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Average length of hospital stay was 1.9 days with intermittent monitoring and 2.0 days with continuous monitoring.

Pulse ox spot checks okay for bronchiolitis

BY PATRICE WENDLING
IMNG Medical News

NEW ORLEANS – Intermittent spot checks are as safe as continuous pulse oximetry monitoring in children hospitalized with bronchiolitis, according to interim results from an ongoing randomized controlled trial.

Among 104 patients, the average length of stay was 1.9 days with intermittent monitoring and 2.0 days with continuous monitoring ($P = .98$).

There was no difference in ICU admissions and no deaths, Dr. Russell McCulloh said at Pediatric Hospital Medicine 2013.

The Choosing Wisely campaign recommends against continuous pulse oximetry use in otherwise healthy children hospitalized with bronchiolitis. Still, a variety of monitoring strategies exist for pulse oximetry in hospitalized patients, with rates of hospitalization more than tripling after institutionalization of pulse oximetry in emergency departments. Prior studies have also shown that pulse oximetry increases readmission rates and may prolong time to discharge, he said.

Dr. McCulloh and his associates in Rhode Island, Texas, and Missouri sequentially and separately randomized 104 patients within 24 hours of

See **Pulse oximetry** • *page 8*

Neuropathy warning strengthened for fluoroquinolones

Onset seen within days of starting drug.

BY ALICIA AULT
IMNG Medical News

The Food and Drug Administration is requiring a stronger warning about the potential for peripheral neuropathy with fluoroquinolone antibiotics that are taken orally or by injection.

The warning does not apply to topical formulations, which have not been associated with neuropathy. Drug labels and patient medication guides must be updated, said the agency.

The potential for neuropathy was first added to the labels of all drugs in the class in 2004. The new warning was necessary because "the potential rapid onset and risk of permanence were not adequately described" in the 2004 label iteration, the FDA noted.

Before requiring new warnings, the FDA reviewed its Adverse Event Reporting System (FAERS, formerly known as AERS) database.

The agency found that cases of fluoroquinolone-associated peripheral neuropathy with an outcome of "disability" had been reported to the AERS database between January 2003 and August 2012, although the FDA did not say how many cases it found. The

See **Neuropathy** • *page 5*

INSIDE

Report: Malpractice awards hit new lows

BY MARY ELLEN SCHNEIDER
IMNG Medical News

Malpractice lawsuit awards are at an all-time low, according to an analysis from the consumer watchdog group Public Citizen.

But the news isn't all good. Despite the fact that malpractice awards fell 28.8% between 2003 and 2012, the drop in payments isn't translating into a decline in overall health care costs or improvements in safety, according to Public Citizen.

"We now have a decade's worth of data debunking the litigation canard," said Taylor Lincoln, research director for Public Citizen's Congress Watch division and the report's author. "Policy makers need to focus on reducing medical errors, not reducing

See **Report** • *page 31*

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Is the change in 6MWD predictive of long-term outcomes in PAH?

It's time to move beyond short-term functional endpoints

The continued use of change in 6MWD as a primary endpoint in PAH clinical trials is being challenged by leading researchers.[1-3] Recent studies suggest this measure does not explain a large proportion of the treatment effect on clinical outcomes.[1,3] While experts acknowledge the clinical importance of 6MWD, they suggest the exploration of alternative primary endpoints.[1,2,4]

Now is the time for a new perspective on change in 6MWD as a primary endpoint. The PAH expert community has called for future PAH studies to deliver data on the long-term effect of therapy on clinical outcomes, such as hospitalizations and mortality.[2,5,6] Actelion is committed to investigating this evolving perspective in PAH.

References: 1. Gabler NB, French B, Strom BL, et al. Validation of six-minute-walk distance as a surrogate endpoint in pulmonary arterial hypertension trials. *Circulation*. 2012;126:349-356. **2.** McLaughlin VV, Badesch DB, Delcroix M, et al. End points and clinical trial design in pulmonary arterial hypertension. *J Am Coll Cardiol*. 2009;54:S97-S107. **3.** Savarese G, Paolillo SP, Costanzo P, et al. Do changes of 6-minute walk distance predict clinical events in patients with pulmonary arterial hypertension? *J Am Coll Cardiol*. 2012;60:1192-1201. **4.** Snow JL, Kawut SM. Surrogate end points in pulmonary arterial hypertension: assessing the response to therapy. *Clin Chest Med*. 2007;28:75-89. **5.** Gomberg-Maitland M, Dufton C, Oudiz RJ, Benza RL. Compelling evidence of long-term outcomes in pulmonary arterial hypertension? *J Am Coll Cardiol*. 2011;57:1053-1061. **6.** Galiè N, Manes A, Negro L, Palazzini M, Bacchi-Reggiani M, Branzi A. A meta-analysis of randomized controlled trials in pulmonary arterial hypertension. *Eur Heart J*. 2009;30:394-403.

PERSPECT

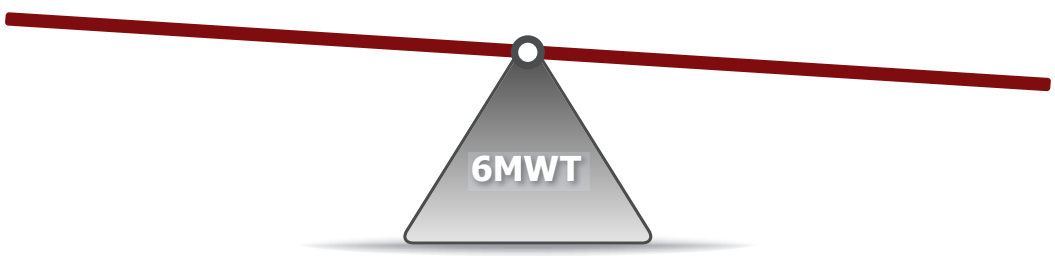
Benefits and limitations of 6MWT endpoint[2,4]

PROS

- Ease of use, low cost
- Allows assessment of daily functioning
- Accepted by regulatory agencies

CONS

- Results affected by musculoskeletal factors
- High within-subject variability
- May have a threshold effect
- Variability based on other activities on the day of testing



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ACTELION

Dependency predicts smoking-cessation weight gain

BY SHARON WORCESTER
IMNG Medical News

Smokers who are heavily addicted to nicotine are significantly more likely to gain weight when they try to quit, researchers report.

Investigators studying 186 patients who successfully quit smoking after receiving nicotine replacement therapy at an outpatient clinic found that mean body mass index increased significantly from 23.5 kg/m^2 at an initial consultation to 23.9 kg/m^2 at 3 months after the start of therapy. A high Fagerstrom Test for Nicotine Dependence (FTND) score, indicating severe dependency, was found on multivariate analysis to be the strongest predictor of increase (using a gender-adjusted standardized coefficient), Dr. Maki Komiyama of Kyoto (Japan) Medical Center and colleagues reported their findings in the open access journal PLoS One (doi:10.1371/journal.pone.0072010).

The findings are important because associated weight gain is linked with greater risk of glucose intolerance and a reduction in the beneficial effects that quitting has on pulmonary function, they reported.

The ability to predict which patients are likely to gain weight during smoking-cessation therapy – and performing weight control accordingly at the outset – could lead to improved outcomes, and the findings of this study may be useful for discriminating such patient groups.

Study participants were 132 men and 54 women with a mean age of 59.6 years who visited the smoking-cessation clinic at the National Hospital Organization Kyoto Medical Center between July 2007 and November 2011 and successfully quit smoking.

Other factors found on univariate analysis to be significantly associated with BMI increase included triglyceride level, high-density lipoprotein cholesterol, and daily cigarette consumption. "To further investigate … we performed multivariate analysis. The results demonstrated that the triglyceride level and FTND score were factors determining the postcessation BMI increase, and that the FTND score was the strongest one," the investigators wrote.

An FTND score of 8 or more (on a scale of 1-10) was associated with larger postcessation BMI increase, and the increase was statistically significant when compared with the level of BMI increase in those with a score of 7 or less, they noted.

With the exception of two patients who did not receive treatment, participants were treated with either oral varenicline (95 patients) or nicotine patch (89 patients). No difference was seen between the groups with respect to BMI increase, but the varenicline group had higher nicotine dependency.

They also noted that, in their study, "although a significant increase in BMI was confirmed after smoking-cessation therapy, the BMI increase was only 0.4 kg/m^2 (1.1 kg), which is much smaller than reported in previous studies for people who quit smoking on their own initiative (2.8-3.8 kg)."

Additional study is needed to determine the appropriate timing for initiating interventions against post–smoking cessation weight gain.

The study was supported by a grant-in-aid from the National Hospital Organization and the Pfizer Health Research Foundation. The authors reported that varenicline is manufactured by Pfizer but confirmed "that this does not alter their adherence to all the PLoS One policies on sharing data and materials."

VIEW ON THE NEWS

Dr. Vera DePalo, FCCP, comments: In addition to helping stratify patients likely to have post-cessation weight gain, the Fagerstrom Test for Nicotine Dependence may be a tool in the journey toward smoking cessation. The test, a short survey of tobacco use, may be helpful in aiding patients to understand the hold their tobacco-use habit has and move them toward attempts at smoking cessation at an earlier point in time. Targeted weight control strategies may help improve overall cessation success rates.

IN THIS ISSUE

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Dr. W. Michael Alberts, FCCP, is Medical Editor in Chief of *CHEST Physician*.

CHEST PHYSICIAN

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EDITORIAL OFFICES 5635 Fishers Lane, Suite 6100, Rockville, MD 20852, 240-221-4500, fax 240-221-2548

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Quinolones earn new warning label

Neuropathy *from page 1*

reports indicated a rapid onset of peripheral neuropathy, often within a few days of starting the quinolone. Some cases reported neuropathy that continued for a year, even though the medication had been stopped.

The database was not able to show whether neuropathy was permanent, however, because it is designed to collect spontaneous reports.

Some cases reported neuropathy that continued for a year, even though the medication had been stopped.

The FDA said it had not been able to identify any risk factors for the development of peripheral neuropathy. But the onset of the condition seemed to have no correlation with the patient's age or how long they took the antibiotic.

The updated warnings apply to all approved fluoroquinolones: levofloxacin (Levaquin), ciprofloxacin (Cipro), moxifloxacin (Avelox), norfloxacin (Noroxin), ofloxacin (Floxin), and gemifloxacin (Factive).

According to the FDA, 23 million outpatients were prescribed an oral quinolone in 2011. A total of 70% received ciprofloxacin; 28% were prescribed levofloxacin; and 9% were given moxifloxacin. Gemifloxacin, ofloxacin, and norfloxacin each accounted for less than 1% of those patients in 2011.

There were 3.8 million inpatients who received an injectable quinolone in 2011. The most-prescribed was levofloxacin, accounting for 63% of prescriptions, followed by ciprofloxacin (28%) and moxifloxacin (13%).

The agency recommended that patients who develop neuropathy symptoms stop taking the quinolone and be treated with a different antibiotic, unless the benefit outweighs the risk.

Patients taking the medications who develop symptoms are urged to tell their physician immediately.

aault@frontlinemedcom.com

VIEW ON THE NEWS

Dr. Marcos I. Restrepo, FCCP, comments: This upgraded recommendation warning alerting for the risk of peripheral neuropathy associated with the use of systemic fluoroquinolones is a matter of public health concern.

Clinicians should balance risks and benefits before prescribing oral or injected fluoroquinolones, alert the patients about related peripheral neuropathy symptoms after ordering fluoroquinolones, and advise on prompt reporting in order to stop the medication immediately.

A better understanding of the risk factors and prognosis associated with the use of fluoroquinolones should be a priority because of the high utilization of systemic fluoroquinolones in clinical practice.

Most pulmonary embolism patients can be sent home

BY MITCHEL L. ZOLER

IMNG Medical News

AMSTERDAM – Two-thirds of patients who presented to the emergency department of a U.S. tertiary care hospital with an acute pulmonary embolism had no acute deterioration and required no short-term hospital-based interventions, in an analysis of 298 patients seen over a 2-year period.

The finding "supports the assertion that outpatient treatment of patients with pulmonary embolism [PE] is safe," said Dr. Christopher Kabrhel at the 24th Congress of the International Society on Thrombosis and Haemostasis. "We want to identify patients for whom nothing bad will happen. We showed that two-thirds of patients did well and didn't need anything from the hospital and didn't benefit from being in the hospital. We need to identify some of these patients," soon after they present in the emergency department, said Dr. Kabrhel, a surgeon and emergency-medicine physician at Massachusetts General Hospital and Harvard Medical School in Boston. If reliable risk markers can be found with further research, "perhaps we can identify half of the two-thirds–a third of all patients who come to the emergency department with a PE–who we know will be safe with outpatient treatment so we can send those patients home from the emergency department and not admit them."

'We showed that two-thirds of patients did well and didn't need anything from the hospital and didn't benefit from being in the hospital.'

Most symptomatic U.S. patients who come to an emergency department, and are diagnosed with a PE are immediately admitted to the hospital. In the current study, the hospitalization rate was 92% with a median length of stay of 3 days. "We need a better rule to decide whether a patient needs hospitalization. We need to find which patients benefit from hospitalization," Dr. Kabrhel said in an interview.

He and his associates reviewed 298 adults 18 years or older who presented to the Massachusetts General Hospital emergency department during October 2009 through December 2011 with a radiographically proven PE diagnosed within 24 hours of arrival. They averaged 59 years old, half were women, and the most common comorbidity was malignancy in 107 patients (36%).

