VOL. 10 • NO. 3 • MARCH 2015

CHEST™ Physician

THE NEWSPAPER OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS

Gradual smoking cessation

COURTESY OF JAMA

Varenicline for 24 weeks boosted quit rates in smokers, according to Dr. Jon O. Ebbert of the Mayo Clinic. See page 6, and watch the video at chestphysician.org.

Medicare now covers CT for lung cancer screening

Benefit is limited to select beneficiaries.

BY M. ALEXANDER OTTO
Frontline Medical News

Effective immediately, Medicare will cover annual lung cancer screening with low-dose CT for certain beneficiaries, according to a Feb. 5 national coverage determination.

To qualify, beneficiaries must be 55-77 years old, have a smoking history of at least a 30 pack-years, exhibit no signs or symptoms of lung cancer, and currently smoke or have quit within 15 years. They also must have a written screening order from their provider.

Coverage includes a counseling visit for shared decision making, so patients know beforehand the "benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive[s], and total radiation exposure," among other things, according to the decision memo from the Centers for Medicare & Medicaid Services.

Imaging centers are required to collect data on each screening and submit it to a CMS-approved registry.

"This is an important new Medicare preventive benefit since lung cancer is the third most common cancer and the leading cause of cancer

See **Medicare** • *page 7*

INSIDE

Smoking linked to 'new' causes of death

BY MARY ANN MOON
Frontline Medical News

Smoking causes death from many diseases that until now have not been linked officially to tobacco use, including digestive disorders, liver cirrhosis, infections, renal failure, and breast and prostate cancers, according to a report published online Feb. 11 in the New England Journal of Medicine.

"Our results suggest that the number of persons in the United States who die each year as a result of smoking cigarettes may be substantially greater than currently estimated," said Brian D. Carter of the epidemiology research program, American Cancer Society, Atlanta, and his associates.

The 2014 Surgeon General's report estimated that smoking causes more than 480,000 deaths every year in the United States, based on mortality figures from 21 diseases that have been formally established as caused by smoking: 12 types of cancer, 6 types of cardiovascular disease, diabetes, chronic obstructive pulmonary disease,

See **Smoking** • *page 7*

Steroid cut CAP therapy failures

BY MARY ANN MOON
Frontline Medical News

A 5-day course of methylprednisolone reduced the rate of treatment failure in adults with severe community-acquired pneumonia and a high initial inflammatory response.

"If replicated, these findings would support the use of corticosteroids as adjunctive treatment in this clinical population," said Dr. Antoni Torres of Institut Clinic del Torax, Hospital Clinic, Barcelona, and his associates.

Dr. Torres and his colleagues studied the use of corticosteroids in the subgroup of patients who present with severe disease and a proinflammatory profile characterized by a serum C-reactive protein level over 150 mg/dL – the patients most likely to benefit from anti-inflammatories and least likely to be harmed by steroid-induced superinfection.

See **Therapy failures** • *page 9*

CHEST Physician
151 Fairchild Ave.,
Suite 2,
Plainview, NY 11803-1709

CHANGE SERVICE REQUESTED

Presorted Standard
U.S. Postage
PAID
Permit No. 384
Lebanon Jct. KY

Reduce lung function decline

Delay IPF Progression with Esbriet

Indication

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

Select Important Safety Information

Elevated liver enzymes: Increases in ALT and AST >3× ULN have been reported in patients treated with Esbriet. Rarely these have been associated with concomitant elevations in bilirubin. Patients treated with Esbriet had a higher incidence of elevations in ALT or AST than placebo patients (3.7% vs 0.8%, respectively). No cases of liver transplant or death due to liver failure that were related to Esbriet have been reported. However, the combination of transaminase elevations and elevated bilirubin without evidence of obstruction is generally recognized as an important predictor of severe liver injury that could lead to death or the need for liver transplants in some patients. Conduct liver function tests (ALT, AST, and bilirubin) 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 patients treated with placebo (1%). Patients should avoid or minimize exposure to sunlight (including sunlamps), use a sunblock (SPF 50 or higher), and wear clothing that protects against sun exposure. Patients should avoid concomitant medications that cause photosensitivity. Dosage reduction or discontinuation may be necessary.

Gastrointestinal disorders: Gastrointestinal events of nausea, diarrhea, dyspepsia, vomiting, gastroesophageal reflux disease, and abdominal pain were more frequently reported in patients treated with Esbriet. Dosage reduction or interruption for gastrointestinal events was required in 18.5% of patients in the Esbriet 2403 mg/day group, as compared to 5.8% of patients in the placebo group; 2.2% of patients in the Esbriet 2403 mg/day group discontinued treatment due to a gastrointestinal event, as compared to 1.0% in the placebo group. The most common (>2%) gastrointestinal events that led to dosage reduction or interruption were nausea, diarrhea, vomiting, and dyspepsia. Dosage modifications may be necessary in some cases.

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

Drug interactions: Concomitant administration with strong inhibitors of CYP1A2 (eg, fluvoxamine) significantly increases systemic exposure of Esbriet and is not recommended. Discontinue prior to administration of Esbriet. If strong CYP1A2 inhibitors cannot be avoided, dosage reductions of Esbriet are recommended. Monitor for adverse reactions and consider discontinuation of Esbriet as needed.

Introducing Esbriet® (pirfenidone) capsules 267 mg

Proven to delay progression in IPF[2]

- Fewer patients had a meaningful decline in lung function with Esbriet at 52 weeks vs placebo (17% vs 32% of patients had ≥10% decline in %FVC, $P<0.001$). Treatment effect was evident at 13 weeks ($P<0.001$) and increased through trial duration[1,2,*,†]
- More patients had stable lung function with Esbriet than with placebo at 52 weeks (23% vs 10%)[1,*,‡]
- In clinical trials, elevated liver enzymes, photosensitivity reactions, and gastrointestinal disorders have been reported with Esbriet[1]
- Esbriet has been approved outside the US since 2011, with approximately 15,000 patients treated with pirfenidone worldwide[3]

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

*The efficacy of Esbriet was evaluated in three phase 3, randomized, double-blind, placebo-controlled trials. In ASCEND, 555 patients with IPF were randomized to receive Esbriet 2403 mg/day or placebo for 52 weeks. Eligible patients had %FVC between 50%-90% and DL_{CO} between 30%-90%. The primary endpoint was change in %FVC from baseline to week 52.

Concomitant administration of Esbriet and ciprofloxacin (a moderate inhibitor of CYP1A2) moderately increases exposure to Esbriet. If ciprofloxacin at the dosage of 750 mg twice daily cannot be avoided, dosage reductions are recommended. Monitor patients closely when ciprofloxacin is used.

Agents that are moderate or strong inhibitors of both CYP1A2 and CYP isoenzymes involved in the metabolism of Esbriet should be avoided during treatment.

The concomitant use of a CYP1A2 inducer may decrease the exposure of Esbriet, and may lead to loss of efficacy. Concomitant use of strong CYP1A2 inducers should be avoided.

Specific populations: Esbriet should be used with caution in patients with mild to moderate (Child-Pugh Class A and B) hepatic impairment. Monitor for adverse reactions and consider dosage modification or discontinuation of Esbriet as needed. The safety, efficacy, and pharmacokinetics of Esbriet have not been studied in patients with severe hepatic impairment. Esbriet is not recommended for use in patients with severe (Child-Pugh Class C) hepatic impairment.

Esbriet should be used with caution in patients with mild (CL_{cr} 50-80 mL/min), moderate (CL_{cr} 30-50 mL/min), or severe (CL_{cr} less than 30 mL/min) renal impairment. Monitor for adverse reactions and consider dosage modification or discontinuation of Esbriet as needed. The safety, efficacy, and pharmacokinetics of Esbriet have not been studied in patients with end-stage renal disease requiring dialysis. Use of Esbriet in patients with end-stage renal disease requiring dialysis is not recommended.

Smoking causes decreased exposure to Esbriet, which may alter the efficacy profile of Esbriet. Instruct patients to stop smoking prior to treatment with Esbriet 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. You may also report side effects to Genentech at 1-888-835-2555.

Please see Brief Summary of Prescribing Information on adjacent pages for additional important safety information.

†Rank ANCOVA with lowest rank imputation for missing data due to death. Patients who died were counted in the ≥10% decline category.
‡Stable was defined as no decline in lung function.

References: 1. Esbriet full Prescribing Information. InterMune, Inc. October 2014. **2.** King TE Jr, Bradford WZ, Castro-Bernardini S, et al. A phase 3 trial of pirfenidone in patients with idiopathic pulmonary fibrosis. *N Engl J Med.* 2014;370:2083-2092. Erratum in: *N Engl J Med.* 2014;371:1172. **3.** InterMune, Inc. Data on file.

Genentech
A Member of the Roche Group

Esbriet®
(pirfenidone) capsules 267 mg

Rx only

BRIEF SUMMARY

The following is a brief summary of the full Prescribing Information for ESBRIET® (pirfenidone). Please review the full Prescribing Information prior to prescribing ESBRIET.

INDICATIONS AND USAGE

ESBRIET is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Elevated Liver Enzymes

Increases in ALT and AST >3 × ULN have been reported in patients treated with ESBRIET. Rarely these have been associated with concomitant elevations in bilirubin. Patients treated with ESBRIET 2403 mg/day in the three Phase 3 trials had a higher incidence of elevations in ALT or AST ≥3 × ULN than placebo patients (3.7% vs. 0.8%, respectively). Elevations ≥10 × ULN in ALT or AST occurred in 0.3% of patients in the ESBRIET 2403 mg/day group and in 0.2% of patients in the placebo group. Increases in ALT and AST ≥3 × ULN were reversible with dose modification or treatment discontinuation. No cases of liver transplant or death due to liver failure that were related to ESBRIET have been reported. However, the combination of transaminase elevations and elevated bilirubin without evidence of obstruction is generally recognized as an important predictor of severe liver injury, that could lead to death or the need for liver transplants in some patients. Conduct liver function tests (ALT, AST, and bilirubin) prior to the initiation of therapy with ESBRIET in all patients, then monthly for the first 6 months and every 3 months thereafter. Dosage modifications or interruption may be necessary for liver enzyme elevations *[see Dosage and Administration sections 2.1 and 2.3 in full Prescribing Information]*.

Photosensitivity Reaction or Rash

Patients treated with ESBRIET 2403 mg/day in the three Phase 3 studies had a higher incidence of photosensitivity reactions (9%) compared with patients treated with placebo (1%). The majority of the photosensitivity reactions occurred during the initial 6 months. Instruct patients to avoid or minimize exposure to sunlight (including sunlamps), to use a sunblock (SPF 50 or higher), and to wear clothing that protects against sun exposure. Additionally, instruct patients to avoid concomitant medications known to cause photosensitivity. Dosage reduction or discontinuation may be necessary in some cases of photosensitivity reaction or rash *[see Dosage and Administration section 2.3 in full Prescribing Information]*.

Gastrointestinal Disorders

In the clinical studies, gastrointestinal events of nausea, diarrhea, dyspepsia, vomiting, gastro-esophageal reflux disease, and abdominal pain were more frequently reported by patients in the ESBRIET treatment groups than in those taking placebo. Dosage reduction or interruption for gastrointestinal events was required in 18.5% of patients in the 2403 mg/day group, as compared to 5.8% of patients in the placebo group; 2.2% of patients in the ESBRIET 2403 mg/day group discontinued treatment due to a gastrointestinal event, as compared to 1.0% in the placebo group. The most common (>2%) gastrointestinal events that led to dosage reduction or interruption were nausea, diarrhea, vomiting, and dyspepsia. The incidence of gastrointestinal events was highest early in the course of treatment (with highest incidence occurring during the initial 3 months) and decreased over time. Dosage modifications may be necessary in some cases of gastrointestinal adverse reactions *[see Dosage and Administration section 2.3 in full Prescribing Information]*.

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Liver Enzyme Elevations *[see Warnings and Precautions]*
- Photosensitivity Reaction or Rash *[see Warnings and Precautions]*
- Gastrointestinal Disorders *[see Warnings and Precautions]*

Clinical Trials 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 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.

ESBRIET was studied in 3 randomized, double-blind, placebo-controlled trials (Studies 1, 2, and 3) in which a total of 623 patients received 2403 mg/day of ESBRIET and 624 patients received placebo. Subjects ages ranged from 40 to 80 years (mean age of 67 years). Most patients were male (74%) and Caucasian (95%). The mean duration of exposure to ESBRIET was 62 weeks (range: 2 to 118 weeks) in these 3 trials.

At the recommended dosage of 2403 mg/day, 14.6% of patients on ESBRIET compared to 9.6% on placebo permanently discontinued treatment because of an adverse event. The most common (>1%) adverse reactions leading to discontinuation were rash and nausea. The most common (>3%) adverse reactions leading to dosage reduction or interruption were rash, nausea, diarrhea, and photosensitivity reaction.

The most common adverse reactions with an incidence of ≥10% and more frequent in the ESBRIET than placebo treatment group are listed in Table 1.

Table 1. Adverse Reactions Occurring in ≥10% of ESBRIET-Treated Patients and More Commonly Than Placebo in Studies 1, 2, and 3

Adverse Reaction	% of Patients (0 to 118 Weeks)	
	ESBRIET 2403 mg/day (N = 623)	Placebo (N = 624)
Nausea	36%	16%
Rash	30%	10%
Abdominal Pain[1]	24%	15%
Upper Respiratory Tract Infection	27%	25%
Diarrhea	26%	20%
Fatigue	26%	19%
Headache	22%	19%
Dyspepsia	19%	7%
Dizziness	18%	11%
Vomiting	13%	6%
Anorexia	13%	5%
Gastro-esophageal Reflux Disease	11%	7%
Sinusitis	11%	10%
Insomnia	10%	7%
Weight Decreased	10%	5%
Arthralgia	10%	7%

[1] Includes abdominal pain, upper abdominal pain, abdominal distension, and stomach discomfort.

Adverse reactions occurring in ≥5 to <10% of ESBRIET-treated patients and more commonly than placebo are photosensitivity reaction (9% vs. 1%), decreased appetite (8% vs. 3%), pruritus (8% vs. 5%), asthenia (6% vs. 4%), dysgeusia (6% vs. 2%), and non-cardiac chest pain (5% vs. 4%).

Postmarketing Experience

In addition to adverse reactions identified from clinical trials the following adverse reactions have been identified during postapproval use of pirfenidone. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency.

