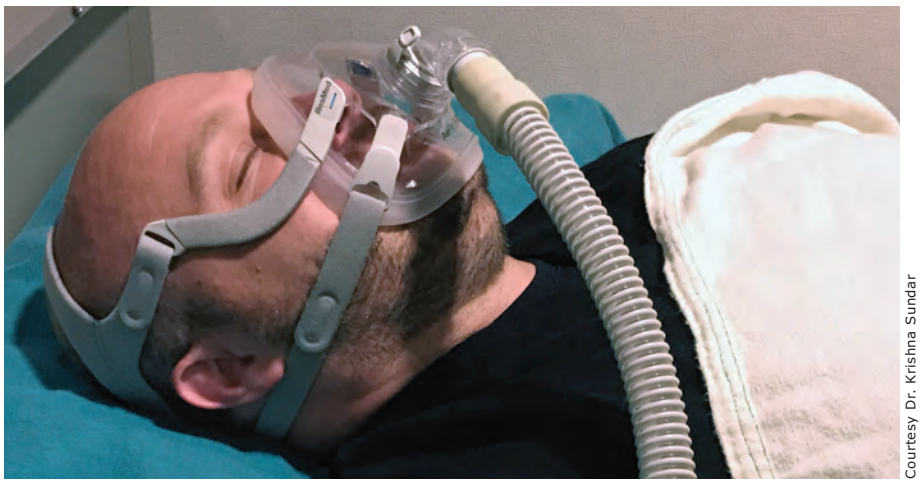
CPAP adherence varies by age, geographic location

BY DOUG BRUNK
MDedge News


Courtesy Dr. Krishna Sundar

SAN ANTONIO – Continuous positive airway pressure (CPAP) adherence varies by age, sex, and date of setup, results from an analysis of national data showed.

However, whether the sources of variability stem from patient factors such as disease severity and socioeconomic status, provider factors, environmental factors, or selection biases in those who are diagnosed with obstructive sleep apnea and treated with CPAP remains to be understood, lead study author Sanjay R. Patel, MD, said at the annual meeting of the Associated Professional Sleep Societies.

In 2015, the American Academy of Sleep Medicine (AASM) endorsed CPAP adherence as a process measure, and the Centers for Medicare and Medicaid Services has used CPAP adherence as an outcome measure to limit long-term coverage of the therapy. It defines CPAP adherence as 4 or more hours of use on greater than 70% of nights in a consecutive 30-day period within the first 90 days. "Strengths of CPAP adherence as an outcome measure include the fact that it is easy to measure and it predicts improvement in sleepiness, quality of life, and blood pressure control," said Dr. Patel, who directs the University of Pittsburgh's Center for Sleep and Cardiovascular Outcomes Research. "One issue as to whether we should use CPAP adherence as an outcome-based quality of care measure is, does variability reflect performance at the provider and/or health care system?"

In an effort to describe CPAP adherence rates in general clinical practice as well as sources of variability, Dr. Patel and colleagues evaluated telemonitoring data maintained by Philips Respironics. The study population consisted of 714,270 patients initiated on CPAP therapy between November 2015 and August 2018 who had at least one usage session of CPAP or APAP.

Overall, 90-day adherence to CPAP was 72.5%. Age, sex, and state of residence were all significantly associated with adherence rates (*P* less than .05). Specifically, adherence rates ranged from 54.8% among those 18-30 years of age to 79.1% among those 61-70 years of age. "There was a plateauing of adherence rates among those in their 70s, and men tended to have a higher adherence level than women across all age groups (73.3% vs. 71.4%, respectively)," he said. "Also, people who got started on CPAP in January had a higher level of adherence than people who got started in May. The differences are relatively small compared to the large age differences, but there was a consistent trend."

When the researchers carried out age- and sex-adjusted analyses, they observed that adherence rates were lowest in the Northeast and Southwest and highest in the Upper Midwest and Mountain West. Adherence rates ranged from 50.8% in the District of Columbia and 60.5% in New York up to 81.2% in Idaho and 81.9% in South Dakota.

"The question is, is this variability explained by quality measures?" Dr. Patel asked. "We tried to answer this question by seeing whether the variability in adherence by location correlated with other metrics of health care quality." To accomplish this, they used Dartmouth Atlas, a project that uses Medicare data to understand drivers of health care spending and quality. To understand geographic variability in CPAP adherence, they mapped ZIP codes onto hospital referral regions (HRRs), which are regional health care markets for tertiary medical care. Each HRR has at least one hospital that performs major cardiovascular procedures and neurosurgery. ZIP codes were mapped to 306 HRRs where the majority of residents get their tertiary care.

The researchers observed that Medicare enrollees who saw a primary care physician in the past 12 months had higher rates of adherence, compared with those who did not. "Twenty-three percent of the variance in CPAP adherence across the country can be explained by this measure of having a primary care doctor," Dr. Patel said. In addition, patients who received care from HRRs located in the middle of the United States had high adherence rates. Top performers were facilities located in Madison, Wis.; Wausau, Wis.; Dubuque, Iowa; and Bloomington, Ill. Poor performers included facilities located in the boroughs of Manhattan and the Bronx, in New York; Muskegon, Mich.; Miami; and Buffalo, N.Y.

"Some of the geographical variability may be due to patient factors such as race, income, and education level," Dr. Patel said. "That will need to be appropriately addressed in developing a quality of care measure. Nevertheless, some of the geographic variability appears to be related to health care system and provider factors. This variability could be potentially reduced through implementation of a CPAP adherence quality outcome measure."

Dr. Patel disclosed that he has received grant/research support from Bayer Pharmaceuticals and Philips Respironics, and has served as a consultant to the American Academy of Sleep Medicine.

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SOURCE: Patel SR et al. SLEEP 2019, Abstract 0513.

Continued from page 14

"which corresponds to moderately severe levels," Dr. Ong said. "The ESS was highly elevated and fit well with the scales for sleep impairment as well as fatigue on the PROMIS. Overall, there was nice congruence across these measures."

On the SF-36, the researchers observed that there were deficits in physical and emotional aspects of role limitations, and in energy/fatigue. "One thing we did find was a significant difference in general functioning, where patients with type 1 narcolepsy were worse off than those with type 2 narcolepsy (*P* less than .05)."

Qualitative data from focus groups revealed several key themes, including the perception that narcolepsy is poorly understood by the public and health care providers.

"People have the perception that, if you have narcolepsy, you just feel fine and then you fall asleep," Dr. Ong said. "They don't understand that it's a constant thing. Negative social stigma was also common. As a result, we found a lot of negative impact on self-esteem and self-efficacy. People talked about being hesitant to tell other people about their diagnosis, feeling that they're ashamed of having narcolepsy. They felt less capable. One person said, 'I get tired trying to explain why I'm tired.' "

Another common theme that emerged was the challenge of optimal treatment for their narcolepsy. Most patients met with sleep doctors or clinics every 3-6 months. "They said that this was generally good for discussing medications and symptom management, but there didn't seem to be much time to talk about psychosocial aspects," Dr. Ong said. "That seemed to be one area of need. There was also a strong dissatisfaction with mental health providers. People talked about how their mental health provider really didn't understand narcolepsy. It did seem to reduce rapport and the ability to trust their therapist. Some talked about the challenges of accessibility. In some cases, people said their narcolepsy symptoms created challenges with appointment attendance."

In terms of preferences for a psychosocial intervention, respondents generally "preferred some kind of online or Internet delivery," he said. "They prefer a team approach with a clinician who's knowledgeable about both sleep and mental health."

Dr. Ong acknowledged certain limitations of the study, including its small sample size and the fact that it was not adequately powered to detect differences between type 1 and type 2 narcolepsy.

The study was funded by a grant from Wake Up Narcolepsy. Dr. Ong reported having no relevant financial disclosures.

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SOURCE: Ong JC et al. SLEEP 2019, Abstract 0624.

ONCE-DAILY
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Relief that matters

The FIRST AND ONLY once-daily nebulized LAMA, for a full 24 hours of lung function improvement[1]

Proven 24-hour control[1]
Consistent improvement in trough FEV_1 vs placebo over 24 hours on days 84/85[1,2]

The primary endpoint was change from baseline in trough (predose) FEV_1 at day 85 vs placebo: YUPELRI demonstrated a statistically significant difference vs placebo in study 1 (146 mL, *P*<.0001 [YUPELRI, n=189; placebo, n=191]) and study 2 (147 mL, *P*<.0001 [YUPELRI, n=181; placebo, n=187]).[1,2]

In study 1, LS mean changes from baseline in FEV_1 ranged from 55.8 mL to 240.4 mL in the YUPELRI group, and from -113.6 mL to 59.6 mL in the placebo group. In study 2, LS mean changes from baseline in FEV_1 ranged from 19.8 mL to 148.5 mL in the YUPELRI group, and from -176.4 mL to -13.0 mL in the placebo group.

In studies 1 and 2, a prespecified exploratory analysis using serial spirometry was performed on a substudy population (YUPELRI, n=89; placebo, n=83) over 24 hours on days 84/85. In a pooled analysis, YUPELRI demonstrated consistent improvement in trough FEV_1 vs placebo over the 24-hour period.

Demonstrated safety profile[1]
Refer to the Important Safety Information below for additional information

Once-daily dosing[1]
Administered with any standard jet nebulizer with a mouthpiece

Up to 100% of patients with Medicare Part B are expected to be covered*
Permanent J-CODE J7677

*This is not a guarantee of coverage. Site of care will determine coverage. Check with your patient's insurance provider for coverage rules and restrictions. In certain limited instances, YUPELRI may be covered through a patient's Medicare Part D pharmacy benefit.

Indication

YUPELRI® inhalation solution is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Important Safety Information

YUPELRI is contraindicated in patients with hypersensitivity to revefenacin or any component of this product.

YUPELRI should not be initiated in patients during acutely deteriorating or potentially life-threatening episodes of COPD, or for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled short-acting $beta_2$-agonist.

As with other inhaled medicines, YUPELRI can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs following dosing with YUPELRI, it should be treated immediately with an inhaled, short-acting bronchodilator. YUPELRI should be discontinued immediately and alternative therapy should be instituted.

YUPELRI should be used with caution in patients with narrow-angle glaucoma. Patients should be instructed to immediately consult their healthcare provider if they develop any signs and symptoms of acute narrow-angle glaucoma, including eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema.

Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur.

Immediate hypersensitivity reactions may occur after administration of YUPELRI. If a reaction occurs, YUPELRI should be stopped at once and alternative treatments considered.

