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CHEST Physician

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Patients on the ABC protocol left the ICU 3.8 days sooner, according to Dr. E. Wesley Ely, FCCP (left), and Dr. Timothy D. Girard.

'Wake Up and Breathe' Improved ICU Outcomes

BY ROBERT FINN
Elsevier Global Medical News

SAN FRANCISCO — Medical ICU patients leave the hospital more than 4 days early if they receive spontaneous awakening trials and spontaneous breathing trials every day, according to a study reported by Dr. E. Wesley Ely, FCCP, at the International Conference of the American Thoracic Society.

The multicenter, controlled trial involved 335 patients randomized to either standard goal-directed sedation or the "ABC" (awakening, breathing, controlled) approach.

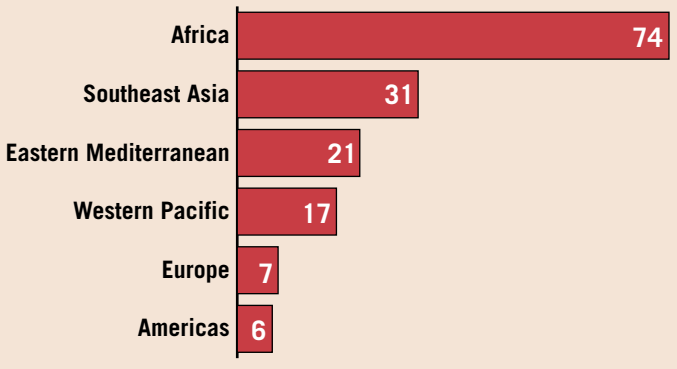
Compared with the control patients, the ABC patients left the ICU an average of 3.8 days sooner (9.1 days vs. 12.9 days), were discharged from the hospital 4.4 days sooner (14.8 days vs. 19.2 days), and spent 3.1 more days alive and off the ventilator (14.7 days vs. 11.6 days). There was no significant difference in the percentage of patients who survived for 28 days or more (72% for the ABC patients, 65% for controls).

"When you reduce the length of stay by 4 days, that's a huge deal," Dr. Ely of Vanderbilt University, Nashville, Tenn., said in a press briefing. "You can save somewhere in the neighborhood of $5,000-$15,000 per patient via protocols like this. This could have billions of dollars of implications for health care."

See **ICU Outcomes** • *page 9*

VITAL SIGNS

Number of Deaths From Tuberculosis in 2005
(per 100,000 population)



Note: Based on data from the World Health Organization.
Source: Kalorama Information

ELSEVIER GLOBAL MEDICAL NEWS

Studies Challenge 4-Hour Antibiotic Guideline for CAP

Policy had 'little impact on survival.'

BY BRUCE K. DIXON
Elsevier Global Medical News

CHICAGO — Early antibiotic therapy does not improve survival in emergency department patients with community-acquired pneumonia, suggesting that the reallocation of resources for that purpose is unnecessary, according to two studies presented at the annual meeting of the Society for Academic Emergency Medicine.

"Our results suggest that the time to antibiotics in the 0- to 24-hour range has little impact on survival from community-acquired pneumonia," said Dr. Marie Elie and colleagues at the New Jersey Medical School, Newark.

Largely as a result of a 2004 study (Arch. Intern. Med. 2004;164:637-44), the Centers for Medicare and Medicaid Services and the Joint Commission recommend that patients with community-acquired pneumonia be given an appropriate antibiotic within 4 hours of their arrival in the emergency department. CMS and the Joint Commission set the measure identification number for this 4-hour guideline as quality measure PN-5b.

The 2004 retrospective study had mined the medical records from a national random sample of 18,000 Medicare patients older than 65 years who were hospitalized with community-acquired pneumonia (CAP) between 1988 and 1999.

Consistent with CMS guidelines, CAP patients in the study were identified as those with a discharge diagnosis between ICD-9 (CAP) codes 480 and 486, and pneumonia diagnosed within 24 hours of ED presentation, in order to distinguish CAP from hospital-acquired pneumonia, said Dr. Elie, director of emergency critical care at New Jersey Medical School.

The study cohort, drawn from three urban New York hospitals, consisted of 4,300 patients

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Screen Scleroderma Patients for PAH

BY MIRIAM E. TUCKER
Elsevier Global Medical News

BALTIMORE — Scleroderma patients should have yearly screening for pulmonary arterial hypertension with echocardiography and tests of pulmonary function, Dr. Kwas Huston advised at a conference on rheumatic diseases sponsored by Johns Hopkins University.

At Johns Hopkins' Scleroderma Center, all patients undergo annual screening for pulmonary arterial hypertension (PAH) with pulmonary function testing (PFT) and two-dimensional echocardiography. Those who are asymptomatic with mild changes and right ventricular systolic pressure (RVSP) less than 40 mm Hg are followed again at 6 months, while those who are symptomatic with signs and/or abnormal two-dimensional echocardiography (RVSP greater than 40 mm Hg) undergo right heart catheterization to confirm the diagnosis.

"We now have treatments we didn't have 5 or 10 years ago. … The evaluation is important to identify pulmonary hypertension and for prognosis," said Dr. Huston, of the division of rheumatology at Johns Hopkins.

In the UNCOVER study published by Dr. Huston's group, 122 of 791 patients with scleroderma and mixed connective tissue disease who were seen in 50 community rheumatology practices had an existing diagnosis of PAH. But when the remaining 669 patients without a diagnosis of PAH subsequently underwent echocardiography, 89 were found to have previously unrecognized

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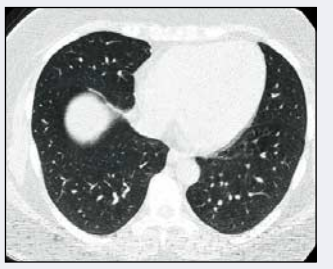

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CAP Measure Questioned

Antibiotic Guideline • *from page 1*

given antibiotics within 48 hours of hospital arrival. Antibiotics were given to 13% of patients within 1 hour, 33% within 4 hours, 42% within 8 hours, and 56% within 24 hours.

The overall mortality rate was 7.6%. For patients with systemic inflammatory response syndrome (SIRS) in the ED, the mortality rate was 12%; without SIRS, it was significantly lower, at 5%. In addition, there was a significant relationship between increasing Acute Physiology and Chronic Health Evaluation (APACHE) II scores and decreasing survival.

There was no statistically significant linear effect of time to antibiotics on mortality, whether time to antibiotics was examined as the only explanatory variable or after adjustment for initial APACHE II score and SIRS, the authors said.

A second study determined mortality rates and geometric length of stay (GLOS) for adult ED patients admitted to Union Memorial Hospital in Baltimore with a diagnosis of pneumonia.

Mortality rates and GLOS were determined for 1,781 patients and compared annually over 3 years during 2003-2006 with expected mortality rates and expected GLOS calculated using the CareScience risk-adjustment methodology (Quovadx Inc.).

CareScience is an Internet-based risk-adjustment program in which about 150 U.S. hospitals participate; each submitted information about resource use, pharmacy, radiology, device, procedure, discharge diagnosis, and demographics, said Dr. William Frohna, chief of emergency medicine at Union Memorial Hospital.

The retrospective, observational study used patient selection criteria of the Joint Commission's National Hospital Quality Measures, hospital records, and the CareScience database to determine outcomes at a time when performance improvement efforts significantly cut the time to antibiotics in the ED in accordance with PN-5b.

In the first year, 67% of about 600 patients discharged from the Union Memorial Hospital ED with a diagnosis of pneumonia received an antibiotic within 4 hours. In the second and third years, the percentage rose to 77% and 91%, respectively, Dr. Frohna said.

"Our mortality went from 6.8% in year 1 to 8.4% in year 2, then dropped back to 6.8% in year 3, and the mortality differences were not statistically significant," he said. The expected mortality rates were 7.6%, 8.1%, and 5.9%. Geometric length of stay remained below the comparative group and declined each year, from 4.1% to 3.7%.