Blood and Lymphatic System Disorders
Agranulocytosis

Immune System Disorders
Angioedema

Hepatobiliary Disorders
Bilirubin increased in combination with increases of ALT and AST

DRUG INTERACTIONS

CYP1A2 Inhibitors

Pirfenidone is metabolized primarily (70 to 80%) via CYP1A2 with minor contributions from other CYP isoenzymes including CYP2C9, 2C19, 2D6 and 2E1.

Strong CYP1A Inhibitors

The concomitant administration of ESBRIET and fluvoxamine or other strong CYP1A2 inhibitors (e.g., enoxacin) is not recommended because it significantly increases exposure to ESBRIET *[see Clinical Pharmacology section 12.3 in full Prescribing Information]*. Use of fluvoxamine or other strong CYP1A2 inhibitors should be discontinued prior to administration of ESBRIET and avoided during ESBRIET treatment. In the event that fluvoxamine or other strong CYP1A2 inhibitors are the only drug of choice, dosage reductions are recommended. Monitor for adverse reactions and consider discontinuation of ESBRIET as needed *[see Dosage and Administration section 2.4 in full Prescribing Information]*.

Moderate CYP1A Inhibitors

Concomitant administration of ESBRIET and ciprofloxacin (a moderate inhibitor of CYP1A2) moderately increases exposure to ESBRIET *[see Clinical Pharmacology section 12.3 in full Prescribing Information]*. If ciprofloxacin at the dosage of 750 mg twice daily cannot be avoided, dosage reductions are recommended *[see Dosage and Administration section 2.4 in full Prescribing Information]*. Monitor patients closely when ciprofloxacin is used at a dosage of 250 mg or 500 mg once daily.

Concomitant CYP1A2 and other CYP Inhibitors

Agents or combinations of agents that are moderate or strong inhibitors of both CYP1A2 and one or more other CYP isoenzymes involved in the metabolism of ESBRIET (i.e., CYP2C9, 2C19, 2D6, and 2E1) should be discontinued prior to and avoided during ESBRIET treatment.

CYP1A2 Inducers

The concomitant use of ESBRIET and a CYP1A2 inducer may decrease the exposure of ESBRIET and this may lead to loss of efficacy. Therefore, discontinue use of strong CYP1A2 inducers prior to ESBRIET treatment and avoid the concomitant use of ESBRIET and a strong CYP1A2 inducer *[see Clinical Pharmacology section 12.3 in full Prescribing Information]*.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects: **Pregnancy Category C.**

There are no adequate and well-controlled studies of ESBRIET in pregnant women. Pirfenidone was not teratogenic in rats and rabbits. Because animal reproduction studies are not always predictive of human response, ESBRIET should be used during pregnancy only if the benefit outweighs the risk to the patient.

A fertility and embryo-fetal development study with rats and an embryo-fetal development study with rabbits that received oral doses up to 3 and 2 times, respectively, the maximum recommended daily dose (MRDD) in adults (on mg/m^2 basis at maternal doses up to 1000 and 300 mg/kg/day, respectively) revealed no evidence of impaired fertility or harm to the fetus due to pirfenidone. In the presence of maternal toxicity, acyclic/irregular cycles (e.g., prolonged estrous cycle) were seen in rats at doses approximately equal to and higher than the MRDD in adults (on a mg/m^2 basis at maternal doses of 450 mg/kg/day and higher). In a pre- and post-natal development study, prolongation of the gestation period, decreased numbers of live newborn, and reduced pup viability and body weights were seen in rats at an oral dosage approximately 3 times the MRDD in adults (on a mg/m^2 basis at a maternal dose of 1000 mg/kg/day).

Nursing Mothers

A study with radio-labeled pirfenidone in rats has shown that pirfenidone or its metabolites are excreted in milk. It is not known whether ESBRIET is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue ESBRIET, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness of ESBRIET in pediatric patients have not been established.

Geriatric Use

Of the total number of subjects in the clinical studies receiving ESBRIET, 714 (67%) were 65 years old and over, while 231 (22%) were 75 years old and over. No overall differences in safety or effectiveness were observed between older and younger patients. No dosage adjustment is required based upon age.

ESBRIET® (pirfenidone)

Hepatic Impairment

ESBRIET should be used with caution in patients with mild (Child Pugh Class A) to moderate (Child Pugh Class B) hepatic impairment. Monitor for adverse reactions and consider dosage modification or discontinuation of ESBRIET as needed *[see Dosage and Administration section 2.2 in full Prescribing Information]*.

The safety, efficacy, and pharmacokinetics of ESBRIET have not been studied in patients with severe hepatic impairment. ESBRIET is not recommended for use in patients with severe (Child Pugh Class C) hepatic impairment *[see Clinical Pharmacology section 12.3 in full Prescribing Information]*.

Renal Impairment

ESBRIET should be used with caution in patients with mild (CL_{cr} 50–80 mL/min), moderate (CL_{cr} 30–50 mL/min), or severe (CL_{cr} less than 30 mL/min) renal impairment *[see Clinical Pharmacology section 12.3 in full Prescribing Information]*. Monitor for adverse reactions and consider dosage modification or discontinuation of ESBRIET as needed *[see Dosage and Administration section 2.3 in full Prescribing Information]*. The safety, efficacy, and pharmacokinetics of ESBRIET have not been studied in patients with end-stage renal disease requiring dialysis. Use of ESBRIET in patients with end-stage renal diseases requiring dialysis is not recommended.

Smokers

Smoking causes decreased exposure to ESBRIET *[see Clinical Pharmacology section 12.3 in full Prescribing Information],* which may alter the efficacy profile of ESBRIET. Instruct patients to stop smoking prior to treatment with ESBRIET and to avoid smoking when using ESBRIET.

OVERDOSAGE

There is limited clinical experience with overdosage. Multiple dosages of ESBRIET up to a maximum tolerated dose of 4005 mg per day were administered as five 267 mg capsules three times daily to healthy adult volunteers over a 12-day dose escalation.

In the event of a suspected overdosage, appropriate supportive medical care should be provided, including monitoring of vital signs and observation of the clinical status of the patient.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Liver Enzyme Elevations

Advise patients that they may be required to undergo liver function testing periodically. Instruct patients to immediately report any symptoms of a liver problem (e.g., skin or the white of eyes turn yellow, urine turns dark or brown [tea colored], pain on the right side of stomach, bleed or bruise more easily than normal, lethargy) *[see Warnings and Precautions]*.

Photosensitivity Reaction or Rash

Advise patients to avoid or minimize exposure to sunlight (including sunlamps) during use of ESBRIET because of concern for photosensitivity reactions or rash. Instruct patients to use a sunblock and to wear clothing that protects against sun exposure. Instruct patients to report symptoms of photosensitivity reaction or rash to their physician. Temporary dosage reductions or discontinuations may be required *[see Warnings and Precautions]*.

Gastrointestinal Events

Instruct patients to report symptoms of persistent gastrointestinal effects including nausea, diarrhea, dyspepsia, vomiting, gastro-esophageal reflux disease, and abdominal pain. Temporary dosage reductions or discontinuations may be required *[see Warnings and Precautions]*.

Smokers

Encourage patients to stop smoking prior to treatment with ESBRIET and to avoid smoking when using ESBRIET *[see Clinical Pharmacology section 12.3 in full Prescribing Information]*.

Take with Food

Instruct patients to take ESBRIET with food to help decrease nausea and dizziness.

Manufactured for:
InterMune, Inc.
Brisbane, CA 94005 USA

INTERMUNE®

Varenicline facilitates gradual smoking cessation

BY MARY ANN MOON
Frontline Medical News

A 24-week course of varenicline improved quit rates among smokers who preferred to gradually reduce their use of cigarettes.

In an industry-sponsored, randomized, double-blind, controlled trial, participants who were given varenicline showed higher quit rates at the end of treatment as well as 1 year later, compared with those given placebo, said Dr. Jon O. Ebbert of the Mayo Clinic, Rochester, Minn., and his associates.

Current U.S. clinical practice guidelines recommend that smokers set an immediate quit date and quit abruptly, "even though only 8% of smokers report being ready to quit within the next month."

The findings of this study show that a more gradual, reduce-to-quit approach also can be effective, and "would be expected to be of interest to 14 million of the 42 million current smokers in this country," the investigators noted.

The study was performed at 61 medical centers in 10 countries during a 2-year period.

The 1,510 participants would not quit abruptly, as is recommended, but were willing to reduce their smoking and make a quit attempt within the next 3 months. They were asked to reduce their smoking rate by 50% or more by week 4, to further reduce it by 75% or more by week 8, and to quit altogether by week 12.

Study participants, who smoked 10 or more cigarettes per day at baseline, were randomly assigned to receive varenicline (760 patients) or a placebo (750 patients) for 24 weeks. All received written materials and smoking cessation counseling focused on reduction techniques, problem solving, and skills training provided during 18 clinic visits and 10 telephone sessions of 10 minutes' duration.

The primary efficacy endpoint was the continuous abstinence rate during weeks 15-24, which was self-reported by the participants and confirmed using exhaled carbon monoxide measurements. This rate was significantly higher for the varenicline group (32.1%) than for the placebo group (6.9%). The continuous abstinence rate remained significantly higher through 1 year of follow-up for varenicline (27%) than for placebo (9.9%).

The median time to abstinence was significantly shorter with varenicline (50 days) than with placebo (85 days). Results of sensitivity analyses confirmed those of the primary analysis, the investigators said (JAMA 2015 Feb. 17;313:687-94).

The percentage of participants who reported adverse events was higher with varenicline (82.3% vs. 72.5%), and the difference was largely accounted for by increases in nausea, abnormal dreams, insomnia, constipation, vomiting, and weight gain.

Rates of serious adverse events were similar between the two study groups, as were rates of treatment discontinuation (8.4% for varenicline and 7% for placebo). In particular, rates of suicidal ideation or behavior and depression scores were not significantly higher with varenicline. The study findings indicate that prescribing varenicline "with a recommendation to reduce the number of cigarettes smoked per day, with the eventual goal of quitting, could be a useful therapeutic option for this population of smokers," Dr. Ebbert and his associates said.

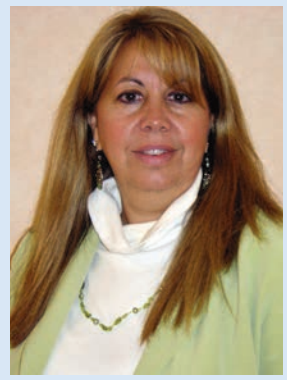
A limitation of this study was that patients were excluded from participating if they had severe psychiatric, pulmonary, cardiovascular, or cerebrovascular disease, which hinders the generalizability of the results to a broader population of smokers.

In addition, study participants received significant counseling support that would not necessarily be available to patients in real-world clinical practice, so quit rates would be expected to be lower in actual practice.

This study was funded by Pfizer, maker of varenicline (Chantix). Pfizer also participated in the design and conduct of the study; the collection, analysis, and interpretation of the data; and manuscript preparation. Dr. Ebbert reported receiving grants from Pfizer, JHP Pharmaceuticals, and Orexigen, as well as personal fees from GlaxoSmithKline. His associates reported ties to industry sources.

IN THIS ISSUE

CHEST Physician Is Online
CHEST Physician is available on the Web at chestphysician.org.



Dr. Vera A. De Palo, MBA, FCCP, is Medical Editor in Chief of *CHEST* Physician.

CHEST™ Physician
THE NEWSPAPER OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS

E-mail: chestphysiciannews@chestnet.org

CHEST Physician, the newspaper of the American College of Chest Physicians, provides cutting-edge reports from clinical meetings, FDA coverage, clinical trial results, expert commentary, and reporting on the business and politics of chest medicine. Each issue also provides material exclusive to CHEST members. Content for **CHEST Physician** is provided by Frontline Medical Communications Inc. Content for News From Chest is provided by the American College of Chest Physicians.

POSTMASTER: Send change of address (with old mailing label) to CHEST Physician, Subscription Service, 151 Fairchild Ave., Suite 2, Plainview, NY 11803-1709.
CHEST Physician (ISSN 1558-6200) is published monthly for the American College of Chest Physicians by Frontline Medical Communications Inc., 7 Century Drive, Suite 302, Parsippany, NJ 07054-4609. Subscription price is $230.00 per year. Phone 973-206-3434, fax 973-206-9378.
Editorial Offices 5635 Fishers Lane, Suite 6100, Rockville, MD 20852, 240-221-2400, fax 240-221-2548

Scan this QR Code to visit chestnet.org/chestphysician

Frontline Medical Communications Society Partners
Director, FMC Society Partners Mark Branca
Editor in Chief Mary Jo M. Dales
Executive Editors Denise Fulton, Kathy Scarbeck

Creative Director Louise A. Koenig
Print Production Manager Rebecca Slebodnik
Senior Director of Sales Tim LaPella, 484-921-5001, tlapella@frontlinemedcom.com
Display Advertising Managers Lauren Provenzano, 609-306-5776, lprovenzano@americanmedicalcomm.com, Michael O'Brien, 978-578-4514, mobrien@americanmedicalcomm.com
Advertising Offices 7 Century Drive, Suite 302, Parsippany, NJ 07054-4609 973-206-3434, fax 973-206-9378
Classified Sales Representative John Baltazar 917-488-1528, jbaltazar@americanmedicalcomm.com

FRONTLINE MEDICAL COMMUNICATIONS
Stephen Stoneburn, Chairman
Douglas E. Grose, EVP Digital Business Development/CFO
Alan J. Imhoff, President/CEO
JoAnn Wahl, President, Custom Solutions, 973-206-8989 jwahl@frontlinemedcom.com
Dennis Quirk, Vice President, Finance
Jim Chicca, Executive Director, Operations
Jim McDonough, VP, Marketing & Customer Advocacy
Carol Nathan, VP, Custom Programs
Lori Raskin, Corporate Director, Research & Communications
Donna Sickles, VP, Audience Development
Subscription Inquiry Line 1-800-480-4851
In affiliation with Global Academy for Medical Education, LLC.
Sylvia H. Reitman, MBA, Vice President, Medical Education & Conferences
David J. Small, MBA, Vice President, Events

CT screens

Medicare *from page 1*

deaths in the United States," Dr. Patrick Conway, CMS chief medical officer, said in a statement. "We believe this final decision strikes an appropriate balance between providing access to this important preventive service and ensuring, to the best extent possible, that Medicare beneficiaries receive maximum benefit from a lung cancer screening program."