The most common adverse reactions occurring in clinical trials at an incidence greater than or equal to 2% in the YUPELRI group, and higher than placebo, included cough, nasopharyngitis, upper respiratory infection, headache and back pain.

Coadministration of anticholinergic medicines or OATP1B1 and OATP1B3 inhibitors with YUPELRI is not recommended.

YUPELRI is not recommended in patients with any degree of hepatic impairment.

Please see Brief Summary of Full Prescribing Information on the adjacent pages.

Learn more at YUPELRIHCP.com

References: 1. YUPELRI [package insert]. Morgantown, WV: Mylan Specialty L.P.; May 2019. **2.** Data on file.

Mylan®
Theravance Biopharma

YUPELRI® (revefenacin) inhalation solution, for oral inhalation

Initial U.S. Approval: 2018

FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

YUPELRI inhalation solution is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

CONTRAINDICATIONS

YUPELRI is contraindicated in patients with hypersensitivity to revefenacin or any component of this product.

WARNINGS AND PRECAUTIONS

Deterioration of Disease and Acute Episodes

YUPELRI should not be initiated in patients during acutely deteriorating or potentially life-threatening episodes of COPD. YUPELRI has not been studied in subjects with acutely deteriorating COPD. The initiation of YUPELRI in this setting is not appropriate.

YUPELRI is intended as a once-daily maintenance treatment for COPD and should not be used for relief of acute symptoms, i.e. as rescue therapy for the treatment of acute episodes of bronchospasm, and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting beta$_2$-agonist.

COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If YUPELRI no longer controls symptoms of bronchoconstriction, the patient's inhaled, short-acting beta$_2$-agonist becomes less effective, or the patient needs more inhalations of a short-acting beta$_2$-agonist than usual, these may be markers of deterioration of disease. In this setting, a re-evaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dose of YUPELRI beyond the recommended dose is not appropriate in this situation.

Paradoxical Bronchospasm

As with other inhaled medicines, YUPELRI can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs following dosing with YUPELRI, it should be treated immediately with an inhaled, short-acting bronchodilator; YUPELRI should be discontinued immediately and alternative therapy should be instituted.

Worsening of Narrow-Angle Glaucoma

YUPELRI should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g. eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a physician immediately if any of these signs or symptoms develops.

Worsening of Urinary Retention

YUPELRI should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g. difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develops.

Immediate Hypersensitivity Reactions

Immediate hypersensitivity reactions may occur after administration of YUPELRI. If such a reaction occurs, therapy with YUPELRI should be stopped at once and alternative treatments should be considered.

ADVERSE REACTIONS

The following potential adverse reactions are described in greater detail in other sections:

- Paradoxical bronchospasm *[see Warnings and Precautions]*
- Worsening of narrow-angle glaucoma *[see Warnings and Precautions]*
- Worsening of urinary retention *[see Warnings and Precautions]*
- Immediate hypersensitivity reactions *[see Warnings and Precautions]*

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The YUPELRI safety database included 2,285 subjects with COPD in two 12-week efficacy studies and one 52-week long-term safety study. A total of 730 subjects received treatment with YUPELRI 175 mcg once daily. The safety data described below are based on the two 12-week trials and the one 52-week trial.

12-Week Trials

YUPELRI was studied in two 12-week replicate placebo-controlled trials in patients with moderate to very severe COPD (Trials 1 and 2). In these trials, 395 patients were treated with YUPELRI at the recommended dose of 175 mcg once daily.

The population had a mean age of 64 years (range from 41 to 88 years), with 50% males, 90% Caucasian, and had COPD with a mean post-bronchodilator forced expiratory volume in one second (FEV_1) percent predicted of 55%. Of subjects enrolled in the two 12-week trials, 37% were taking concurrent LABA or ICS/LABA therapy. Patients with unstable cardiac disease, narrow-angle glaucoma, or symptomatic prostatic hypertrophy or bladder outlet obstruction were excluded from these trials.

Table 1 shows the most common adverse reactions that occurred with a frequency of greater than or equal to 2% in the YUPELRI group and higher than placebo in the two 12 week placebo- controlled trials.

The proportion of subjects who discontinued treatment due to adverse reactions was 13% for the YUPELRI-treated subjects and 19% for placebo-treated subjects.

Table 1: Adverse Events with YUPELRI ≥2% Incidence and Higher than Placebo

	Placebo (N = 418)	YUPELRI 175 mcg (N = 395)
Respiratory, Thoracic and Mediastinal Disorders		
Cough	17 (4%)	17 (4%)
Infections and Infestations		
Nasopharyngitis	9 (2%)	15 (4%)
Upper respiratory tract infection	9 (2%)	11 (3%)
Nervous System Disorders		
Headache	11 (3%)	16 (4%)
Musculoskeletal and Connective Tissue Disorders		
Back pain	3 (1%)	9 (2%)

Other adverse reactions defined as events with an incidence of ≥1.0%, less than 2.0%, and more common than with placebo included the following: hypertension, dizziness, oropharyngeal pain, and bronchitis.

52-Week Trial

YUPELRI was studied in one 52-week, open-label, active-control (tiotropium 18 mcg once daily) trial in 1,055 patients with COPD. In this trial, 335 patients were treated with YUPELRI 175 mcg once daily and 356 patients with tiotropium. The demographic and baseline characteristics of the long-term safety trial were similar to those of the placebo-controlled 12-week studies described, with the exception that concurrent LABA or LABA/ICS therapy was used in 50% of patients. The adverse reactions reported in the long-term safety trial for YUPELRI were consistent with those observed in the placebo-controlled studies of 12-weeks.

DRUG INTERACTIONS

Anticholinergics

There is potential for an additive interaction with concomitantly used anticholinergic medicines. Therefore, avoid coadministration of YUPELRI with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects *[see Warnings and Precautions]*.

Transporter-Related Drug Interactions

OATP1B1 and OATP1B3 inhibitors (e.g. rifampicin, cyclosporine, etc.) could lead to an increase in systemic exposure of the active metabolite. Therefore, coadministration with YUPELRI is not recommended *[see Clinical Pharmacology.]*

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate and well-controlled studies with YUPELRI in pregnant women. Women should be advised to contact their physician if they become pregnant while taking YUPELRI. In animal reproduction studies, subcutaneous administration of revefenacin to pregnant rats and rabbits during the period of organogenesis produced no evidence of fetal harm at respective exposures approximately 209 times the exposure at the maximum recommended human dose (MRHD) (on an area under the curve [AUC] basis) *(see Data).*

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

In an embryo fetal development study in pregnant rats dosed during the period of organogenesis from gestation days 6 to 17, revefenacin was not teratogenic and did not affect fetal survival at exposures up to 209 times the MRHD (based upon summed AUCs for revefenacin and its active metabolite at maternal subcutaneous doses up to 500 mcg/kg/day).

In an embryo fetal development study in pregnant rabbits dosed during the period of organogenesis from gestation days 7 to 19, revefenacin was not teratogenic and did not affect fetal survival at exposures up to 694 times the MRHD (based upon summed AUCs for revefenacin and its active metabolite at maternal subcutaneous doses up to 500 mcg/kg/day).

Placental transfer of revefenacin and its active metabolite was observed in pregnant rabbits.

In a pre- and postnatal development (PPND) study in pregnant rats dosed during the periods of organogenesis and lactation from gestation day 6 to lactation day 20, revefenacin had no adverse developmental effects on pups at exposures up to 196 times the MRHD (based upon summed AUCs for revefenacin and its active metabolite at maternal subcutaneous doses up to 500 mcg/kg/day).

Lactation

Risk Summary

There is no information regarding the presence of revefenacin in human milk, the effects on the breastfed infant, or the effects on milk production. However, revefenacin was present in the milk of lactating rats following dosing during pregnancy and lactation *(see Data).*

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for YUPELRI and any potential adverse effects on the breastfed infant from YUPELRI or from the underlying maternal condition.

Data

Animal Data

In a PPND study *[see Pregnancy],* revefenacin and its active metabolite were present in milk of lactating rats on lactation day 22. Milk-to-plasma concentration ratios were up to 10 for revefenacin and its active metabolite.

Pediatric Use

YUPELRI is not indicated for use in children. The safety and efficacy in pediatric patients have not been established.

Geriatric Use

Based on available data, no adjustment of the dosage of YUPELRI in geriatric patients is necessary.

Clinical trials of YUPELRI included 441 subjects aged 65 years and older, and of those, 101 subjects were aged 75 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Hepatic Impairment

The systemic exposure of revefenacin is unchanged while that of its active metabolite is increased in subjects with moderate hepatic impairment. The safety of YUPELRI has not been evaluated in COPD patients with mild-to-severe hepatic impairment. YUPELRI is not recommended in patients with any degree of hepatic impairment. *[see Clinical Pharmacology].*

Renal Impairment

No dosage adjustment is required in patients with renal impairment. Monitor for systemic antimuscarinic side effects in COPD patients with severe renal impairment. *[see Clinical Pharmacology].*

OVERDOSAGE

An overdose of YUPELRI may lead to anticholinergic signs and symptoms such as nausea, vomiting, dizziness, lightheadedness, blurred vision, increased intraocular pressure (causing pain, vision disturbances, or reddening of the eye), obstipation or difficulties in voiding. In COPD patients, orally inhaled administration of YUPELRI at a once-daily dose of up to 700 mcg (4 times the maximum recommended daily dose) for 7 days was well tolerated.

Treatment of overdosage consists of discontinuation of YUPELRI along with institution of appropriate symptomatic and/or supportive therapy.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Two-year inhalation studies in Sprague-Dawley rats and CD1 mice were conducted to assess the carcinogenic potential of revefenacin. No evidence of tumorigenicity was observed in male and female rats at inhaled doses up to 338 mcg/kg/day (approximately 35 times the MRHD based upon summed AUCs for revefenacin and its active metabolite). No evidence of tumorigenicity was observed in male and female mice at inhaled doses up to 326 mcg/kg/day (approximately 40 times the MRHD based on summed AUCs for revefenacin and its active metabolite).

Revefenacin and its active metabolite were negative for mutagenicity in the Ames test for bacterial gene mutation. Revefenacin was negative for genotoxicity in the *in vitro* mouse lymphoma assay and *in vivo* rat bone marrow micronucleus assay.

There were no effects on male or female fertility and reproductive performance in rats at subcutaneous revefenacin doses up to 500 mcg/kg/day (approximately 30 times the MRHD on an mg/m^2 basis for revefenacin).

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use) with each new prescription and refill.