"Over the 3 years, our performance measure improved as reported to the National Hospital Quality Measures Program. Our mortality rate remained unchanged and our geometric length of stay decreased," Dr. Frohna said.

"Intuitively, it makes sense that giving antibiotics in a timely fashion is important when a patient has a serious infection," Dr. Frohna said in an interview.

However, Dr. Frohna cautioned physicians to "be on the front lines of making sure that performance measures actually link to improved outcomes." ■

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CHEST PHYSICIAN is available on the Web at www.chestnet.org/about/publications.

Age at Onset Is PAH Risk Factor

Screen • *from page 1*

PAH, for a total prevalence of 27% (Arthritis Rheum. 2005;52:2125-32).

Increased age at the onset of scleroderma is a major risk factor for PAH, with data from one study suggesting that the risk for PAH is increased 52% for every 10 years of age at disease onset, and that patients aged 60 years and older have more than twice the risk of younger patients (Chest 2003;124:2098-104). Other risk factors include severe Raynaud's phenomenon, low pulmonary diffusing capacity, and the calcinosis, Raynaud's disease, esophageal dysmotility, sclerodactyly, and telangiectasia (CREST) syndrome, he said.

Pulmonary function testing is a useful tool both for identifying PAH and for determining prognosis. Among 71 scleroderma patients followed for a mean of 5 years, those with a carbon monoxide diffusing capacity (DLCO) of 40% or less had a 9% survival at 5 years, compared with 75% among those with DLCO greater than 40% (Am. J. Med. 1984;77:1027-34).

The DLCO is also a useful predictor of PAH development. In a retrospective case-control study of 212 scleroderma patients, the mean DLCO among the 106 with PAH was 52% of predicted 4.5 years prior to the PAH diagnosis, compared with 80% of predicted among the 106 scleroderma patients who did not develop PAH (Arthritis Rheum. 2003;48:516-22).

Echocardiography is a useful companion screening tool, with a sensitivity of 90% and specificity of 75% for identifying patients who had PAH on catheterization in a study of 33 scleroderma patients in whom clinical assessment, including ECG, chest x-ray, pulmonary function tests, and high-resolution computed tomography had raised strong suspicion of PAH (Br. J. Rheumatol. 1997;36:239-43).

Echocardiography missed just two patients, both of whom had pulmonary arterial systolic pressures (PASP) in the 30s—All of the patients with PASP greater than 40 mm Hg by echocardiography had abnormal pressures on catheterization, suggesting that "The greater the number, the more accurate the [echocardiography] is likely to be," Dr. Huston noted.

As with pulmonary function testing, echocardiography adds prognostic value. Increased mortality was associated with higher initial reading and with rising pressures in a retrospective study of 930 scleroderma patients, in whom mortality was 20% at 20 months among those who had a single pressure of 30 mm Hg or greater. Rapid rises occurred more frequently in limited than in diffuse scleroderma (Rheumatology [Oxford] 2001;40:453-9).

And, in a prospective study of 794 patients who were followed for 4 years, 3-year survival was inversely proportionate to mean PASP, from 75% among those with PASP less than 32 mm Hg to 61% for 32-44 mm Hg, to just 33% among those with pressures greater than 45 mm Hg (Ann. Rheum. Dis. 2003;62:1088-93).

While the data clearly support the use of echocardiography and PFT for screening scleroderma patients, areas of uncertainty include the role of exercise echocardiography in identifying patients who have elevated right heart pressures on exercise but which are normal at rest, and the significance of a low-normal RVSP or a low DLCO with a normal echocardiography, Dr. Huston said. ■

Dr. Stephen Geraci, FCCP, comments: *The epidemiology of pulmonary hypertension in scleroderma is changing, and a heightened suspicion, through more standardized noninvasive screening, should be considered—particularly in higher risk populations such as those with late-onset disease. Pulmonary function tests and resting transthoracic echocardiography are simple and safe tests in these patients. Unfortunately, the optimal use of these data in directing early therapy remains controversial, as all treatments presently available have modest effect, significant expense, and carry substantial risk.*

AMERICAN COLLEGE OF CHEST PHYSICIANS®

CHEST PHYSICIAN

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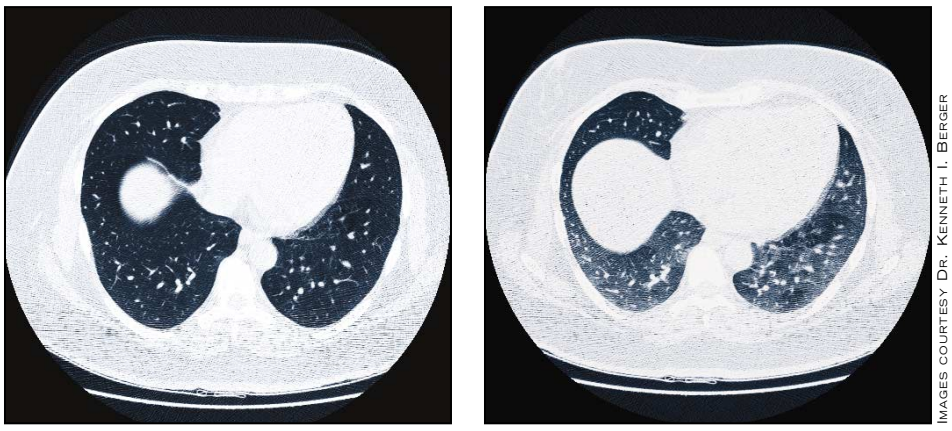
Airway Disease Blamed on World Trade Center Dust

BY ROBERT FINN
Elsevier Global Medical News

SAN FRANCISCO — Distal airway disease is responsible for a reduction in vital capacity in some individuals exposed to dust from the World Trade Center, according to a poster presentation at the International Conference of the American Thoracic Society.

The investigators suggested that the study may be applicable not only to patients exposed to dust from the World Trade Center, but also to patients with other environmental and occupational diseases in which standard pulmonary function tests show no abnormalities despite an apparent reduction in vital capacity.

Investigators from the Bellevue Hospital World Trade Center Environmental Program in New York City performed detailed studies of 14 symptomatic patients who were exposed to dust, smoke, and ash following the terrorist attacks of Sept. 11, 2001. These patients had reduced vital capacitiy but no abnormalities of static pulmonary mechanics, nor did they have radiographic evidence of parenchymal abnormalities. Oscillometry and compliance testing suggested distal airway abnormalities, but these tests are rarely available in the clinic. An association between those test results and findings from CT scans was suggested.



IMAGES COURTESY DR. KENNETH I. BERGER

Inspiratory (left) and expiratory (right) chest CT scans from a patient exposed to dust from the World Trade Center. The expiratory image reveals air trapping.

Seven of the 14 patients exhibited bronchial wall thickening on inspiratory images. Of the 10 patients with expiratory images available, air trapping was noted in 8. In all, 10 of the 14 patients had abnormalities attributable to airway disease.

In an interview, Dr. Kenneth I. Berger, FCCP, the study's senior author, pointed to a case demonstrating the importance of expiratory images. In this patient, the inspiratory images showed no abnormalities. "The lung parenchyma is normal, there are no increased markings, there are no fibrotic changes, there's nothing to explain the loss of vital capacity," he said, pointing to a CT scan (see images). "But when we have the patient on exhalation, you see little pockets remaining that are inflated. This is a demonstration of air trapping. These are very small areas [that] reflect disease in the distal areas of the lung."

Radiologists don't routinely obtain expiratory images, and the abnormalities can easily be missed on inspiratory images. "We have to write out on our request form, 'Rule out air trapping.' Otherwise, they're not going to do the scan," Dr. Berger said.

"Low vital capacity findings on spirometry wouldn't necessarily prompt you to get these expiratory CT pictures," added Dr. Beno W. Oppenheimer, a coauthor of the study. "This pattern classically would prompt a radiologist to do inspiratory films looking for a pattern of reduced lung volume and parenchymal disease. It's unusual that we find airway disease by expiratory CT scans expressing as a reduction in lung volume in subjects exposed to dust."