The study's primary outcome was any clinical deterioration or need for hospital-based intervention during the 5 days following presentation at the emergency department, including the need for advanced cardiac life support, the development of a new cardiac dysrhythmia, the development of hypoxia or hypotension, the need for thrombolysis or thrombectomy, recurrent PE, or death. These

Continued on following page

Tdap or not, antibiotics needed after pertussis exposure

BY BRUCE JANCIN
IMNG Medical Media

VAIL, COLO. – It's a question hospital infection control officers field from physicians and other health care personnel every time a pertussis exposure occurs: "I've been vaccinated, so why do I have to get a course of azithromycin for postexposure prophylaxis?"

The Advisory Committee on Immunization Practices (ACIP) based its updated recommendation for antibiotic postexposure prophylaxis on the findings of a randomized trial known as the Vanderbilt Study. The results, while nondefinitive, suggested that a policy of watchful waiting with daily symptom monitoring for 21 days post exposure may not be as effective as azithromycin postexposure prophylaxis in preventing pertussis infection, Dr. Ann-Christine Nyquist explained at the annual Pediatric Infectious Diseases Conference sponsored by the Children's Hospital Colorado.

The ACIP recommendation is for antibiotic prophylaxis for all pertussis-exposed health care workers likely to secondarily expose high-risk patients, such as neonates and pregnant women. Other vaccinated health care workers could receive either postexposure prophylaxis or 21 days of symptom monitoring with prompt antimicrobial therapy to be started should pertussis symptoms arise.

For Dr. Nyquist, the issue is a no-brainer. The vaccine is not 100% protective, the duration of protection is uncertain, and the adverse impact of a pertussis outbreak in a health care facility is enormous.

"When I put on my hospital epidemiologist hat and I think about pertussis in my hospital, it scares me to death. I would give everyone I was concerned about 5 days of azithromycin at $60 a pop," said Dr. Nyquist, professor of pediatrics at the University of Colorado, Denver.

The children's hospital affiliated with Vanderbilt University, Nashville, Tenn., has a universal tetanus-diphtheria-acellular pertussis (Tdap) vaccine immunization policy for all health care personnel. So it was an ideal location for a randomized comparison of two strategies to prevent infection following pertussis exposure in vaccinated physicians, nurses, and other health care personnel.

Following a pertussis exposure, health care personnel were randomized to 5 days of azithromycin or 21 days of watchful waiting. A bona fide exposure typically involved face-to-face exposure within a few feet when the health care provider wasn't wearing a mask, or ungloved contact with a patient's secretions.

Although 1,091 health care personnel enrolled in the trial, during a 30-month period only 86 subjects were randomized, limiting the statistical power of the findings. The key result: Only 1 of 42 patients who received postexposure prophylaxis met the prespecified definition of pertussis, compared with 6 of 44 in the watchful waiting group.

'I would give everyone I was concerned about 5 days of azithromycin at $60 a pop.'

DR. NYQUIST

However, pertussis infection was defined quite strictly as a positive culture or PCR, a twofold increase in anti–pertussis toxin titer, or a single anti–pertussis toxin titer of at least 94 enzyme-linked immunosorbent assay units per milliliter. In fact, not a single study participant developed symptomatic pertussis, and the investigators concluded that "it is likely that none of the health care personnel who met the predefined serologic or PCR for infection were truly infected with pertussis" (Clin. Infect. Dis. 2012;54:938-45).

Dr. Nyquist noted that the Centers for Disease Control and Prevention has identified health care workers as being at the epicenter of numerous pertussis outbreaks in hospitals. Health care personnel have regular contact with infected patients, and as adults they have waning immunity. The cost per hospital outbreak was calculated by the CDC at $44,000-$75,000.

"But that figure doesn't include the human pain and suffering, which I would multiply maybe times five," she added.

ACIP recommends that all health care personnel with direct patient contact in hospitals or ambulatory settings receive a single dose of Tdap. In addition, at its June meeting ACIP directed the Pertussis Vaccines Work Group to explore the possibility of giving a booster dose of Tdap to health care workers in order to beef up their protection.

Dr. Nyquist reported having no relevant financial relationships with any commercial interests.

bjancin@frontlinemedcom.com

Continued from previous page

events occurred in 99 patients (33%); of these, 28 patients (9% of the total group) had "severe" deterioration or required a "major" intervention. Twelve patients (4%) died within 30 days of their initial emergency presentation. The most common acute complication was the need for respiratory support, in about 55 patients, followed by hypotension, in about 34.

A multivariate analysis identified five baseline factors that significantly correlated with the primary outcome. Patients who had normal vital signs at baseline had a 79% reduced rate of significant deterioration or need for hospital-based intervention.

The other four factors were linked with increased rates of deterioration and need for intervention: Right heart strain caused by the PE and identified by an echocardiogram boosted the risk of a bad outcome more than fourfold, coronary disease and cerebrovascular disease each were tied to a more than threefold increased rate, and residual deep vein thrombosis was linked with a more than doubled rate of bad outcomes.

The subset of patients with the most severe outcomes had only one direct correlation with bad outcomes, right heart strain on echo. This subset of patients also showed a protective link against bad outcomes when their systolic blood pressure never fell below 90 mm Hg.

MITCHEL L. ZOLER/IMNG MEDICAL MEDIA

Most PE patients are immediately admitted, said Dr. Christopher Kabrhel.

In contrast to these factors linked to 5-day outcomes, two different types of patient factors were significantly linked with 30-day mortality: having a malignancy and having chronic lung disease.

"Previously validated clinical prediction rules that looked at outcomes after PE were primarily validated based on 30-day mortality or recurrent PE, and included factors like having cancer, heart failure, or chronic lung disease. But these scores are only able to predict the outcomes we examined with 70% sensitivity," Dr. Kabrhel said.

He found this out by running the numbers he collected through three validated scores for predicting PE outcome: the Geneva Prediction Score (Ann. Intern. Med. 2006;144:165-71), the Severity Index (Am. J. Respir. Crit. Care Med. 2005; 172:1041-6), and the Simplified Pulmonary Embolism Severity Index (Arch. Intern. Med. 2010;170:1383-9). "Predictors of all-cause 30-day mortality are different than predictors of short-term outcomes" in PE patients, he said.

"We found that echo is a very good predictor of short-term outcomes, and also abnormal vital signs. The key point is we need to look at outcomes that are relevant to the decisions made" in the emergency department, Dr. Kabrhel said. "Looking at 30-day mortality in patients who are only hospitalized for 3 days doesn't really inform the decision on who should be in the hospital. I would suggest caution on using [prediction] tools validated against 30-day mortality and recurrent PE to determine what to do acutely. We need better rules to decide which PE patients need hospitalization."

Dr. Kabrhel said he has been a consultant to Diagnostica Stago, and is an officer for LitPulse.

mzoler@frontlinemedcom.com

Spot checks suffice in bronchiolitis

Pulse oximetry *from page 1*

floor admission to continuous monitoring with a pulse oximeter in place, regardless of oxygen saturation status, or to intermittent monitoring with scheduled nursing vital signs checks every 4 hours, supplemental oxygen and continuous monitoring if blood oxygen saturation was consistently below 90%, and a return to spot checks once the patient was weaned from oxygen. Pulse oximetry was monitored at the bedside, not centrally.

The intermittent and continuous monitoring groups had similar rates of utilization of diagnostic tests including chest x-rays (58% vs. 48%, respectively), multiplex viral testing (34.6% vs. 46.2%), rapid respiratory syncytial virus testing (25% vs. 29%), and blood cultures (29% vs. 25%), said Dr. McCulloh, who started the study while an infectious disease fellow at Rhode Island Hospital in Providence and is now with Children's Mercy Hospital in Kansas City, Mo.

Therapeutic measures were also similar in the two groups, including use of IV fluids (65.4% intermittent vs. 73% continuous), supplemental oxygen (33% vs. 36.5%), bronchodilators (88.5% vs. 90.4%), and antibiotics (21.2% vs. 17.3%).

PATRICE WENDLING/IMNG MEDICAL MEDIA

"We're ... saying don't do continuous monitoring," said Dr. Russell McCulloh.

Children monitored continuously incurred no additional health care costs compared with those intermittently monitored, Dr. McCulloh said at the meeting. The average cost of all diagnostic testing, including pulse oximetry monitoring, was similar: $203.80 for continuous monitoring and $179.80 for intermittent monitoring.

The lack of a significant difference is not surprising since the children didn't enter the study until after they were admitted to the hospital, and much of the diagnostic testing occurs in the emergency department and not on the hospital floor, he said in an interview.

Dr. McCulloh observed that parental acceptance of the monitoring strategy varied by patient age. Parents of younger children were happier with continuous monitoring, while those with older children were more comfortable with intermittent spot checks.

At baseline, children monitored intermittently were significantly older (6.6 months vs. 3.5 months) and more likely to have otitis media on admission (23% vs. 7.7%). Family history of wheeze was similar in both groups (54% vs. 40.4%), as was tobacco exposure (31% vs. 25%).

Among staff, experience played a key role in monitoring adherence and acceptance. "We tended to have newer nurses coming on to the floor who were very uncomfortable with children of any age going onto the intermittent arm," Dr. McCulloh said. "Most of the older nurses were like, 'Of course.'

"We're not talking about not doing cardiac apnea monitoring if someone wants to do that; we're just saying don't do continuous monitoring."

Random checks on the floor and outreach with respiratory and nursing staff helped maximize adherence, he noted.

The study is expanding to include Children's Mercy Hospital, with a goal of 266 patients and completion anticipated in spring 2014.

Dr. McCulloh reported that the study is supported by a Thrasher Research Fund Early Career Award.

pwendling@frontlinemedcom.com

VIEW ON THE NEWS

Dr. Susan Millard, FCCP, comments: This study highlights that "more" is not necessarily "better." Even though the *P* values did not meet significance, in the long run, "more" is actually more expensive but not safer.

Findings question use of nasal IPPV in preemies

BY WHITNEY McKNIGHT
IMNG Medical News

The incidence of severe lung injury in extremely premature neonates with bronchopulmonary dysplasia given nasal intermittent positive-pressure ventilation is not significantly different for those who receive nasal continuous positive airway pressure, a randomized study of more than 1,000 infants shows.

"This research is significant, as it refutes the common assumption that the noninvasive therapies being used are reducing severe lung injury in these tiny babies," said lead author Dr. Haresh Kirpalani, attending neonatologist at the Children's Hospital of Philadelphia, in a statement. "The study alerts us that we still need to develop new therapies for babies to avoid lung injury and [bronchopulmonary dysplasia]."

Physicians often introduce the noninvasive therapies of nasal intermittent positive-pressure ventilation (IPPV) and nasal continuous positive airway pressure (CPAP) early in the lives of extremely low-birth-weight neonates. Their goal is to avoid potentially severe scarring and inflammation of the lungs that can result from the more invasive respiratory technique of endotracheal intubation and mechanical ventilation.

Previously, a meta-analysis of trials of early nasal CPAP vs. intubation and ventilation showed that nasal CPAP is associated with a lower risk of bronchopulmonary dysplasia (BPD). Still, Dr. Kirpalani and his colleagues quoted several studies showing that 34%-83% of extremely low-birth-weight infants given nasal CPAP require subsequent intubation. Meanwhile, nasal IPPV has been associated with nasal trauma and necrotizing enterocolitis. Only small randomized trials have compared nasal CPAP with nasal IPPV in low-birth-weight infants.

Researchers in the current study enrolled infants in 10 countries between May 7, 2007, and June 29, 2011. Eligible infants weighed less than 1,000 grams, had a gestational age of less than 30 weeks, and were candidates for noninvasive respiratory support. Infants expected to die were excluded, as were those with congenital abnormalities, a need for surgery, or a neuromuscular disorder. Key baseline characteristics in the study were similar, although the proportion of male infants was higher in the nasal IPPV group (52.6%) than in the nasal CPAP group (46.1%).

Of the 497 infants assigned to nasal IPPV, 38.4% of those for whom sufficient data were available reached the primary outcome of death before 36 weeks of postmenstrual age or survival with BPD (N. Engl. J. Med. 2013;369:611-20). In a similar group of 490 infants given nasal CPAP, 36.7% reached the primary outcome.

Dr. Kirpalani and his associates found no significant difference in rates of other neonatal complications.

Of the surviving infants, 58.3% in the nasal IPPV group needed postrandomization intubation, as did 59.1% in the nasal CPAP group. According to the researchers, the high number of reintubations in both groups indicates the difficulty in discontinuing respiratory support, despite the equally high use of caffeine at least once to mitigate the level of BDP in both groups.

The researchers noted that despite guidelines for weaning, extubation, and reintubation, a potential for bias existed because their study did not permit blinding. However, the authors wrote, one strength of their study was their objective assessment of BPD in their study groups, determined by a standardized, blinded oxygen-reduction test. In the 20 infants for whom oxygen-reduction data were unavailable, similar data were obtained in a secondary analysis that used National Institutes of Health criteria for BPD.