The decision has been in the works for a while. In 2011, the National Cancer Institute–sponsored National Lung Screening Trial (NLST) showed that people aged 55-74 years with a history of heavy smoking are 20% less likely to die from lung cancer if they are screened with low-dose helical CT instead of standard chest x-ray (N. Engl. J. Med. 2011;365:395-409).

Previous studies had shown that screening with standard chest x-rays does not reduce mortality from lung cancer.

'This is an important new Medicare preventive benefit.'

DR. CONWAY

Results from NLST and other studies prompted the U.S. Preventive Services Task Force in 2013 to recommend annual low-dose CT screening for adults aged 55-80 years with a 30-pack-year history; the recommendation in turn led to formal requests to CMS for coverage. In proposing coverage, the task force received almost 500 public comments "generally supportive of [expanding] Medicare coverage to include lung cancer screening," it said.

Low-dose CT is performed at acquisition settings to minimize radiation exposure. For lung cancer screening, CMS is requiring a volumetric CT dose index (CTDIvol) of ≤ 3.0 mGy for standard-size patients – defined to be 5 feet 7 inches tall and approximately 155 pounds – with appropriate reductions or increases for smaller or larger patients.

aotto@frontlinemedcom.com

'New' causes of death

Smoking *from page 1*

and pneumonia. Mr. Carter and his associates pooled data from five large cohort studies to examine possible associations between smoking and an additional 31 cause-of-death categories. They now estimate that an additional 60,000-120,000 deaths each year can be attributed to smoking.

For their study, the investigators assessed 421,378 men and 532,651 women aged 55 years and older at baseline whose smoking status was carefully recorded and who were followed from 2000 to 2011 in the Cancer Prevention Study II Nutrition Cohort, the Nurses' Health Study I, the Health Professionals Follow-Up Study, the Women's Health Initiative, and the National Institutes of Health-AARP Diet and Health Study.

As expected, smokers had a two-fold to threefold higher mortality from any cause, compared with nonsmokers. Smokers also had a markedly higher risk of death than nonsmokers from all 21 causes already established as attributable to tobacco use, such as lung cancer, oral cancer, ischemic heart disease, atherosclerosis, and stroke. But approximately 17% of smokers' excess mortality was accounted for by several diseases that previously have not been attributable to tobacco use.

For example, the risk of death due to intestinal ischemia was approximately six times higher among smokers than among nonsmokers, a remarkably strong association that was also reported in the Million Women Study. "Smoking acutely reduces blood flow to the intestines, and evidence suggests that smoking causes risk factors that can often lead to intestinal ischemia, including atherosclerosis, platelet aggregation, and congestive heart failure," Mr. Carter and his associates said (N. Engl. J. Med. 2015 Feb. 12 [doi:10.1056/NEJMsa140721]).

The mortality risk from liver cirrhosis, after adjusting for alcohol consumption, was more than three times higher in smokers.

In this study, smoking also more than doubled the risk of dying from other digestive diseases. Previous studies have suggested a link between smoking and digestive disorders such as Crohn's disease, peptic ulcers, acute pancreatitis, paralytic ileus, bowel obstruction, choletlithiasis, diverticulitis, and gastrointestinal hemorrhage. "Although these diseases are not common causes of death, they account for millions of hospitalizations each year," the investigators noted.

The mortality risk from liver cirrhosis, after the data were adjusted to account for alcohol consumption, was more than three times higher in smokers than in nonsmokers. Even smokers who did not drink alcohol were at significantly increased risk of cirrhosis, compared with nonsmokers.

The risk of death due to infection was 2.3 times higher in smokers than in nonsmokers. This strong association was dose dependent, as infection-related mortality rose with increasing smoking intensity. And among study participants who had quit smoking, infection-related mortality declined as the number of years since cessation increased.

The rate of death due to renal failure was twice as high among smokers as among nonsmokers.

The rate of death due to hypertensive heart disease, the only category of heart disease not already established as smoking related, was 2.4 times higher in smokers. The latter association "is relevant for assessing the public health burden of smoking, since a considerable number of deaths in the United States are attributable to hypertensive heart disease," according to Mr. Carter and his associates.

Smoking also was strongly associated with "multiple diseases too uncommon to examine individually." This included all rare cancers combined, rare digestive diseases, and respiratory diseases other than those already known to stem from smoking.

In women, smoking raised breast cancer mortality, with a relative risk of 1.3. This association was strongly dose dependent. In men, smoking raised prostate cancer mortality, with a relative risk of 1.4.

This study was limited in that most of the participants were white and better educated than the general population, which may affect the applicability of the results to other populations.

VIEW ON THE NEWS

Dr. Vera A. DePalo, MBA, FCCP, comments: We have long known of the health complications of chronic lung disease, cancer, and heart disease related to smoking. In an American Cancer Society–supported analysis of pooled data from a number of large cohort studies, not only is it clear that the burden of tobacco use has been underestimated, but a number of diseases not previously thought to be associated with tobacco use have now been linked to smoking.

VITALS

Key clinical point: Smoking is now thought to cause many deaths from infections; renal failure; liver cirrhosis; digestive diseases; and breast, prostate, and other cancers.

Major finding: Several diseases that previously have not been attributable to tobacco use accounted for 17% of smokers' excess mortality.

Data source: An analysis of pooled data from five large cohort studies involving 954,029 people aged 55 years and older followed for 12 years to examine associations between smoking and 52 possible causes of death.

Disclosures: This study was supported by the American Cancer Society. Mr. Carter reported having no financial disclosures; one of his associates reported receiving grant support from Novo Nordisk.

Ventilator driving pressure linked to ARDS outcome

BY MARY ANN MOON
Frontline Medical News

One variable involved with mechanical ventilation – driving pressure – may predict mortality in adult respiratory distress syndrome.

Research suggests that scaling ventilator tidal volumes (V_T) to patients' body weight will minimize ventilator-induced lung injury. But patients with ARDS have a marked decrease in the proportion of lung available for ventilation, as is indicated by their lower respiratory-system compliance (C_{RS}), which is not related to their body weight.

"Therefore, we hypothesized that normalizing V_T to C_{RS} and using the ratio as an index indicating the 'functional' size of the lung would provide a better predictor of outcomes in patients with ARDS than VT alone, said Dr. Marcelo B.P. Amato of the cardiopulmonary department, University of Sao Paulo (Brazil) Heart Institute, and his associates.

This ratio, also known as the driving pressure, is easily calculated at the bedside.

The researchers explored whether driving pressure or other variables related to mechanical ventilation, including variables set by the ventilator operator, could be statistically linked to survival outcomes and therefore serve as a risk predictor.

They first devised a survival-prediction model using data from a cohort of 336 ARDS patients participating in four randomized clinical trials examining different ventilation strategies.

They then tested their findings using a validation cohort of 861 patients from a single large trial, then

Continued on following page

VIEW ON THE NEWS

Premature to reset

We strongly urge caution against accepting the idea that clinicians should now set ventilators to limit driving pressure in patients with ARDS, even though that is an appealing concept.

The findings of Amato et al. derive from a meta-analysis, not from prospective randomized controlled trials. Their results should form the basis for a robust debate regarding the design of future trials so that, before we take action, we first ensure that limiting driving pressure will actually be beneficial.

Dr. Stephen H. Loring is in the department of anesthesia, critical care, and pain medicine at Beth Israel Deaconess Medical Center and at Harvard, both in Boston. Dr. Atul Malhotra, FCCP, is in the division of pulmonary critical care and sleep medicine at the University of California, San Diego, in La Jolla. Both Dr. Loring and Dr. Malhotra reported having no financial disclosures. They made these remarks in an editorial accompanying Dr. Amato's report (N. Engl. J. Med. 2015 Feb. 19 [doi:10.1056/NEJMe1414218]).

Continued from previous page

tested them again in a more recent validation cohort of 2,365 patients participating in four more randomized trials comparing different ventilation strategies.

Driving pressure was the only ventilation variable found to be strongly associated with survival.

Higher driving pressures strongly predicted higher mortality: Every 1–standard deviation increase in driving pressure was related to increased mortality, with a relative risk of 1.41.

Even in patients receiving lung-protective plateau pressures and low tidal volumes, higher driving pressure was associated with increased mortality, with a relative risk of 1.36, Dr. Amato and his associates said (N. Engl. J. Med. 2015 Feb. 19 [doi:10.1056/NEJMsa1410639]).

These findings can only suggest that driving pressure is a critical mediator of various ventilator strategies, since they are derived from a post hoc observational statistical analysis and cannot establish causality, the researchers said.

Now, prospective clinical trials are needed to determine whether adjusting ventilator settings to lower driving pressure will improve survival in ARDS.

Inflammatory CAP

Therapy failures *from page 1*

In a randomized double-blind trial at three teaching hospitals in Spain, 120 such patients were randomly assigned to receive 5 days of either IV methylprednisolone (61 patients) at a dose of 0.5 mg/kg every 12 hours or a matching placebo (59 patients), in addition to antibiotics.

The most common cause of pneumonia in both study groups was *Streptococcus pneumoniae*, and the most frequent empiric antimicrobial treatment was a combination of ceftriaxone, levofloxacin, and azithromycin. As expected, CRP and IL-10 levels decreased more in patients who received the corticosteroid than in those who received placebo.

The primary endpoint was treatment failure, both within 72 hours (early) and at 72-120 hours (late) after initiation of therapy. This rate was significantly lower in patients who received methylprednisolone (8 patients, or 13%) than in those who received placebo (18, or 31%). This reduction was largely attributed to the prevention of radiographic progression and late septic shock.

However, there were no significant differences in the secondary outcomes of time to clinical stabilization, length of ICU stay, length of hospitalization, and in-hospital mortality, the investigators said (JAMA 2015 Feb. 17 [doi:10.1001/jama.2015.88]).

It is likely that the most feared adverse effect of corticosteroid therapy – immunosuppression leading to superinfection – wasn't an issue in this study because of the short course of treatment and the relatively low dose of methylprednisolone used.

These findings are important because any efficacious adjunctive treatment may help reduce the high mortality associated with severe community-acquired pneumonia. It is estimated that despite effective antibiotic treatment, 12%-36% of patients admitted to an ICU with this disease will die within a short period, Dr. Torres and his associates noted.

A larger study is underway to confirm the results.

Sorting out optimal TB testing can be tricky

BY DOUG BRUNK
Frontline Medical News

LAS VEGAS – In the clinical opinion of Dr. Andi L. Shane, tuberculin skin testing and interferon gamma release assay diagnostics and surveillance for *Mycobacterium tuberculosis* infection are game changers in the ongoing effort to reduce TB infections.

"From 1982 to 2013, we've had a very nice decline in TB cases. However, we still have quite a bit of work to do," Dr. Shane said at an update sponsored by the American Academy of Pediatrics California District 9.

Case rates are high in California, Nevada, Texas, Florida, New York, Washington, New Jersey, and the District of Columbia. Those under 5 years old and those aged 15-24 years are more likely to be affected.

"It's really important to identify TB as soon as possible, especially in children," said Dr. Shane of the department of pediatrics, division of infectious diseases, Emory University, Atlanta. "An interferon gamma release assay (IGRA) or a tuberculin skin test (TST) may be used in situations where assessment for MTB [*M. tuberculosis*] exposure is indicated. IGRA is preferred in persons who received BCG vaccine and who have low rates of test completion, while TST is preferred for testing of children younger than age 5."

TB in people younger than age 15 years is a marker for transmission of TB, usually from an adult. "So when we identify a case of TB in children, that requires a contact investigation," she said. "We're more concerned with children under the age of 5 with TB because they are more likely to have disseminated disease."

Latent TB means that the patient has been exposed to the disease but that his or her body has been able to control the infection; no systemic manifestations of infection are present. Identifying the difference between latent tuberculosis infection (LTBI) and actual tuberculosis disease is one of the most challenging aspects to explain to families. The reason is that children or adults who have LTBI are not infectious, whereas someone who has pulmonary or laryngeal TB is considered to be an infectious risk to other individuals.

Dr. Shane went on to discuss limitations of the TST. For one, the test may be placed incorrectly, resulting in an inflammatory response or no response, "and there is reader variability," she said. "The reading needs

VIEW ON THE NEWS

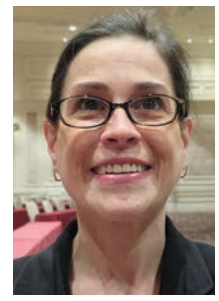
Dr. Susan Millard, FCCP, comments: Health care providers need to be ever vigilant of those "red snappers" when seeing pediatric patients so this article is timely in regards to the ins and outs of interferon gamma release assay (IGRA) testing.

to occur 48-72 hours after placement of the test. So, if you place it on a Thursday, that means you really are not going to read it at the optimal time unless the child comes to you on a weekend or the test is read by somebody else."

As an alternative, two IGRAs have been developed that measure how the immune system reacts to MTB. One is QuantiFERON, which is widely used in the United States; the other is the T-SPOT.TB test, which is widely used in Europe. A positive result on either test indicates that there has been interaction with MTB bacteria but it does not differentiate between LTBI and active TB disease.

"A negative IGRA tells you there is no reaction to the test and MTB is not likely, while an indeterminate result is when you're unable to interpret the result due to low positive [mitogen] or increased negative control [nil] compared to TB response," Dr. Shane said. "This usually indicates that there's some problem with the assay itself. It can also indicate that the individual may not have an immune system that can respond to and produce interferon gamma."

Assessment of IGRA accuracy is challenged by the lack of a standard for the diagnosis of LTBI and active TB. "We just don't have a lot of good data from resource-endowed settings," Dr. Shane explained. "We have good data from areas where TB is prevalent." According to the Centers for Disease Control and Prevention and the AAP, IGRAs are probably reliable in children over the age of 5 years, but a TST is still recommended in children under the age of 5.



IGRA is preferred in those given BCG vaccine and with low rates of test completion; TST is preferred in children under 5.

DR. SHANE

The IGRAs' specificity is much higher than TSTs, Dr. Shane said. "However, in some cases a TST might be more sensitive for detecting more remote MTB infections than an IGRA, but IGRAs may be better at detecting a recent infection. Like the TST, an IGRA also shows that if you're infected with TB you have 5-10% chance of developing active TB in your lifetime."