According to Dr. Berger, the investigators have completed a study on a larger group of patients exposed to World Trade Center dust. That research uncovered distal oscillometric and compliance abnormalities despite normal vital capacity and normal ratios of expiratory volume in 1 second to forced vital capacity. A paper describing those results will soon be published in the journal CHEST, he added. ■

Steroid Monotherapy Deemed Least Costly Asthma Treatment

SAN FRANCISCO — Researchers analyzing the costs of treating asthma patients in a large medical care organization concluded that monotherapy with inhaled corticosteroids results in the lowest total cost, according to a poster presentation by Dr. Robert S. Zeiger at the International Conference of the American Thoracic Society.

After taking into account the cost of various drug regimens and other costs of treating asthma patients, and after adjusting for all available confounders such as asthma severity, patient demographics, plan coverage, and comorbidities, Dr. Zeiger of Kaiser Permanente Southern California (San Diego) and his colleagues determined that the average savings would be $400 per asthma patient per year with inhaled corticosteroid monotherapy.

The total annual cost of treatment averaged $3,745 per asthma patient in 2004.

Of the more than 3 million members enrolled in Kaiser Permanente Southern California, the investigators identified 96,631 patients with asthma but without chronic obstructive pulmonary disease or cystic fibrosis who were enrolled continuously during the years 2002-2004.

The investigators divided the patients into those receiving monotherapy with a short-acting β-agonist (SABA), long-acting β-agonist (LABA), inhaled corticosteroids (ICS), leukotriene modifier (LM), mast cell stabilizer (MCS), theophylline, and various combinations of those drugs.

The total cost of care was highest for patients receiving theophylline monotherapy, an additional $2,000 or more annually compared with those receiving ICS monotherapy. Total costs of patients receiving LM monotherapy were about $1,300 more than ICS monotherapy, and patients receiving ICS plus theophylline, ICS plus LABA plus LM, or ICS plus LABA plus theophylline had total costs of about $1,000 more than ICS monotherapy.

The study was supported by a research grant from a Sanofi-Aventis, and one of the seven coauthors was an employee of that company.

—Robert Finn

FDA Acts to Remove Unapproved Timed-Release Guaifenesin Products

BY ELIZABETH MECHCATIE
Elsevier Global Medical News

With one exception, timed-release drug products available in the United States that contain the expectorant guaifenesin have not been approved by the Food and Drug Administration and should be taken off the market, according to an agency announcement.

About 20 companies manufacture these products, most of which are available only by prescription. The products include Guaifenex (manufactured by Ethex Corp.), Crantex and Guaifen (Breckenridge Pharmaceutical Inc.), Amibid and Amitex (Actavis Group), Duraphen (Proethic Pharmaceuticals Inc.), Wellbid (Prasco), Ambi (Ambi Pharmaceuticals Inc.), and Maxifed (MCR American Pharmaceuticals Inc.). Many of the products include other active ingredients, the FDA announcement noted.

The FDA ordered manufacturers of these unapproved products to stop making them no later than Aug. 27 and to cease interstate shipment by Nov. 25, although some inventory will remain in pharmacies after that time.

The action does not affect immediate-release formulations of guaifenesin, only timed-release formulations, which are also described as extended release, long acting, or sustained release.

The only timed-release products containing guaifenesin that have been formally approved by the FDA are those marketed over the counter as Mucinex or Humibid, by Adams Respiratory Therapeutics. Beside Mucinex and Humibid, which contain only guaifenesin, the company makes Mucinex-D, which also contains pseudoephedrine, and Mucinex-DM, which also contains dextromethorphan.

Timed-release products need to be approved because the FDA needs to ensure that "the product releases its active ingredients safely and effectively, sustaining the intended effect over the entire time in which the product is intended to work," according to the FDA statement. Dose dumping is a major concern with these products, Deborah M. Autor, an attorney and director of the office of compliance in the FDA's Center for Drug Evaluation and Research (CDER), said during a telebriefing.

The FDA did not look into whether there were any reports of adverse events linked to the unapproved guaifenesin products; adverse event reports did not spur this action, Ms. Autor said.

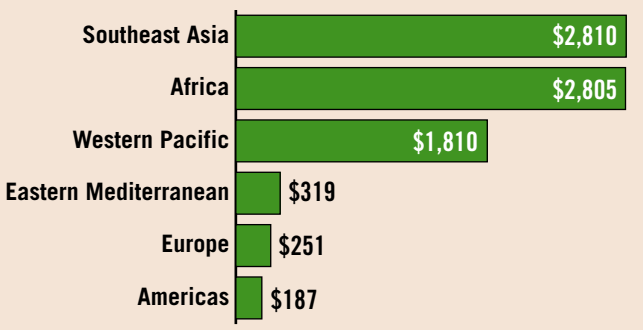
The guaifenesin products are the latest target of the FDA's initiative to get unapproved, potentially dangerous drugs off the market, an effort that was announced in June 2006. Other medications targeted since then have included unapproved products containing carbinoxamine, quinine, and ergotamine. ■

The FDA's Web site on unapproved drugs is available at www.fda.gov/cder/drug/unapproved_drugs/default.htm.

DATA WATCH

Potential Markets for Tuberculosis Testing And Therapeutic Products

(revenues in millions of U.S. dollars)



Note: Based on 2005 data for these World Health Organization regions.
Source: Kalorama Information

ELSEVIER GLOBAL MEDICAL NEWS

Primary Care Management Flawed for Asthma, COPD

Half of asthma patients and a quarter of COPD patients never received a lung function test.

BY ROBERT FINN
Elsevier Global Medical News

SAN FRANCISCO — Only 33% of patients with chronic obstructive pulmonary disease and only 53% of patients with asthma were receiving appropriate medications from their primary care physicians in the year before visiting a subspecialty clinic, according to a poster presentation by Dr. V.J. Bonne at the International Conference of the American Thoracic Society.

Of 478 patients studied, only 25% of those with asthma and 35% of those with chronic obstructive pulmonary disease (COPD) had received a lung function test during the past year.

Furthermore, 46% of patients with asthma and 27% of patients with COPD had never received a lung function test in their lives, according to Dr. Bonne and coauthors from the Medical College of Wisconsin, Milwaukee.

Patient education also was deficient, the study revealed. Forty-seven percent of patients with asthma and 59% of those with COPD had not been taught about their medications, and 29% of patients with asthma and 30% of those with COPD had not been shown the proper use of their medical devices. Only 9% of patients with asthma and 4% of those with COPD had an action plan for treating their illness.

The patient pool in the study (72% with asthma and 28% with COPD) had been referred to a guidelines-directed clinical management and education program in Milwaukee County, Wis. The program followed guidelines set by the National Asthma Education and Prevention Program and the Global Initiative for Chronic Obstructive Lung Disease.

The investigators assessed the patients' clinical and functional morbidity retrospectively at program entry and prospectively at subsequent visits. Prospective data were available on 71 of the patients with asthma and on 40 of those with COPD who had completed a full year on the program.

At the end of that year, 60% of patients with asthma and 40% of those with COPD had improved symptoms. Patients with asthma had significant decreases in the annual number of emergency department visits (a mean of 2.2 in the year before entering the program, and 0.7 during the program year). Patients with COPD had a similar decline, from an average of 2.9 ED visits annually to 1.2.

The authors found it particularly telling that even cigarette smokers had significant improvements in many indices of morbidity under guideline-directed therapy, independent of their success in quitting. This suggests that guideline-directed therapy should never be withheld from smokers, even if they continue to smoke. Those who succeed in quitting, however, showed a greater improvement in symptom severity and hospitalization rates than those who continued to smoke.

The authors disclosed that their poster was funded by educational grants from AstraZeneca, Novartis, and GlaxoSmithKline.

Theophylline, Ipratropium Raised Mortality in COPD

BY ROBERT FINN
Elsevier Global Medical News

SAN FRANCISCO — Patients with chronic obstructive pulmonary disease did worse when their regimens included theophylline or ipratropium, according to two poster presentations by Todd A. Lee, Pharm.D., at the International Conference of the American Thoracic Society.