Not for Acute Symptoms

Inform patients that YUPELRI is not meant to relieve acute symptoms of COPD and extra doses should not be used for that purpose. Advise patients to treat acute symptoms with an inhaled, short-acting beta$_2$-agonist such as albuterol. Provide patients with such medicine and instruct them in how it should be used.

Instruct patients to seek medical attention immediately if they experience any of the following:

- Decreasing effectiveness of inhaled, short-acting beta$_2$-agonists
- Need for more inhalations than usual of inhaled, short-acting beta$_2$-agonists
- Significant decrease in lung function as outlined by the physician

Tell patients they should not stop therapy with YUPELRI without healthcare provider guidance since symptoms may recur after discontinuation.

Paradoxical Bronchospasm

As with other inhaled medicines, YUPELRI can cause paradoxical bronchospasm. If paradoxical bronchospasm occurs, instruct patients to discontinue YUPELRI.

Worsening of Narrow-Angle Glaucoma

Instruct patients to be alert for signs and symptoms of acute narrow-angle glaucoma (e.g. eye pain or discomfort, blurred vision, visual halos, or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develops.

Worsening of Urinary Retention

Instruct patients to be alert for signs and symptoms of urinary retention (e.g. difficulty passing urine, painful urination). Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develops.

Instructions for Administering YUPELRI

It is important for patients to understand how to correctly administer YUPELRI using a standard jet nebulizer [see Instructions for Use]. Instruct patients that YUPELRI should only be administered via a standard jet nebulizer. Patients should be instructed not to inject or swallow the YUPELRI solution. Patients should be instructed not to mix other medications with YUPELRI.

Patients should not inhale more than one dose at any one time. The daily dosage of YUPELRI should not exceed one unit-dose vial. Inform patients to use the contents of one vial of YUPELRI orally inhaled daily at the same time every day. Patients should throw the plastic dispensing vials away immediately after use. Due to their small size, the vials pose a danger of choking to young children.

REV-2019-0194

Children with Down syndrome may need more screening for sleep-disordered breathing

BY RANDY DOTINGA
MDedge News

Children with Down syndrome often have sleep-disordered breathing (SDB), and a new study suggests that long-term monitoring via sleep studies is warranted because the condition frequently persists and recurs.

"Current screening recommendations to assess for SDB at a particular age may not be adequate in this population," the authors of the study stated, adding that "persistence/recurrence of SDB is not easily predicted."

The study, led by Joy Nehme, BSc, of Children's Hospital of Eastern Ontario, was published in Pediatric Pulmonology.

According to the study, research suggests that 43%-66% of children with Down syndrome have SDB, a category that encompasses sleep apnea (both obstructive and central) and hypoventilation. Those numbers are several times higher than the prevalence of SDB in children in the general population (1%-5%).

"Because SDB is associated with cardiometabolic and neurocognitive morbidity, its prompt and accurate diagnosis is important," the researchers wrote. However, diagnosis requires a sleep study, which is not always performed although the American Academy of Pediatrics recommends children with Down syndrome undergo one by age 4.

Treatments include adenotonsillectomy (considered first-line), positive airway pressure, and lingual tonsillectomy.

The study aims to fill in gaps in knowledge about the condition over the long term since "there is little available literature on the trajectory of SDB in children and youth with Down syndrome over time."

DenKuvaiev/Thinkstock

The researchers launched a retrospective study of 560 children with Down syndrome who were treated from 2004 to 2015 at Children's Hospital of Eastern Ontario. Of those, 120 showed signs of SDB and underwent sleep studies (48% male, median age 6.6 years [range 4.5-10.5], median total apnea-hypopnea index events per hour = 3.4 [1.6-10.8]).

Of the 120 children, 67 (56%) had obstructive-mixed SDB, 9 (8%) had central sleep apnea, and 5 (4%) had hypoventilation. The others (39, 32%) had no SDB.

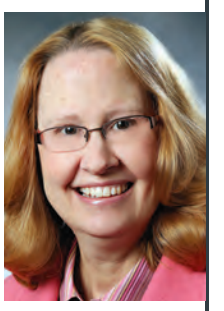
Fifty-four children underwent at least two sleep studies during the period of the study, with at least one undergoing seven. Researchers found weak, nonsignificant evidence that SDB persistence/occurrence varied by age (odds ratio per year = 1.15; 95% confidence interval, 0.96-1.41; $P = .13$). As for treatment, adenotonsillectomy was most common, although "previous studies have ... shown that moderate to severe OSA in children with Down syndrome is likely to persist after a tonsillectomy." In regard to obstructive sleep apnea specifically, the authors wrote, "our study ... showed that OSA-SDB persisted or recurred in the vast majority of children. Further, persistence/recurrence could not be predicted by clinical features or SDB severity in our study. This, therefore, highlights the need for serial longitudinal screening for SDB in this population and for follow-up PSG to ensure the success of treatment interventions."

The study authors reported no disclosures.

chestphysiciannews@chestnet.org

SOURCE: Nehme J et al. Pediatr Pulmonol. 2019 Jun 6. doi: 10.1002/ppul.24380.

VIEW ON THE NEWS



Susan Millard, MD, FCCP, comments: Infants, toddlers, children, and adolescents with Down syndrome have a variety of reasons for sleep-disordered breathing including, for example, a large tongue, hypotonia, increased incidence of congenital heart disease, and airway malacia, adenotonsillar hypertrophy, and even palatine tonsillar hypertrophy (albeit rare). It is important to be ever-vigilant about sleep disorders in these patients.

How to have 'the talk' with vaccine skeptics

BY BRUCE JANCIN
MDedge News

LJUBLJANA, SLOVENIA – An effective strategy in helping vaccine skeptics to come around to accepting immunizations for their children is to pivot the conversation away from vaccine safety and focus instead on the disease itself and its potential consequences, Saad B. Omer, MBBS, PhD, asserted at the annual meeting of the European Society for Paediatric Infectious Diseases.

"Why do we cede ground by focusing too much on the vaccine itself? At the end of the day, vaccination is a means to prevent disease. So I suggest that we talk about the disease. I call it the disease salience approach," said Dr. Omer, professor of global health, epidemiology, and pediatrics at Emory University in Atlanta.

It's a strategy guided by developments in social psychology, persuasion theory, and communication theory. But if applied incorrectly, the disease salience approach can backfire, causing behavioral paralysis and an inability to act, he cautioned.

Dr. Omer explained that it's a matter of framing.

"Always include a solution to promote self-efficacy and response-efficacy. After you inform parents of disease risks, provide them with actions they can take. Now readdress the vaccine, pointing out that this is the single best way to protect yourself and your baby," he said. "The lesson is that, since vaccines are a social norm, reframe nonvaccination as an active act, rather than vaccination as an active act."

Don't attempt to wow parents with statistics on how vaccine complication rates are dwarfed by the disease risk if left unvaccinated, he advised. Studies have shown that's generally not effective. What actually works is to provide narratives of disease severity.

"We are excellent linguists, but really, really poor statisticians," Dr. Omer observed.

Is it ethical to talk to parents about disease risks to influence their behavior? Absolutely, in his view.

"We're not selling toothpaste. We are in the business of life-saving vaccines. And I would submit that if it's done correctly it's entirely ethical to talk about the disease, and sometimes even the severe risks of the disease, instead of the vaccine," he said.

If parents cite a myth about vaccines, it's necessary to address it head on without lingering on it. But debunking a myth is tricky because people tend to remember negative information they received earlier.

"If you're going to debunk a myth, clearly label it as a myth in the headline as you introduce it. State why it's not true. Replace the myth with the best alternative explanation. Think of it like a blank space where the myth used to reside. That space needs to be filled with an alternative explanation or the myth will come back," Dr. Omer said.

He is a coauthor of a book titled, 'The Clinician's Vaccine Safety Resource Guide: Optimizing Prevention of Vaccine-Preventable Diseases Across the Lifespan.'

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FROM THE PRESIDENT

IPF—Success or failure?

BY CLAYTON T. COWL, MD, MS, FCCP

Last month, I attended the funeral of my uncle who died at age 88 from pulmonary fibrosis, a condition that he battled for more than a decade. Having the honor of delivering a tribute to his life during the ceremony, I included an explanation of the basics of the disease to the audience that had packed the church located in an upscale neighborhood in the Chicago suburbs.

Dr. Cowl

Afterward, I wondered if medical science and we as medical providers are making any real progress in fighting this relentless fibrotic interstitial lung disease. After all, I had watched him gradually decline, first plagued by an endless nonproductive cough, then exertional dyspnea, exertional hypoxia, and followed by hypoxia at rest. Eventually, he was short of breath with moving from his bed to the bathroom – even on high flow supplemental oxygen. It was a slow, gradual process of asphyxiation.

He had every resource available to him. He was seen by the best subspecialty providers in his community and saw experts in major medical centers across the country. He had been given the seemingly usual trial of corticosteroids initially, and then for unclear reasons, several inhalers. Maybe because his doctors didn't have much else to offer. He was then treated with pirfenidone, and later switched to nintedanib when the side effects were too much for him to handle. Lung transplant was considered and then ruled out. With more respiratory symptoms, and despite my caution against it, he even tried experimental therapy with stem cells – an unproven treatment with additional potential for untoward consequences. At that point, he considered my suggestion to hold off, shrugged, and indicated that if he had the wherewithal and means to try it, why not?

Besides watching the desperation of finding that elusive therapy that will somehow erase the progressive symptoms of shortness of breath and cough, what I realized from being on the "other side of the gurney" with a family member is that sometimes obtaining basic treatments like supplemental oxygen can be more challenging than obtaining the more expensive pharmacologic therapies. And, that having to use supplemental oxygen is like being tethered, especially if your portable oxygen delivery device is unreliable or battery power is questionable. I've thought about folks with lung disease who do not have a "best practice" resource that includes unlimited medical direction and access to care. What about the people who can't afford experimental therapies, who cannot easily navigate the medical maze, or who do not have someone to phone and call to help them when their portable oxygen concentrator develops a fatal hardware error?

I pondered the reality of his illness. Yes, at some point all of us will die. But in the end, were his treatments a success? What exactly does success look like when it comes to treatment of idiopathic pulmonary fibrosis? Did we as a medical community slow down his inevitable decline in lung function? Did we make a meaningful difference? Ultimately, does it matter if someone has a better FEV_1, or trek 30 feet farther on a 6-minute walk for a few more months? Maybe. Then, as I traveled with my uncle on his medical journey, I realized that, yes, even the small things really do matter, retrospectively.