As a significant amount of blood is required to perform an IGRA, that might not always be optimal in a young child, she said. "Low CD4 counts and other immunodeficiencies have also been associated with false-negative TST and indeterminate/false-negative IGRA results."

For contact investigations, IGRAs offer increased specificity, are completed during a single visit, and their response is not boosted if an additional evaluation is needed 8-10 weeks after exposure. If the TST or IGRA is positive, additional diagnostic efforts are needed "to differentiate between LTBI and active MTB," said Dr. Shane, who recommended the Curry International Tuberculosis Center as a resource for clinicians (www.currytbcenter.ucsf.edu/).

If the TST or IGRA is negative, "it's not sufficient to exclude MTB infection. If you have a discordant TST and IGRA result, consider history and epidemiologic risk factors. Treat with clinical suspicion or risk of a poor outcome (those younger than age 5 and those infected with HIV)."

dbrunk@frontlinemedcom.com
On Twitter @dougbrunk

SLEEP STRATEGIES: Multilevel surgical approach to OSAS

BY DR. BORIS CHERNOBILSKY

Despite significant technologic, diagnostic, and therapeutic advancements, obstructive sleep apnea syndrome (OSAS) remains difficult to treat. The surgical "gold standard" for the treatment of severe OSAS remains tracheotomy. While completely bypassing all sites of upper airway obstruction, this treatment entails a significant alteration in lifestyle, may not be palatable to patients, and has cultural implications. The noninvasive "gold standard" has been positive airway pressure (PAP). When properly titrated and fitted, PAP is curative of OSAS provided the patient is compliant with therapy. Unfortunately, studies demonstrate noncompliance rates in the 40% to 54% range, which significantly drop to 84% at 1 year of use (Terri et al. *Proc Am Thoracic Soc.* 2008;5[2]: 173).


DR. CHERNOBILSKY

Alternate treatments have been proposed. These include mandibular advancement devices (MAD) and upper airway surgery. Surgery has been proposed as both adjunctive treatment to PAP and as a potential curative alternative, which does not require "maintenance" on the part of the patient but requires long-term follow-up and observation, especially in the event of symptom recurrence or major fluctuations in body mass index (BMI).

Surgery has fallen in and out of favor in the last 3 decades due to mixed observational and experimental data, particularly the difficulty in constructing good clinical surgical series, as well as the morbidity often associated with these procedures. The challenge of surgical treatment is patient selection, as well as proper surgical procedure selection for each patient. OSAS is a complex disease process composed of both fixed and fluctuating variables. In brief, it is a complex interplay of static factors such as craniofacial anatomy, cephalometrics and nasal anatomy with soft tissue fluctuations dependent on weight, age (tonsil and adenoid size, palatal length), syndromes (macroglossia, palatal function), and varying distribution of fat in the three tongue fat pads and visceral vs peripheral body fat distribution. Couple this with conditions that affect muscle tone, cardiopulmonary function, "tracheal tug," and even normal nightly variations in tone with the onset of REM and physiologic transitions that occur from one sleep stage to another, one begins to understand that the patient with OSAS requires an individualized multidisciplinary approach.

Proper understanding of the patient's physiology and anatomy is crucial to success with treatment. The physical examination starts with inspection of the face: does the patient appear syndromic, have significant hemifacial microsomia, major maxillary or mandibular hypoplasia (or both)? These factors can lead to significant difficulty in fitting a PAP mask or MAD. Options for correction include maxillary-mandibular advancement (MMA) or isolated mandibular advancement / reconstruction. MMA is an oromaxillofacial procedure that shifts the entire maxilla and mandible forward; the soft palate, base of the tongue, and, to an extent, the larynx move forward, resulting in multilevel correction. It has the added benefit of potentially improving a patient's occlusion and cosmetic appearance, as the chin and cheek bones advance to a more favorable position. While this is a major procedure for the patient, success rates have been reported upwards of 90% (Lei et al. *Sleep Breath.* 2000;4:137).

The nasal exam is crucial. While we start off as obligate nose breathers in infancy, this preference never goes away. Studies demonstrate that PAP requirements between nasal and oronasal masks are equivalent, but patient preference weighs heavily toward nasal masks where leak is significantly reduced (Bakker et al. *Sleep Breath.* 2012;16[3]:709.

The exam should start with the external nose looking for dorsal deviations (congenital or traumatic), a significant ptotic tip, or lateral nasal wall collapse. Repair of the nasal valve or even functional rhinoplasty are the procedures of choice for these problems.

The internal nasal exam consists of evaluation for turbinate hypertrophy, significant nasal septal deviation, widening of the middle turbinates from concha bullosa, the presence of mucosal edema from allergy or infection, extensive crusting from nasal dryness or septal perforation, significant nasal polyposis or even a nasal tumor. Initiation of PAP therapy is very often a "one-shot deal" and patients who were otherwise motivated to use PAP failed because their nasal obstruction was not diagnosed. Ideally, the exam should include nasal endoscopy.

Intranasal surgical techniques include septoplasty, turbinate reduction, polypectomy, and functional endoscopic sinus surgery. While AHI is usually not significantly affected by nasal surgery, there are major improvements in quality of life scores and PAP compliance (Poirier, et al. *Laryngoscope.* 2014;124[1]:317). Rare patients, especially those with complete obstruction, can be cured in mild to moderate cases. In most, it is an important adjunct to the treatment of the patient with OSAS.

The challenge of surgical treatment is patient selection, as well as proper surgical procedure selection for each patient.

The exam should then proceed to the oral cavity and oropharynx. Careful note should be taken of the dentition and occlusion class, arching of the hard palate (especially in children), tongue size (Friedman or Mallampati class), length of soft palate, and uvula and tonsil size. In children and young adults, adenotonsillectomy or tonsillectomy alone can be curative as a first line therapy. Compliance issues with PAP are especially problematic in these populations. High arched palates in children can be managed with rapid maxillary expansion which can significantly broaden both the nasal and oral airway. MMA for retro/micrognathia was discussed previously.

The patient should next have a flexible laryngoscopic exam, usually a continuation of the nasal endoscopy. The nasopharynx is inspected for adenoid hypertrophy, polyps, cysts, and tumors. The palate is inspected from above. The exam proceeds to the level of the pharynx and hypopharynx with attention paid to the pharyngeal and lingual tonsils and the base of tongue position. Finally, the larynx is inspected for position of the epiglottis, laryngeal masses, vocal fold immobility, laryngomalacia, and arytenoid redundancy and prolapse with inspiration. A drug-induced sleep endoscopy (DISE) should be performed at a later date to assess these same structures dynamically in a state mimicking sleep to help guide appropriate surgical technique. DISE was reviewed in a previous issue and will not be discussed in detail.

Nasopharyngeal lesions are treated with surgical excision. The velopharynx is usually addressed with uvulopalatopharyngoplasty which often, but not always, includes the tonsils. Various techniques have been developed to address circumferential vs anteroposterior(AP) collapse of the palate and uvula. Present practices favor soft tissue/muscle rearrangement over soft tissue ablation. One such technique preferred by the author is expansion sphincter pharyngoplasty. Lingual tonsillectomy addresses large lingual tonsils, if present.

Many operations exist to address the tongue base, and consensus as to best practice is yet to be reached. Generally, two broad categories exist: suspensory or ablative. Suspension can be accomplished with sutures along the base of tongue, hyoid fixation to the anterior mandible or thyroid cartilage, and genioglossus advancement. A novel technology recently FDA-approved shows immense promise. Upper-airway stimulation uses electrodes on the hypoglossal nerve to protrude the tongue, timing it with each respiration through an intercostal muscle sensor lead (Strollo Jr et al. STAR Trial Group. *N Engl J Med.* 2014;370[2]:139).

Ablation can be accomplished by reducing the base of tongue through the delivery of energy, such as use of radiofrequency or excising tissue through techniques like midline glossectomy. This can be accomplished both directly and with robot-assisted techniques using the daVinci system transorally (TORS).

Laryngeal techniques include epiglottopexy or epiglottectomy in cases where the epiglottis retroflexes and obstructs the airway on inspiration. Laryngeal lesions are generally addressed with excision. Vocal fold paralysis in the midline can be addressed with cordotomy or arytenoidectomy. Prolapsing redundant tissue can be tightened using a laser. Laryngomalacia can be addressed surgically, as well.

Finally, the neck should be examined. Masses, tracheal deviation, evidence of prior tracheotomy, hyoid position, circumference, and lymphadenopathy should all be noted. Masses, especially goiters, can compress the internal jugular veins leading to laryngeal and pharyngeal

Sleep strategies *continued on page 13*

Upper airway stimulation an OSA option

BY DOUG BRUNK
Frontline Medical News

CORONADO, CALIF. – Some patients with treatment-refractory obstructive sleep apnea may be candidates for upper airway stimulation, though those with complete concentric palatal collapse may not respond, according to Dr. Marion Boyd Gillespie.

"There's been sound research showing that patients with obstructive sleep apnea have reduced neural tone," Dr. Gillespie, who directs the snoring clinics at the Medical University of South Carolina, Charleston, said at the Triological Society's Combined Sections Meeting. "During these apneic events, there's a reduction in the neural tone of the genioglossus muscle, which is the main dilator of the upper airway. With upper airway stimulation, we're trying to account for that loss of neural tone by providing more neural impulse to these muscle groups that perform the dilator functions."

In 2014, the Food and Drug Administration cleared an upper airway stimulation system manufactured by Inspire Medical Systems, a pacemaker-like device that's implanted in the subclavicular space. The system features a stimulator lead that attaches to the right hypoglossal nerve and a sensing lead that goes between the external and internal intercostal muscles to detect breathing, said

Continued on following page

Sleep strategies *continued from page 12*

edema. Surgical removal of the mass is the treatment of choice.

In summary, OSAS is a complex disease that often requires multiple therapeutic modalities. Proper patient selection and a thorough physical exam are crucial to proper treatment choice. Surgery can be both adjunctive and curative. Patients often have multiple levels of airway obstruction that can be treated simultaneously or staged. Careful follow-up and involvement of a multidisciplinary care team will result in the highest success rates for these patients with complex disease.

Dr. Chernobilsky is Director of Sleep and Airway Surgery, Mount Sinai Beth Israel, Assistant Professor of Otolaryngology-Head and Neck Surgery, Icahn School of Medicine at Mount Sinai, New York, New York.

Editor's comments

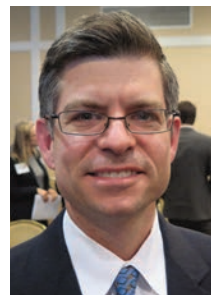
Although positive airway pressure is the gold standard treatment for obstructive sleep apnea, poor compliance with this modality provides the impetus for alternative treatments that are both effective and acceptable to patients. Upper airway surgery is a viable alternative for select patients, either as a primary treatment modality or as adjunctive therapy. In this installment of sleep strategies, Dr. Boris Chernobilsky discusses and clarifies, from a surgical perspective, the surgical techniques available, as well as the systematic approach, in the evaluation of the patient with sleep apnea.

Dr. Jeremy A. Weingarten, FCCP

Continued from previous page

Dr. Gillespie, professor of otolaryngology–head and neck surgery at the university. "The sensing lead detects the respiratory wave, and the stimulatory lead starts stimulation at the end of expiration, because that's when the airway is in its most collapsible state. It continues about two-thirds of the way through the inspiratory cycle to keep the airway open."

Titration of the device is very similar to continuous positive airway pressure, he continued. Once implanted, the patient "will go back to the sleep lab where a tech who's trained in the device will ramp up stimulation until observed apneas and hypopneas are adequately reduced. You would think that isolated stimulation of the hypoglossal nerve would only open up the airway at the level of the tongue. However, our initial investigation showed that there is dilation at the velopharynx



There's been sound research showing that patients with OSA have reduced neural tone.

DR. GILLESPIE

as well," Dr. Gillespie said. By moving the tongue out of the posterior airway, "you're moving the dorsum of the tongue away from the velopharynx. You're also getting active traction on the palatoglossal fold," he added.

Results of the initial trial of the system in 126 patients with a mean body mass index of 28.4 kg/m^2 were published last year (N. Engl. J. Med. 2014;370:139-49). At 12 months of follow-up, patients experienced a 68% overall reduction in their apnea-hypopnea index (AHI) score, from a preoperative mean of 29 to a postoperative mean of 9. In addition, patients had a 70% overall reduction in their oxygen desaturation index (ODI). The researchers also observed normalization of patient-based outcomes, with improvement in the Functional Outcomes of Sleep Questionnaire score and reduction of the Epworth Sleepiness Scale score to a level of 10 on average. "We also saw a re-

Continued on following page

Before surgery, 72% of patients had severe, annoying snoring; after surgery, 15% had severe, annoying snoring.

Continued from previous page

duction of snoring," said Dr. Gillespie, who was a member of the research team. "Snoring went from 72% of patients having severe, annoying snoring to the point where a bed partner leaves the room, to 15% postoperatively." Even so, 96% of patients who had a previous history of uvulopalatopharyngoplasty (UPPP) or laser-assisted uvulopalatoplasty (LAUP) still had tongue-based collapse after 12 months of follow-up. "But we found that their response to this therapy was just as good as people who had never had a UPPP or LAUP," Dr. Gillespie said at the meeting, jointly sponsored by the Triological Society and the American College of Surgeons. "So it seems like patients who have failed UPPP are still good candidates for upper airway stimulation therapy."

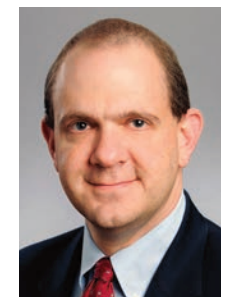
Dr. Gillespie noted that selection criteria for the trial were limited to patients with a BMI of less than 32 kg/m^2 and to those who did not have complete circumferential collapse at the level of the soft palate on preoperative drug-induced endoscopy. These criteria were based on an earlier pilot study that showed that patients with complete circumferential collapse at the level of the soft palate did not respond to upper airway stimulation (J. Clin. Sleep Med. 2013;9:433-8).

Dr. Gillespie is a consultant for and has received research support from Inspire Medical Systems, Olympus, and Surgical Specialties. He is also a consultant for Medtronic.

dbrunk@frontlinemedcom.com
On Twitter @dougbrunk

VIEW ON THE NEWS

Dr. David A. Schulman, FCCP, comments: The data presented by Dr. Gillespie add to the growing body of literature showing the benefits of stimulation of the upper airway muscles during sleep in a selected subgroup of obstructive sleep apnea (OSA) patients, demonstrating improvements in both physiologic and functional parameters.