In the first study, ipratropium (Atrovent) was associated with an adjusted 45% increased relative risk of death over 2.5 years, and theophylline was associated with an adjusted 23% increased relative risk of death, wrote Dr. Lee and his colleagues at Northwestern University, Chicago.

On the other hand, the use of inhaled corticosteroids was associated with an adjusted 13% decrease in the relative risk of death.

In the second study, all patients taking multidrug regimens that included theophylline had significantly higher mortality rates than did patients taking the same regimen without theophylline.

For example, the adjusted increased relative risk of death of a regimen including inhaled corticosteroids, long-acting β-agonists, and theophylline was 31% compared with a regimen including just inhaled corticosteroids and long-acting β-agonists.

In many of the regimens, the addition of theophylline also was associated with a significant increase in the rate of COPD exacerbations.

Both studies involved a retrospective analysis of patients with COPD in the Veterans Affairs health care system. The first study used a random sample of 7,840 of these patients, and the second study used all 169,842 patients divided into six treatment groups based on their medication regimens. Each of the treatment groups included at least 10,000 patients.

Results were adjusted for age, the chance that patients were receiving theophylline at baseline, and COPD exacerbations in the preceding 6 months.

The ipratropium finding is consistent with other studies that have raised concerns about the safety of this agent, the investigators wrote.

IN MANY OF THE REGIMENS, THE ADDITION OF THEOPHYLLINE WAS ASSOCIATED WITH A SIGNIFICANT INCREASE IN THE RATE OF COPD EXACERBATIONS.

Tiotropium (Spiriva), a similar anticholinergic drug, has been introduced recently, they noted.

Regarding theophylline, the investigators noted that their studies did not include quality of life measures or the potential benefits of theophylline on the activities of daily living. "However," they wrote, "in order to justify the use of theophylline in patients with COPD it would have to have substantial benefits in those areas to overcome the potential risk that may be associated with the use of this medication."

Dr. Lee disclosed that he is the recipient of research grants from a consortium of pharmaceutical companies for studies on COPD.

EMRs Help Hospitals Steer Smokers to Cessation Counseling

WASHINGTON — Adding a smoking cessation component to electronic medical record systems improves the likelihood that hospitalized individuals with a history of smoking will receive cessation counseling, according to the results of a study presented at a conference sponsored by the National Patient Safety Foundation.

Because hospitalization forces patients to temporarily abstain from smoking, identifying smokers when they are hospitalized with other illnesses may help them to quit, Dr. Vikram Verma wrote in a poster.

Dr. Verma and colleagues at Kings County Hospital Center in Brooklyn, N.Y., reviewed 420 patient charts during the 6-month period prior to adding a smoking cessation component to the electronic medical record (EMR).

The investigators identified 62 smokers (15%) among the 420 patients. Of the smokers, a total of 24 (39%) received nicotine replacement therapy, while 29 smokers (48%) refused NRT. For the other nine smokers, the smoking cessation issue remained unaddressed.

The EMR included a mandatory "tobacco evaluation" field, which served to guarantee that the smoking status was assessed by a health care practitioner in all patients.

In addition, an electronic inpatient admission order that contains a reminder to prescribe transdermal NRT appears in the electronic records of all patients who are smokers. Any patients who are "positive" in the record's smoking history field are automatically referred to a smoking cessation counselor.

During the 6-month period after adding the smoking cessation field to the EMR, the researchers identified 85 smokers when they reviewed another 420 patient charts.

The issue of smoking cessation was addressed in 100% of those patients, although only 20 smokers (24%) were receptive to NRT, while 65 patients (76%) refused NRT.

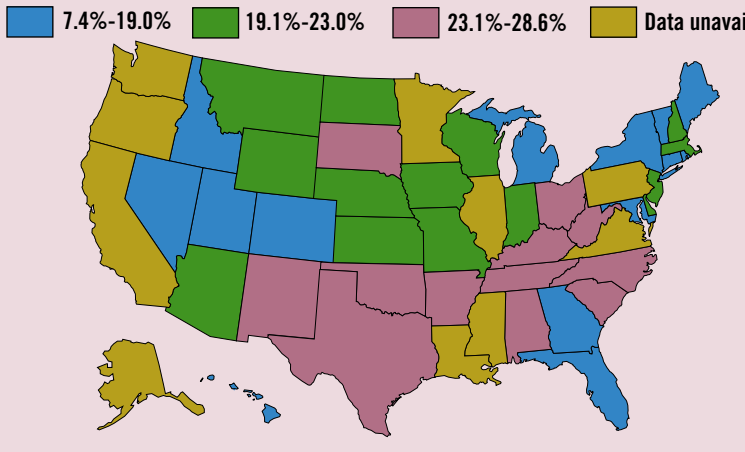
"The program facilitated our efforts in providing smoking cessation counseling and offering NRT to all these identified patients," the researchers said.

Furthermore, the addition of smoking status to the electronic medical record helped health care practitioners retrieve information more easily, which may aid future long-term investigations of patients' smoking status after they leave the hospital.

—Heidi Splete

DATA WATCH

Percentage of High School Students Who Smoke



Note: Based on 2005 data from the Youth Risk Behavior Surveillance System for high school students who smoked cigarettes on 1 or more of the 30 days preceding the survey.
Source: American Cancer Society

ELSEVIER GLOBAL MEDICAL NEWS

Ambrisentan Approved for Pulmonary Hypertension

The drug has been shown to improve exercise capacity and delay clinical worsening.

BY ELIZABETH MECHCATIE
Elsevier Global Medical News

Last month, the Food and Drug Administration approved the endothelin receptor antagonist ambrisentan for treating pulmonary arterial hypertension, based on two studies of almost 400 patients that found treatment significantly increased physical activity capacity and delayed worsening of pulmonary hypertension.

This is the sixth drug approved by the FDA for treating PAH; the others are epoprostenol, treprostinil, iloprost, bosentan, and sildenafil, which have all been approved over the last decade.

Another endothelin receptor antagonist, sitaxsentan, is approved in Europe, Canada, and Australia, and has been under review at the FDA. But in June, the manufacturer of sitaxsentan, Encysive Pharmaceuticals, announced that the company had received a third "approvable" letter for the drug from the FDA, stating that the effectiveness of the drug had not been demonstrated, but that there was some evidence that the drug improved exercise tolerance, and that the company should conduct another trial, according to an Encysive press release.

Over the last decade, the treatment options for PAH have expanded from a treatment that is administered in an intravenous infusion—epoprostenol—to treatments that include oral and inhaled medications, with wide use of combination therapy, because not all patients respond to monotherapy, said Dr. Lewis J . Rubin, FCCP, professor of medicine at the University of California, San Diego.

He added that expertise is needed to know which are the best drugs to use and how to tailor and layer therapy for an individual patient, because "it's not one size fits all."

The approved indication for ambrisentan is for treatment of PAH (WHO Group 1) in patients with WHO class II or III symptoms to improve exercise capacity and delay clinical worsening. Ambrisentan is being marketed under the trade name Letairis by Gilead Sciences Inc., which acquired Myogen Inc., the developer of the drug, in 2006. The recommended dosage regimen is to start at 5 mg once a day, and if tolerated, to consider increasing the dosage to 10 mg once a day.

Because it is teratogenic and has a potential risk of liver toxicity, the drug is available only through a restricted distribution program, the Letairis Education and Access Program (LEAP). Health care professionals, pharmacists, and patients must enroll in this program before they can prescribe, dispense, or receive the drug.

In a statement issued by the FDA announcing the approval, Dr. John Jenkins, director of the FDA's Office of New Drugs, said that ambrisentan "is similar to an existing drug, but offers the potential for fewer drug interactions."