I think in my uncle's case, his eventual demise came, but only after great successes by the medical community. The inevitable was delayed for several years at a minimum. He remained comfortable. He was able to do things on his "bucket list" that he would not likely have been able to enjoy without treatment. It allowed him to take an Honor Flight to Washington, DC, to be remembered for his heroic service in the Korean War. It allowed him to attend the 150th annual convention of the American Legion last summer, as he completed his service as the Commander of his local post. On a personal and maybe more selfish level, it allowed me to be able to enjoy dinner with him on two or three occasions while visiting Chicago during CHEST business meetings at the headquarters location. How much value do we place on being able to hear a few more family stories, to watch someone who you know is going to die smile and laugh, and share memories together for what could be the final time?

Continued on following page

Your CHEST BOR working for you

BY BURTON LESNICK, MD, FCCP
CHEST Regent-at-Large

The CHEST Board of Regents (BOR) held their summer meeting for 3 days starting June 20 in Coeur D'Alene, Idaho. The key drivers of the BOR are to continuously assess and adjust our strategic plan to further CHEST's mission and to be good fiducial stewards in allocating resources. At this meeting, the BOR continued its efforts in both of these areas.

CHEST's mission is to champion the prevention, diagnosis, and treatment of chest diseases through education, communication, and research. The budget for fiscal year 2019-2020 facilitates the expansion of this mission by allocating more resources for e-learning and for the improving engagement and member experience.

Specifically, the Board is placing significant emphasis for more content to be digital, downloadable, digestible, and (hopefully) addictive. Aside from allocating capital for updates of existing equipment, Board Designated


Dr. Lesnick

Funds were made available for an aggressive redesign of content delivery. Over the next 2 years, CHEST will achieve single sign on for all our learning platforms; enhance mobile access; and deploy mobile apps for gaming, personalized learning, and just-in-time education. The effort also aims to streamline journal and topic workflows and launch personalized content recommendations for our members.

Our formal strategic planning continued with an external review of our recent environmental scan and 5-year plan by a select group of entrepreneurs and innovators. Board members engaged in a rich debate about ways to better focus the organization. The group noted that the best time for strategic initiatives is now, while the association is doing well and highly functioning, rather than waiting for difficult times to initiate a potentially more painful course correction.

Education is the base for our entire enterprise. The BOR had a vigorous discussion about the development of a clinician educator track with certification and was introduced to CHEST's new Chief Learning Officer. The CHEST staff plans a deeper dive into needs assessment and developing a business plan around this program.

Communication is also a core part of our mission. The BOR recognizes that more needs to be done to support the NetWorks. For this year's annual meeting, plans have been made to move the NetWork meetings into two time slots, unopposed by other scientific content, and to rename these meetings "NetWork Featured Lecture and Open Forum." The rationale for the name change is to make the meetings more inviting by referring to them as "open forums." CHEST 2019 will feature improved signage in common areas to highlight the NetWork meetings, providing times and locations. The goal is to at least double attendance. Dr. Stephanie Levine, President-Elect of CHEST, is forming a task force to explore other ways of enhancing NetWork engagement.

In order to expand CHEST educational impact, the Board launched a new global events strategy. These global educational programs were another focus of the Board of Regents. Staff provided updates on the CHEST Congress Thailand 2019 in collaboration with the Thoracic Society of Thailand. There were more than 1,000 delegates representing 57 countries. The meeting was supported by our partner, Kenes, which will also be helping with smaller regional meetings, including the June meeting in Athens in collaboration with the Hellenic Thoracic Society. CHEST is in the advanced stages of planning a CHEST Congress in Bologna, Italy, in summer 2020 in conjunction with our colleagues in that country. CHEST is putting together a 5-year plan for regional meetings with a variety of local medical societies throughout the world. To support this, the Governance Committee recommended augmenting the Council of Global Governors with an Executive Committee. This group will serve as a small, strategic set of individuals, appointed by the Governance Committee, to assist in furthering the global strategy and efforts of the organization. Going forward, the Chair of the Executive Committee will serve as a member of the Board of Regents for a 2-year term, to better represent international concerns at a board level.

The BOR addressed additional items, including reviewing the process for selecting Master FCCPs and providing a very positive update on our CHEST 2019 meeting in New Orleans. They also enhanced coordination with the CHEST Foundation Board of Trustees (BOT) via joint meetings. The CHEST Foundation BOT celebrated success in matching funds for the one million dollar grant to establish the Erin Popovich Endowment. Additional fundraising plans include holding five separate events in the next year, including a repeat of last year's Feldman Family Foundation Poker Night.

From The President *Continued from previous page*

Through this experience, I have been reminded to recognize that there are many small, silent victories for our medical community in the war against devastating disease. We need to celebrate even the tiny advances. The medical community did not let him down. It rallied to give him the best we could offer with the tools we had at hand. And, keeping in mind those yet to develop this condition, it's time to keep working hard to make a difference. Whether doing basic research, creating the medications of the future to treat respiratory illness, diagnosing conditions earlier and more accurately, or providing compassionate, patient-centered care, let's keep our focus on crushing lung disease -- a little bit at a time.

In Memoriam: Mark J. Rosen, MD, Master FCCP


Dr. Rosen

Past President (2006-2007) of the American College of Chest Physicians, leader, educator, mentor, and friend, Dr. Mark Rosen, Master FCCP, died on July 3, 2019. Dr. Rosen's distinguished career in pulmonary and critical care medicine spanned more than 4 decades, marked by his deep commitments to medical education and patient care. His research and administrative accomplishments at New York City and Long Island hospitals were many, but clinical medicine and teaching were always at the top of his list. Mark's unmistakable way of incorporating both clarity and humor into his roles of clinician, teacher, colleague, and friend provided us all with respect and adoration for this unforgettable individual.

Mark's distinguished leadership involvement with CHEST began well before his term as President. Two years after completing his fellowships in pulmonary and critical care medicine, he became an FCCP in 1982, and his engagement with the American College of Chest Physicians began. During the 1990s and into the 2000s, Mark provided CHEST with his teaching expertise serving as faculty and director for the Pulmonary Board Review Courses. In 1998, he was Chair of the CHEST Annual Meeting, and from 1999 to 2005, he served on the ACCP-SEEK Editorial Boards for Pulmonary Disease and Critical Care Medicine. Mark served on the CHEST Board of Regents for many years, on the CHEST Foundation Board of Trustees, and as a Chair or member on numerous CHEST committees, some of which included Education, Nominations, Membership, Marketing, and Finance. He was the CHEST Governor for the City of New York and Chair of the Council of Governors. His leadership in all of these capacities was exemplary, as was his guidance as CHEST President from 2006 to 2007. Most recently, Mark served as CHEST Director of Global Education and Strategic Development (2011-2014) followed by CHEST Medical Director (2014-2016). Mark strived to uphold and strengthen the quality of the education that CHEST provided to all health-care professionals. His imprint on the educational and clinical foundations of CHEST, along with the many friendships he made along the way, will be remembered always.

CHEST extends heartfelt condolences to Mark's wife of 37 years, Ilene, and the Rosen family and many friends and colleagues.

CHEST Foundation at Board Review

The CHEST Foundation is excited to be a part of this year's CHEST Board Review in Phoenix, and we can't wait to see you! We are hosting two receptions and invite you to attend and learn more about how the CHEST Foundation supports you, your colleagues, your patients, and the greater community while also taking the time to relax with your peers and board review faculty. The receptions are scheduled for Saturday, August 17 (for Sleep and Critical Care Board Review), and Wednesday, August 21 (for Pulmonary Board Review) immediately following your scheduled sessions. Please join us for hors d'oeuvres and beverages. This year, we are featuring surprise, guest speakers from CHEST leadership who will share why they are passionate about the Foundation's mission and offer simple ways you can become further involved with the CHEST Foundation. You won't want to miss this networking opportunity and the chance to learn more about what the Foundation has been doing!

This summer, we are focused on supporting young and early-career clinicians and are raising money at this year's at Board Review to support travel grants to CHEST 2019. These travel grants provide early-career clinicians the funds needed to attend CHEST 2019. This program further develops the future leaders of CHEST and allows clinicians to take full advantage of career-development and networking opportunities that the annual meeting offers. If you're interested in how you can make a difference in someone's life, visit our website (foundation.chestnet.org), or find us at Board Review! We would love to share more with you about all the great work the Foundation is doing.

We can't wait to see you in Phoenix to celebrate all your hard work!

The robots are coming: How artificial intelligence will shape the future of chest medicine (and CHEST)*

BY CHAD JACKSON, MS, RRT, FCCP

The robots are coming – at least according to a report,[1] which states that Google created an artificial intelligence model that was able to detect lung cancer and cut back on false-positives at a rate that beat experienced radiologists.

As a fan of Star Wars, sci-fi, and innovation, in general – I say, bring it on! It's an exciting trend in medicine to see technology that has already changed the way we work and live enter into the world of health care. And, this is not about replacing humans either (like what occurs in a lot of sci-fi); this technology will potentially provide clinicians with the tools they can use to improve outcomes for their patients.

The researchers for this study used a system called convolutional neural networks to study patterns in 3D CT scans. One advantage computers has over humans is that a computer can process the entire scan all at once while trained radiologists need to review individual slices of each scan to make their diagnosis.

While this technology will need more testing and large-scale trials before being used to diagnose patients' disorders, the early results are encouraging. The researchers also picked a cancer that impacts so many of CHEST's members and their patients. Lung cancer kills more Americans than any type of cancer while accounting for more than 25% of all cancer deaths annually.[2] In a statistic that many people find shocking, lung cancer actually kills more women than breast, ovarian, and uterine cancers combined.[3] Given the devastation of this disease, we can use all of the help we can get. Another positive from this study that might be overlooked is the rate of improvement for false-positive results. This could be a major benefit of both saving the time and preventing invasive treatments or attempts to confirm a diagnosis.

This news is exciting for everyone trying to (as we say at CHEST) crush lung disease, but seeing AI in medicine is not surprising, because we are already using it at CHEST. The AI projects at CHEST include analyzing the types of activities that are most beneficial to members and building predictive analytics models for a project. These were only initial forays into using this new technology. One of the even more mind-blowing developments has been rolling out natural language processing[4] for our internal data reporting.

This is a new development, and much like the Google lung cancer study, we cannot tell you what the end result will be. What we can say is that it's likely to change the way we work and provide new opportunities to create analytics solutions for our partners.

CHEST is not "just" a medical association: we are also an innovative group using the latest tools to create a better future for members, partners, and, ultimately, patients and their families.

Mr. Jackson is CHEST Chief Innovation Officer & Vice President of Market Growth and Innovation.