Given the well-described issues with continuous positive airway pressure (CPAP) adherence and the lesser efficacy of currently available CPAP alternatives, patients with obstructive sleep apnea and their providers have long awaited access to hypoglossal nerve stimulators to add to the armamentarium of options for management of the disorder. While early data continue to show promise for this treatment, a number of physiologic and anatomic characteristics serve as relative contraindications, limiting the generalizability of study results to some patient populations (such as those with body mass index greater than 32 kg/m^2 or those with concentric collapse of the soft palate). While upper airway stimulation is not likely to be the first-line OSA treatment for the majority of patients, it is an important step forward for those unwilling or unable to use CPAP.

Award-winning pulmonology program, year after year.

Children's Health℠ is proud to have one of the largest Cystic Fibrosis programs in the nation. As the first hospital in the nation to have all 165 respiratory therapists Neonatal/Pediatric Specialty (NPS) certified, we're committed to making life better for children every day.

Visit childrens.com/pulmonology to learn more

children'shealth℠
Children's Medical Center Dallas

Panel backs antifungal for invasive aspergillosis

BY ELIZABETH MECHCATIE
Frontline Medical News

SILVER SPRING, MD. – A novel treatment for invasive aspergillosis and invasive mucormycosis gained the support of a Food and Drug Administration advisory panel, although members were ambivalent about the mucormycosis indication, based on the small study size.

The FDA's Anti-Infective Drugs Advisory Committee voted 11-0 that there was "substantial evidence" that isavuconazonium, an antifungal prodrug, was safe and effective for the treatment of invasive aspergillosis. A phase III study compared isavuconazonium to voriconazole, the standard of care, in more than 500 patients.

The panel voted 8-2, with one abstention, that there was substantial evidence isavuconazonium is safe and effective for treating patients with invasive mucormycosis, with panelists citing concerns about a study size of only 37 patients and historical controls. If approved for mucormycosis, the panel said that the manufacturer, Astellas, should be required to conduct a phase IV trial further evaluating treatment in this population.

ELIZABETH MECHCATIE/FRONTLINE MEDICAL NEWS

Reviewers from the FDA's Division of Anti-Infective Products listen to testimony at the advisory committee meeting.

Isavuconazonium is a prodrug of isavuconazole, a triazole antifungal, and would be available as an oral capsule and as a powder formulation reconstituted for intravenous administration through an in-line filter.

For aspergillosis, "I do believe that this drug provides a reasonable alternative ... without additional toxicities," said panelist Dr. Paige Waterman of the Global Emerging Infections Surveillance and Response System at the Walter Reed Army Medical Center, Silver Spring, Md. Labeling should make clear that the drug should not be used in people under age 18 years or in pregnant women, and that a filter should be used with IV administration. Also, labeling should state a risk of hepatotoxicity, which appears in the labeling of other drugs in the same class.

Because isavuconazonium has been associated with a shortened QT interval, Dr. Waterman said that screening ECGs should be recommended. There should be extra caution when prescribing the drug to those of Asian descent, since drug concentrations were higher in those patients.

For treatment of invasive mucormycosis, those voting in favor of approval cited the significance of the condition and the reasonable efficacy results. Panelists also noted that more clinical data are clearly needed and that the lack of data directly comparing isavuconazonium to amphotericin B – the only FDA-approved drug for this indication – was problematic.

Isavuconazonium "really does fill an unmet need; I have high hopes that it is at least as good as amphotericin. But I do think we need more data to confirm that," said Dr. Michael Neely, chair of antimicrobial stewardship at Children's Hospital, Los Angeles, who voted for this indication.

If approved, isavuconazonium would provide an alternative to voriconazole for treating aspergillosis. Further, the IV formulation of isavuconazonium does not contain cyclodextrin, which is present in the IV formulation of voriconazole and limits its use in patients with moderate to severe renal dysfunction, according to Astellas. Safety concerns include QT-segment shortening and particulate formation in the IV formulation, according to the FDA.

The randomized, double-blind, international, noninferiority study compared treatment with isavuconazonium to voriconazole in 516 adults with invasive aspergillosis. In the randomized study, 11% of patients were in the United States and Canada, 20% had had an allogeneic bone marrow transplant, and 70% had an uncontrolled malignancy (Infect. Drug Resist. 2013;6:16374). The primary effectiveness endpoint, all-cause mortality through day 42, was 19% in those on isavuconazonium, compared with 20% in those on voriconazole. There were fewer events in those on isavuconazonium requiring discontinuation of the drug (14% vs. 23%). Decreases in the QT segment occurred in 7.5% of those on isavuconazonium, compared with 4.5% of those on voriconazole, but were not associated with events.

The prospective, open-label, single-arm study evaluated isavuconazonium in 37 patients with proven or probable mucormycosis infections; 59% had a hematologic malignancy, and about 40% were neutropenic at baseline. All-cause mortality at day 42 was 38%, which was similar to the mortality rate for amphotericin in the literature, according to Astellas.

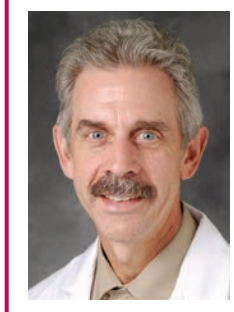
Besides voriconazole, drugs approved for aspergillosis include amphotericin, itraconazole, and caspofungin. Astellas will market isavuconazonium as Cresemba if approved.

emechcatie@frontlinemedcom.com

FDA NEWS

VIEW ON THE NEWS

Dr. Daniel Ouellette, FCCP, comments: Serious fungal infections are being increasingly recognized in patients who are immunocompromised or critically ill, but effective treatments with an acceptable side-effect profile have been sparse. Just a few years ago, the mainstay of treatment was amphotericin, an agent whose use has been associated with a variety of complications. However, novel agents have been developed that hold promise. The recent development of isavuconazonium, a prodrug of isavuconazole, may lead to further augmentation of the clinician's armamentarium in fighting these illnesses.



ABIM responds to criticism, makes changes to MOC

BY ALICIA GALLEGOS
Frontline Medical News

In a frank announcement, the American Board of Internal Medicine has apologized to doctors for a Maintenance of Certification program that "clearly got it wrong," and pledged to make the program more consistent with internists' practice and values.

Among the immediate changes: updates to its internal medicine exam; suspension of the practice assessment, patient voice, and patient safety requirements for at least 2 years; and MOC enrollment fees set at or below the 2014 levels through at least 2017.

Dr. David A. Fleming, president of the American College of Physicians (ACP), called the move monumental and historic.

"This turnaround has occurred in the face of mounting pressure and discontent expressed by a growing number of U.S. internists concerned about the MOC process," Dr. Fleming said in an interview. "With the new changes in MOC, internists are still being held accountable and responsible for maintaining professional competence, but by removing the practice assessment and patient [safety] requirements that are not well supported by evidence, we go a long way in taking the pressure off very busy physicians who already feel burdened by many layers of regulatory and administrative reporting that many view as burdensome and a barrier to our first duty – caring for patients."

In a statement, ABIM President and CEO Richard J. Baron said it was clear that aspects of the program were not meeting physicians' needs.

"We got it wrong and sincerely apologize," Dr. Baron said in the statement. "We are sorry. ABIM is changing the way it does its work so that it is guided by, and integrated fully with, the medical community that created it. The goal is to co-create an MOC program that reflects the medical community's shared values about the practice of medicine today and provides a professionally created and publicly recognizable framework for keeping up in our discipline."

As part of the newly announced changes, ABIM will make its internal medicine exam more reflective of physician practice, with changes to be incorporated in fall 2015, according to the announcement. The decision to suspend the practice assessment, patient voice, and patient safety requirements means internists who have not completed activities in these areas

'If you got something wrong, you apologize for it' and you commit to trying to get it right.

DR. BARON

will not have their certification status changed. Diplomates who are currently uncertified but who have satisfied all requirements for MOC except for the practice assessment requirement will be issued a new certificate this year. Within the next 6 months, ABIM will also change the language used to publicly report a diplomate's MOC status on its website from "meeting MOC requirements" to "participating in MOC."

By the end of 2015, ABIM said it will ensure new and more flexible ways for internists to demonstrate self-assessment of medical knowledge by recognizing most forms of Accreditation Council for Continuing Medical Education–approved continuing medical education. An online FAQ provides more information on the changes.

ABIM initially revamped its certification policies beginning in January 2014, shortening the time physicians had to earn MOC points and publishing online whether doctors were meeting requirements. The actions meant that every 2 years physicians certified by ABIM had to earn at least some points by completing some of the educational activities approved for MOC credit, and at the 5-year mark, earn 100 points. Previously, physicians were given 10 years to earn 100 points. Physicians were also listed publicly as either "certified, meeting maintenance of certification requirements" or "certified, not meeting MOC requirements."

The changes were met with almost immediate backlash. Doctors expressed frustration that the requirements were burdensome, expensive,

Continued on following page

October start favored for ICD-10

BY GREGORY TWACHTMAN
Frontline Medical News

WASHINGTON – The transition to the ICD-10 coding set should take place as planned on Oct. 1, witnesses testified at a hearing of the House Energy and Commerce Committee's Subcommittee on Health.

The message was welcome to committee leadership, who invited testimony almost solely from experts who support that position.

Subcommittee members from both sides of the aisle expressed a desire to not delay the implementation any further, though some at the Feb. 11 hearing questioned whether the Centers for Medicare & Medicaid Services was ready for the transition.

Subcommittee member Rep. Michael Burgess (R-Tex.), an ob.gyn., said he had no questions about the readiness of Medicare contractors and insurance companies for the transition, but "all roads eventually lead to the Centers for Medicare & Medicaid Services. And if you will pardon me, that does appear to be a weak link in the chain because from HealthCare.gov to the Sunshine Act reporting website, when CMS flips a switch, something breaks."

Continued from previous page

and irrelevant. By January 2015, a Web-based petition against the program garnered more than 19,000 signatures and has drawn thousands of comments in protest of the new requirements. A second petition had nearly 6,000 signatures with doctors taking a "pledge of noncompliance" with the requirements.

A January perspective piece in the New England Journal of Medicine expressed that the MOC program is essentially a money-generating activity for the ABIM and that the organization has lost contact with the realities of day-to-day clinical practice.

In an interview, Dr. Baron said such feedback drove ABIM to make the changes. He acknowledged that it would take time to build back trust within the community.

"Part of why we're taking the steps we're taking is that it's critical to have trust with the community," Dr. Baron said. "Part of how you do that is if you got something wrong, you apologize for it, you acknowledge you got it wrong, and you commit to making changes and try to get it right."

Dr. Baron noted that ABIM will be working with medical societies and directly with diplomates to seek input regarding the MOC program through meetings, webinars, forums, online communications channels, surveys, and other mediums.

"I fervently hope that we will come together as a community to figure out how to build a program that embodies and actualizes the values that internists have," he said in the interview. "We're going to need a lot of community participation to make that work and I hope that people will step up."

agallegos@frontlinemedcom.com
On Twitter @legal_med

While no representative from the CMS testified, a report from the Government Accountability Office suggested that the agency is positioned to make the transition to ICD-10 by the Oct. 1 deadline, although continued testing is warranted. That report was commissioned by the Senate Finance Committee, which also expressed support for an Oct. 1 start date for ICD-10.

Kristi Matus, chief financial and administrative officer for Athenahealth, testified to the general readiness of the health IT community to make the switch to ICD-10. The government should either "maintain the current date for ICD-10 implementation or cancel it once and for all. Pull the trigger or pull the plug," Ms. Matus said.

Dr. William J. Terry Sr., a urologist from Mobile, Ala., testified on behalf of the American Urological Association and expressed concern that not all physicians are ready.

He suggested that a transition period might allow physicians and other providers to run ICD-9 and ICD-10 simultaneously to ensure that physicians do not inadvertently lose any payments because of coding errors that might occur as they learn the new system.

gtwachtman@frontlinemedcom.com

GOP lawmakers offer ACA alternative plus tort reform

BY MARY ELLEN SCHNEIDER
Frontline Medical News

Three Republican lawmakers are proposing an alternative to the Affordable Care Act that would undo the individual and employer mandates, cap medical liability damages, and offer a slimmed-down set of consumer insurance protections.

Sen. Orrin Hatch (R-Utah), chair of the Senate Finance Committee; Rep. Fred Upton (R-Mich.), chair of the House Energy and Commerce Committee; and Sen. Richard Burr (R-N.C.), a Senate Finance Committee member, proposed the Patient Choice, Affordability, Responsibility, and Empowerment (CARE) Act to repeal and replace the health law.

"Our nation's health care system was broken before Obamacare, and

the President's health care debacle has only made things worse," Sen. Burr said in a statement. "The Patient CARE Act repeals Obamacare and addresses the fundamental cost drivers that Obamacare failed to address. We can lower costs and expand access to quality coverage and care by empowering individuals and their families to make their own health care decisions."

The Patient CARE Act outlines some federal medical liability reforms, including a cap on noneconomic damages and limits on attorneys' fees. It also seeks to encourage new models for resolving disputes on the state level, such as expert panels to evaluate injury claims and administrative health courts.

The proposal offers a more limited range of consumer insurance protections than does the ACA, including:

• Adopting an age rating ratio of 5-1 for premiums, which would limit plans from charging older individuals any more than five times what a younger person pays. Under the ACA, the age rating ratio is 3-1.

• Banning the use of lifetime dollar limits on health coverage.

• Allowing states to opt out of the ACA's dependent coverage provision, which lets young adults stay on their parents' health plans up to age 26.


SEN. HATCH

• Providing guaranteed renewability, with plans able to cancel coverage only in cases of fraud, misrepresentation, or failure to pay premiums.

• Banning denials of coverage based on preexisting medical conditions as long as the individual has been continuously covered for 18 months. The proposal includes a one-time open enrollment for people currently uninsured.

mschneider@frontlinemedcom.com
On Twitter @maryellenny

VIEW ON THE NEWS

Dr. Michael E. Nelson, FCCP, comments: With a new Congress controlled by Republicans, and given the prior attempts to overturn the Patient Protection and Affordable Care Act (a.k.a. "Obamacare"), it is not surprising that early in this legislative session an alternative plan has been proposed. One could argue some of the points of the proposal but not the accuracy of the statement made by one of the bill's authors that "our nation's health care system was broken before Obamacare." While this bill does address some issues of importance to physicians, it is certainly disappointing that this bill does not address the Sustainable Growth Rate formula (SGR). This looming threat of a 20% or more cut in physician reimbursement will do more harm to patient access and care than any other aspect addressed in this bill. Unfortunately, physicians rarely advocate at the federal level for themselves or their patients. Perhaps, with the introduction of this bill, it is the time to start.