In an interview, Dr. Rubin said that the drug Dr. Jenkins was referring to was bosentan (Tracleer), the endothelin receptor antagonist approved for PAH in 2001, which can interact with sildenafil, increasing the metabolism of sildenafil and reducing the metabolism of bosentan. (Sildenafil, marketed as Viagra for erectile dysfunction, is marketed as Revatio for PAH.) The two can be taken together, but optimal dosing is "challenging," he said.

Other potential advantages are that ambrisentan is taken once a day, compared with twice a day for bosentan, and the incidence of liver function abnormalities—the major potential toxicity of the endothelin receptor antagonist class—appears to be lower with ambrisentan based on available data, Dr. Rubin said. He added, however, that bosentan has been available longer, so there are more long-term data available on the drug.

Both appear to be equally efficacious, he said.

Dr. Rubin was the principal investigator of the ARIES-1 and ARIES-2 trials, which "demonstrated that ambrisentan is effective in a number of parameters of disease severity in patients with pulmonary hypertension and that it is a safe drug," he said. He also served as a consultant to Gilead in the development of the drug.

The incidence of liver function abnormalities appears to be lower with ambrisentan.
DR. RUBIN

In the 12-week studies, 393 people with PAH received placebo or ambrisentan added to current treatment (which could not include any of the drugs approved for PAH).

Compared with placebo, those on ambrisentan had significant improvements in the primary end point, the 6-minute walk distance, at 12 weeks: For those on the 5-mg dose, the mean change from baseline compared with placebo was 27 and 45 meters more than placebo in the two studies that evaluated this dose. Among those on 10 mg, the mean change from baseline was 39 meters more than those on placebo (an increase of 44 meters vs. a drop in 8 meters among those on placebo). In addition, there was a significant delay among those on ambrisentan in the time to clinical worsening of PAH.

The most common side effects associated with the drug were peripheral edema, a known class effect of endothelin receptor antagonists, which was usually mild to moderate; nasal congestion; sinusitis; and flushing, according to the FDA.

The rate of treatment discontinuations that were due to side effects was similar (about 2%) for those on placebo and the drug.

Monthly liver function testing is necessary during treatment with ambrisentan.

This is a pregnancy category X drug; before the start of treatment, pregnancy must be ruled out in women who can become pregnant, who should then use at least two reliable methods of contraception during treatment and should be tested for pregnancy monthly. (Women who have had a tubal sterilization or use a copper T 380 IUD or LNg-20 IUD do not have to use a second method.)

Endothelin receptor antagonists block the receptor for endothelin, which is overproduced in the lungs of patients with pulmonary hypertension, thus stimulating the growth and proliferation of the blood vessels in the pulmonary endothelium, Dr. Rubin said.

Because it is considered an orphan drug and meets an unmet medical need, ambrisentan was given a priority review: It was reviewed by the FDA within 6 months, rather than having the typical 1-year review process. ■

Does Influenza Vaccination Reduce Health Care Utilization?

BY MIRIAM E. TUCKER
Elsevier Global Medical News

BALTIMORE — Influenza vaccination is associated with lower rates of hospitalization and outpatient visits for flulike illness, but only after statistical adjustment for the fact that people who get vaccinated are less healthy than are those who don't, Dr. Roger P. Baxter said at a conference on vaccine research sponsored by the National Foundation for Infectious Diseases.

Raw data from Kaiser Permanente's medical records of approximately 500,000 adults aged 65 and older during each of four consecutive influenza seasons showed that hospitalization and outpatient visit rates were actually higher for those who received the influenza vaccine than for those who didn't, primarily because the population is sicker.

"People who get the flu vaccine are less healthy and utilize the medical system much more than those who don't get the vaccine," said Dr. Baxter, associate director of the Vaccine Study Center at Kaiser Permanente, Oakland, Calif. "It's a real confounder in all these studies."

Unadjusted data showed that hospitalization rates were higher for those who were vaccinated.
DR. BAXTER

Another study confounder is the fact that the vaccine works better in some years than in others, a phenomenon believed to be caused at least in part by how good a "match" there is between the vaccine and the season's circulating strains.

Unadjusted, the rates of hospitalization per 1,000 person-years during the influenza season ranged from 169/1,000 vaccinated vs. 159/1,000 unvaccinated in 2003-2004 (risk ratio 1.06 in favor of no vaccination), to 182/1,000 vs. 150/1,000 in 2002-2003 (1.22 in favor of no vaccination).

Even after adjustment for age, gender, and three underlying diagnoses (diabetes, coronary artery disease, and heart failure), all of the values for the vaccine's effectiveness were negative, giving the counterintuitive impression that the vaccine actually causes disease.

The values were –8.4% for preventing all hospital stays, –25.5% for all pneumonia and influenza outpatient visits, –21.4% for other respiratory outpatient visits, and –23.3% for all respiratory visits, all significant values.

But a second analysis that focused on healthcare utilization outside of the flu season suggests that "people who get the vaccine are high utilizers" year-round, Dr. Baxter said. He and his associates compared the data during each year's influenza season with the off-season control period of June 1-Aug. 31. This analysis showed that the difference in utilization between vaccinated and unvaccinated patients was even greater during the off-season than during influenza season, with a risk ratio of about 1.25 for each of the four seasons.

Estimates of the vaccine's effectiveness in preventing any hospitalization increased substantially after adjustment for age, gender, and underlying diagnosis: Effectiveness was 16.8% in 2000-2001, 6.3% in 2001-2002, 1.9% in 2002-2003, and 26.9% in 2003-2004. All of those values except for the 2002-2003 season were significant. During the 2000-2001 and 2003-2004 seasons, the vaccine was also highly effective in preventing all hospitalizations for pneumonia and influenza, all respiratory stays, all outpatient visits for pneumonia and influenza, and all other outpatient respiratory visits, he said.

These data show that the vaccine works much better in some years than in others, perhaps in part because of the degree of "match" between the strains selected for the vaccine in the early spring and those that actually end up circulating the following late autumn.

Dr. Baxter and his associates are further analyzing the Kaiser Permanente data to examine vaccine effectiveness in younger, healthier people, as well as adding mortality to the outcomes and looking more closely at the relationship between "good" vs. "bad" vaccine matches in the face of more or less virulent circulating influenza strains. Conducting such studies is "not easy," he noted.

The Kaiser Permanente Vaccine Study Center receives research grants from the influenza vaccine manufacturers Sanofi-Pasteur, GlaxoSmithKline, Novartis, and MedImmune. ■

Clues to Missed PE Often Found in Vital Signs

Patients often have a pulse that is too high and a temperature that is only mildly elevated.

BY TIMOTHY F. KIRN
Elsevier Global Medical News

SAN DIEGO — More than 400,000 cases of pulmonary thromboembolism are missed by doctors every year in the United States.

Over the past few years, it has become clearer why many of those cases are missed and how they could be diagnosed, Dr. Daniel J. Sullivan said at a congress of the American College of Emergency Physicians.

Most often, the patient has an abnormal vital sign that should alert emergency physicians, for example, to the possibility of pulmonary embolism (PE), but that single, critical sign sometimes is missed in the complexity of the situation, said Dr. Sullivan, a faculty member in the department of emergency medicine at Rush Medical College, Chicago.

"Syncope, dyspnea, rapid pulse, risk factors such as immobilization—please think PE," he said. "Every case seems to have good clues."

Dr. Sullivan presented two cases to illustrate his point. The first case involved a nurse who came into the emergency department (ED) complaining of pain, redness, and possible infection of a wound on her leg.

She had been in a car accident 2 weeks before. In the accident, she sustained two fractures of the arm, a dislocated hip, and a laceration on the shin.

In the patient history, the examining physician noted that the patient had a closed reduction of a hip fracture and had spent a week in the hospital before being discharged 1 week earlier.

The patient's initial vital signs were a temperature of 98.3° F and blood pressure of 140/80 mm Hg. Most important, her respiratory rate was 20 breaths per minute, and her pulse was 88 beats per minute.

Her respiratory rate was the clue the physician overlooked, Dr. Sullivan cautioned, together with the fact that her history said she had had hip surgery recently—and thus had spent time immobilized. In addition, the patient arrived in a wheelchair.