Robots have long been an interest of the author – both professionally and as a hobby. As a part of the CHEST Foundation's Lung Health Experience, Chad Jackson constructed a simple robot that included pig lungs to simulate human lung activity.

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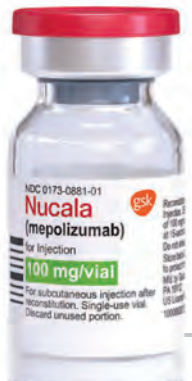

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Vaping in 2019: Risk vs reward

BY JASON CLARK, MD

The prevalence and popularity of electronic cigarettes or "vaping" have grown dramatically over the last several years in the United States. Although new studies targeting these products are being done at increasing frequency, there remains a relative paucity of data regarding the long-term risks. Proponents argue that they can be used as a cessation tool for smokers, or failing that, a safer replacement for traditional cigarettes. Opponents make the case that the perception of safety could contribute to increased use in people who may have otherwise never smoked, leading to an overall increase in nicotine use and addiction. This is most readily seen in the adolescent population, where use has skyrocketed, leading to concerns about how electronic cigarettes are marketed to youth, as well as the ease of access.

Dr. Clark

Basics of vaping (devices)

In its most basic form, an electronic cigarette consists of a battery that powers a heating coil. This heating coil applies heat to a wick, which is soaked in liquid, "vape juice," converting it into a vapor that is then directly inhaled. However, there can be many variations on this simple theme. Early generation products resembled traditional cigarettes in size and shape and were marketed as smoking cessation aids. Newer devices have abandoned this look and strategy. Preloaded cartridges have been replaced by large tanks that the user can fill with the liquid of their choosing. Multiple tanks can be purchased for a single device, enabling the user to have multiple flavors or various levels of nicotine dosing on hand for quick changing, depending on user preference or mood. Additionally, there are variable voltage settings, resulting in different styles of vapor and/or "throat hit" (the description of the desired burning vs smooth effect of the vapor on the oropharynx). This type of device invites experimentation. Multiple flavors can be used in isolation or mixed together at various temperatures. It no longer resembles classic cigarettes, and the flavor and experience are more prominently promoted. One can see that this device has more appeal to a "never smoker" than the original products, and there is concern that it is being marketed as such with some success (Dinakar C, et al. *N Engl J Med.* 2016;375[14]:1372).

E-liquid

Perhaps more important than the devices themselves is an understanding of the components of the liquid used to generate the inhaled aerosol. Typically, four components are present:

- Propylene glycol
- Vegetable glycerin
- Flavoring
- Nicotine

The first two components are generally considered nontoxic, based on their use as food additives. However, inhalation is a novel route of entry, and the long-term effects on the respiratory tract are unclear.

The third component, "flavorings," is a catch-all term for the hundreds of different flavors and styles of e-liquids available today, ranging from menthol to fruit or candy and everything in between. It is difficult to account for all the potential effects of the numerous flavorings being used, especially when some are combined by the end user to various degrees. Nicotine is present, specified in varying doses. However, vaping style, experience, and type of device used can dramatically affect how much is absorbed, making dosages difficult to predict. Additionally, labeled doses are prone to wide ranges of error (Schraufnagel DE, et al. *Am J Respir Crit Care Med.* 2014;190[6]:611).

What are the risks?

Cancer

A handful of known carcinogens can be found in inhaled vapor, including formaldehyde, acetaldehyde, acrolein, toluene, and nitrosamines. However, they are present in far lower concentrations than in traditional cigarettes (Goniewicz ML, et al. *JAMA Netw Open.* 2018;1[8] e185937). This leads to the natural assumption that vaping, while not benign, poses a much lower cancer risk when compared with smoking. Whether that is borne out in the long term remains to be seen.

Pulmonary function

The long-term effect on pulmonary function is not known. Small studies have shown no significant changes to spirometry after acute exposure to vapor. More data are needed in this area (Palazzolo DL. *Frontiers Public Health.* 2013;1[56]1-20).

Wound healing

An animal study has shown evidence of poor wound healing extrapolated from skin flap necrosis in rats. Exposure to vapor vs smoke yielded similar results, and both were worse than the sham arm (Troiano C, et al. *JAMA Facial Plast Surg.* 2019;21[1]:5). While it is difficult to know how to apply this clinically, it may be prudent to advise patients to abstain while in preparation for elective surgery.

Cardiovascular/stroke

Much of the cardiovascular toxicity from cigarette use is tied to the myriad of complex toxic particles produced in inhaled smoke, the vast majority of which are not present in e-cigarette vapor. While nicotine itself has known acute cardiovascular effects, including tachycardia and vasoconstriction, a tolerance to these effects occurs over time. Previous evaluations of nicotine replacement therapies and smokeless tobacco for their cardiovascular effects have had mixed results. But, there appears to be a trend toward minimal cardiovascular risk when using "cleaner" products, such as nicotine replacement therapy compared with smokeless tobacco (Benowitz NL, et al. *Nature Rev Cardiol.* 2017;14[8]:447). Whether this can be extrapolated to electronic cigarette use is unknown but is encouraging.

Alternative toxicity

In addition to the above risks that are in comparison to traditional smoking, vaping also introduces novel toxicities. There are case reports of lipoid pneumonia, ARDS, hypersensitivity pneumonitis, eosinophilic pneumonia, and diffuse alveola hemorrhage. Burns from malfunctioning devices must also be considered, as there is a wide array of products available, at differing levels of build quality.

Toxic oral ingestion of nicotine, especially by children, has led to increased calls to poison centers. For a small child, this can be fatal. Regulation of labels and containers could curtail this issue. But, public education regarding the toxicity of these substances when ingested in large quantities is also important. If there is a lack of understanding about this danger, then typical safeguards are easily overlooked by individual users.

Are there benefits?

Smoking cessation

Compared with other products, such as nicotine patches, gum, and pharmaceutical methods, e-cigarettes most closely mimic the actual experience of smoking. For some, the habit and ritual of smoking is as much a part of the addiction as nicotine. Vaping has the potential to help alleviate this difficult aspect of cessation. Data involving early generation products failed to show a significant advantage. Newer devices that are more pleasurable to use and offer more efficient nicotine delivery may be more effective. Indeed, a recent study in the New England Journal of Medicine from this year demonstrated improved smoking cessation compared with traditional methods, using second generation vape devices (Hajek P, et al. *N Engl J Med.* 2019;380[7]629). It will be interesting to see if this can be repeatable going forward and if protocols can be established to maximize effectiveness.

It is difficult to make definitive conclusions or recommendations regarding electronic cigarette use at the present time. The risk of cancer and cardiopulmonary disease is likely to be significantly lower but not eliminated. Use as a smoking cessation aid is starting to show promise. Even without cessation, ongoing vaping is likely to be safer than ongoing smoking. Two caveats to this remain: some patients, in an effort to quit smoking, may take up vaping but eventually become "dual users." This scenario has been associated with higher toxic exposure and possibly worse outcomes. The second caveat is that while there is promise to using this as a cessation tool, it should not yet replace other more well-studied, first-line agents in this regard. It should, perhaps, target patients who are motivated to quit but have failed more traditional methods. Finally, there continues to be concern that vaping could appeal to never smokers, given its perceived safety profile and ease of use in public places. This could lead to an overall increase in nicotine addiction, which could be a significant step backwards.

Dr. Clark is Assistant Professor, Pulmonary and Critical Care Medicine, UT Southwestern Medical Center, Dallas, Texas.

What's new for CHEST 2019?

BY KRISTIN CROWE
Marketing Communications Senior Specialist

Head to New Orleans this October for CHEST Annual Meeting 2019 for the latest original research, postgraduate courses, interactive case-based discussions, simulation sessions, CHEST Games, and more! CHEST 2019 allows clinician members of the entire health-care team to stay up to date on pulmonary, critical care, and sleep medicine. There are many new and exciting things happening at CHEST 2019, and we are excited to give you a sneak peek.

The simulation sessions are better than ever and include a full day of cadaver-based courses and brand new hands-on sessions in bronchoscopy, advanced critical care echocardiography, and airway management, that will put your skills to the test. You don't want to miss these simulation sessions that allow you to learn from our expert faculty to advance and develop valuable skills and apply your knowledge.

Visit CHEST in the exhibit hall to see the new additions we have added to amplify your experience. The new FISH Bowl innovation competition will allow you to learn about new solutions and ideas that were submitted in education and clinical disease for pulmonary, critical care, and sleep medicine. The finalists will be presenting live in Experience CHEST and competing for prizes in each category. CHEST Games will be back again in a new space in the exhibit hall. Be sure to bring your team to play the popular Nodal Nemesis and the other games that test your skills in new and creative ways.

CHEST 2019 plans to make your life easier by providing you with the latest updates in patient care, but we are also planning on making it easier in other ways. New this year, you can update your professional headshot in our new complimentary headshot booth. Plan to visit the new CHEST Wellness Zone. This area is designed to help you relax and recharge while at CHEST and includes meditation, posture consultants, aromatherapy, foot massage, and yoga. Attend CHEST 2019 with some peace of mind knowing that your children can be cared for at the Kiddie Corp childcare program for kids ages 6 months to 12 years.

According to William Kelly, MD, FCCP, CHEST 2019 Program Chair, "We are excited about these new opportunities that will help you improve your patient care. We're taking concrete steps to make your learning, your practice, and your life a little easier."

We look forward to seeing you at CHEST 2019 in New Orleans, Louisiana, October 19-23!

Update from AMA Annual Meeting 2019

BY NEERAJ R. DESAI, MD, MBA, FCCP; AND RICHARD W. NEWMAN

The American Medical Association (AMA) conducted the Annual Meeting of the AMA House of Delegates from June 8-12 in Chicago. The House of Delegates (HOD) is the principal policymaking body of the AMA, consisting of more than 600 delegates and accompanying alternate delegates who represent the medical specialty societies (including CHEST); the state and territorial medical associations; the uniformed services; and other stakeholder organizations. Leading policymakers including Centers for Medicare & Medicaid Services (CMS) Administrator Seema Verma and the Surgeon General of the United States, Vice Admiral Jerome M. Adams, MD, also participated in the meeting.

This year, the delegates (CHEST has three delegate positions) considered more than 200 policy proposals (resolutions and reports) in a multistep process: caucuses, Reference Committees, and hearings before the full House of Delegates.

The caucuses are an important first step in the HOD process. The Chest/Allergy Section Council (participants at this meeting were from the AAAAI, AAOA, AASM, ACAAI, ATS, CHEST, and SCCM) met the day before the Reference Committee hearings to:

- Decide what resolutions and reports are most important to the chest diseases, critical care medicine, sleep medicine, and allergy communities;

Surgeon General of the United States, Vice Admiral Jerome M. Adams, MD, testifying at AMA Public Health Reference Committee hearing, Chicago, June 9, 2019.