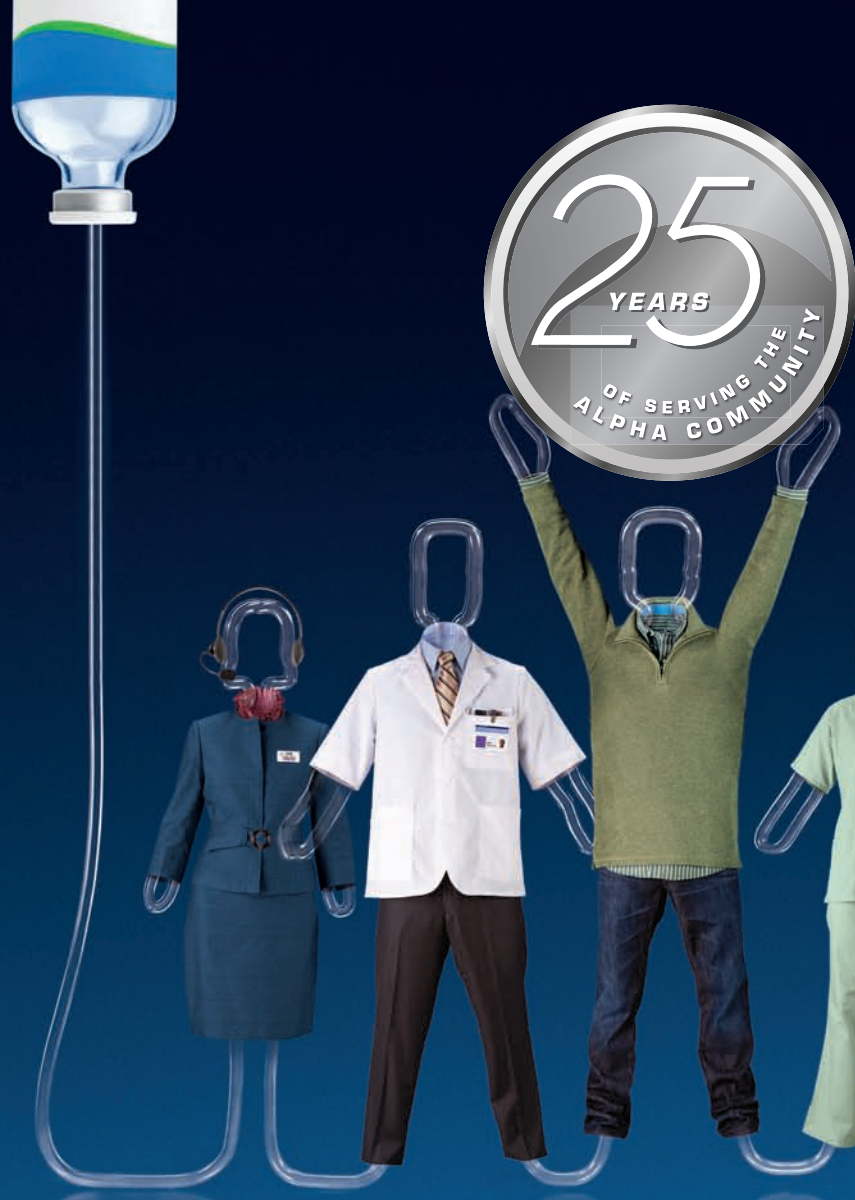
They concluded that although the overall rates of the primary outcome of death or survival with BPD were similar, "our results are compatible with an efficacy that ranges from a 21% reduction to a 35% increase in the risk of this outcome with the use of nasal IPPV versus nasal CPAP. These findings call into question the current widespread use of nasal IPPV."

The study was funded by the Canadian Institutes of Health Research. Dr. Kirpalani had no conflicts of interest.

wmcknight@frontlinemedcom.com

VIEW ON THE NEWS

Dr. Susan Millard, FCCP, comments:
This large, robust study shows that the management of acute respiratory failure in premature infants screams for more evidence-based medicine!



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The effect of augmentation therapy with any alpha$_1$-proteinase inhibitor (alpha$_1$-PI) on pulmonary exacerbations and on the progression of emphysema in alpha$_1$-antitrypsin deficiency has not been demonstrated in randomized, controlled clinical trials. PROLASTIN-C is not indicated as therapy for lung disease in patients in whom severe alpha$_1$-PI deficiency has not been established.

PROLASTIN-C may contain trace amounts of IgA. Patients with known antibodies to IgA, which can be present in patients with selective or severe IgA deficiency, have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. PROLASTIN-C is contraindicated in patients with antibodies against IgA.

The most common drug related adverse reactions during clinical trials in ≥1% of subjects were chills, malaise, headache, rash, hot flush, and pruritus. The most serious adverse reaction observed during clinical studies with PROLASTIN-C was an abdominal and extremity rash in one subject.

PROLASTIN-C is made from human plasma. Products made from human plasma may carry a risk of transmitting infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see brief summary of PROLASTIN-C full Prescribing Information on adjacent page.

References: 1. Data on file, Grifols. **2.** Campos MA, Alazemi S, Zhang G, Wanner A, Sandhaus RA. Effects of a disease management program in individuals with alpha-1 antitrypsin deficiency. *COPD*. 2009;6:31-40.

GRIFOLS

www.grifols.com

PROLASTIN®-C

Alpha$_1$-Proteinase Inhibitor (Human)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PROLASTIN®-C (Alpha$_1$-Proteinase Inhibitor [Human]) safely and effectively. See full prescribing information for PROLASTIN-C.

PROLASTIN®-C (Alpha$_1$-Proteinase Inhibitor [Human]) Lyophilized Preparation

For Intravenous Use Only

Initial U.S. Approval: 1987

----------INDICATIONS AND USAGE ----------

PROLASTIN-C is an alpha$_1$-proteinase inhibitor that is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to deficiency of alpha$_1$-proteinase inhibitor (alpha$_1$-antitrypsin deficiency). The effect of augmentation therapy with any alpha$_1$-proteinase inhibitor (Alpha$_1$-PI) on pulmonary exacerbations and on the progression of emphysema in alpha$_1$-antitrypsin deficiency has not been demonstrated in randomized, controlled clinical trials. PROLASTIN-C is not indicated as therapy for lung disease in patients in whom severe Alpha$_1$-PI deficiency has not been established.

----------CONTRAINDICATIONS ----------

IgA deficient patients with antibodies against IgA.

---------WARNINGS AND PRECAUTIONS -------

- IgA deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions.
- This product is made from human plasma and may contain infectious agents, e.g., viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

----------ADVERSE REACTIONS----------

The most common drug related adverse reactions during clinical trials in ≥ 1% of subjects were chills, malaise, headache, rash, hot flush, and pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Therapeutics Inc. at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------USE IN SPECIFIC POPULATIONS -------

- Pregnancy: No human or animal data. Use only if clearly needed.

GRIFOLS

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08941114-BS
Revised: June 2012

Think ceftaroline in suspected drug-resistant CAP

BY BRUCE JANCIN
IMNG Medical News

ESTES PARK, COLO. – Ceftaroline is hands-down the most exciting and important of the four systemic antibacterial agents to reach the U.S. market since the great 7-year drought in approvals ended in 2008, an infectious disease expert says.

Ceftaroline is a novel cephalosporin with unique binding to penicillin-binding proteins, including the altered versions that confer resistance

Cost barrier: Ceftaroline costs about $84 per day, or four times more than ceftriaxone.

DR. BESSESEN

in methicillin-resistant *Staphylococcus aureus* (MRSA) and penicillin- and cephalosporin-resistant *Streptococcus pneumoniae*. Thus, ceftaroline is a potent and effective drug in the increasingly common situation of beta-lactam-resistant community-acquired pneumonia (CAP) or complicated skin and soft tissue infections, noted Dr. Mary T. Bessesen, chief of the infectious diseases section at Denver V.A. Medical Center.

She reports having no financial relationship with the maker of ceftaroline.

In the pivotal FOCUS 1 and FOCUS 2 trials conducted in patients with CAP not due to MRSA, ceftaroline proved noninferior overall to ceftriaxone (Rocephin). Of note, in the 14% of FOCUS participants with CAP due to *S. aureus*, ceftaroline proved to be significantly more effective than ceftriaxone. Importantly, the same was true among the one-third of FOCUS participants in whom *S. pneumoniae* was isolated (Clin. Infect. Dis. 2010;51:1395-405).

"I think if you're going to impact mortality in CAP, pneumococcus has to be the primary target. Ceftaroline is a good alternative when penicillin-resistant *S. pneumoniae* is suspected or proven," Dr. Bessesen said at a conference on internal medicine sponsored by the University of Colorado.

Other common pathogens in CAP that are sensitive to ceftaroline are *Hemophilus influenza* and *Moraxella catarrhalis*. The Gram-negative pathogens *E. coli*, *Klebsiella pneumoniae*, and *Enterobacter cloacae* are also ceftaroline sensitive, with activity similar to ceftriaxone and ceftazidime.

Not only is MRSA sensitive to ceftaroline, so are methicillin-sensitive *S. aureus*, vancomycin-intermediate *S. aureus*, vancomycin-resistant *S. aureus*, linezolid (Zyvox)–resistant *S. aureus*, and daptomycin (Cubicin)–nonsusceptible *S. aureus*.

Ceftaroline does not cover the atypical pneumonia pathogens *Mycoplasma pneumoniae*, *Chlamydia pneumoniae*, and *Legionella pneumoniae*, nor does it cover *Pseudomonas aeruginosa* or extended-spectrum beta-lactamase-producing *Enterobacteriaceae*, stressed Dr. Bessesen.

The current CAP guidelines don't include recommendations for ceftaroline, because the drug received Food and Drug Administration approval for treatment of CAP and complicated skin and soft tissue infections after the guidelines were issued.

Clinical trials investigating ceftaroline in CAP caused by MRSA would be welcome, Dr. Bessesen noted, because the current CAP guidelines don't include any recommendations for CAP pneumonia.

'If you're going to impact mortality in CAP, pneumococcus has to be the primary target. Ceftaroline is a good alternative when penicillin-resistant *S. pneumoniae* is suspected or proven.'

"It really leaves us wondering in high-risk cases what's best to do," she said. "There's been some controversy about vancomycin versus linezolid when you suspect MRSA pneumonia. Ceftaroline would be a nice way to get around all of that."

Ceftaroline is administered intravenously twice daily, with dose adjustment for renal function. The drug's pharmacokinetics are favorable for intramuscular injection, but there are limited clinical data for this route, and it is not FDA approved.

Ceftaroline costs about $84 per day, or four times more than ceftriaxone, Dr. Bessesen said. As a result, formulary committees are reluctant to put ceftaroline on the list.

That makes Dr. Bessesen see red.

"I've never been on a drug company speakers bureau. I've never had any research money from drug companies. I speak only as someone who's interested in us being able to continue to treat bacterial infections when I say we've got to change our attitude. We have to be willing to pay something for these antibiotics," she asserted.

With regard to the other three systemic antibiotics approved by the FDA in the 5 years since the 7-year drought ended, bedaquiline (Sirturo) is the most important globally, because it is indicated for multidrug-resistant tuberculosis. Fidaxomicin is an effective drug for *Clostridium difficile* diarrhea; it's eight times more potent than vancomycin against *C. difficile*, has minimal systemic absorption, and offers the major advantage of producing little negative impact on favorable gut flora. Telavancin is a once-daily agent for hospital-acquired and ventilator-associated bacterial pneumonia.

Dr. Bessesen reported having no conflicts of interest.

bjancin@frontlinemedcom.com

VIEW ON THE NEWS

Dr. Vera DePalo, FCCP, comments: New antibiotics with proven effects afford us additional choices in the armamentarium when dealing with antibiotic resistance. A new cephalosporin, ceftaroline, offers another option when treating antimicrobial-resistant *S. aureus*.

NLST details: LDCT detects threefold more early lung cancers

BY MARY ANN MOON
IMNG Medical News

Low-dose CT screening of adults at high risk for lung cancer was three times better than radiography at detecting early, more treatable malignancies in the National Lung Screening Trial, according to a report published in the New England Journal of Medicine.

The initial findings from the NLST showed that low-dose CT (LDCT) lung screening reduced lung-cancer mortality by 20%, relative to radiographic screening. The investigators now report more detailed findings from the first two rounds of screening, which show that this decrease in lung cancer mortality "was coupled with a shift to detection of earlier-stage non-small-cell lung cancers," which are potentially curable, said Dr. Denise R. Aberle of the department of radiological sciences, University of California, Los Angeles, and her associates.

In the NLST, 53,454 adults at high risk for lung cancer were randomly assigned to undergo three annual screenings using either LDCT or radiography at 33 medical centers across the country. The screening took place between August 2002 and September 2007.

At the first round of screening, the sensitivity of LDCT was 94.4%, the specificity was 72.6%, the positive predictive value was 2.4%, and the negative predictive value was 99.9%. In comparison, the sensitivity of radiography was 59.6%, the specificity was 94.1%, the positive predictive value was 4.4%, and the negative predictive value was 99.8%.

At the second round of screening, LDCT's sensitivity was 93%, specificity was 83.9%, positive predictive value was 5.2%, and negative predictive value was 99.9%. In comparison, radiography's sensitivity was 63.9%, specificity was 95.3%, positive predictive value was 6.7%, and negative predictive value was 99.8%.

During the first round of screening, nearly half (47.5%) of the staged cancers detected on LDCT were stage IA, compared with only 23.5% of those detected on radiography. In contrast, only 31.1% of the staged cancers detected on LDCT were advanced stage III or IV cancers, compared with 59.1% of those detected on radiography.

This discrepancy in the distribution of early- vs. late-stage cancers persisted during the second round of screening, Dr. Aberle and her associates reported (N. Engl. J. Med. 2013 Sept. 4 [doi: 10.1056/NEJMoa1208962]).

In the future, "the performance characteristics of LDCT may be enhanced by determining the most appropriate risk cohort, refining both algorithms for interpreting the results of screening and definitions of positive findings, and determining the appropriate duration and timing of screening," they added.

The NLST was funded by the National Cancer Institute. Dr. Aberle reported no potential financial conflicts of interest; one of her associates reported ties to Endocyte, Frontier Science, and other companies.

Heart failure: Five interventions that improve care

BY BRUCE JANCIN
IMNG Medical News

ESTES PARK, COLO. – Introducing five evidence-based interventions in patients with heart failure with reduced ejection fraction would dramatically cut admissions for heart failure, according to Dr. JoAnn Lindenfeld, vice president of the Heart Failure Society of America.