PRESIDENT'S REPORT: Collaborating to achieve great things

BY DR. CURTIS N. SESSLER, FCCP

One of the most satisfying roles of a leader is to see the hard work of dedicated individuals pay off with a successful event or product. I find this particularly gratifying when the work is the result of collaboration among key groups who bring different perspectives and, by virtue of combining forces, make a greater impact on important issues.

Recently, I had the honor of being one of several representatives of our organization to the annual business meeting of the Forum of International Respiratory Societies (FIRS), in Cape Town, South Africa. CHEST is one of seven founding professional societies that represent all regions of the world – from the Pan African Thoracic Society (PATS) to the Asia Pacific Society of Respirology (APSR) and the European Respiratory Society (ERS) – all "united for lung health." Established in 2001, the Forum is dedicated to controlling respiratory disease worldwide and promotes advocacy in matters of respiratory health. CHEST leaders have played prominent roles in FIRS activities that help influence international health policy and contribute to better care of patients worldwide. For example, CHEST Past President Darcy Marciniuk chaired and was lead author of the recent sentinel FIRS document, *Respiratory Diseases in the World: Realities of Today – Opportunities for Tomorrow*, which draws attention to the magnitude and opportunities for improving management of the five main global respiratory diseases: COPD, asthma, TB, respiratory infections, and lung cancer.


DR. SESSLER

Among its list of activities to promote lung heath, FIRS develops position statements that influence key organizations like the World Health Organization and United Nations in important areas, with recent examples of statements on e-cigarettes and on Ebola virus disease. Additionally, FIRS and member organizations actively support greater awareness of important respiratory problems internationally through promotion of events like "World No Tobacco Day" and "World Asthma Day." Watch for CHEST sponsorship of "World Lung Cancer Day." Clearly, this group of professional societies that spans the globe has a louder voice to call attention to respiratory illness and improve health than that of a single organization.

CHEST is dedicated to improving the care of our critically ill patients and through the Critical Care Societies Collaborative (CCSC) has contributed to the advancement of intensive care medicine on many fronts. Founded in 2000, the CCSC – composed of the four major American professional and scientific critical care societies (American Association of Critical-Care Nurses (AACN), American Thoracic Society (ATS), Society of Critical Care Medicine (SCCM), and the American College of Chest Physicians (CHEST) – represents greater than 150,000 critical care professionals and has addressed a myriad of important topics. Noteworthy efforts by the CCSC include publishing statements on critical care research, critical care training and competency, ICU tele-medicine, and ICU workforce shortage, as well as directly addressing research needs with key leaders within the National Institutes of Health and other federal funding agencies and collaborating with the CDC on issues related to nosocomial pneumonia.

The CCSC recently contributed to the "Choosing Wisely" campaign – which is dedicated to addressing common but overutilized tests and treatments, aiming to eliminate low-value but expensive care. With four professional societies, CCSC represented the largest collaborative group to contribute to the Choosing Wisely series and the first to include a professional nursing society (AACN) – accurately reflecting the multiprofessional nature of ICU care.

One of the current CCSC projects focuses on the challenging nature of work in the ICU setting and its impact on care providers. In fact, in a recent survey, intensivists had the highest rate of burnout among all specialties. I have the honor of chairing our multiprofessional CCSC work group tasked with examining the frequency, causes, and consequences of burnout syndrome among ICU health-care workers. Our intentions are to raise awareness among administrators and policymakers of ICU Burnout Syndrome and to help establish the framework for potential solutions to this pervasive and critical problem.

The power of collaboration of CHEST with other professional societies extends to another core mission of our organization, that of synthesizing the medical literature and developing well-reasoned recommendations for clinicians through publication of evidence-based clinical practice guidelines. A recent noteworthy example is the comprehensive set of recommendations for the Prevention of Acute Exacerbation of Chronic Obstructive Pulmonary Disease developed in collaboration with the Canadian Thoracic Society (CTS) and published in *CHEST* (*Chest.* Oct 2014. Online First). Similarly, CHEST recently collaborated with the ATS to publish a combined CHEST and ATS policy statement on high-quality lung cancer screening, also published in *CHEST* (*Chest.* 2015;147[2]:295). In addition to providing practical information necessary for high quality lung cancer screening for practitioners and institutions, this important evidence-based document was highly influential in guiding CMS to make recent changes in coverage.

The Forum of International Respiratory Societies develops position statements that influence key organizations . . . recent examples include statements on e-cigarettes, and on Ebola virus disease.

Finally, collaboration can assume the form of guidance and assistance in development of new programs. In 2013, leaders and experts in graduate medical education from CHEST, in collaboration with leaders from the Chinese Thoracic Society (CTS), developed and initiated a plan to create the first formal Pulmonary and Critical Care Medicine (PCCM) fellowship training programs in China. Leaders from major teaching hospitals in China were recruited, curricula developed, and the first class of PCCM fellows enrolled. The challenges and the magnitude of the task require dedication and true collaboration that include genuine appreciation for differences in culture, in expectations, and ongoing mutual respect. It is exciting to anticipate the results of this collaboration with the graduation of the first class of PCCM fellows coinciding with CHEST World Congress 2016 in Shanghai.

Make Plans Now to Attend CHEST 2015

October 24-28
Montréal, Canada

Montréal is a lively city with multicultural influences that make the city tick. What better place for CHEST 2015, where we'll connect a global community in clinical chest medicine? As always, our program will deliver current pulmonary, critical care, and sleep medicine topics, presented by world-renowned faculty using innovative instruction formats—like hands-on simulation and interactive case discussions—to offer popular options for learning. Take advantage of these opportunities now:

Call for Abstracts

Submission Deadline: April 1
Submit an abstract of your original investigative work for presentation at the meeting. Accepted abstracts will be published in an online supplement to *CHEST*. Three types of abstracts will be considered:
• Slide presentations
• Poster presentations
• Poster discussions
Learn more and submit at chestmeeting.chestnet.org.

Call for Case Reports

Submission Deadline: April 1
Submit case reports for presentation during special sessions. Accepted case reports (excluding clinical case puzzlers) will be published in an online supplement to CHEST. Four types of case reports will be considered:
• Affiliate case reports
• Medical student/resident case reports
• Global case reports
• Clinical case puzzlers
Learn more and submit at chestmeeting.chestnet.org.

CHEST™ Annual Meeting 2015

Call for Moderators

Moderators are needed on-site during the meeting. Responsibilities include reviewing the abstracts and case reports prior to the meeting, then facilitating discussion, questions, and answers within your assigned session(s). All slide sessions and most poster sessions will have two moderators. Moderators will be recognized in the CHEST 2015 program and will receive a reduced registration rate to the meeting. Travel reimbursement will not be offered. Learn more at chestmeeting.chestnet.org.

The CHEST Foundation 2015 Grants Program

Application Deadline: April 30
The CHEST Foundation tradition of recognizing and rewarding health-care professionals for scholarly projects and research continues. Grants for both leaders in chest medicine and young investigators are available, including:
• CHEST Foundation and the Alpha-1 Foundation Research Grant in Alpha-1 Antitrypsin Deficiency - $25,000 1-year grant
• CHEST Foundation Research Grant in Women's Lung Health - $10,000 1-year grant
• CHEST Foundation Research Grant in Pulmonary Fibrosis - $30,000 1-year grant
• CHEST Foundation Research Grant in Chronic Obstructive Pulmonary Disease - $50,000 1-year grant
• CHEST Diversity Committee Minority Investigator Research Grant - $25,000 1-year grant
• Community Service Grant Honoring D. Robert McCaffree, MD, Master FCCP - up to $15,000 1-year grant
• CHEST Foundation Research Grant in Pulmonary Arterial Hypertension - $50,000 1-year grant
• Eli Lilly and Company Distinguished Scholar in Critical Care Medicine - $150,000 for 3 years
See which grants you are eligible for, and apply today at chestnet.org/grants.

Play CHEST Challenge

Game Ends: May 30
CHEST affiliate members, play CHEST Challenge to test your knowledge of pulmonary, critical care, and sleep medicine while competing for prizes.
The three top-scoring programs will compete in the CHEST Challenge Championship at CHEST Annual Meeting 2015. All championship players will receive:
• Airfare and registration to CHEST Annual Meeting 2015 in Montréal, Canada
• Complimentary hotel
• Cash prizes
Game on! Learn more at chestchallenge.org.

Meet ABIM's Pulmonary Disease Board

BY DR. SERPIL C. ERZURUM
Chair, ABIM Pulmonary Disease Board

As you have likely heard, the American Board of Internal Medicine (ABIM) has recently introduced a number of changes to its Maintenance of Certification (MOC) program, but what you may not know is that its governance structure has also undergone some important changes, including the formation of new specialty boards.

In the past, the specialty boards or test writing committees were charged with developing new exam questions, and due to the amount of time and effort involved in this process, they had little time to weigh in on specialty-specific issues related to certification and MOC.

One of the major criticisms of the MOC program is that certain requirements do not have options relevant to specific specialties or that on-the-ground physicians were not engaged in the process. In direct response to that criticism, ABIM established these specialty boards so they could:

• Define, refine, and set standards for certification and MOC in the discipline;
• Perform oversight/review of performance assessments in the discipline; and to
• Build partnerships with societies and other organizational stakeholders.

The secure examination will continue to be developed by a separate, dedicated group of physicians but will now be referred to as exam committees, ie, Pulmonary Disease Board Exam Committee.

As the Chair of the ABIM's Pulmonary Disease Board, I am excited to take this opportunity to introduce the role of this newly formed specialty board, as well as introduce its members.

The ABIM Pulmonary Disease Board, along with nine other specialty boards, held their inaugural meetings this fall. Each of the specialty boards consist of practicing ABIM Board-Certified physicians, an intraprofessional team member, and a patient representative.

Members of the ABIM Pulmonary Disease Board include:

Dr. Serpil C. Erzurum, Chair, Cleveland, OH
I am board-certified in Internal Medicine, Pulmonary Disease, and Critical Care Medicine, practice Pulmonary Medicine at the Cleveland Clinic and serve as the Alfred Lerner Chair of the Department of Pathobiology in the Lerner Research Institute.

Dr. Kevin M. Chan, FCCP, Ann Arbor, MI
Dr. Chan, who is board-certified in Internal Medicine, Pulmonary Disease, and Critical Care Medicine, is Fellowship Program Director for the Division of Pulmonary and Critical Care Medicine, and Medical Director of Lung Transplantation at the University of Michigan.

Dr. John Allen Cooper, Birmingham, AL
Dr. Cooper, who is board-certified in Internal Medicine and Pulmonary Disease, is Professor of Medicine at the University of Alabama Medical School, and Chief of the Pulmonary Section at the Birmingham Veteran's Administration Medical Center.

Dean R. Hess, PhD, RRT, FCCP, Boston, MA
Dr. Hess, our intraprofessional member, is Assistant Director of Respiratory Care, Massachusetts General Hospital, and Associate Professor of Anesthesia, Harvard Medical School.

(From Left to Right) Dr. Chan, Dr. Hess, Dr. Tanoue, Dr. Cooper, Dr. Erzurum, Mrs. Lambert, Dr. Nelson, and Dr. Siu

Tommye Lambert, MBA, MDIV, Hoover, AL
Mrs. Lambert, our patient representative, is a leader in the caregiver community who focuses on patient-doctor communication and collaboration and was primary caregiver for 28 years to her daughter who suffered with cystic fibrosis. Mrs. Lambert earned her MDIV at Beeson Divinity School, Samford University, and her Executive MBA from the University of Alabama.

Dr. Michael E. Nelson, FCCP, Shawnee Mission, KS
Dr. Nelson, who is board-certified in Internal Medicine, Sleep Medicine, Pulmonary Disease, and Critical Care Medicine, is a practicing physician in Shawnee Mission, Kansas, and Medical Director of the Sleep Laboratory of the Shawnee Mission Medical Center.

Dr. Stanton T. Siu, Oakland, CA
Dr. Siu, who is board-certified in Internal Medicine, Pulmonary Disease, and Critical Care Medicine, is Chief of Pulmonary Medicine and Director of Graduate and Undergraduate Medical Education for Kaiser Permanente East Bay in Northern California, and Full Clinical Professor at the University of California San Francisco.

Dr. Lynn T. Tanoue, FCCP, New Haven, CT
Dr. Tanoue, who is board-certified in Internal Medicine, Pulmonary Disease, and Critical Care Medicine, is Professor of Medicine and Clinical Chief of the Section of Pulmonary, Critical Care, and Sleep Medicine, and Vice-Chair for Clinical Affairs in the Department of Internal Medicine at Yale School of Medicine. As a long-time member and current Chair of ABIM's Pulmonary Disease Board Exam Committee, Dr. Tanoue works closely with me in planning and carrying out the work of the Pulmonary Disease Board.

I am honored to lead such a diverse group of professionals from across the spectrum of pulmonary disease and look forward to sharing updates with you as we embark on our work of ensuring the relevancy of MOC to pulmonary disease physicians across the country.

Further information about ABIM's new governance structure may be found via the ABIM website: www.abim.org/about/governance.

This Month in *CHEST*: Editor's Picks

BY DR. RICHARD S. IRWIN, MASTER FCCP
Editor in Chief

Platelet Count Mediates the Contribution of a Genetic Variant in *LRRC16A* to ARDS Risk. By Dr. Y. Wei et al.

Impact of COPD on the Mortality and Treatment of Patients Hospitalized With Acute Decompensated Heart Failure: The Worcester Heart Failure Study. By Dr. K. A. Fisher et al.

The Prognostic Value of Undetectable Highly Sensitive Cardiac Troponin I in Patients With Acute Pulmonary Embolism. By Dr. E. U. Hakemi et al.

Treatment of Alveolar-Pleural Fistula With Endobronchial Application of Synthetic Hydrogel. By Dr. H. J. Mehta et al.

COMMENTARY
Evolution in Reimbursement for Sleep Studies and Sleep Centers. By Dr. J. M. Parish et al.