Instead, the physician focused on her complaint about her leg. He assumed he saw signs of cellulitis, and treated that with no further work-up.

The patient went home, only to develop respiratory distress 12 hours later. She was brought back to the ED and died of a massive pulmonary embolism.

The second case Dr. Sullivan outlined was like the first, in that the history should have given the clinician pause.

The patient in the second case was a 55-year-old obese woman who came to the emergency department complaining of nausea, vomiting, and diarrhea that had continued for 4 days.

When the patient arrived at the ED, both the triage nurse and the examining physician noted that they saw no specific signs of illness—the patient's color was good, and she had no upper airway congestion, chest pain, sweating, or cyanosis.

Her abdominal exam was normal, her laboratory tests were normal, and a chest x-ray showed nothing.

However, the physician did note that the patient was in moderate distress. The patient's respiratory rate, noted by the triage nurse, was 34 breaths per minute.

But the nurse recorded that as a normal rate, and nobody questioned it. Moreover, the patient's pulse was 96 beats per minute, and her temperature was not very high, at 100° F.

The medical history taken in the emergency department did not include the fact that the patient had had a prior PE.

That was a fatal error, Dr. Sullivan continued, because the medical history did say that she was obese and had a clinical picture that did not really fit an infection.

When the woman became short of breath before leaving the emergency department, no one informed the physician. She collapsed and died as she was leaving the hospital.

In both of the cases, the patients' breathing and/or vital signs offered warnings that should have prevented premature diagnosis, Dr. Sullivan said.

One particularly tricky situation occurs when the patient might have pneumonia or some other infection, he cautioned.

In cases that turn out to involve pulmonary embolism, patients often have a pulse that is too high and a temperature that is only mildly elevated.

That combination should always raise a red flag for possible PE, Dr. Sullivan cautioned.

Sleep Apnea Is Strong Predictor of Diabetes

Large study reveals 2.7-fold increase in risk.

BY ROBERT FINN
Elsevier Global Medical News

SAN FRANCISCO — People with obstructive sleep apnea have almost three times the risk of developing type 2 diabetes, according to a poster presentation by Dr. Nader Botros at the International Conference of the American Thoracic Society.

This increase in the risk of diabetes is independent of obesity, hypertension, age, race, and gender, said Dr. Botros of Yale University, New Haven, Conn., in a press briefing.

Analysis shows that independent of other factors, obstructive sleep apnea (OSA) increases the risk of developing diabetes by 2.7 times. This is about the same magnitude as the increase in risk that is conferred by obesity alone, which was 2.9-fold in the study.

The investigation involved a total of 544 patients who were referred to the sleep laboratories at the Veterans Affairs Connecticut Healthcare System in West Haven, for an evaluation of suspected sleep-disordered breathing.

None of the patients who were included in the study had a known history of type 2 diabetes. Each patient underwent full attended polysomnography and was followed for up to 5 years.

The investigators compared the 402 patients who were diagnosed with OSA with the 142 patients who did not qualify for the diagnosis.

Confirming other studies that showed similar results, patients with OSA were significantly older and heavier than the control patients were.

Significantly greater percentages of patients with OSA were men and had hypertension at baseline.

The investigators divided the patients into quartiles on the basis of their apnea-hypopnea index (AHI), a measurement of sleep apnea severity.

Compared with patients who were in the lowest quartile (AHI less than 7), patients in the highest quartile (AHI at least 46) had 4.6 times the risk of developing diabetes. Patients in the second and third quartiles had hazard ratios that were intermediate in value, and the trend was statistically significant.

Analysis shows that some of the risk conferred by sleep apnea can be explained by hypoxia.
DR. BOTROS

When the degree of hypoxia as measured by oxygen saturation was added to the multivariate analysis, OSA alone no longer emerged as a significant predictor of the development of type 2 diabetes, while hypoxia conferred a 2.9-fold increase in risk.

This result indicates that at least some of the risk that is conferred by sleep apnea can be explained by the existence of hypoxia.

The exact link between sleep apnea, hypoxia, and type 2 diabetes remains unknown, Dr. Botros said.

Evidence exists, however, that sleep apnea activates the body's fight-or-flight response.

This response in turn triggers a cascade of events in the body, including the production of high levels of cortisol, which has been tied to the development of insulin resistance and glucose intolerance. These prediabetic conditions, if left untreated, can lead to the development of full-blown diabetes.

"Our next step will be to determine whether the treatment of sleep apnea can improve an individual's diabetic parameters and consequently the negative health affects of diabetes," Dr. Botros said in a prepared statement. ■

Snoring or Stridor? It May Be A Lifesaving Distinction

BY KATE JOHNSON
Elsevier Global Medical News

MONTREAL — The distinction of nocturnal stridor from simple snoring can allow the initiation of potentially lifesaving therapy in patients with multiple system atrophy, according to Dr. Michael H. Silber.

"If you miss this diagnosis, the patient could die," stressed Dr. Silber, professor of neurology at the Mayo Clinic in Rochester, Minn., and codirector of the Sleep Disorders Center there.

Multiple system atrophy (MSA) is the most important cause of stridor, in the setting of sleep disturbance, said Dr. Silber.

The neurodegenerative condition causes contraction of the vocal cords and restriction of airflow through the larynx during inspiration. If stridor in MSA is not properly treated, it can result in sudden nocturnal death, sometimes within days of diagnosis, Dr. Silber said at the Eighth World Congress on Sleep Apnea.

The strained, harsh, high-pitched, inspiratory sound of stridor should be easily distinguishable from snoring by trained sleep technicians—but only if the technicians can hear it.

"If you don't have a microphone … you may miss the stridor altogether. There is absolutely no way from simply looking at a polysomnogram that you can differentiate stridor from snoring," he said.

"It's also absolutely vital to question these patients and their bed partners, about the presence of stridor—and I try to demonstrate the sound," Dr. Silber noted.

It is important to recognize the potential for undiagnosed MSA and stridor in any sleep clinic patient who is suffering from parkinsonism, said Dr. Silber.

"Some come with undiagnosed parkinsonism, and others come with what they think is the more common Parkinson's disease," he said in an interview.

"We pick up the presence of stridor, and that's a strong marker that probably they don't have ordinary Parkinson's disease but have MSA."

Other sleep disturbances are commonly seen in conjunction with multiple system atrophy and stridor, he said, including sleep apnea.

"A very high percentage of these patients also have REM sleep behavior disorder and act out their dreams—so there are a number of reasons why they may end up in a sleep center."

The diagnosis of MSA-related stridor is made simply by listening for its distinct sound.

However, it should be followed by laryngoscopy to assess the state of the patient's vocal cords during wakefulness, Dr. Silber said.

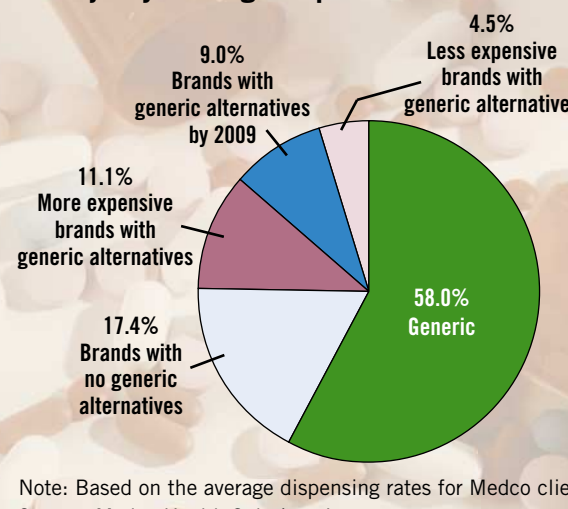
"If the vocal cords are fixed and don't move at all, that's a very serious issue and one would move toward a recommendation of tracheostomy," he said.

If the vocal cords appear normal during wakefulness, then the stridor is being caused by their paradoxical movement during sleep, Dr. Silber said.