Here are the five interventions: recognizing when to switch from furosemide to another oral loop diuretic; up-titrating beta-blocker therapy to the maximum recommended dose as quickly as possible; adding a low-dose aldosterone antagonist to the treatment regimen; identifying and treating iron deficiency; and prescribing digoxin in symptomatic patients with a low ejection fraction, Dr. Lindenfeld said at a conference on internal medicine sponsored by the University of Colorado.

Loop diuretics

Furosemide, everybody's favorite low-cost loop diuretic, turns out to have an enormously variable oral bioavailability, ranging from 10% to 90% from patient to patient. It also varies substantially from day to day within the same individual. In contrast, torsemide (Demadex) and bumetanide (Bumex) have a consistently high oral bioavailability of roughly 90%. They are useful alternatives in poorly compensated heart failure patients.

"When your patient says they're not diuresing and you're pretty sure they're taking their drugs, or if they've had more than one recent admission for heart failure and they're having trouble with congestion and fluid retention, think about switching to bumetanide or torsemide," said Dr. Lindenfeld, professor of medicine and medical director of the heart transplant program at the university.

In poorly compensated heart failure, torsemide and bumetanide are useful alternatives to furosemide.

DR. LINDENFELD

"In my own practice, when I have a patient admitted for acute decompensated heart failure with congestion and I don't find another reversible cause, I will usually switch them," noted Dr. Lindenfeld, who also is codirector of its Center for Women's Health Research.

In a classic study, 234 patients hospitalized for acute decompensated heart failure were randomized at discharge to torsemide or furosemide in equivalent doses. The torsemide group subsequently had a 52% lower rate of heart failure hospitalization (Am. J. Med. 2001;111:513-21).

Bumetanide is now a pretty inexpensive drug, Dr. Lindenfeld noted. In making the switch, remember that 40 mg of furosemide is equivalent to 1 mg of bumetanide or 20 mg of torsemide.

Beta-blocker up-titration

Beta-blocker and angiotensin-converting enzyme (ACE) inhibitor therapy both have a class IA recommendation in heart failure. But what's the best way to juggle the timing of dual dose increases?

"None of the guidelines says how to manage up-titration, but I strongly believe that once you have somebody on a reasonable dose of an ACE inhibitor – say, 5 mg of lisinopril or the equivalent – then you should go to the beta-blocker and up-titrate it to its maximum," she said. "Then later, come back to the ACE inhibitor and get the patient on the maximum dose of that."

The rationale for this approach is based on a comparison of the outcomes of the landmark beta-blocker trials versus ATLAS, a 3,104-patient trial conducted in the pre-beta-blocker era in which patients were randomized to low-dose lisinopril at 2.5-5 mg/day or high-dose therapy at 32.5-35 mg/day to determine which was better. After 4 years of follow-up, the high-dose group showed a 24% reduction in the risk of heart failure hospitalizations, but no significant advantage in terms of all-cause mortality (Circulation 1999;100:2312-8).

Contrast those results with the outcomes of the major clinical trials for carvedilol, metoprolol, and bisoprolol, each of which featured up-titration to the target dose within 8 weeks whenever possible. All three studies were halted within less than a year because of a roughly 35% reduction in mortality, compared with placebo. And that mortality benefit became apparent at 3 months.

"These are huge reductions in mortality," Dr. Lindenfeld noted. "You don't want to have a patient come back every 4 weeks to up-titrate their ACE inhibitor for 5 months and miss the opportunity to get the patient on an effective dose of a beta-blocker, when the lifesaving benefit begins so early."

The recommended maximum doses in heart failure patients are carvedilol (Coreg) at 25 mg twice daily, or 50 mg twice daily for patients weighing more than 85 kg; 200 mg/day for extended-release metoprolol (Toprol XL); and 10 mg/day for bisoprolol (Zebeta). The three beta-blockers are similar in their efficacy for treating heart failure, she said. However, bisoprolol has the

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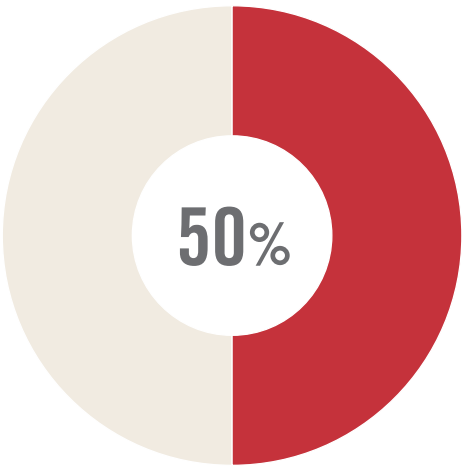

Note: Based on data for 1,506 patients.
Source: Am. Heart J. 2013;165:575-82

'I think if you restricted the study to hospitalized heart failure patients, the iron deficiency rate would be even higher.'

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Continued from previous page

fewest pulmonary effects and is thus the best choice in patients with chronic obstructive pulmonary disease (COPD), even though it lacks a specific Food and Drug Administration–approved indication for heart failure, she said.

Aldosterone antagonists

In terms of mortality benefit, the randomized trial data show that the aldosterone antagonists are nearly as good as beta-blockers. Yet they remain widely underutilized in the United States, according to Dr. Lindenfeld.

Indeed, three major randomized trials showed roughly a 25% reduction in total mortality, compared with placebo, in patients on standard background therapy including a beta-blocker and ACE inhibitor, along with a 20% decrease in risk of sudden cardiac death. The doses used were spironolactone at 12.5-25 mg/day or eplerenone (Inspra) at 25-50 mg/day.

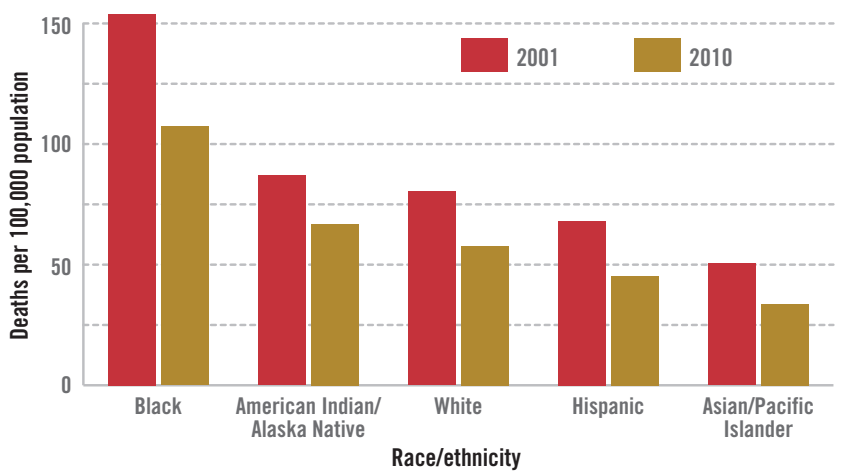
An intriguing retrospective analysis conducted in close to 7,000 patients with heart failure following an acute myocardial infarction concluded that getting the aldosterone antagonist onboard early in that situation is key. Patients who started on the drug less than 7 days post MI had a 29% reduction in total mortality and a 47% decrease in sudden cardiac death, compared with those started on day 7 or later (Eur. J. Heart Fail. 2009;11: 1099-105). That benefit is believed to be the result of early left ventricular remodeling.

A definitive European prospective, randomized trial looking at the impact of starting an aldosterone antagonist within 7 days after acute MI is due to be presented later this year. The inside word is the results are favorable, she noted.

Hyperkalemia is a legitimate concern when prescribing an aldosterone antagonist. These agents should be avoided in a patient who has a creatinine level above 2.5 mg/dL or an estimated glomerular filtration rate below 30 mL/min per 1.73 m^2, or if other potassium-sparing drugs are onboard. Potassium levels should be checked after the first 3-7 days of therapy, again at 1 month, and then every 3 months, as well as anytime a patient becomes dehydrated.

DATA WATCH

Avoidable deaths from cardiovascular disease



Note: Based on data from the National Vital Statistics System.
Source: MMWR 2013 Sept. 3 (early release);62

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VIEW ON THE NEWS

Dr. Jun Chiong, FCCP, comments: Heart failure (HF) is the most common cause of hospitalization in the U.S. and most developed nations. The cost of care for these patients has accelerated tremendously and is becoming a major focus of health care reform. The five methods of interventions presented by Dr. Lindenfeld are effective and simple interventions that result in hospitalization reduction. However, HF is a complex condition with multiple medical and social factors and the latter have not been addressed well in the medical community at this point.

Iron replacement

A new European study is illuminating on this issue: Among a cohort of

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1,506 patients with chronic heart failure, fully 50% were determined to have iron deficiency, as defined by a ferritin level less than 100 mcg/L, or a ferritin level of 100-299 mcg/L with a transferring saturation lower than 20%. In a multivariate regression analysis, iron deficiency was a strong independent predictor for mortality, associated with a 42% increased risk (Am. Heart J. 2013;165:575-82).

"I think if you restricted the study to hospitalized heart failure patients, the iron deficiency rate would be even higher. It's just appalling how many people we send home iron deficient without iron replacement therapy," Dr. Lindenfeld asserted.

A definitive European prospective, randomized trial looking at the impact of starting an aldosterone antagonist within 7 days after acute MI is due to be presented later this year.

She noted that in the European FAIR-HF trial involving 459 hospitalized iron-deficient heart failure patients randomized at discharge to intravenous iron corrective and maintenance therapy or to a matching placebo, the iron replacement group demonstrated significant improvement in quality of life and exercise capacity. The benefits were seen regardless of whether a patient's baseline hemoglobin was high or low.

In addition, the rate of the combined endpoint of first hospitalization for worsening heart failure or death was 7.5% in the iron recipients, compared with 13.9% in placebo-treated controls – a difference that didn't achieve statistical significance because the study was underpowered to evaluate that endpoint (N. Engl. J. Med. 2009;36:2436-48).

"Iron replacement is a distinct advantage for these patients, so you should be looking for iron deficiency. You probably don't need to use IV iron, but if your patient is in the hospital anyway, IV iron is pretty benign and will get him iron-repleted almost immediately," Dr. Lindenfeld noted.

Before sending iron-deficient patients home on oral iron, make sure they can absorb it. Many older individuals can't. Indeed, among patients hospitalized at the University of Colorado heart failure service, only 13% can actually absorb oral iron, she said.

A simple way to tell is to draw a serum iron level, give the patient an iron tablet, and check the serum iron level again in 1-3 hours. It should roughly double, Dr. Lindenfeld said.

Digoxin

In the classic digoxin trial involving close to 7,000 patients, heart failure hospitalization was a prospectively defined endpoint. In patients who had a left ventricular ejection fraction of 25%-45%, hospital admission for heart failure was reduced by 26% in patients assigned to digoxin. In patients whose LVEF was less than 25%, the reduction in hospitalization was 39%.

"So don't forget that digoxin is still a good drug in patients with low ejection fraction or who have substantial symptoms," Dr. Lindenfeld said.

"If we had a drug approved today that didn't change mortality but reduced hospital admissions by 39%, we'd all be giving it."

She reported consulting for Medtronic, St. Jude, Boston Scientific, Gambro, and ResMed.

bjancin@frontlinemedcom.com

Sleep problems common but untreated in lupus

BY MARY ANN MOON
IMNG Medical News

Women who have systemic lupus erythematosus report greater sleep disturbance than did healthy women, with more than 75% of them experiencing poor sleep quality, according to a report published in the Egyptian Rheumatologist.

In a study of 30 Egyptian women with SLE and 30 healthy, age-matched women, the SLE patients had higher scores on the Pittsburgh Sleep Quality Index (PSQI), indicating clinical sleep impairment, said Dr. Hanan A. Kotb of the department of rheumatology and rehabilitation, Cairo University, and associates.

Yet despite the high frequency and clinical severity of their sleep problems, only 30% of the SLE patients reported using any sleep medication. This indicates that clinicians routinely underestimate sleep disturbance in this patient population, the investigators said.

Dr. Kotb and colleagues assessed sleep problems in these 60 study subjects using the PSQI, which measures seven sleep components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The global score on this instrument ranges from 0 to 21 points, and a cutoff score of 6 or higher differentiates clinical sleep impairment with a sensitivity of 89.6% and a specificity of 86.5%.

The investigators assessed pain severity by using the visual analogue scale.

Among the SLE patients in this study, 13 (43%) had mild disease activity and 14 (47%) had moderate disease activity as measured by the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI). The remaining three patients (10%) had severe disease activity.

All of the SLE patients were taking corticosteroids.

Compared with the control subjects, the SLE patients had significantly higher PSQI scores, indicating poorer sleep quality. The mean PSQI score was 8.47 among SLE patients, compared with 5.1 among healthy women (Egypt. Rheumatologist 2013;35:127-32 [doi: 10.1016/j.ejr.2013.02.003]).

The differences between the two study groups were significant for most of the seven individual sleep components measured. The single most prominent component of sleep disturbance in this study population was daytime dysfunction.

In a refined analyses disease activity and scores on an index of organ damage were significant contributors to sleep disturbance. In contrast, the use of corticosteroids, subject age, and subject education level showed no association with sleep problems.

These findings indicate that the routine management of SLE should include the assessment and management of sleep problems, Dr. Kotb and associates said.

No funding sources or financial conflicts of interest were reported.

THORACIC ONCOLOGY UPDATE:

New Molecular Testing Guideline for Non-small Cell Lung Cancer Patients

The increasing momentum toward molecularly based classification and treatment of non-small cell lung cancer (NSCLC) is driven by our enhanced understanding of the molecular pathways involved in lung cancer pathogenesis, and of the proliferation and survival of cancer cells.[1,2] This has given rise to important challenges in establishing and implementing standards: What biomarkers should we test for? Which patients should be tested? When is testing appropriate?