- Determine (if possible) a unified position (support/oppose);
- Develop talking points; and
- Identify who will speak for the caucus (or as individuals if there were differing positions) at the various Reference Committee meetings.

Under the leadership of Tina Shah, MD, MPH, from the Society of Critical Care Medicine, the caucus decided to focus on 16 reports and resolutions that were slated for discussion at 7 different Reference Committees. The caucus used the GroupMe mobile, a group messaging app, to stay in touch during the meeting to ensure that someone from the caucus would be at all pertinent sessions and to communicate progress and results in real time.

The topics of the reports and resolutions selected by the Caucus for involvement included:

- Returning Liquid Oxygen to the Medicare Fee Schedule
- COPD National Action Plan
- Low Nicotine Product Standard
- Addressing the Vaping Crisis
- Regulating Liquid Nicotine and E-Cigarettes
- Put Over-the-Counter Inhaled Epinephrine Behind Pharmacy Counter
- Change in Marijuana Classification to Allow Research
- Promotion of Early Recognition and Treatment of Sepsis by Out-of-Hospital Healthcare Providers
- The Climate Change Lecture for US Medical Schools
- Physician-Assisted Suicide
- End-of-Life Care

The Reference Committees, where both AMA members and nonmembers (with permission) may testify, are organized by topic:

- Medical Service
- Legislation, Legal, and Regulatory Issues
- Medical Education
- Public Health
- Science and Technology
- AMA Governance and Finance
- Medical Practice
- Constitution and Bylaws

The Reference Committees hear testimony on each resolution, adjourn, and then meet privately (often into the wee hours) to develop recommendations to the full House. Their options include:

- Recommend Adoption
- Recommend Adoption With Amendment
- Recommend Referral (further study by one of several Councils)
- Recommend Referral for Decision (by the Board of Trustees after further study)
- Recommend for Non-Adoption

During the following 3 days, the full House of Delegates considers the Reference Committee recommendations. Any delegate may object to any recommendation and cause it to be debated and voted on by the full House of Delegates. Details about the outcomes of the 200+ resolutions are available at the AMA website (ama-assn.org).

The compendium of policies covers the entire range of topics impacting the practice of medicine – ethics, legislation, regulation, public health, individual health, and medical education among them. The full range of policies may be found in the AMA's Policy Manual available on the AMA website (ama-assn.org).

CHEST members with an interest in the AMA policy-making process may observe any AMA-HOD meeting or participate in the AMA's democratic processes. Attendees will also be able to increase their knowledge and skills with no cost at scores of educational sessions and will also be able to connect with more than 1,500 peers and other meeting attendees from across the country. CHEST members with the time (there are two 5-day meetings each year) and interest are invited to apply to be an official CHEST delegate to the AMA. Contact Jennifer Nemkovich at jnemkovich@chestnet.org for details.

Dr. Desai is with the Chicago Chest Center and Suburban Lung Associates; and the Division of Pulmonary, Critical Care, Sleep and Allergy, University of Illinois at Chicago. He is also the CHEST Delegate to the AMA House of Delegates. Mr. Newman is the Senior Director of Strategy, Product, & Global Development at CHEST.

CRITICAL CARE COMMENTARY

Changing clinical practice to maximize success of ICU airway management

BY ARTHUR J. TOKARCZYK, MD, FCCP; AND STEVEN B. GREENBERG, MD, FCCP, FCCM


Dr. Tokarczyk


Dr. Greenberg

Airway management is a complex process that, if not performed in a proper and timely manner, may result in significant morbidity or mortality. The risk of intubation failure and associated adverse events is higher in critically ill patients due to differences in patient condition, environment, and practitioner experience. Even when controlling for provider experience, intubating conditions are worse and success rates are lower in the ICU compared with the controlled environment of the operating room (Taboada, et al. *Anesthesiology.* 2018;129[2]:321). Furthermore, the risk of injury and adverse events increases with the number of intubation attempts during an emergency (Sakles JC, et al. *Acad Emerg Med.* 2013;20[1]:71). Unfortunately, the paucity of high-grade evidence leads practitioners to rely on practice patterns developed during training and predicated on common sense airway management principles. The difficulty in evaluating airway management in the critically ill lies in the multi-step and complex nature of the process, including the pre-intubation, intubation, and post-intubation activities (Fig 1). Several recent publications have the potential to change airway management practice in the ICU. We will address the latest information on preoxygenation, use of neuromuscular blockade (NMB), and checklists in this setting.

Preoxygenation: Overrated?

Rapid-sequence intubation (RSI) is a technique intended to minimize the time from induction to intubation and reduce the risk of aspiration by primarily avoiding ventilation. The avoidance of bag-mask ventilation during this apneic period is common, due to concerns that positive pressure can produce gastric insufflation and regurgitation that may lead to aspiration. To attenuate the risk for critical desaturation, preoxygenation is classically provided prior to induction of anesthesia in the operative procedural areas. Although the benefit can be seen in patients undergoing elective intubation, critically ill patients often have difficulty in significantly raising the blood oxygen content despite preoxygenation with 100% oxygen delivered via face mask. As a result, the oxygen saturation can drop precipitously during the process of ICU intubation, especially if multiple or prolonged intubation attempts are required. These factors all contribute to the risk of hypoxemia and cardiac arrest during ICU intubations (De Jong A, et al. *Crit Care Med.* 2018;46[4]:532), which has led to the debate about the avoidance of ventilation during RSI in the critically ill. Recently, Casey and colleagues (Casey JD, et al. *N Engl J Med.* 2019;380[9]:811) evaluated the use of bag-mask ventilation (BMV) during RSI. In this ICU study, intubations were randomized to either include BMV or no ventilation after induction. The results suggested that the frequency of critical desaturation was lower in the patients receiving BMV after induction

Continued on following page

This month in the journal *CHEST*®

Editor's picks

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

COMMENTARY

Imaging of Pulmonary Hypertension: Pictorial Essay
By Dr. E. Altschul, et al.

ORIGINAL RESEARCH

Epidemiology of Quick Sequential Organ Failure Assessment Criteria in Undifferentiated Patients and Association With Suspected Infection and Sepsis
By Dr. V. Anand, et al.

Infectious Disease Hospitalizations: United States, 2001 to 2014
By Dr. J. L. Kennedy, et al.

Overdiagnosis of COPD in Subjects With Unobstructed Spirometry: A BOLD Analysis
By Dr. L. Sator, et al.

TRANSLATING BASIC RESEARCH INTO CLINICAL PRACTICE

Common Pathogenic Mechanisms Between Idiopathic Pulmonary Fibrosis and Lung Cancer
By Dr. A. Tzouvelekis, et al.

Continued from previous page

without a concomitant increase in frequency of aspiration. Although not powered to evaluate the difference in the incidence of aspiration, this study supports the use of BMV during the apneic phase of intubation, thereby decreasing the risk for critical desaturation.

Neuromuscular blockade: Yes or no?

Awake intubation, with or without sedation, is often employed for managing the airway in high-risk patients. This technique allows the patient to maintain spontaneous ventilation in the event of repeated intubation attempts and has a lower hypotension risk. However, many critically ill patients cannot be managed in this manner due to lack of patient cooperation, emergent airway management requirements, or practitioner inexperience with this technique. As a result, many of these patients will require an induction agent, and concomitant administration of a neuromuscular blocking agent (NMB) to optimize intubating conditions. However, the avoidance of NMBs in emergent airway scenarios was not uncommon among attending physicians and trainees (Schmidt UH, et al. *Anesthesiology*. 2008;109[6]:973). The American College of Chest Physicians (CHEST) Difficult Airway Course faculty also suggest to not use NMB because of the high risk of failure to ventilate/oxygenate. Without NMB, the patient might be allowed to recover to spontaneous ventilation. This approach is taken in the American Society of Anesthesiologists Practice Guidelines for the Management of the Difficult Airway but is not necessarily applicable to the critically ill patient (Apfelbaum JL, et al. *Anesthesiology.* 2013;118[2]:251-70). In the event of "can't intubate, can't oxygenate" (CICO), the critically ill patient in extremis may not tolerate an attempt to return to spontaneous ventilation because spontaneous ventilation may have been initially inadequate.

In 2010, Jaber and colleagues demonstrated a lower incidence of hypoxemia and severe hemodynamic collapse with the implementation of an intubation bundle that included the use of NMBs for all rapid-sequence inductions (Jaber S, et al. *Int Care Med*. 2010;36:248). The safety of using paralytics in critically ill patients was later investigated by Wilcox and colleagues in a prospective, observational study that suggested a decrease in the incidence of hypoxemia and complications when employing NMB (Wilcox SR, et al. *Crit Care Med*. 2012;40[6]:1808). Although Wilcox et al.'s study was hypothesis-generating by the nature of its design, it was consistent with both Jaber's findings and a more recent observational study performed by Moser et al (Mosier JM, et al. *Ann Am Thorac Soc.* 2015;12[5]:734). Furthermore, there is no evidence that NMBs worsen bag mask ventilation in the critically ill patient. NMBs in addition to induction agents might be associated with optimal intubating conditions, reduced complications, and allow for placement of a supraglottic airway device or surgical airway in the event of a CICO (Higgs A, et al. *Br J Anaesth*. 2018;120[2]:323).

Checking the checklists

Checklists are another intervention with the potential to improve outcomes or reduce adverse events. Airway management is often a complex process with significant opportunities for failure. Therefore, having reminders or checklists available to the provider may encourage the use of best practices. Jaber demonstrated that a straightforward, 10-point intubation bundle reduced the incidence of severe complications associated with emergent intubation in the ICU. In the 4th National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society, the use of checklists was recommended as a method to reduce adverse events and increase successful airway management (Cook TM, et al. *Br J Anaesth*. 2011;106[5]:632). In fact, several mnemonics have been developed to aid the practitioner, including the '7 Ps' in the Manual of Emergency Airway Management (Walls RM, et al. Manual of Emergency Airway Management. 2012) and APPROACH from the CHEST Airway Management Training Team. More recently, Janz and colleagues developed and employed a checklist in a multicenter study and compared it with usual practice (Janz DR, et al. *CHEST.* 2018;153[4]:816). Although the checklist was associated with improved provider compliance with airway assessment, preparation, and verbalization of a plan, it did not go far enough to include the known interventions for optimizing preoxygenation and hemodynamic stability. Two elements that might be included in a checklist include fluids and vasopressors administration during the pre-intubation and post-intubation period, and preoxygenation with noninvasive ventilation. The former is associated with a lower incidence of hypotension, while the latter may reduce the incidence of severe hypoxemia in ICU intubations (Baillard C, et al. *Am J Respir Crit Care Med*. 2006;174[2]:171).