EVIDENCE-BASED MEDICINE
Tools for Assessing Outcomes in Studies of Chronic Cough: CHEST Guideline and Expert Panel Report. By Dr. L-P Boulet et al.

NAMDRC Roundtable on 'Respiratory Compromise'

BY DR. DENNIS E. DOHERTY, FCCP
NAMDRC President

PHIL PORTE
NAMDRC Executive Director

NAMDRC brought together representatives of key medical societies, including CHEST, ATS, AARC, SCCM, AACN, SHM (hospitalists), PPAHS (patient safety), and ACEP (emergency physicians) to address respiratory compromise, that cascade of events that moves from respiratory insufficiency to respiratory failure to respiratory arrest. Recognizing that respiratory compromise occurs in various settings, the conference, Feb 26-27 in Orlando, Florida, focused on the hospital setting.

In addition to society representatives, the NAMDRC leadership, in consultation with recognized experts, also invited key opinion leaders to participate, including physicians, respiratory therapists, and nurses.

There were several challenges facing the participants, perhaps paramount was to define the concept of "respiratory compromise." Some have signaled, "I know it when I see it," but the expectation was to formulate a specific clinical definition of the respiratory deterioration, and devise a recognition pathway that can easily be used in the hospital setting to identify patients earlier in the course of this cascade.


DR. DOHERTY


MR. PORTE

How to identify high risk patients is critical to the discussion, because it is generally believed that this is where resources need to be focused, both from a personnel and monitoring perspective. Can consensus be drawn to determine which patient characteristics can reliably classify that patient into a high risk for respiratory compromise, and, if so, those characteristics should be delineated. The corollary challenge is to identify the low risk patients so that inappropriate resources are not focused where efforts might not be necessary.

Individual hospital policies are integral to this issue, as the relative value of rapid response teams appears to vary greatly. Add to the equation a recent *Wall Street Journal* article (http://online.wsj.com/search/term.html?KEYWORDS=Heart%20attack) that highlighted the success of managing heart attacks outside the hospital but the notable challenges of managing those events when they occur within the inpatient population.

Another key challenge facing roundtable participants was to focus their discussions on what clinical parameters should be monitored and which, if any, should be put on the back burner. There was a relatively wide variation of views regarding what should be monitored, what thresholds are problematic and indicative of a declining patient, and what actions need to be taken, and how swiftly, to abate the downward cascade of respiratory compromise. A related challenge facing participants was, "should the industry be moving toward refinement of their monitoring technologies to give physicians and the health-care team more valuable and more timely information? Are we monitoring the right parameters, or are we monitoring what the technology allows us to monitor? Are there gaps that can be addressed?"

It is likely that not only will the proceedings be documented for submission for publication, but this may very well lead to other conferences that focus on respiratory compromise in other settings. Both the skilled nursing facility and long-term acute care hospital settings provide care for a spectrum of pulmonary/ventilator patients, and the characteristics of their potential cascade of deterioration may or may not be the same as in an acute care hospital. The challenges are similar, but solutions may be different – a subject for further discussion.

This conference was just one example of NAMDRC's approach to a range of pulmonary-related clinical issues. While NAMDRC's broad mission is to "improve access to quality care for patients with respiratory disease by removing regulatory and legislative barriers to appropriate treatment," the roundtable does fit

Respiratory Compromise *continued on page 30*

CLASSIFIEDS

Also available at MedJobNetwork.com

PROFESSIONAL OPPORTUNITIES

Advance your career. Enhance your lifestyle.

Mount Nittany Health Pulmonologist Opportunity

Mount Nittany Physician Group is seeking a pulmonologist to join its growing practice. The group is physician-led and professional managed with more than 120 employed providers in 23 specialties. The Physician Group and Mount Nittany Medical Center, a 260 bed acute care hospital are of Mount Nittany Health, a growing health system serving central Pennsylvania.

Our 6-physician pulmonary practice currently provides a range of pulmonary medicine services including interventional procedures, allergy/immunology, and sleep medicine, as well as outpatient pulmonary medicine/procedures and inpatient pulmonary consults.

State College, Pa., is home to The Pennsylvania State University, one of the nation's largest educational institutions. Affectionately nicknamed "Happy Valley," our vibrant college town offers a diverse culture, a beautiful natural environment, excellent public and private schools, affordable real estate, countless options for dining, theatre, sports and recreation, nightlife and more. This is all located within a safe, friendly community that makes the area perfect for raising a family.

MOUNT NITTANY HEALTH

Contact:
Lorelei Shaw, Director of Physician Recruitment
814.278.4866 | lshaw@mountnittany.org
mountnittany.org/careers

GUNDERSEN HEALTH SYSTEM®

PULMONARY/CRITICAL CARE PHYSICIAN

Gundersen Health System is seeking a BC/BE Pulmonary/Critical Care physician. Join a well-established group of board certified pulmonary and critical care physicians. Opportunity for critical care only is also available. Practice highlights:

- Your practice will include critical care, inpatient and outpatient pulmonary medicine
- Navigational, interventional bronchoscopies and other invasive procedures on a rotational basis
- Very minimal weekend call
- Part time sleep practice is optional
- Active participation in the teaching program
- Clinical research opportunities are available

Gundersen Health System, based in LaCrosse, WI, is a physician-led, integrated healthcare system employing over 450 physicians. Gundersen offers an excellent work environment, competitive salary and great benefits package. Most importantly, you will find a rewarding practice and an excellent quality of life.

Kalah Haug (608)775-1005, kjhaug@gundersenhealth.org
Gundersenhealth.org/MedCareers
EEO/AA/Veterans/Disabilities

Gundersen Lutheran Medical Center, Inc. | Gundersen Clinic, Ltd. | 12242_1014

KEEP UP-TO-DATE
Watch our Classified Notices for Postgraduate Course Information.

Live. Work. Play.

Job Opportunity in South Florida
Critical Care Medicine - Nocturnist

An MHS representative will be attending the SCCM's 2015 Critical Care Congress, visit us at booth #230

About the Opportunity:
Memorial Healthcare System's Intensivist Program has expanded. The program is currently comprised of 23 full time intensivists and five critical care ARNPs, providing 24/7 ICU coverage at multiple locations within the Memorial Healthcare System. In addition to critical care, many of our intensivists hold multiple board certifications including infectious diseases, pulmonology, surgery and neuro-critical care.

The available positions are full-time employed positions with competitive benefits and compensation package, sovereign immunity, paid CME and state-of-the-art equipment (including EPIC EMS, digital Olympus bronchoscopes, intubation scopes, Glidescopes, Sonosite Ultrasounds, etc).

Qualifications & Responsibilities:
The program is seeking dedicated critical care nocturnist to join the existing team. The nocturnist will integrate into the existing operational structure as the program expands to cover additional critical care units. Critical care coverage is provided in 12 hour in-hour shifts, 7pm to 7am – averaging approximately 15 shifts per month. The successful candidates will have excellent clinical skills, a broad knowledge base in critical care and be dedicated to providing high quality, evidence based care. Candidates must be BC/BE.

About Memorial Healthcare System:
Memorial Healthcare System is a 1,900-bed healthcare system located in South Florida and is highly regarded for its exceptional patient- and family-centered care. Memorial's patient, physician and employee satisfaction rates are some of the most admired in the country, and the system is recognized as a national leader in quality healthcare. To learn more, please visit mhs.net.

To inquire or learn more about this opportunity, visit memorialphysician.com

Memorial Healthcare System

FIND YOUR NEXT JOB AT

MEDJOBNETWORK.com
Physician • NP/PA Career Center

The first mobile job board for Physicians, NPs, and PAs

Mobile Job Searches—access MedJobNetwork.com on the go from your smartphone or tablet

Advanced Search Capabilities—search for jobs by specialty, job title, geographic location, employers, and more

Scan this QR code to access the mobile version of MedJobNetwork.com

CHEST Physician CLASSIFIEDS

For Deadlines and More Information,
Contact: John Baltazar
Tel: (917) 488-1528
Email: jbaltazar@americanmedicalcomm.com

FRONTLINE MEDICAL COMMUNICATIONS

OHIO CRITICAL CARE MEDICINE - DAYTON, OH

Excellent opportunity for BC/BE CCM physician to join growing 36+ physicians' private practice CCM/ID/Hospitalist/Endocrine group. Dayton is located in southwestern, OH. The metropolitan area of 800,000 offers many cultural, sports and recreational activities, excellent public and private school systems and affordable housing. Competitive salary and outstanding benefit package. Not a J-1 Visa opportunity.

Send CV or call:
Becky Kronauge
Practice Administrator
33 West Rahn Rd
Dayton, OH 45429
PH:(937)433-8990 ext.124
FAX:(937) 433-8691
Email: **rkronauge@sdacc.com**
Web: **www.sdacc.com**

Connect with your colleagues when you need them most!

> Learn more about NetWorks: **chestnet.org/NetWorks**
> Log in to the e-Community: **ecommunity.chestnet.org**

CHEST

It's a Brand New Day for CHEST Logo Products

> Purchase at: **chestcollection.com**

CHEST AMERICAN COLLEGE of CHEST PHYSICIANS

Disclaimer CHEST PHYSICIAN assumes the statements made in classified advertisements are accurate, but cannot investigate the statements and assumes no responsibility or liability concerning their content. The Publisher reserves the right to decline, withdraw, or edit advertisements. Every effort will be made to avoid mistakes, but responsibility cannot be accepted for clerical or printer errors.

CLASSIFIEDS

Also available at MedJobNetwork.com

PROFESSIONAL OPPORTUNITIES

EVANGELICAL COMMUNITY HOSPITAL

PENNSYLVANIA
CENTRAL PENNSYLVANIA

EVANGELICAL COMMUNITY HOSPITAL is recruiting a full time **Critical Care** and **Pulmonology/Critical Care Physician** focusing on pulmonary care and covering critical care patients. Entertain hiring a EM/Critical Care Physician, Intensivist or Pulmonologist for outpatient procedural services, in-patient pulmonary medicine and/or intensivist services. Critical Care Physician to work in ICU with other Intensivists 7 on 7 off. Critical component works with 2 full time Intensivists in 12-bed ICU; collaboration with experienced Hospitalist group (hospital-employed). Must be BE/BC in field of specialty with Fellowship training. New grads welcome!

Contact: Dennis Burns
Physician Recruitment
570-522-2739
dennis.burns@evanhospital.com

Central Maine Medical Center
The Central Maine Medical Family

Inpatient Pulmonary/Critical Care Position in Maine:

Join a vibrant Inpatient Pulmonary and Critical Care group of five in beautiful Maine! Central Maine Medical Center (CMMC) is seeking a BC/BE Pulmonary/Critical Care Physician to help provide pulmonary and critical care services to medical, surgical, trauma, and cardiac patients.

CMMC is a 250 bed, full service regional referral center with busy trauma, cardiothoracic, interventional radiology, vascular, and neurosurgical programs. We have a state-of-the art 19 bed ICU and a separate 16 bed cardiothoracic unit.

Competitive salary and benefits including CME, paid vacation, student loan repayment, 403b match, and relocation fees. Work schedule revolves around a 6 day on and 6 day off philosophy, with no longer than 12 hour shifts per day. There is no outpatient clinic work.

Residents and visitors enjoy an extraordinary lifestyle that revolves around top school systems, ski resorts, lake and ocean water sports, theatre, and world-class dining.

Interested applicants may submit CV to Julia Lauver, Medical Staff Recruiter, Central Maine Medical Center, 300 Main Street, Lewiston, ME 04240. Email: JLauver@cmhc.org . Fax: 207/795-5696. Call: 800/445-7431. Visit our website, www.cmmc.org.

Disclaimer

Chest Physician assumes the statements made in classified advertisements are accurate, but cannot investigate the statements and assumes no responsibility or liability concerning their content. The Publisher reserves the right to decline, withdraw, or edit advertisements. Every effort will be made to avoid mistakes, but responsibility cannot be accepted for clerical or printer errors.

Breaking news.
Insightful commentary.

Available 24/7 From the #1 Respiratory News Publication

> chestphysician.org

CHEST

CHEST Physician
CLASSIFIEDS

For Deadlines and
More Information, Contact:
John Baltazar
Tel: (917) 488-1528
jbaltazar@americanmedicalcomm.com

FRONTLINE MEDICAL COMMUNICATIONS

Live. Work. Play.

Leading South Florida Healthcare System Seeks Cardiac Intensivists

About the Opportunity:
Memorial Healthcare System is seeking two critical care physicians, dedicated to night shifts, to join the critical care team. Successful candidates will have excellent clinical skills, a broad knowledge base in critical care and be dedicated to providing high quality, evidence-based care. Applicants must be BC/BE in critical care medicine. Previous experience in managing cardiac surgery patients is a plus, but not a requirement. Physician(s) would have exposure to all aspects of the care of cardiac surgery patients, including mechanical devices, advanced heart failure patients, ECMO and transplant.

- 12 hour in-house shifts (7pm-7am), no responsibilities outside of in-house shifts
- Approximately 15 shifts per month (more if desired)
- There is a highly competitive salary differential for the nocturnist position

These are full-time employed positions within the multi-specialty Memorial Physician Group. The positions offer competitive benefits, and a compensation package that is commensurate with training and experience. Professional malpractice and medical liability is covered under sovereign immunity.

About Memorial's Cardio-Thoracic ICU
Memorial Healthcare System, a 1,900-bed multihospital system located in South Florida, is highly regarded for its exceptional patient- and family-centered care. Memorial's patient, physician and employee satisfaction rates are among the most admired in the country, and the system is recognized as a national leader in quality healthcare. To learn more about Memorial Healthcare System visit **MHS.net.**

About South Florida
South Florida offers an outstanding quality of life rich in cultural and recreational amenities. Residents enjoy pristine beaches, top-rated golf courses, museums, world-class dining and myriad family-friendly communities. Florida also has no state income tax.

To inquire about this opportunity or learn more, visit **memorialphysician.com**

Memorial Healthcare System
Memorial Cardiac and Vascular Institute
MEMORIAL REGIONAL HOSPITAL | MEMORIAL HOSPITAL WEST

UNIVERSITY of COLORADO HEALTH

Fort Collins, Colorado

Colorado Health Medical Group is seeking a Pulmonologist/Critical Care trained physician. Sleep Medicine training desirable but not required. Will rotate in two hospitals and our Loveland based clinic. Call is 1:11 nights and 1:5-6 weekends. Physician will be doing general Pulm/CC procedures and read sleep studies from outlying facilities.