In this case, treatment with continuous positive airway pressure may eliminate the stridor, he added. ■

DATA WATCH

The Majority of Drugs Dispensed in 2006 Were Generic



Note: Based on the average dispensing rates for Medco clients.
Source: Medco Health Solutions Inc.

ELSEVIER GLOBAL MEDICAL NEWS

Risk of MI, Death Linked to Severity of Sleep Apnea

SAN FRANCISCO — Obstructive sleep apnea is associated with a 30% increased risk of myocardial infarction or death even after adjustment for many cofactors, Dr. Neomi A. Shah said at the International Conference of the American Thoracic Society.

Moreover, the greater the severity of obstructive sleep apnea (OSA), the greater the risk of MI or death, said Dr. Shah of Yale University, New Haven, Conn.

The increased risk associated with OSA "is at the same level as having had a heart attack in the past," Dr. Shah said at a press briefing.

The observational cohort study involved 1,640 patients referred for polysomnography, and compared the 844 patients who did not qualify for an OSA diagnosis with the 796 patients who did. Investigators followed the patients for 5 years. The mean apnea-hypopnea index (AHI) of the patients with OSA was 47.8, compared with 5.1 among the control patients.

After adjustment for many cardiovascular risk factors and other confounders, including diabetes and body mass index, OSA was associated with a 40% increased risk of myocardial infarction or death.

Furthermore, there was a dose-response relationship between the severity of OSA as judged by AHI and the adjusted risk of myocardial infarction or death.

Compared with patients in the lowest quartile, who had an AHA of 0-4, patients in the highest quartile, with an AHI greater than 30, had a 90% increased risk of myocardial infarction or death. Patients in the second quartile (AHA 5-14) had a 20% greater risk, and patients in the third quartile (AHA 15-30) had a 50% greater risk. The trend was statistically significant.

The results emphasize that patients with OSA should get treatment, Dr. Shah said.

—Robert Finn

Consumer Health Web Page Debuts

The U.S. Food and Drug Administration has launched a Web page, Consumer Health Information for You and Your Family (www.fda.gov/consumer), and a related e-newsletter, FDA Consumer Health Information (www.fda.gov/consumer/consumerenews.html). The Web page provides links allowing users to access information about the various products that FDA regulates, including food, human and animal drugs, medical devices, and vaccines. The e-newsletter replaces the agency's print magazine. ■

ABC Protocol Outlined

ICU Outcomes • *from page 1*

The study's lead investigator was Dr. Timothy D. Girard of Vanderbilt.

Earlier studies had demonstrated that daily breathing trials improved the outcomes of ventilated patients, and that a daily lifting of medically induced comas improved the outcomes of patients in critical care. This was the first trial to put both of those protocols together.

"For years we have not optimized the removal of those sedatives, analgesics, and the ventilator," Dr. Ely said. "Instead, we allow the patients on average to probably get 2 or 3 days of additional unnecessary time on the ventilator, all the while being exposed to these high doses of very potent psychoactive drugs.

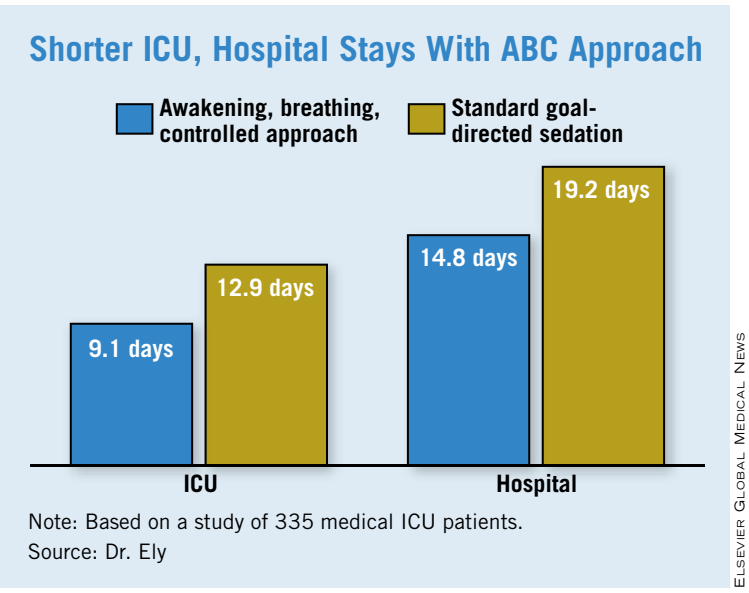
"I think in general that it is safe to assume that on average patients receive too long of a duration and too high of a dose of these medicines, and while it's well intentioned, I think we're overshooting," he added. "People generally think of these drugs as not harmful, but we're actually finding that ICU delirium, which is a result of these drugs, is a very important predictor of death."

The ABC protocol is easy to implement in most patients, Dr. Ely said. All it takes is the will to make the change among the physicians, nurses, and respiratory therapists who manage patients in the ICU.

About half the patients enrolled in the trial had sepsis or acute respiratory distress syndrome. Other common diagnoses were myocardial infarction/congestive heart failure, chronic obstructive pulmonary disease/asthma, and altered mental status. Surgical ICU patients were excluded from the study because the investigators did not want to discontinue analgesia in patients with incisions.

Dr. Ely emphasized that patients under the ABC protocol must be watched closely for signs of distress. "A very important point here is that we did not sacrifice patient comfort," he said. If patients exhibited signs of distress such as rapid breathing or sweating, sedation and analgesia were resumed, beginning at half the previous dose.

While some physicians object to strict protocols, referring to them as "cookbook medicine," Dr. Ely instead described the ABC approach as a guideline, a default set of parameters to follow. Physicians would take this default plan to the bedside and use their best clinical judgment to decide if an individual patient might require something different. ■



Dr. Stephen Pastores, FCCP, comments: *In critically ill, mechanically ventilated patients, strategies incorporating daily interruption of sedative infusions and trials of spontaneous breathing have been independently demonstrated to decrease the duration of mechanical ventilation and ICU length of stay.*

The current study showed that employing both strategies concurrently ("ABC" approach) in critically ill MICU patients resulted in a higher number of ventilator-free days and lower ICU and hospital length of stay compared to standard goal-directed sedation, although overall mortality was similar.

Thus, unless contraindicated by the patient's condition, these strategies should be incorporated into the routine care of critically ill medical patients on mechanical ventilation.

Invasive Candidiasis Rates Higher at Academic Centers

BY BRUCE JANCIN
Elsevier Global Medical News

DALLAS — The incidence of invasive candidiasis is more than 50% greater in academic medical centers than in community hospitals, although the distribution of *Candida* species is similar in both settings, according to the national Candida Surveillance Study.

During the survey period, which covered the years 2004 through 2006, a majority of cases in both academic and community hospitals were caused by species other than *C. albicans*, most commonly *C. glabrata*.

The *C. glabrata* infections accounted for almost 25% of all cases of invasive candidiasis nationally, Patricia Hoover reported at the annual meeting of the Society of Hospital Medicine.

This 1-in-4 proportion of invasive candidiasis caused by *C. glabrata* is of clinical relevance because this organism is less susceptible to fluconazole than is *C. albicans* or other *Candida* species, according to Ms. Hoover of Merck & Co., which sponsored the national study.

Two independent risk factors for invasive *C. glabrata* infection emerged from the study. The incidence was 46% greater in women than in men, and the infection was 25% more common in patients who were aged 18 or older than in those younger than 18.

On the basis of these findings, it's advisable for physicians who treat primarily adults and/or practice at an institution with a high rate of candidiasis caused by *C. glabrata* to consider using an antifungal agent other than fluconazole for empiric therapy until the laboratory identifies the specific causative *Candida* species, Ms. Hoover continued.

The Candida Surveillance Study involved 33 nationally representative academic and 8 community hospitals.

Collectively, these hospitals contributed a total of 3,503 isolates from patients with invasive candidiasis for species identification at a core laboratory.

The annualized incidence of invasive candidiasis in community hospitals was 11.5 cases/10,000 discharges, compared with 18.2 cases/10,000 discharges in the academic hospitals.