Guideline for Molecular Testing in NSCLC

Last year, the National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommended that all advanced or metastatic NSCLC that is determined by histology to be non-squamous or NOS undergo biomarker testing for EGFR mutation and ALK gene rearrangement. These guidelines were recently updated to recommend EGFR and ALK testing in patients with squamous cell carcinoma if they never smoked and if small biopsy specimens were used to assess histology.[3]

And now a new guideline from the College of American Pathologists, together with the International Association for the Study of Lung Cancer and the Association for Molecular Pathology (CAP/IASLC/AMP) makes similar recommendations.[4-6]

> **"EGFR mutation and ALK rearrangement testing should be ordered at the time of diagnosis for patients presenting with advanced-stage disease."**[4-6]
>
> – *CAP/IASLC/AMP Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors*

According to the CAP/IASLC/AMP Molecular Testing Guideline, EGFR and ALK testing is recommended for lung adenocarcinomas and mixed lung cancers with an adenocarcinoma component, regardless of histologic grade in the setting of lung cancer resection specimens. In cases of limited specimen size (biopsies, cytology) where an adenocarcinoma component is not evident but cannot be ruled out, clinical criteria (e.g., young age, lack of smoking history) may be used to select patients for testing. However, patients with lung adenocarcinoma should not be excluded from testing on the basis of clinical characteristics.[4-6]

The Guideline suggests EGFR mutation and ALK rearrangement testing, to be ordered at the time of diagnosis for patients presenting with advanced-stage disease, or at the time of recurrence or progression in patients who were not tested at the time of an earlier diagnosis. Moreover, the Guideline encourages EGFR and ALK testing of patients with stage I, II, or III disease at diagnosis, but the decision to do so should be made locally by each laboratory, in collaboration with its oncology team.[4-6]

The growing consensus that molecular profiling — testing the tumor for all appropriate biomarkers — should be part of the clinician's standard approach to pathologic evaluation at both diagnosis and recurrence is now supported by guidelines from across the clinical spectrum of NSCLC.[1-6]

In academic research hospitals, reflex testing for EGFR and ALK is increasingly the norm. Further, multiplex molecular profiling assays may make the prospective genotyping of tumors possible, to aid clinical decision-making and management.[7]

PULMONOLOGY VIEWPOINT:

Frank P. Hull, MD
Clinical Professor of Medicine
Nova Southeastern University
Broward Health and Kindred Hospitals
Ft. Lauderdale, FL

Lung cancer is a deadly disease and it is in our patients' best interest to determine if they are candidates for biomarker-driven therapies. Pulmonologists are the gateway to lung cancer diagnosis and treatment. Most patients with a lung nodule or mediastinal adenopathy, for example, are referred to a pulmonologist, whose responsibility is to make the right diagnosis and determine whether a patient needs a surgical referral for resection or an oncologic referral for chemotherapy. My institution has begun reflex testing. We need to have strategies to perform molecular testing upfront so that we can offer biomarker-driven therapies to appropriate patients.

PATHOLOGY VIEWPOINT:

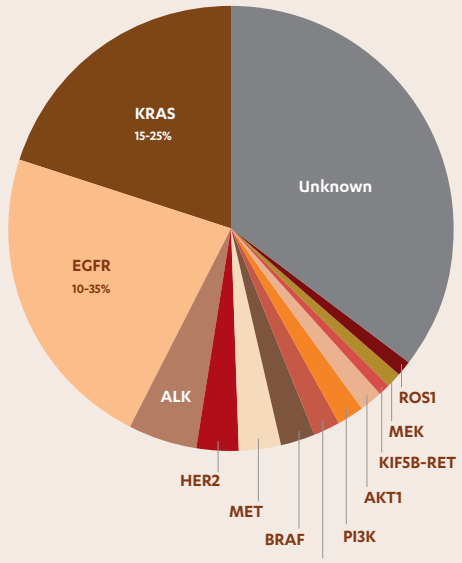
Pranil Chandra, DO
Director, Molecular
Pathology Services
PathGroup
Nashville, TN

As pathologists we are custodians of tissue, and we need to be judicious in how we use it. Given that we are the first to see the specimen, molecular testing can be pathology-driven — and by establishing reflex testing for EGFR and ALK, it should fall seamlessly into the workflow. At PathGroup, we've developed testing recommendations, guides, and educational materials on molecular testing for NSCLC, which have been distributed system-wide to all our pathologists and scientists. We plan to regularly update our protocols based on emerging literature and updated national recommendations. Molecular testing in NSCLC is progressing in a manner analogous to what happened with ER, PR, and HER2 testing in breast cancer.

Over 50% of NSCLC Cases Are Linked to Known Molecular Biomarkers[8]

It is no surprise that EGFR and ALK receive the most attention in the clinical setting today, as they are associated with FDA-approved biomarker-driven treatments.

At Least 10 Known Molecular Biomarkers in NSCLC



But according to recent studies, more than 50% of NSCLC cases are linked to one of at least 10 currently known biomarkers for NSCLC — and many of these patients may test positive for genetic abnormalities that are "drivers" for their cancers and may be treated with approved or investigational agents in clinical trials.[1,8] Now that more than half of NSCLC cases can be linked to one or more of these biomarkers, it is possible to subdivide the histological subtypes of NSCLC — adenocarcinoma, squamous cell carcinoma, and large cell carcinoma — into clinically relevant molecular subsets.[7]

These molecular subsets show the considerable heterogeneity of non-small cell tumors and suggest why patients with similar clinical stage and tumor histology can have dramatically different clinical outcomes.[9] For patients whose tumors test positive for a biomarker that is treatable with approved or investigational agents, the potential benefits of testing are self-evident.[3,7,10]

The Future

Research continues, and collaborative initiatives such as the Lung Cancer Mutation Consortium (LCMC), the Cancer Genome Atlas (TCGA), and the work of research hospitals and scientists, is making great progress in the discovery of lung cancer biomarkers.[11,12] The ultimate goal of this approach to treatment is to identify every driver mutation for non-small cell lung cancer, and design a corresponding treatment for each of these oncogenes.[1,7,9]

For the over 220,000 people diagnosed with lung cancer each year, these advances can mean more treatment options.[7,13] But only if patients are tested is it possible for them to potentially benefit from these developments.

For the patient point of view on molecular testing:
Visit www.lungcancerprofiles.com

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Dr. Michael Baumann, incoming President, weighs in

Michael H. Baumann, MD, MS, FCCP, will be inaugurated as the 76th President of the American College of Chest Physicians during CHEST 2013. He is Professor of Medicine within the Division of Pulmonary, Critical Care, and Sleep Medicine at the University of Mississippi Medical Center (UMMC), Jackson, MS.

Dr. Baumann received his MD degree from the University of Nevada-Reno School of Medicine, where he also served his internship. He completed his residency at the University of California-Davis and completed a fellowship at the Division of Pulmonary and Critical Care Medicine, Medical University of South Carolina, Charleston.

Dr. Baumann has held numerous leadership positions in the ACCP, including chairing the Quality Improvement Committee; Performance Measures Development Task Force for Pulmonary and Critical Care Medicine; Health and Science Policy Committee (now the Guidelines Oversight Committee); CHEST 2006; Scientific Presentations and Awards Committee; Council of Governors; Clinical Pulmonary Medicine NetWork; and Membership Committee. He has served on many other ACCP task forces and subcommittees and presently is a member of the *CHEST* and the ACCP-SEEK Editorial Boards.

Dr. Baumann has been active outside of the ACCP. He received a Master's degree with a focus on quality improvement from Dartmouth College in 2004 and served as the Chief Quality Officer from 2007 to 2013 for the University Hospitals and Health System at UMMC. Dr. Baumann has more than 90 publications, including peer-reviewed articles, chapters, and reviews. His particular interests include pleural disease, evidence-based medicine, quality improvement and performance measures, and health-care reform issues.

DR. BAUMANN

We asked Dr. Baumann about his thoughts for this upcoming ACCP presidential year.

1. What would you like to accomplish as President of the ACCP?

First, I would reword this question, slightly. What would you like to accomplish as part of the ACCP *team* this year? This upcoming year's efforts, as occurred with our immediate Past President, Dr. Darcy Marciniuk, and other ACCP Past Presidents, will be a team effort by members of the ACCP presidential lineup and other ACCP leaders, including the members of the Board of Regents, our superb ACCP staff, and, most importantly, our members.

I will work diligently to enable the College to continue to deliver on its core commitment—providing the best clinical education in pulmonary, critical care, and sleep medicine to enable our members to deliver the best patient-focused care possible.

A second very important goal is to foster the successful completion of several very exciting large projects the College has undertaken to strengthen its educational focus, including the completion of our new headquarters with its state-of-the-art Innovation, Simulation, and Training Center, and the deployment of our association management system, the College's future electronic central nervous system designed to coordinate all of our projects, including our many member-focused activities.

2. What do you consider to be the greatest strength of the ACCP, and how will you build upon this during your Presidency?

The College's greatest strength is its innovative development and delivery of clinical education to health-care providers globally, enabling expert care for patients. We as a team can build upon this strength by listening carefully to our members and the educational needs they voice. By continuing to monitor clinical advances and other developments in the health-care world, including the rapidly changing health-care delivery climate, we can better *anticipate* the educational needs of our members. Our journal, *CHEST*, annual CHEST conference, many simulation programs, board review courses, and other innovative programs provide excellent tools to deliver on our core educational goal.

By continuing to monitor clinical advances and other developments in the health-care world, including the rapidly changing health-care delivery climate, we can better *anticipate* the educational needs of our members.

The most important effort I can provide for ensuring continued superlative educational success is to maintain a sharp focus on this goal by limiting distractions that could take us off target.

3. What are some challenges facing the ACCP, and how will you address these challenges?

As noted in the previous question, there is a host of potential distractions in the health-care world today that can dilute the College's continued educational success.

The ACCP is a very successful organization, but this success can be jeopardized by trying to accomplish too many goals. Losing our focus can lead to achieving very little of value. Health-care delivery is changing rapidly, and our members have to adapt to these new challenges. As a College, we can have little meaningful impact on the "politics" of these changes, but we can have tremendous positive impact by providing focused, accurate, and timely member education about these changes. Such focus will enable our members to successfully adapt and continue to provide quality patient care.

4. And finally, what is your charge to the members and new Fellows of the ACCP?

The ACCP and its nearly 19,000 members exist to help you provide the best patient care possible by delivering superb clinical education in pulmonary, critical care, and sleep medicine. Let us help you help your patients. How? Get involved! The College offers many doors toward engagement. Just open one!

If you aren't sure how to start, we have a superb staff and excellent leadership more than willing to answer your questions. Also, our doors are open to nonmember health-care provider engagement. Remember, health-care delivery is a team sport, and we welcome all team members to become involved. As a member of a health-care team and the ACCP team, I welcome your ideas and concerns.

Finally, I end with warm congratulations to our new Fellows to be inducted at CHEST 2013-—a job well done!

'Beyond Our Walls': Capital campaign goal is within reach

At more than $3.6 million and 75% of our campaign goal reached, great progress has been made in the Beyond Our Walls Capital Campaign over the past several months.

From individual giving, to corporate donations, to our paver brick program, the support and momentum have been impressive.

Highlights include:

- A $1 million gift from Boston Scientific Corporation in support of advanced pulmonary procedures training in our new Innovation, Simulation, and Training Center.
- A $1 million gift from Olympus Corporation of the Americas in support of educational programming in the new training center.
- Individual donors have generously contributed over $1 million to the campaign.
- 100% participation by the ACCP Board of Regents members, as well as 100% participation by The CHEST Foundation Board of Trustees members.

There is still time to support the Beyond Our Walls campaign. Your philanthropic investment in the Beyond Our Walls Capital Campaign can make an important difference and improve care for patients and their families. To reach our campaign goal, we need your support and commitment to this worthy endeavor.

A paver brick program has been established and personalized bricks are available to highlight your support. The customized pavers will be on display in the entrance to the new building.

Visit http://beyondourwalls.chestnet.org to view a live feed of the building site and to learn more. Contact Megan Schagrin at (847) 498-8314 or by email at mschagrin@chestnet.org to learn about additional donor opportunities.

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FROM THE EVP/CEO: Leading with collaboration and engagement

BY PAUL A. MARKOWSKI, CAE

The ACCP is fortunate to comprise a diverse community of experts committed to achieving its mission to promote the prevention, diagnosis, and treatment of chest diseases. Individually, our members further the mission around the world by exchanging ideas, learning and advancing knowledge, and mentoring one another. As a whole, the ACCP achieves the same through collaboration and engagement with other medical societies. These are valuable partnerships that support, advance, and enrich our mission.

A very recent collaboration is with SEPAR, the Spanish Society of Pneumology and Thoracic Surgery. The ACCP and SEPAR are hosting the inaugural CHEST World Congress, March 21-24, 2014, in Madrid, Spain. By working with a local medical society that shares our desire to advance global lung health, we can better understand the learning needs of a broader base of clinicians and deliver a more targeted, relevant program. This union of experts strengthens our education impact on a worldwide scale and advances chest medicine around the world. Now *that's* an exciting, results-focused collaboration.