Keeping apprised of evidence and adjusting practice are crucial to the competent clinician engaging in airway management, as they minimize the risk of harm while maximizing the benefit to the patient. However, the methods to achieve these goals are not always intuitive. Definitive high-level evidence is sparse. The use of neuromuscular blockade and BMV after induction has historically been controversial, but more recent evidence is favoring these approaches for RSI. The use of checklists or guidelines may ensure that the necessary safety steps are followed, especially at institutions that may not have experts in airway management. Over time, the hope is that many of our traditional practices are either supported by quality evidence or better techniques evolve.

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Figure 1. ICU intubation process

Pre-intubation
- Evaluation of the airway
- Preoxygenation
- Positioning of patient
- Preparation of equipment and plan

Intubation
- Administration of medications
- Intubation

Post-intubation
- Confirmation of tube position
- Sedation
- Hemodynamic support

THE CHEST ***APPROACH***

DL-5 min **Assess** the airway: It's all in your HAND

DL-4 min **Preoxygenate:** Using 100% O2 via 2-person BMV; Use PEEP or NIV; raise HOB 15-30o

DL-3 min **Prepare:**
Patient: Sniffing position, headboard off
Meds: IV, airway drugs, fluids, pressors
Left side: laryngoscope, blades, airways, ETCO2
Right side: ETT, stylet, syringe, suction only

DL-2 min **Review:** Plan, backup plans, and equipment, and team roles

DL-2 min **Oxygen cutoffs:** Identify signals to abort and reinitiate ventilation

DL-1 min **Administer** medication, if indicated

DL **Confirm** after placement with two indicators, including ETCO2

Post DL **Hold** endotracheal tube until secured

CHEST NETWORKS

Bronchoscopy coding and billing tips. HCV+ donors. Women and COPD. Treating penetrating trauma

Practice Operations

Basic bronchoscopy coding and billing: Rules of the road

Although complex, reimbursement for bronchoscopy is based on appropriate billing, coding, and precise documentation. It is of utmost importance to have a detailed understanding of the various codes

Dr. Surani

Dr. Anjum

to optimize reimbursement. We understand this is a moving target and beyond the scope of this article to discuss all the specific details, so we will try to focus on "the road less travelled."

Tip#1: When multiple techniques are performed during a bronchoscopy, only one CPT® code is considered primary and fully paid while the rest are partially paid. However, there are certain CPT codes that are considered "add-ons" and, therefore, do not fall under the multiple bronchoscopy rules and are paid in full on top of the other codes.

Tip#2: When separate biopsies are performed on different sites or lesions during the same procedure, be sure to attach the Modifier 59 (distinct procedural service) code.

Tip#3: If the procedure performed was time consuming and/or difficult, attach the Modifier 22 (unusual procedural services) code as it increases the reimbursement by 20% to 25%.

Tip#4: The CPT codes for bronchoscopy with therapeutic aspiration are **31645** (initial) and **31646** (subsequent). These were revised in 2018. They are valued greater than **31622** (airway inspection).

Tip#5: Previously moderate sedation provided by the bronchoscopist was bundled in the CPT codes, but in 2017, CMS reduced the wRVUs of these codes by 0.25. This change was adapted due to the trend of billing for moderate sedation by separate providers and reflects the increased use of anesthetists in the endoscopy suite.

Different insurance companies have varying requirements regarding a lot of codes, particularly the modifiers. Therefore, physicians, hospitals, and the coders need to be aware of all the rules. Please do not hesitate to contact the Practice Operations NetWork for more information.

Salim Surani, MD, MPH, FCCP
Chair
Humayun Anjum, MD, FCCP
Vice-Chair

Additional reading:

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Transplant

Hepatitis C-positive donor organs and lung transplantation: Are we there yet?

The field of lung transplantation continues to be encumbered by the mismatch between organ supply and demand. Only approximately 15% of potential donor lungs are currently being used for transplantation, resulting in unacceptably high wait list mortality (17.2 deaths per 100 wait list years). To counter this, the transplant community continues to invest in innovations such as ex vivo lung perfusion (EVLP) to increase the availability of suitable lungs for transplantation. At the same time, efforts to modify some of the existing practices are also underway. One area of interest has been the potential use of hepatitis C virus antibody positive (HCV+) donors in solid organ transplantation. Traditionally, the use of HCV+ organs, especially when the donor is nucleic acid test (NAT)-positive, which indicates presence of HCV RNA, has been considered a contra-indication for solid organ transplantation. However, this has resulted in the exclusion of a significant number of potential HCV+ donors (including young and otherwise healthy donor organs), the increased availability of which has been fueled by the opioid epidemic in the United States. While kidney transplantation programs have been relatively more liberal with utilizing this subset of donors (due to requiring lesser degree of immunosuppression), heart and lung transplantation programs have shied away from this practice due to concerns for disease transmission and unfavorable outcomes, including reduced survival of the recipient (Englum BR, et al. *J Heart Lung Transplant*. 2016 Feb;35[2]:228).

Dr. Kumar

Dr. Hayanga

Hepatitis C infection is one of the medical conditions for which the treatment of disease has changed substantially in the last decade. The advent of new classes of medications, direct acting antiviral agents (DAA), has ensured that a sustained virologic response (SVR), across all genotypes, is now possible in up to 98% of those who undergo treatment. Further, DAAs have a comparatively favorable pharmacokinetic profile and are well tolerated. Since the initial reports of success in the use of HCV+ donor organs for lung transplantation, the results of a recently published trial lend further support to the continued use of these organs (Khan B, et al. *Am J Transplant.* 2017 Apr;17[4]:1129). One hundred percent of patients (n=35, 28 lung and 7 heart) who received organs from HCV+ donors (NAT +) and were treated with DAA for 4 weeks (started immediately after transplantation) had an undetectable viral load and excellent graft function at 6 months posttransplantation (Woolley AE, et al. *N Engl J Med.* 2019 Apr 25;380[17]:1606). Similar studies with greater power and longer follow-up need to be conducted to instill greater confidence in the use of HCV+ organs in potential lung recipients. In addition, ethical issues surrounding the use of HCV+ organs should be carefully vetted, as the long-term outcomes regarding use of DAAs are not yet known. It is imperative that transplant centers ensure that patients who consent to receipt of HCV+ organs fully comprehend the implications of doing so and have systematic posttransplant surveillance. It is also critical that ready access to the entire planned course of DAA is secured for recipients, since these agents could be cost-prohibitive in nonresearch settings. Willingness to comply with intense surveillance and therapy should also be assessed. While the notion of using HCV+ donors has gained ground as a promising strategy, transplant centers have been rightfully cautious in its liberal use, until long-term outcomes are better characterized.

Anupam Kumar, MD
Fellow-in-Training Member
J. W. Awori Hayanga, MD, MPH, FCCP
Steering Committee Member

Women's Health

Women and COPD

While age-adjusted death rates from COPD declined for men in the US between 1999 and 2014, they did not change significantly for women. There have been increasing numbers of studies that have focused on differences in COPD risk factors and outcomes between men and women.

Dr. Pisani

Health and disease are impacted by both sex and gender. Sex refers to biological differences, including chromosomal differences, sex organs, and endogenous hormone profiles. Gender refers to social and cultural differences and includes socially constructed roles and behaviors that vary across cultures and over time.

The prevalence of COPD is increasing more rapidly in women. Women are more likely to be misdiagnosed or have a delay in diagnosis (Chapman, et al. *CHEST.* 2001;119[6]:1691). Evidence suggests that women with COPD have more exacerbations, worse health status, and greater dyspnea (Roche, et al. *Respir Res.* 2014;15:20; Celli, et al. *Am J Respir Crit Care Med.* 2011;183[3]:317). Women diag-

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nosed with COPD are more likely to be nonsmokers, and those who smoke are more susceptible to the harmful effects of tobacco (Vestbo, et al. *Am J Respir Crit Care Med.* 2013;187[4]:347).

In examining differences in exacerbation risk/severity between men and women, 48% of patients with incident COPD were women. Women were 17% more likely to have a moderate/severe first disease exacerbation and shorter time from diagnosis to exacerbation. During 3 years of follow-up, women had higher annual rates of moderate to severe exacerbations, most pronounced in ages greater than 40 years to less than 65 years (Stolz et al. Submitted for publication. *CHEST* 2019).

NHLBI convened a workshop of experts to review the current understanding of sex and gender on lung disease. They concluded that sex-specific susceptibility to COPD is poorly understood, and gender-specific approaches to COPD are imperative (Han et al. *Am J Respir Crit Care Med*. 2018;198[7]:850).

Margaret Pisani, MD, MS, FCCP
Vice-Chair

Dr. Powers

Dr. Maves

survival. The majority of military combat injuries has been due to blast injury (62%-74%), with a minority (22%-23%) due to gunshots (Eastridge et al. *J Trauma Acute Care Surg.* 2012;73:S431; Champion et al. *J Trauma.* 2003;54:S13). These data suggest that widespread use of pre-hospital extremity tourniquets for hemorrhage control in the treatment of gunshot wounds may not result in the anticipated survival improvement that has led to its widespread advocacy. Basic tenets of trauma care, such as rapid control of the airway and treatment of penetrating trauma to the thorax and abdomen, will continue to be of paramount importance.

Michael Powers, MD
Ryan Maves, MD, FCCP
Michael Tripp, MD, FCCP
Steering Committee Members

Disaster Response and Global Health

Treating penetrating trauma

The management of penetrating trauma is an unfortunate but all too common facet of critical care practice. A recent emphasis has been placed on the use of extremity tourniquets for hemorrhage control. It has been embraced by organizations such as the Hartford Consensus Joint Committee, in which hemorrhage control is viewed as the critical step in eliminating preventable prehospital death, secondary only to neutralizing the threat posed by the shooter (Brinsfield et al. *Bull Am Coll Surg.* 2015;100(1 Suppl):24). Interestingly, a recent retrospective review of mass shootings incorporating 12 events and 139 fatalities indicated that only 20% of victims sustained an injury to an extremity, while 58% were shot in the head or chest. Only 7% of deaths occurred in victims with potentially survivable wounds, while the vast majority of fatalities followed wounds to the chest (89%), and there were no reported events of potential survivors exsanguinating from extremity wounds (Smith et al. *J Trauma Acute Care Surg.* 2016; 81:86). This differs from recent military data, where the use of extremity tourniquets has been widely lauded for improving

Dr. Powers is a United States military service member. This work was prepared as part of his official duties. Title 17 U.S.C. §105 provides that 'Copyright protection under this title is not available for any work of the United States Government.' Title 17 U.S.C. §101 defines a U.S. Government work as a work prepared by a military service member or employee of the U.S. Government as part of that person's official duties. The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Departments of the Navy, the Department of Defense, nor the U.S. Government.