If interested, email your CV to
Briann.Leone@uchealth.org

CHEST PREP – Disease-State Education for Industry

BY LISA STANICK, MBA
Director, PREP Operations

Did you know the American College of Chest Physicians (CHEST) has provided disease-state-specific education for pharmaceutical and medical device representatives for over 12 years?

The CHEST Professional Representative Education Program, or PREP, is an unbranded disease-state clinical immersion program. The PREP Team works with pharmaceutical and medical device companies to understand their learning objectives and the educational needs of their representatives. A customized program to address those specific needs is then developed.

Each program uses different learning methods – problem-based case studies, patient testimony, simulation, and faculty-led workshops – to create a dynamic learning environment that increases interaction and develops deeper comprehension. The PREP curriculum is based on evidence-based clinical practice guidelines and consensus statements. Each program is created by clinical thought leaders and delivered by expert faculty, typically drawn from our CHEST membership. PREP courses are held at leading hospitals and academic medical centers throughout the country, as well as at the CHEST Innovation, Simulation, and Training Center in Glenview, Illinois.

Participants who complete the course objectives, including the post-course knowledge assessment, are awarded a Certificate of Completion valid for a 3-year period. More importantly, they gain the most current, in-depth clinical information needed to engage with health-care professionals knowledgeably, confidently, and meaningfully. This translates to better-educated representatives who interact with you as you make clinical decisions that enhance patient outcomes.

CHEST has trained over 4,000 sales representatives over the past 2 years. Not only has CHEST conducted PREP programs for disease states such as atrial fibrillation, venous thromboembolism, and COPD, PREP programs are also available for women's health, oncology, and interventional radiology through strategic agreements with the American Congress of Obstetricians and Gynecologists (ACOG), the American Society of Clinical Oncology (ASCO), and the Society of Interventional Radiology (SIR). The PREP Team recently conducted a Prostate Cancer PREP course at Huntsman Cancer Institute in Salt Lake City, Utah. This course is the first of four to be conducted over the next months at academic medical centers around the country. Over 100 sales representatives will participate in this PREP, which was developed and is being conducted through CHEST's agreement with ASCO.

The PREP Team continues to expand its offerings. If you would like to develop curriculum content or participate as faculty for a PREP course or to receive more information about how your hospital or medical center can become a course site, please contact me at lstanick@chestnet.org or 224/521-9518.

NAMDRC

Respiratory Compromise *from page 27*

into the mission because of growing concerns that we are facing challenges that are solvable if we take the initiative to address solutions to these challenges. Another broad challenge facing NAMDRC is its belief that the growing area of home mechanical ventilation is being shaped by archaic and outdated legislation and regulation. In a discussion with Marilyn Tavenner, CMS Administrator (and critical care nurse by training) last August, she conceded that the laws and regulations have not kept pace with innovations as basic as noninvasive mechanical ventilation. The idea that mechanical ventilation involves intubation or tracheostomy is universally recognized as archaic. As archaic is the concept that, by definition, ending mechanical ventilation leads to imminent death. Amending the existing laws and regulations in this area may become a high priority for NAMDRC over the next few years.

For membership information, visit the NAMDRC website at www.namdrc.org or call 703/752-4359.

CLASSIFIEDS

Also available at MedJobNetwork.com

PROFESSIONAL OPPORTUNITIES

U.S. Department of Veterans Affairs

Overton Brooks VA Medical Center in Shreveport, LA is seeking full-time BE/BC staff physicians in the following areas:

Pulmonary/Sleep Medicine or Sleep Medicine Position

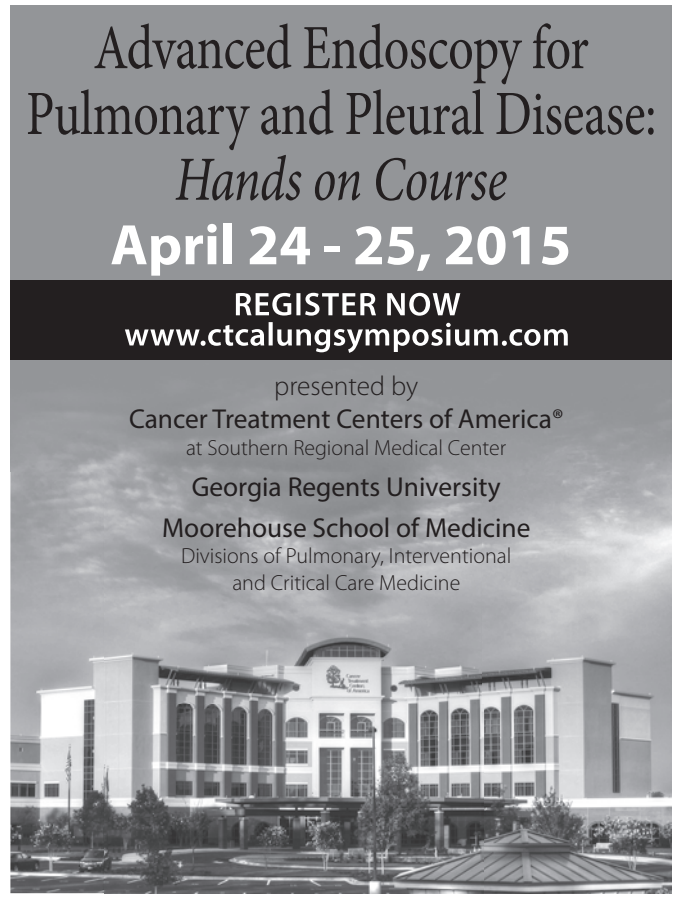
Applicant must be BC/BE in Pulmonary and Sleep Medicine OR Sleep Medicine alone. Position involves teaching students, residents and Pulmonary & Sleep fellows. Duties include hospital consultations, clinic responsibilities, and proficiency in pulmonary and/or sleep diagnostic procedures. Experience in EBUS and Ultrasonography would be desirable if trained in Pulmonary.

Key requirements: BC in Internal Medicine and BE/BC in Pulmonary and/or Sleep Medicine, US citizenship, proficiency in English, full & current unrestricted licensure. Applicant must also qualify for an appointment with LSU Health Center, Shreveport.

Pulmonary/Critical Care or Critical Care Position

Applicant must be BC/BE physician in either Pulmonary/Critical Care or Critical Care alone teaching students, residents and Pulmonary & Critical Care fellows while at the VA. Duties include hospital consultations, clinic responsibilities, and proficiency in pulmonary and critical care procedures as appropriate. Experience in EBUS and Ultrasonography would be desirable if trained in Pulmonary. Experience in ultrasonography would be desirable. Experience in extracorporeal modalities a plus.

Key requirements: BC in Internal Medicine and BE/BC in Pulmonary/Critical Care or Critical Care Medicine, US citizenship, proficiency in English, full & current unrestricted licensure. Applicant must qualify for an academic appointment with LSU Health Center, Shreveport



CHEST Physician

CLASSIFIEDS

For Deadlines and More Information, Contact:
John Baltazar
Tel: (917) 488-1528
jbaltazar@americanmedicalcomm.com

FRONTLINE MEDICAL COMMUNICATIONS

NETWORKS: Outbreak research, social media, lung transplant, OSA

Disaster Response

Chasing the tail of Ebola's epi curve: Outbreak research

In 2014, the American College of Chest Physician's Task Force on Mass Critical Care published it's second supplement on Care of the Critically Ill and Injured During Pandemics and Disasters (Christian et al. *Chest*. 2014;146:8S).

The initial aim was for this supplement to be evidence-based; however, due to the paucity of high quality evidence in the field of outbreak response and disaster management, ultimately, consensus-based guidelines were developed.

Today, as the world has faced its largest outbreak of Ebola costing upwards of tens of thousands of lives, once again, we find ourselves in a situation where just when research efforts are ramping up, the tail of the epidemiologic curve for the outbreak is rapidly falling off. While this is excellent news for those living in the affected countries, it unfortunately means that similar to efforts during SARS and H1N1, the potential to advance our clinical management and treatment options through research is likely to fall short of both the potential and need to do so.


DR. CHRISTIAN

Conducting research during disasters and outbreaks is fraught with challenges ranging from the sudden and, arguably, unpredictable nature of these events, through to the time required for ethics approval (Cook et al. *Crit Care Med*. 2010;38:e138) and execution of the studies. Despite these challenges, we must not accept failure and work to ensure the research is an essential component of the public health emergency response (Lurie et al. *N Engl J Med*. 2013;368[13]:1251).

A promising effort is now underway through a collaboration between the International Federation of Acute Care Trialists [InFACT] (*Lancet*. 2010;375[9708]:11) and the International Severe Acute Respiratory and Emerging Infection Consortium [ISARIC] (https://isaric.tghn.org/) to put in place a "sleeper study" to be tested annually on severe acute respiratory infections but will otherwise lie in wait ready to spring into action at the onset of the next emerging infection. This holds promise for potentially enabling a true rapid research response.

Dr. Mike Christian, MSc (Public Health), FCCP
NetWork Vice-Chair
Chief Safety Officer
Niagara Health System
Critical Care & Infectious Diseases
Attending Physician
Corporate Services

Practice Operations

Why Your Practice Should Be Involved in Social Media

Social media has been taking on an increasingly important role in medicine. Patients use social media to learn and share information, while medical establishments use it to help build their brands. Yet we, as individual practitioners, have been slow to adapt to the expanding role of social media in our profession.

There are three key reasons why we need to be more involved in using social media tools.

First, more patients are getting health-care information through it. Connections that are made through social media tend to be more valued than other sources. Practitioners know all too well that medical advice obtained through social media may be as highly regarded as their own advice to their patients. This provides an important opportunity. Using social media, we can provide useful information and contradict false information. For example, using your practice's Facebook page, you could provide information about sleep apnea or dispel vaccine myths.


DR. RAMACHANDRAN

Second, patients use social media to choose health-care providers. One in six patients now post online reviews about their health-care encounters. Inviting patients to give you positive reviews now can help counteract negative reviews later. In addition, registering at rating sites can elevate your Google profile and allows you to educate prospective patients about the services you offer.

Third, social media is where our patients are. It's time we were there, too.

Dr. Pradeep Ramachandran,
Steering Committee Member
Social Media Co-Editor, CHEST

Transplant

What is the skinny on weight in adult lung transplant?

More than two-thirds of American adults are overweight (body mass index [BMI] 25 mg/kg2 or greater) (Ogden et al. *JAMA*. 2014; 311[8]:806).

Trends in patients presenting for initial lung transplant evaluations are only slightly better, with 55% of candidates categorized as overweight (Chandrashekaran et al. *J Heart Lung Transplant*. Nov 17, 2014; epub ahead of print). This raises the question--does increased weight confer increased risk in lung transplantation?


DR. KENNEDY

Kanasky and colleagues first described a possible mortality risk posed by excess weight in lung transplant candidates in 2002 (*Chest*. 2002;121[2]:401).

Subsequently, obesity was also associated with an increased risk of primary graft dysfunction (Lederer et al. *Am J Respir Crit Care Med*. 2011;184[9]:1055).

Recently, Singer and colleagues demonstrated that class II or III obesity (BMI greater than 35 kg/m2) was associated with an increased risk of death in lung transplant, but class I obesity (BMI between 30 and 34.9 kg/m2) was not (A*m J Respir Crit Care Med*. 2014;190 [9]:1012).

Last month, the International Society for Heart and Lung Transplant published updated lung transplant candidate selection guidelines that now list obesity class II or III as absolute contraindications to lung transplantation (Weill et al. *J Heart Lung Transplant*. 2015; 34[1]:1). Obesity class I remains a relative contraindication.

Interestingly, Chandrashekaran and colleagues showed that weight loss in the overweight and class I obesity group was associated with improved mortality, suggesting ongoing weight loss should be encouraged.

The clinical bottom line: all overweight lung transplant candidates should be encouraged to lose weight. Those with a BMI greater than 35 should be deferred from transplant listing until weight loss is achieved.

Dr. Cassie Kennedy, FCCP
Steering Committee Member

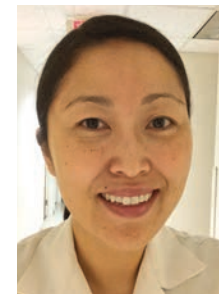
Women's Health

How prevalent is sleep apnea in women? It's how you slice and dice it.

More than 90% of women with OSA are reportedly undiagnosed (Young et al. *Sleep*. 1997;20[9]:705). There are, of course, many factors that contribute to this.

One less apparent reason is how we define and measure sleep apnea. More and more, there is an attempt to phenotype sleep apnea; an aim to be able to use the multitude of data gathered from overnight polysomnography to better prognosticate cardiovascular, mental, and other health outcomes. For example, there is evidence to suggest respiratory event-related arousals (RERAs) worsen fatigue and depression and result in greater use of hypnotics, antidepressants, and stimulants (Guilleminault et al. *J Psychiat Res*. 2006;40[3]:273).

A greater proportion of women than men are likely to have RERAs than frank apneas. As a result, the inclusion of RERAs into the hypopnea definition in the 2012 American Academy of Sleep Medicine scoring guidelines may lead to a greater proportion of women being diagnosed with OSA, as well as with more severe OSA.


DR. WON

A study from the Wisconsin Sleep Cohort demonstrated that AHI in REM sleep (but not in NREM sleep) confers a dose-dependent risk of hypertension (Mokhlesi et al. *Am J Respir Crit Care Med*. 2014;190[1]:1158). The clinical implication is that women, particularly younger premenopausal women who are more prone to REM-related OSA (O'Connor et al. *Am J Respir Crit Care Med*. 2000;161[5]:1465), may not be adequately treated since current standards qualify treatment based on total AHI, which is often driven by NREM AHI.

Meanwhile, we are moving more toward home sleep testing where arousals and sleep stages are often not measured. When the way we measure disease is moving dichotomously from our attempts to more precisely define and characterize OSA, we are challenged to consider how this impacts the diagnosis of sleep apnea in women.

Dr. Christine Won
Steering Committee Member

NOW AVAILABLE!

SPIRIVA® Respimat®

(tiotropium bromide)
Inhalation Spray is available
as of **January 2015.**

Boehringer Ingelheim

SPIRIVA® RESPIMAT®
(tiotropium bromide) INHALATION SPRAY