MR. MARKOWSKI

Our other collaborations are equally productive. For more than a decade, the ACCP has been part of FIRS, the Forum of International Respiratory Societies. FIRS is a collaboration of seven respiratory societies from around the world to promote advocacy of global respiratory health and the identification of new areas for global initiatives. FIRS attracted international attention in 2010 with the first annual World Spirometry Day, to raise world health awareness during the Year of the Lung. Under the direction and leadership of our President, Dr. Darcy Marciniuk, FCCP, the ACCP is chairing the development of a world report to be presented at the World Health Assembly to Address Non-Communicable Diseases in 2014. Our collaboration and engagement within FIRS is giving us a high-profile opportunity to put lung health on a global agenda. I look forward to where that will lead.

Through our engagement with the Critical Care Societies Collaborative (CCSC), we have addressed a wide range of the issues affecting critical care medicine. The CCSC leverages the collective voice of the ACCP, American Thoracic Society, Society of Critical Care Medicine, and the American Association of Critical-Care Nurses – more than 150,000 critical care professionals – to elevate awareness of challenges in the field and to empower change.

The ACCP has been instrumental in the CCSC collaboration by addressing the critical care workforce shortage, participating in discussions with the US Department of Health and Human Services on the prevention of ventilator-associated pneumonia, and serving on a task force to define an agenda or blueprint for critical care research. The CCSC is recognized by government agencies and has a close working relationship with the Department of Health and Human Services and the Centers for Disease Control and Prevention. By participating in this collaboration, the ACCP is positioned to make a positive difference for critical care providers and the patients they serve.

Occasionally, we collaborate with other societies in our work to publish evidence-based guidelines and consensus statements. Working with respected organizations allows us to assemble the appropriate experts and access a wider range of resources to enrich our work and improve our impact. We're partnering with the Canadian Thoracic Society to publish new *CHEST* guidelines in early 2014 on acute exacerbation of COPD.

These collaborations strengthen our relationships with our peers in medical societies and enhance our work to advance lung health. I am proud of the impact our collaborations regularly make around the world.

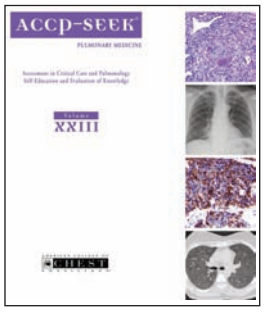
For updates on these partnerships, follow me on Twitter (@PMarkowskiACCP) where I post comments about the partnership, or ask me in person at CHEST 2013. I am anxious to tell you more during the meeting, October 26-31, in Chicago, our home neighborhood.

Now available: *ACCP-SEEK XXIII: Pulmonary Medicine*

Now available in the ACCP store is *ACCP-SEEK Volume XXIII: Pulmonary Medicine*! Check out the latest volume of SEEK for 158 new questions written by experts in the field of pulmonary medicine.

This is an invaluable study and self-assessment tool derived from the ABIM blueprint for pulmonary medicine. CME credit is available until December 2015 by completing the 20-question posttest on our Learning Management System.

To order, or for more information, go to https://accp.chestnet.org/storeWA/.



CHEST Journal app updated

An update to the *CHEST* Journal app for iOS devices is now available in the iTunes® store. This update features several enhancements.

Users can now:

- See at a glance how many new Online First articles have been added since their last visit.
- Hide ads when in reading mode.
- Share content directly to their Twitter or Facebook accounts.
- View the ACCP's Twitter feed.
- Adjust the font size when reading articles.

Since the new *CHEST* app was launched in July 2012, it has had more than 27,500 downloads.

Current app users will be prompted to update the app from within the app store.

New users can download the *CHEST* app at itunes.apple.com/us/app/chest/id541113522?mt=8.

CHEST 2013: Inspire Chicago

CHEST 2013

October 26 - 31
Chicago, Illinois

While you may be prepared to enjoy Chicago's iconic culinary staples – like deep dish pizza, hotdogs, and Italian beef – let out your inner foodie while you're attending CHEST 2013, and explore a wide-range of Chicago's culinary treasures.

Chicago's dining scene features celebrity chefs, world-renowned restaurants, and ethnic dining from around the globe.

Want recommendations from those who know best? Here are some top picks from our favorite, local Chicagoans – ACCP staff!

- 312 Chicago – authentic Italian cuisine
- Au Cheval – hip take on diner food
- The Aviary – high-tech cocktails
- BIN 36 – wine and contemporary, American cuisine
- Chicago Cut – steakhouse overlooking the Chicago River
- Chicago Q – modern, urban BBQ
- Girl & the Goat – fun foods from Top Chef Award Winner, Stephanie Izard
- RPM Italian – Giuliana and Bill Rancic's Italian restaurant
- Sable – Top Chef contestant Heather Turhene's American gastro-lounge
- Tortoise Club - American fare in a classic Chicago clubhouse
- Trencherman – contemporary, American food in a former Turkish bathhouse

Read more information about the staff's top picks at chestmeeting.chestnet.org.

If you're set on getting some authentic Chicago eats, check out these classics:

©Adam Alexander Photography

Deep dish pizza:

- The Original Gino's East of Chicago – deep dish slices in a unique, casual ambiance
- Lou Malnati's Pizzeria – pizza pies in a family-owned restaurant

Chicago-style hot dogs:

- Portillo's – famous, dive eatery with jumbo franks
- Hot Doug's – Chicago-style hot dogs made with every topping

Italian beef:

- Al's Beef – located in little Italy, and claims to be the inventor of the sandwich
- Mr. Beef on Orleans – small dive with big flavors

If you'd like more recommendations or further reading about Chicago dining, explore all that Chicago has to offer at ChooseChicago.com. The site has a search engine where you can pick a food category (French, pizza, wine bar, etc.); certification (Green Restaurant, Zagat, etc.); and Chicago neighborhood.

While Chicago cuisine keeps your stomach satisfied, CHEST 2013 will be sure to fill your educational needs. CHEST 2013, taking place October 26-31, will serve up cutting-edge sessions and surround you with an international community of the best minds in pulmonary, critical care, and sleep medicine. Find everything you need to know to make the best clinical decisions and inspire your patient care. Learn more at chestmeeting.chestnet.org.

Spotlight on occupational and environmental lung disease

The ACCP recently sponsored the Occupational and Environmental Lung Disease Conference 2013, which was held June 21 to 23 in Toronto, ON, Canada. Presentations and discussions addressed a diverse range of issues in this dynamic field.

Occupational respiratory disease continues to be relevant and important. Taking a targeted occupational history is critical to identifying work relatedness. Occupational asthma is a common cause of new onset adult asthma and should always be suspected in that setting.

Work-exacerbated asthma is also common. The role of assessing airway inflammation in work-related asthma continues to evolve. The European Respiratory Society and the ACCP have recently published statements on diagnosis and treatment of work-related asthma.

There is increasing recognition of work-related COPD. Approximately 25% of people with COPD have never smoked; up to 50% of COPD in this group may be related to occupational exposures. Hypersensitivity pneumonitis, various forms of pneumoconiosis, and a range of disorders related to production agriculture continue to be relevant problems and should be considered in appropriate settings.

When evaluating impairment in patients making disability claims, it helps to be systematic and to be aware of the criteria used by the relevant compensation systems, since they vary.

DR. WEISSMAN

DR. KUSCHNER

Indoor environmental exposures are important causes of respiratory disease. Household exposure to biomass burning is a major worldwide cause of COPD mortality and reduced quality of life. Indoor dampness and mold are accepted risk factors for upper and lower respiratory diseases, including allergic rhinitis, asthma, hypersensitivity pneumonitis, and others. Indoor dampness and mold can generally be assessed based on visual inspection and smell.

Environmental sampling is not routinely required for an indoor air quality survey and, if conducted, should address a hypothesis and be interpreted in the context of the entire investigation. Other household exposures, such as from using cleaning and personal care products or in association with hobbies, can also cause respiratory problems.

Global climate change has emerged as a key environmental issue: "The uncertainty is not that global warming will be responsible for exacerbating the global public health problems of poverty, infectious and noncommunicable diseases, but by how much." (Anstey et al. *Global Health*. 2013;9[9]:4). The mainstream scientific view is that human generation of greenhouse gases, such as CO_2, underlies global climate change. Outdoor air pollution also remains important.

WHO estimates that one type of air pollution, particulate matter (PM) exposure, accounts for 800,000 deaths per year worldwide. Patients with cardiopulmonary diseases are more susceptible to PM. Treatment with some medications, such as beta-blockers, statins, and bronchodilators, may reduce PM effects.

New occupational respiratory diseases continue to emerge. The World Trade Center disaster has provided important lessons in the long-term health problems faced by emergency responders and the importance of planning in advance to protect them.

It is important to anticipate the potentially hazardous exposures and health impacts of new technologies, such as silica exposure during natural gas extraction by hydraulic fracturing and from nanotechnology. Thus, occupational and environmental lung disease remains highly relevant and there is still much to be done in the field.

Dr. David N. Weissman, FCCP
Director, Division of Respiratory Disease Studies
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
Morgantown, WV

Dr. Ware G. Kuschner, FCCP (Co-Chair)
Professor of Medicine
Division of Pulmonary and Critical Care Medicine
Stanford University School of Medicine
Chief, Pulmonary Section, Veterans Affairs
Palo Alto Health Care System

SLEEP STRATEGIES: Time to wake up to the transformation of OSA diagnosis and management

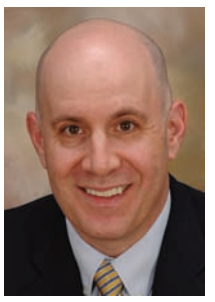
BY DR. NEIL FREEDMAN, FCCP

The standard approach to identification and treatment of the patient with OSA is rapidly evolving, driven by health-care economics and advancements in technology. Home sleep apnea testing (HST) and out-of-center treatment with autotitrating positive airway pressure (APAP) therapy will soon become the standard for patients with a high pretest probability of uncomplicated, moderate-to-severe OSA.

While many in the sleep community had hoped HST would be a passing fad, the rapid expansion and implementation of this modality should come as no surprise.

In 2007, the American Academy of Sleep Medicine (AASM) published recommendations for practitioners considering HST. In 2008, the Centers for Medicare and Medicaid Services (CMS) approved the use of HST for the diagnosis of OSA (Collop et al. *J Clin Sleep Med*. 2007;3[7]:737). Several randomized controlled trials, both prior to and since the CMS decision, have demonstrated similar outcomes between HST and in-lab polysomnography (PSG) for the diagnosis in patients who have a high clinical suspicion of OSA in the absence of various comorbidities (Mulgrew et al. *Ann Intern Med*. 2007;146[3]:157; Berry et al. *Sleep*. 2008;31[10]:1423).

Few in the sleep community rushed to adopt these methods as viable alternatives for the diagnosis and initial management of OSA. Reimbursement for HST remains far below that of PSG, even after adjusting for the lower cost of its performance, leading to difficulties in implementing home-testing programs by practices whose income streams are based predominantly on in-lab testing. Other barriers that have hindered the acceptance and implementation of HST include poor educational efforts by manufacturers and professional societies, leaving providers uncertain about which diagnostic technologies would be best for a given practice model. In addition, there has been a relative paucity of educational programs designed to teach practitioners how to interpret the signals and data from these devices.


DR. FREEDMAN

Despite these initial barriers, the use of HST is now rapidly expanding as commercial insurance companies and large health-care plans begin to mandate their use to curb costs. Unfortunately, the explosive rate of implementation has had adverse financial outcomes on some practices that have had difficulty adapting their practice models, as highlighted by the sudden closing of Sleep Health Centers, a multicenter sleep company based in Massachusetts, whose decline was predominantly due to local insurers dictating the use of HST (Quan et al. *J Clin Sleep Med*. 2013;9[6]:301). Many sleep centers are finding it similarly difficult to rapidly adapt their business models to estimated reductions in polysomnography volumes of up to 50%.

Complicating the financial ramifications of the expanding use of HST, some device manufacturers and private testing companies are circumventing sleep centers and marketing their products and services directly to primary care providers.

While this approach has raised concern among some members of the sleep community, placing OSA testing in the hands of primary care providers may be reasonable given the shortage of board-certified sleep specialists; other common chronic diseases, such as diabetes and hypertension, are managed by these physicians with specialist consultation as needed. This approach may allow more at-risk patients to be tested for OSA in a timely fashion although its success will depend on ensuring that these providers receive adequate education on the appropriate longitudinal management of sleep-disordered breathing.

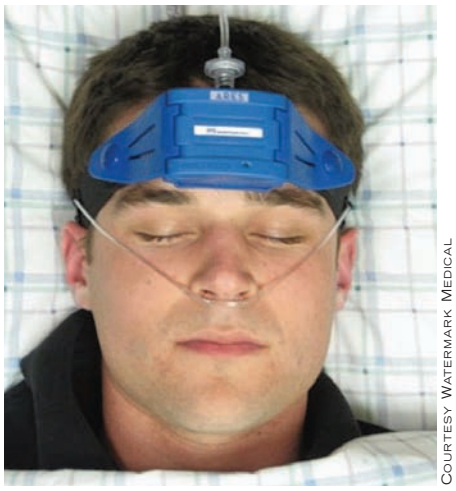
The process of implementing CPAP is also changing. Out-of-center treatment with APAP devices will become more common for the same group of patients targeted for HST. Several randomized controlled trials have demonstrated that APAP therapy, either long-term or transiently used to determine a fixed CPAP pressure, results in similar outcomes to in-lab CPAP titration (Kuna et al. *Am J Respir Crit Care Med*. 2011;183[9]:1238; Rosen et al. *Sleep*. 2012;35[6]:757).

Clinician education is the main barrier to successful implementation of APAP therapy in lieu of in-lab titration. Since different APAP technologies use different proprietary algorithms, treating providers will require such education to ensure that these devices are utilized in the proper patient populations and that their data are interpreted correctly.