2019 Journal *CHEST*® impact factor update

The journal *CHEST*® has been awarded an impact factor of 9.657, the highest in its history, which equates to a 26% increase over last year's record-breaking score. *CHEST*® is ranked 4th out of 33 journals in the Critical Care category and 5th out of 63 journals in the Respiratory System category.

Congratulations to all who contributed to this outstanding achievement.

New Editor in Chief takes the reins

CHEST welcomed Peter J. Mazzone, MD, MPH, FCCP, in July, as the new Editor in Chief of the journal *CHEST*®. Dr. Mazzone is the Director of the Lung Cancer Program and Lung Cancer Screening Program for the Respiratory Institute at the Cleveland Clinic in Ohio. His clinical interests include nodule management and the prevention, screening, diagnosis, staging, and characterization of lung cancer; his research has focused on the development of molecular biomarkers for lung cancer detection.

Dr. Mazzone

Dr. Mazzone has been a member of CHEST since 1999 and an FCCP since 2004. He has served in several CHEST leadership positions, including member of the CHEST Lung Cancer Living Guidelines Steering Committee and program chair for the CHEST 2017 annual meeting, among others. Dr. Mazzone has provided some insights into the structure and strategies of the journal going forward, so don't miss his editorial in the July issue of *CHEST*®.

ENVIRONMENTAL SCAN

Drivers of change in the economy and workforce

BY THERESE BORDEN

The health-care workforce is being transformed by profound demographic changes and the steady growth of the health sector in the United States. In addition, the movement of physicians out of private practice to employment by medical centers has accelerated. A new generation of health-care professionals is demanding a sustainable work/life balance. These trends will combine to change the work environment of chest physicians.

CHEST INSPIRATION: Pacing the Future

Spending

The United States spends about twice as much on health care as any other industrialized nation, and this fact is driving an increasingly urgent public discussion about options and means of reducing costs.[1] Medicare and Medicaid already account for about a quarter of federal government spending, and those numbers are expected to rise as baby boomers age.[2] Employer spending on health care as a percentage of wages has doubled since the 1980s.[3]

Workforce supply

An expanding health-care sector means a growing demand for health-care labor. Health-care occupations are projected to grow 18% from 2016 to 2026, faster than the average for all occupations and adding 2.4 million new jobs to the economy.[4] Expert testimony before the US Senate Health, Education, Labor and Pensions in May 2018 projected shortages of physicians in the coming years. According to estimates of the Health Resources and Services Administration (HRSA), there is a need for 13,800 additional primary care physicians in areas—especially rural—that are designated as health professional shortage areas. Signs of a worsening situation include projected shortages of 20,000 primary care physicians by 2025, according to HRSA, and 42,600 to 121,300 physicians by 2030, according to the Association of American Medical Colleges. The demand for physicians will exceed supply by 46,000 (on the low estimate) to 90,000 (on the high estimate) by 2025. An update to that research increased the projected shortage range to 61,700 – 94,700 by 2025.[5] These shortages will result in recruiting challenges for many medical centers, especially those in rural areas.

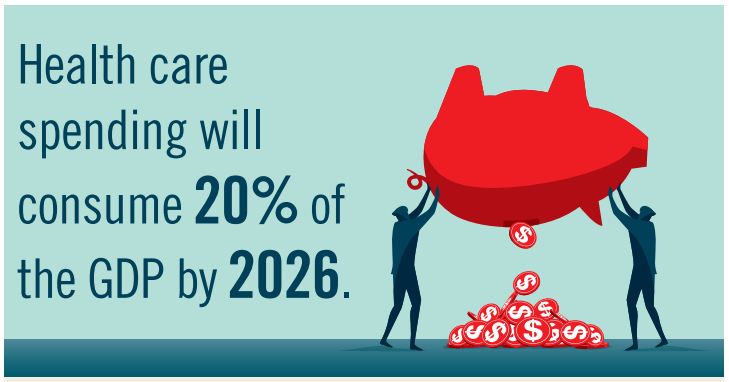
Employment

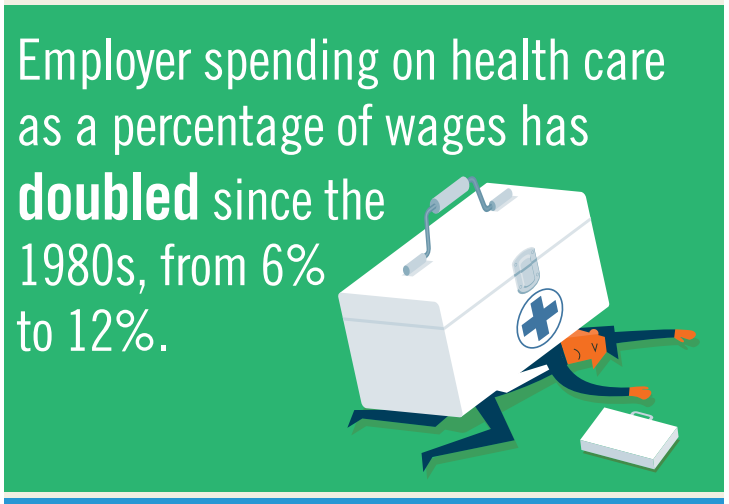
Private practice is becoming the less common structure of employment for physicians. According to the American Medical Association data, physician ownership of practices dropped below 50% for the first time in 2016.[6] The trend toward employed vs private practice physicians is expected to continue. The size of practices is growing, with about one-third of physicians working in a hospital-owned practice or employed directly by a hospital and around 40% in practices of 10 physicians or more.[7] Three of every 10 physician practices were hospital-owned in 2106.[8] Physicians are being called upon to do more data entry and administrative work; 21% of physicians' time is now spent on nonclinical paperwork.[9] The ripple out effects of what amounts to a seismic shift in the work structure and work environment for physicians are only beginning to be studied in terms of overall personal satisfaction and impact on patient care.

Dr. Levine

Stephanie M. Levine, MD, FCCP, the President-Elect of the American College of Chest Physicians and Professor of Medicine in the Division of Pulmonary Diseases and Critical Care Medicine at the University of Texas Health Science Center in San Antonio, recognizes the significance of the move from private practice to employment and suggests that advantages could be offset by some potential negatives for practicing chest physicians. She notes, "Pros include potentially more job security, more predictable work hours, perhaps a reduction in some

of the traditional administrative 'hassles' with running a private practice, and possibly a better and healthier work/life balance. Some think that physician input and leadership in the employed model may have more influence on a health-care system than in an individual private practice. Nonclinical work may be decreased, but it is not clear that this is true."





MDedge News

She commented on the potential down side to the trend, including "a loss of autonomy, a potential loss of personal ownership of our patients' health, and the loss of a unique personal culture of private practice. Physicians may be subject to metrics imposed by the employer. We may see more job turnover since physicians could be less invested emotionally and financially; fewer patients seen since the structure is often salary-based and not based on productivity; and increased shift work, set work hours, and schedules. Thus, the employer-based model may actually contribute to the ongoing physician shortage."

Dr. Levine stressed the role of training programs to prepare physicians for what may be ahead. "Training programs must prepare physicians for what to expect as employees," she noted.

Changing expectations

An evolution of expectations about a healthy work/life balance has occurred in many professions, including the health-care profession. While younger practitioners may be more likely to embrace the changes occurring within health care, they are often more vocal about their desire for a healthy work/life balance and may be less likely to spend time away from family and friends rather than completing administrative tasks. Parenting is increasingly regarded by women and men as compatible with a full and rewarding career as a physician. These changing expectations about work/life balances mean health-care institutions will have to adjust their own expectations in order to recruit and maintain top quality staff.

Stress and burnout

Workforce shortages, overwhelming administrative tasks, and a variety of forces that come with employment in a large medical system are causing stress and burnout in many physicians. In a 2018 Medscape study of more than 15,000 physicians, 42% reported burnout, and 15% admitted to experiencing either clinical or colloquial forms of depression.[10] Dr. Levine acknowledges that many chest physicians are at risk for burnout. "In our field of medicine, particularly with those who practice in an intensive care setting, we are faced with the high stress and emotional experiences we encounter in the life and death nature of our jobs. We care for the sickest patient population and are often facing life and death clinical needs, as well as end-of life discussions and care. Burnout is a potential threat to both patient safety and the quality of health care that we practice."

Dr. Levine strongly urges colleagues to remain vigilant to this potentially devastating condition in their fellow physicians and in themselves. She said, "If you suspect you are feeling the symptoms of burnout, or have been told so by a colleague, then talk to a peer or colleague, take personal time to do something you enjoy, and/or join a support group. But better than that, try to preempt burnout by developing a strong emotional peer support group in or out of work, practicing mindfulness training, and paying attention to wellness and self-care."

Burnout is finally being recognized by medical institutions as a significant factor in physician health and performance and in the recruitment and attrition of staff. Dr. Levine sees progress in how health-care institutions deal with burnout, wellness, and work/life balance among staff and trainees. In a hopeful note, Dr. Levine suggested that institutional responses to burnout and the workplace factors that fuel burnout may improve work conditions for physicians in the future.

These trends in the US economy and workforce will mean a steady growth of the health-care sector for the foreseeable future, continued political and social pressure to control costs, fewer physicians in private practice, and, potentially, a move away from unhealthy work/life ratios currently so common among physicians.

Dr. Levine concluded that it is up to training programs to prepare trainees for these changes and other possible future disruptions in the practice of medicine.

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Note: Background research performed by Avenue M Group.

CHEST Inspiration is a collection of programmatic initiatives developed by the American College of Chest Physicians leadership and aimed at stimulating and encouraging innovation within the association. One of the components of CHEST Inspiration is the Environmental Scan, a series of articles focusing on the internal and external environmental factors that bear on success currently and in the future. See "Envisioning the Future: The CHEST Environmental Scan," *CHEST Physician*, June 2019, p. 44, for an introduction to the series.

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Legionella pneumophila
Mycoplasma pneumoniae

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Coronavirus
Human Metapneumovirus
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Influenza A
Influenza B
Parainfluenza virus
Respiratory Syncytial virus

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