In order to implement this expansion of out-of-center diagnostics and treatment for OSA, several commercial insurance companies have partnered with sleep benefits management services to oversee the process. In many cases, this outsourcing has led to mandatory precertification prior to sleep testing, mandatory use of predetermined HST providers, limitations on reimbursement for testing, and limiting diagnostics and treatment to specific types of devices. Practices that implement their own HST and APAP programs should expect that these management companies will track outcomes, including turnaround time, failure rates, diagnostic errors, and PAP adherence. While many payers follow recommended utilization guidelines designed by our professional societies, some insurance and management companies have implemented their own non-evidence-based protocols for determining which patients are deemed candidates for these approaches.

The bottom line for practitioners is that costs related to overhead will go up and reimbursement will go down; the new successful business model will be based on volume, complying with insurers' policies, and achieving predetermined clinical outcomes.

Unfortunately, as providers are changing their approach to OSA management and being required to document outcomes for their patients on PAP therapy, the process for obtaining PAP devices and supplies has become further complicated by the rollout of a second round of competitive bidding by CMS. For those who are not familiar with this process, CMS recently assigned contracts to durable medical equipment (DME) providers who were willing to accept an average 47% reduction in reimbursement for PAP devices and supplies in 91 markets around the country. As of July 1, only those DME providers granted contracts by CMS are able to provide PAP devices and supplies to Medicare and Medicaid patients. This has caused significant confusion for both providers and patients as the DME community consolidates. The long-term implications on service and PAP adherence, potentially leading to adverse outcomes for our patients, are not yet clear.


COURTESY WATERMARK MEDICAL

Home sleep apnea testing is embraced by insurers as a way to cut costs.

All of these changes will affect practitioners who care for patients with OSA. Whether the sleep medicine community likes it or not, an out-of-center approach will be standard for most patients with uncomplicated OSA. So how should we, as sleep medicine providers, respond to

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this changing landscape?

(1) **Embrace home sleep apnea testing.** Unfortunately, those providers who cannot successfully incorporate HST into their practices or choose to ignore current market trends will likely have the process taken out of their hands by commercial insurance and sleep benefits management companies.

(2) **Become familiar with various testing/treatment devices and delivery models to determine which approach will be best for your patients and practice.** Many clinicians will have to incorporate more than one type of HST technology into their practices to accommodate different patient populations as well as payer mixes. The ACCP currently offers didactic and hands-on programs specifically directed at this educational need.

(3) **Remain a strong advocate for your patients.** In cases where in-lab PSG is clearly the appropriate test for your patient, speak to the insurance and sleep benefits management companies. Your best defense is knowledge; make sure you understand the current guidelines as well as the strengths and weaknesses of the various HST and APAP technologies.

(4) **Become a center of excellence for the management of OSA.** One of the best ways to achieve this designation in the eyes of the payers is to have your center receive AASM accreditation, for both overall sleep disorders management as well as the separate accreditation for out-of-center testing for OSA diagnosis.

(5) **Collect data on your practice's HST study success and PAP compliance.** Many sleep medicine specialists have been practicing for years without clear outcomes data that could objectively demonstrate how they are performing. Such data can serve as a benchmark of your current efficiency and allow you to develop practice improvement plans, enhancing patient outcomes. Objective outcomes data will become increasingly important over time and will be used by insurers to measure your outcomes compared with others in your area; these data will also likely be used as an economic driver to negotiate future contracts with insurers.

(6) **Encourage professional societies to publish guidelines that provide more comprehensive recommendations for the use of HST and APAP for OSA.** Clinicians need direction on proper device settings, compliance download interpretation, and explanations of what defines adequate therapy. Since the different device manufacturers use proprietary algorithms to define events, clinicians need data validating the PAP-calculated AHI and guidance as to what threshold level of AHI is considered adequate control of disease.

(7) **Sleep medicine professional societies should partner with the primary care community** to provide education about the recognition, diagnosis, and treatment options for patients with suspected OSA.

(8) **Finally, sleep medicine as a specialty must change its approach to OSA management** from a focus on testing to a chronic disease management model focused on improvements in meaningful patient outcomes, such as daytime sleepiness, quality of life, and reductions in cardiovascular disease (Pack. *J Clin Sleep Med*. 2013;9[6]:629).

Dr. Freedman is with Northshore University Healthsystem, Bannockburn, Illinois.

Enlightenment from the Sunshine Act

BY ED DELLERT, RN, MBA, CCMEP
Senior Vice President, Clinical Education, Informatics & Research

As of August 1, 2013, all pharmaceutical and medical device manufacturers and group purchasing organizations are now required to collect data on financial arrangements with physicians and teaching hospitals to comply with the Physician Payments Sunshine Act (''Sunshine Act'').

As you might recall, the ACCP and other CME providers commented during an open period to clarify language regarding CME-accredited activities and the requirements under this legislation. As of February 2013, the Centers for Medicare & Medicaid Services (CMS) published the final rule implementing the Sunshine Act, which was passed as part of the Affordable Care Act.

The Sunshine Act requires manufacturers of drugs, devices, biologics, or medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program to report payments and other transfers of value to physicians and teaching hospitals.

The Sunshine Act also requires manufacturers and government provider organizations (GPOs) to disclose ownership or investment interests held by physicians or their immediate family members. August 1, 2013, is the start date by which manufacturers and GPOs must begin collecting the required data, and they must report data for the remainder of 2013 to CMS by March 31, 2014.

As anticipated, there are many communicating how to best maintain compliance activity among manufacturers and GPOs, including such areas like securing technology platforms and developing internal reporting systems and protocols. I would anticipate over the coming months a number of data collection questions and glitches. As initial reports are complete, it will be important for all physicians to be very aware and take action on reviewing their data to maintain accuracy.

What type of financial data will be reported? Honoraria, meals, travel expenses, grants from manufacturers, ownership and investment interests, gifts, and other transfers of value ($10 or more) to physicians or their immediate family members from pharmaceutical and medical device companies will be subject to being reported and published online beginning September 30, 2014.

Physicians throughout all sectors need to make sure their financial and conflict of interest disclosures and information associated with their national provider identifier (NPI) are continuously updated. It will be their responsibility to check for accuracy noting that they will have a minimum of 45 days to dispute any information before it is made public. Beginning in January 2014, physicians can begin to request from CMS a consolidated report on activities each June for the prior reporting year.

The "Final Rule" provided by CMS earlier this year was 35 pages of regulations and 251 pages of explanations. One can deduce that a significant

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NETWORKS: Palliative care telemedicine, Sleep Med at CHEST 2013

Palliative and End-of-Life Care

Telemedicine as a tool for early family conferences in critically ill patients transferring to a tertiary care center

Evidence suggests that early palliative care consultations for critically ill patients may be associated with reduced health-care costs while improving family satisfaction. However, critically ill patients at smaller rural hospitals who are often transferred to tertiary

care center (TCC) ICUs are often not able to participate in discussions regarding disease processes, prognosis, goals of care, and shared decision making until after they have been transferred. There is a gap in the standard of care related to early communication in this particular group of critically ill patients.

Telemedicine is a tool that we are using to provide family members and treatment teams the opportunity to participate in early family conferences and/or palliative care consultations prior to a patient transferring to a TCC.

At our institution at the University of Vermont, we conducted a small retrospective study of these telemedicine family conferences that showed 64% of patients did transfer to a TCC; however, ultimately 58% transferred back to the referring hospital for end-of-life care. We have also conducted a prospective qualitative study on the experience of participants of these conferences. Family members and clinicians have responded favorably to this form of

Continued from previous page

amount of thought, feedback, data capture, and definitional provision has been put into the implementation of this act. The key message for the physician community and their immediate family members is that they need to be well-informed about what types of data are being published about them going forward.

communication, and we have created a structured intervention for use during these discussions.

We believe this telemedicine intervention will increase family satisfaction, decrease symptoms of posttraumatic stress disorder and anxiety among family members, and align care with patients' wishes. In order to investigate this further, we are currently conducting a prospective comparative study of a structured telemedicine family conference intervention vs conference conducted after transfer.

Prema R. Menon, MD
Steering Committee Member
Continued on following page

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Sleep Medicine

A guide to sleep at CHEST 2013

I hope that you are all gearing up for our meeting this fall in Chicago; as always, the Program Committee has arranged a fantastic meeting with a diverse program, but I wanted to point out a couple of agenda items in the sleep curriculum:

Our postgraduate course on Saturday, October 26, was initially intended as a board review, before the ABIM saw fit to move up the examination date. As a result, this course will instead be a year-in-review, covering the best of the literature over the last 12 months; the session will also be supplemented by the use of an audience response system, allowing the audience to play along and show their knowledge of the newest developments in sleep medicine.

There is a whopping number of great sessions on Sunday, including "Management of Insomnia in 2013," developed from results of our survey in the spring; this session will include a brief primer on cognitive behavioral therapy. Later that day will be one of our NetWork highlights, "Highly Controversial Topics in Sleep Medicine," with discussions on the growing use of sodium oxybate for insomnia and the role of modafinil for cognitive enhancement.

In the afternoon, Dr. Mark Rosekind, member of the National Transportation Safety Board, will be highlighting a session on sleep medicine and transportation safety. The day will be capped off by an evening session led by our NetWork Vice Chair, who will be orchestrating a panel discussion on the future of sleep medicine.

Attendance at Monday's NetWork Open Forum is a must for anyone wanting to become more involved in the Sleep NetWork. The session will offer a chance to meet with NetWork leadership and to hear about the current activities and priorities of the Steering Committee. We are almost always looking for volunteers for one or more of our ongoing projects; attending the session ensures that you can both sign up and express your interest in person! In addition, you get to hear a great lecture from Dr. Fred Turek.

The rest of the meeting is similarly packed; Tuesday will feature a panel discussion on sleep deprivation and the restriction of resident work hours. Wednesday houses our second NetWork highlight, "Intermittent Hypoxia and OSA Comorbidity," which may make many of us rethink our focus on the apnea-hypopnea index as the prime target for therapy of sleep-disordered breathing. Lastly, Thursday will feature a 4-hour symposium, "Sleep Medicine in 2013," highlighted by the debut of the College's newest game show, "Who Wants to be a Somnologist?" with prizes for the winners.

For all of these reasons, 2013 is looking to be a spectacular year for sleep medicine education at CHEST, and there are many more sessions that I haven't enough space to highlight. I sincerely hope that you will join us in Chicago and come by and say "hi" at the NetWork Forum!

Dr. David Schulman, FCCP
Chair

This Month in *CHEST*: Editor's Picks

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

Impact of COPD on Long-term Outcome After ST-Segment Elevation Myocardial Infarction Receiving Primary Percutaneous Coronary Intervention. *By Dr. G. Campo et al.*

Cardiovascular Safety in Patients Receiving Roflumilast for the Treatment of COPD. *By Dr. W. B. White et al.*

Bidirectional Associations Between Clinically Relevant Depression or Anxiety and COPD: A Systematic Review and Meta-analysis. *By Dr. E. Atlantis et al.*

Heterogeneous Pulmonary Phenotypes Associated With Mutations in the Thyroid Transcription Factor Gene *NKX2-1*. *By Dr. A. Hamvas et al.*

COMMENTARY
The Undervaluation of Evaluation and Management Professional Services: The Lasting Impact of Current Procedural Terminology Code Deficiencies on Physician Payment. *By Dr. E. A. Kumetz; and Dr. J. D. Goodson.*

PALLIATIVELY SPEAKING: Advance care planning is measurably good

BY STEPHEN J. BEKANICH, M.D., AND LEIGH A. FREDHOLM, M.D.

Whether we agree or not with the validity of Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) or the penalties of high 30-day readmissions, it would be challenging to find a group where these measures are not popping up on dashboard reports. Can advance care planning aid in bending these metrics in a favorable direction? We would argue in the affirmative.

Approximately 30% of Medicare dollars are spent on the 5% of beneficiaries who die each year (Health Serv. Res. 2004;39:363-75). The last month of life for those Medicare benefits account for one-third of the expenditures.

A longitudinal, multi-institutional study following more than 600 incurable cancer patients looked at whether having a discussion about end-of-life preferences made a difference in quality or cost of care (Arch. Intern. Med. 2009;169:480-8).

Baseline end-of-life discussions were documented with a single question: "Have you and your doctor discussed any particular wishes you have about the care you would want to receive if you were dying?" For those who answered yes, not only did costs turn out to be lower by over 35% but quality of care was rated by family members to be higher and people were more likely to spend their final days at home rather than in the hospital (53.8% versus. 37.8%).

DR. BEKANICH

DR. FREDHOLM

This is particularly impressive against the backdrop, demonstrated in many studies, that, when these conversations do occur they last for only a few minutes, the patients don't have an opportunity to adequately express themselves, caregivers are left wanting more information, and details on specific elements of choices for care are scant.

Perhaps the most tested, sophisticated, and celebrated model for advance care planning is practiced throughout the Gunderson Health System in La Crosse, Wis.

In its model, certified advance care planning facilitators (most of whom are nurses) see patients in all venues, from the home to the hospital. They craft disease-specific advance directives with patients and families, the results of which are shared with the patient's entire community including providers, family members, and others within the community.

Their results, which have been reproduced by other systems using the Gunderson methods, are quite staggering. If we consider the percentage of patients with advanced illnesses who have completed advance directives, the percentage of physicians who are aware of those advance directives, and then have consistency between the directives and which treatments are actually delivered, then we find that national data show us hitting below the 50% mark on all three of these issues (J. Am. Geriatr. Soc. 2010;58:1249-55).

Using Gunderson's advance care planning program, these metrics all skyrocket to 95% or higher.

Translation? When the Dartmouth Atlas Study data from 2007 are used to compare the number of days spent in the hospital and cost of care over the last 2 years of life, the Gunderson numbers are far more attractive. Their patients spend less than 14 days in the hospital and their cost of care is less than $19,000 over those 2 years.

For similar patient populations in other medical centers, the days spent in the hospital are 40-55 and costs exceed $60,000 during the same period of time.

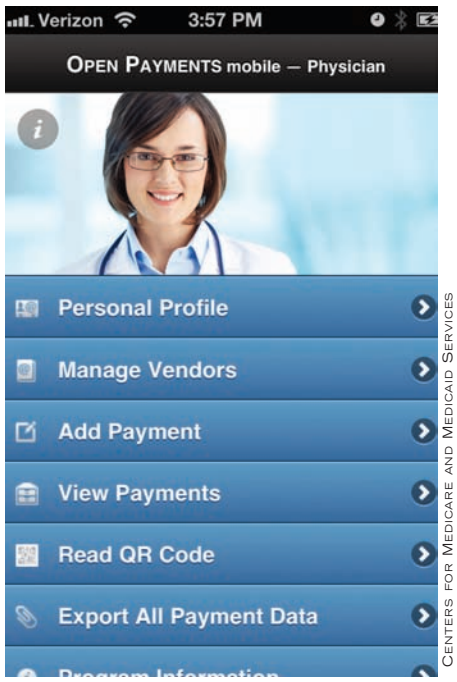
In our quest to build the better system, let's highlight the role of advance care planning and resource it appropriately.

Dr. Bekanich and Dr. Fredholm are codirectors of Seton Health Palliative Care, part of the University of Texas Southwestern Residency Programs in Austin. Their blog appears monthly at ehospitalistnews.com

CMS apps help track payments from industry sources

BY ALICIA AULT
IMNG Medical News

Two new smartphone apps aim to help log drug, device, and diagnostic manufacturer payments to doctors and health care providers, as called for by the Affordable Care Act.



CENTERS FOR MEDICARE AND MEDICAID SERVICES

Record keeping: Users can enter all details of transactions with companies.

To promote transparency in relationships between providers and industry, the ACA requires that manufacturers track and report payments for consulting, honoraria, and more.

Originally known as the Sunshine Act, the effort is now called the Open Payments Program by the Centers for Medicare and Medicaid Services.

While physicians are not required to inventory anything of value they receive from manufacturers, CMS and many medical professional societies advise that they do so.

The app for physicians – Open Payments for Physicians – is designed to help doctors keep tabs on all their transactions in real time.

Users can manually enter all the information regarding a particular transaction, for example, the receipt of a grant payment or a gift that's worth more than $10.

The app is free and can be downloaded from the iTunes App Store or from Google Play.

CMS also created an app for industry representatives to use (Open Payments for Industry).

Industry users and physician users can exchange information with their apps. By using a built-in QR (quick response) code reader, the manufacturer can transfer a record of a transaction to the physician for review, according to the agency.

In a blog post, CMS Program Integrity Director Dr. Peter Budetti said the agency's "foray into mobile technology is about providing user-friendly tools for doctors, manufacturers, and others in the health care industry to use in working with us to implement the law in a smart way."

The idea is that physicians can use the records contained in the app to compare what's reported by manufacturers to CMS. There is a 45-day lag between when the data are reported to CMS and posted publicly. Physicians have that window to challenge the reports before they are posted on the Open Payments website. Corrections can be made later, but the erroneous data will likely stay public for a while.

The first year of the program will be a little bit more forgiving. Data collected beginning Aug. 1 won't be publicly reported until September 2014.

The apps can't be used to directly transfer data to CMS, said the agency, which added that although it developed the apps, it will not "validate the accuracy of data stored in the apps, nor will it be responsible for protecting data stored in the apps."

aault@frontlinemedcom.com
On Twitter @aliciaault

POLICY & PRACTICE

For more health reform news, scan the QR code to listen to a weekly podcast from IMNG Medical Media.

Advising patients on health habits

More than two-thirds of Americans say their physicians usually discuss their health habits, including the benefits of a healthy diet and regular exercise, a Gallup survey finds. Physicians are less likely to discuss smoking – just half of patients reported their physician broaches the topic during visits, although 79% of current smokers say the topic comes up, the poll says. This lack of counseling on smoking could be because smoking is less prevalent than overweight or obesity: Only 19% of Americans say they currently smoke, while 45% say they are overweight, the study authors say. "However, increasing the frequency of these discussions with nonsmokers could prevent more nonsmokers from ever starting and more former smokers from returning to old habits," the authors say.

MDs: EHRs = improved outcomes

Electronic health records improve patient outcomes, but the benefits don't outweigh the costs, according to a survey of physicians conducted by athenahealth, which sells EHRs. Independent physicians are more likely to feel this way than are employed physicians, the survey found. Further, the survey revealed both unfamiliarity and doubts about accountable care models. Three-quarters of physicians say they were at best "somewhat familiar with" an ACO, and 26% say they aren't sure if they're participating in any pay-for-performance programs. The majority of physicians said ACOs will positively affect quality of care but negatively affect profits, and also will create more burden to get paid.

ACOs continue to grow

The number of U.S. ACOs has more than doubled in the past year, and Medicare ACOs now outnumber non-Medicare ACO entities, according to a report from Leavitt Partners, a business intelligence consultancy. Nearly 500 ACOs now are operating, with patients enrolled in accountable care in all 50 states. ACOs are most common in the most populous states, including Florida, California, and the Northeast, the report showed; Boston and Orlando each boast more than 15 ACOs. Medicare ACOs – entities participating either in the Medicare Shared Savings Program or the Pioneer program – account for 52% of the total, according to the report, although the authors note that multiple non-Medicare ACOs are in development and could launch soon.

Incentives spur e-prescribing

Physicians adopted e-prescribing more enthusiastically following the implementation of federal incentive programs, a study in Health Affairs found. Congress authorized e-prescribing incentives in 2008, and as of December 2010, close to 40% of active e-prescribers had adopted the technology in response to the federal program.

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Frank McCormack, MD
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Pulmonary, Critical Care & Sleep Medicine
University of Cincinnati
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The University of Cincinnati has a long history of strong basic science research programs and offers many opportunities for collaboration within the College of Medicine as well as with Cincinnati Children's Medical Center. The PCCSM Division is comprised of 30 full time faculty members and 12 fellows with broad subspecialty interests, and a well-established and growing pulmonary arterial hypertension program.

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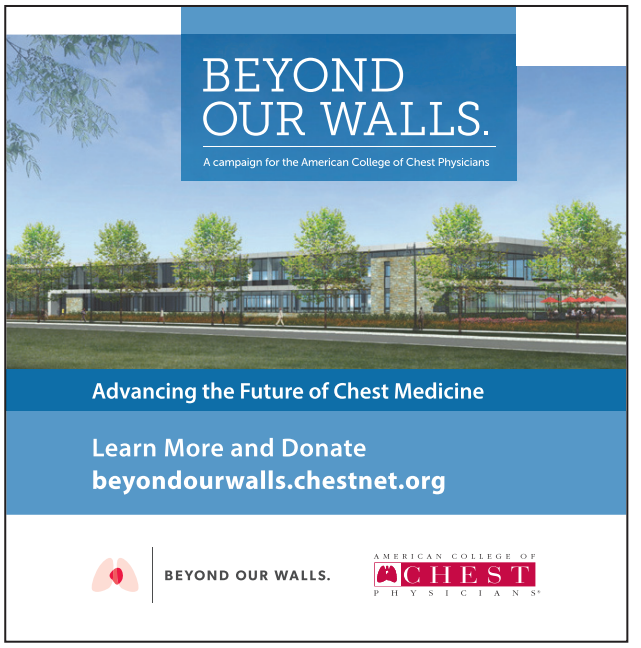

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New lows for malpractice awards

Report *from page 1*

accountability for medical errors."

Examining data from the National Practitioner Data Bank, Public Citizen found that in 2012, both the number of awards (9,379) and the amount of those payouts ($3.1 billion) was the lowest on record, once adjusted for inflation. In 2012, the average payment was about $335,000.

The big driver for the drop in malpractice awards is likely state laws that have imposed caps on the amount of noneconomic damages that patients can receive, according to Public Citizen.

The decline in litigation awards appears to be good news for doctors, who overall experienced a decrease in medical liability insurance premiums during the same period. Physician premiums fell to 0.36% of health care costs, the lowest amount in a decade, the report said.

But consumers are losing out, Public Citizen argued, because health care costs are up 58.3% over the last decade. And reports continue to be published showing high rates of adverse events in U.S. hospitals.

Public Citizen cited a 2010 report from the inspector general of the federal Department of Health and Human Services that found that one in seven hospitalized Medicare beneficiaries experienced a serious adverse event, which contributed to death in 1.5% of patients.

But Texas Medical Association President Stephen L. Brotherton countered that medical liability reform actually creates a safer health care environment by improving access to care.

Texas voters approved comprehensive medical liability reform in 2003, including a cap on noneconomic damages. Before that law was enacted, the state had been losing physicians who couldn't afford their rising malpractice premiums or feared the personal and professional upheaval of a lawsuit, said Dr. Brotherton, an orthopedic surgeon in Fort Worth.

"We were losing people in the prime of their practice," Dr. Brotherton explained.

Many Texas counties had no access to high-risk specialty care, including ob.gyns and neurosurgeons, he noted. And hospitals were having difficulty finding physicians willing to take call in the emergency department. As a result, patients in rural areas couldn't get access to high-risk specialty care, and some physicians were increasing the volume in their practice to unsafe levels to meet financial pressures from rising insurance premiums, Dr. Brotherton said.

A decade after medical liability reform was passed, physicians are returning to Texas, according to the TMA. Since Texas voters passed Proposition 12 in 2003, Texas has licensed more than 28,000 new physicians, an average of about 3,135 per year. And many of these new doctors are filling the gaps in high-risk areas such as obstetrics, Dr. Brotherton said. Since 2003, 35 rural counties have added at least one obstetrician, including 16 counties that previously had no obstetricians.

There's no evidence that having an active plaintiff's bar in a state promotes safer medicine, Dr. Brotherton asserted. "Good doctors are going to where they are wanted," he said.

mschneider@frontlinemedcom.com

VIEW ON THE NEWS

Dr. Lary Robinson, FCCP, comments: The consumer rights advocacy group Public Citizen, based in Washington, reports that the number of inflation-adjusted malpractice suit awards and total monetary payouts in the United States fell 28% between 2003 and 2012. This group felt that the decline in awards was related to new state laws that imposed caps on noneconomic damages. In addition Public Citizen laments that malpractice premiums have declined based on the fact that they fell to 0.36% of the total health care bill, yet overall health care costs are up 58.3%.

In reality, the rise in malpractice premiums in most states has just slowed or leveled out and it has declined in only a few states such as Texas after its tort reform legislation. However, the rise in health care costs has never been directly tied to malpractice awards or premiums, but rather rising overall costs are driven by multiple other patient factors.

The main benefit of malpractice legislation in most states such as Texas has been to improve patient access to high-risk specialty care physicians who are now returning to practice in states where tort reform has passed."

Perceived risks, not damage caps, drive defensive medicine

BY MARY ELLEN SCHNEIDER

IMNG Medical News

Physicians' fears of malpractice lawsuits appear to drive them to order more diagnostic tests, even in states with medical liability damage caps, according to a new study in Health Affairs.

The study, which linked survey data on physician perceptions of malpractice risk to their ordering data, found that physicians had higher rates of diagnostic imaging ordering for patients with lower back pain and headache if they were more concerned about their malpractice risk. But the researchers did not find that defensive ordering declined when states enacted tort reforms such as damage caps (Health Aff. 2013;32:1383-91).

"Our paper suggests that physicians' self-report of their defensive concerns may have a stronger impact than was previously suspected, but it definitely doesn't answer the question of specifically how strong that effect is," said Dr. Emily Carrier, a senior health researcher at the Center for Studying Health System Change. Dr. Carrier is an emergency physician.

The researchers examined the use of diagnostic tests, referrals to the emergency department, and admissions to the hospital for ambulatory patients who saw a physician with complaints of chest pain, headache, or lower back pain. The researchers said they chose these conditions because they represent a range of underlying problems, and because physicians have considerable discretion in how they treat these cases.

Patients with chest pain had a significantly higher chance of being referred to the emergency department, rather than having an outpatient stress test, if their physicians had a high or medium level of malpractice concern. The researchers also observed somewhat higher ordering rates for advanced imaging and hospitalization by physicians with higher malpractice concerns, but the figures were not significantly higher.

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Headache patients whose physicians had high levels of malpractice concern were significantly more likely to receive advanced imaging than were those whose physicians had a low level of concern (11.5% versus 6.4%). But rates of conventional imaging and hospitalization were extremely low for headache patients and were not associated with the level of malpractice concern. Also, the researchers failed to find a significant association between the level of malpractice concern and referrals to the emergency department for headache patients.

Patients with lower back pain were more likely to receive both conventional and advanced imaging services if their physicians had high levels of concern about malpractice lawsuits, compared with patients whose physicians had fewer concerns. There was no significant difference in the likelihood that these patients would be admitted to the hospital for their complaints.

The study also found that damage caps don't seem to be impacting defensive medicine practices.

When the researchers analyzed Medicare claims with the state data on the presence of medical liability damage caps, they found that services often went up in states with caps. The finding may be a case of "reverse causality," the researchers said. In states where there are high levels of defensive medicine, lawmakers are more likely to adopt a damage cap.

The retrospective study includes Medicare Part A and B claims data on nearly 1.9 million beneficiaries who received services from 2007 to 2009.

The National Institute for Health Care Reform funded the study. The authors reported having no conflicts of interest.

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