The prevalence of *C. albicans* in patients with invasive candidiasis who had received antifungal prophylaxis was 39.6%, compared with a 45.9% prevalence in those without prophylaxis.

This difference represented a significant 14% relative risk reduction. Consideration should be given to this finding in selecting empiric antifungal therapy, Ms. Hoover said.

A wide range of underlying diseases was present in patients who developed invasive candidiasis.

Gastrointestinal disorders were the most common, being present in 7.5% of all cases of invasive candidiasis.

Next was diabetes, which was present in 6.4%, and solid organ malignancy, present in 6.0%.

Recent abdominal surgery was deemed the trigger in 4.1% of all cases.

In the 1980s, *C. albicans* was the cause of most cases of invasive candidiasis in the United States.

That changed in the decade of the 1990s, as the proportion of invasive candidal infections that were caused by *C. albicans* fell to about 45%, mainly because of a rise in the incidence of *C. glabrata* infections. ■

CMS to Cover Doppler Monitoring During Surgery, Intensive Care

BY ALICIA AULT
Elsevier Global Medical News

The Centers for Medicare and Medicaid Services is amending its diagnostic ultrasound policy to allow coverage of Doppler monitoring of cardiac output in ventilated patients in intensive care and operative patients with a need for intraoperative fluid optimization.

The agency said that new studies had come to light that led it to reverse its previous decision against national coverage of Doppler monitoring in ventilated patients in intensive care and patients undergoing surgery.

"As we developed this decision, we used the best available medical evidence—in the form of randomized controlled clinical trials—to reevaluate our position on this important noninvasive method of caring for patients in intensive care situations," CMS Acting Administrator Leslie V. Norwalk said in a statement.

Deltex Medical Group PLC, the Chichester, England–based company that makes the Doppler monitoring equipment, petitioned CMS last year to revisit its coverage of diagnostic ultrasound.

According to Deltex Medical, the earlier CMS decision was made before its device, the CardioQ hemodynamic monitor, was available in the medical marketplace.

The CardioQ Doppler monitor was approved by the Food and Drug Administration under the 510(k) process in 2003.

CMS agreed with Deltex Medical that there was now sufficient medical evidence to support coverage of Doppler monitoring.

The agency found a number of prospective, randomized studies showing that when compared with standard cardiac output (CO) monitoring, patients who were managed with the less invasive esophageal Doppler monitoring "had adequate CO, shorter hospital length of stays . . . and, generally, decreased complications."

The CardioQ system uses a disposable ultrasound probe that is inserted into the esophagus. The system determines circulating blood volume, which is a crucial measure during surgical procedures or for ventilated patients in the intensive care unit.

Circulating blood volume is used to guide intravenous fluid replacement and drug therapy.

"We believe that the published literature demonstrates sufficient evidence that hemodynamic monitoring with esophageal Doppler does result in improved health outcomes for Medicare beneficiaries," wrote CMS in its coverage decision. ■

Dr. Stephen Pastores, FCCP, comments: *The CMS decision to allow coverage of Doppler monitoring of cardiac output in ventilated patients in the intensive care unit and operative patients is welcome news for the anesthesiology and intensive care community. This minimally invasive device is designed to provide clinicians with real-time information about left ventricular blood flow and cardiac output to guide fluid and inotropic management. The device is relatively safe and easy to operate, is less expensive than transesophageal echocardiography, and may provide more reliable and useful information than that derived from pulmonary artery catheters.*

Vasopressin Useful in Some Septic Shock

BY ROBERT FINN
Elsevier Global Medical News

SAN FRANCISCO — Added to norepinephrine, low-dose vasopressin decreased mortality in one group of patients with septic shock, Dr. James Russell reported at the International Conference of the American Thoracic Society.

In a multicenter, randomized controlled trial, vasopressin at a dose of 0.03 U/min decreased mortality at 28 days and at 90 days in patients with less severe septic shock, but not in patients with more severe septic shock. The reduction in mortality did not come at the expense of additional serious adverse events, said Dr. Russell of the University of British Columbia, Vancouver.

For the purposes of the trial, patients with more severe septic shock were defined as those needing more than 15 mcg/min of norepinephrine in the hour before randomization. Patients needing 5-15 mcg/min of norepinephrine formed the less severe group.

A total of 779 patients participated in the trial, all of whom were very ill, with Acute Physiology and Chronic Health Evaluation II (APACHE II) scores averaging 27. About half of the patients were in the less severe subgroup.

The less severe patients receiving vasopressin in addition to norepinephrine had a 9% absolute reduction in the risk of death at 28 days (36% to 27%), and a 10% absolute reduction in the risk of death at 90 days (46% to 36%), when compared with patients taking norepinephrine alone.

In the patients in the more severe subgroup, vasopressin was not associated with significant decreases in mortality at either 28 days or 90 days.

Physicians conducting the study were blinded as to whether they were administering vasopressin or norepinephrine. Patients were started at a steady infusion rate of 5 mL/min, corresponding to 0.01 U/min of vasopressin or 5 mcg/min of norepinephrine. The study drug was titrated from 5 to 15 mL/min over the course of 40 minutes in order to reach a mean arterial pressure of 65-75 mm Hg.

Once the patients were stable for 8 hours and receiving open-label vasopressors, they were weaned off the drug. ■

Percutaneous Tracheostomy No Riskier in Morbidly Obese

BY MARY JO M. DALES
Elsevier Global Medical News

SALT LAKE CITY — Bedside percutaneous tracheostomy appeared to carry no more risk for complications in obese and morbidly obese patients than in normal-weight patients, Dr. Christian H. Butcher said at the annual meeting of the American College of Chest Physicians.

He and his associates at West Virginia University, Morgantown, retrospectively studied all patients who underwent bedside percutaneous dilatational tracheostomy in the medical ICU of their hospital from 1998 to 2005. The procedures were done by staff physicians in the division of pulmonary and critical care medicine.

Patients were evaluated by age, gender, body mass index (BMI), primary diagnosis, indication for tracheostomy, and total duration of endotracheal intubation. Prothrombin time (PT), partial thromboplastin time (PTT), platelet count, baseline fraction of inspired oxygen (FiO_2), and positive end-expiratory pressure (PEEP) were recorded for each patient. Procedure-related complications were also recorded.

There were 176 procedures performed; but because of the failure to document height in some patients, BMI measures were available for only 99 patients. Of these patients, 62 were nonobese (BMI <30, mean 24.5), 20 were obese (BMI 30-39.9, mean 33.6), and 17 were morbidly obese (BMI >40, mean 50.8). Mean age, gender, duration of endotracheal intubation, PT, PTT, platelets, FiO_2, PEEP, and creatinine were comparable between the BMI groups.

All procedures were performed under bronchoscopic guidance.

Bleeding complications were similar between the groups (10%-13%). In the normal-weight group, there was one case each of malpositioning, loss of airway requiring emergent reintubation, and pneumothorax. One case of tracheal ring fracture occurred in both the nonobese and obese groups. There were no failures or procedure-related deaths.

Dr. Butcher acknowledged that a retrospective study has the problem of patient selection bias, that these are small numbers of patients treated at a single institution, and that there was no long-term follow-up on this group of patients. ■

Pulmonary Perspectives

The National Certification Process For Asthma Educators

The role of the asthma educator has increased over the past decade, and expertise draws from many areas.

Asthma results in significant morbidity in the United States, and the impact of asthma is more profound on identified racial/ethnic minority populations who bear a disproportionate burden of uncontrolled asthma.

The most prevalent chronic disease of children, asthma is responsible for more school and daycare absenteeism than any other disease (more than 14 million days of school are missed each year due to asthma) (Mannino et al. *Morbid Mortal Weekly* 2002; 51:1-13).

Unfortunately, as we have developed more effective treatments for asthma, we have not seen a corresponding decrease in asthma morbidity.

In a complex disease such as asthma, the treatment regimen is often correspondingly complex and requires many behavioral changes, all of which serve as barriers to adherence.

PRIOR TO NAECB, THERE WERE MULTIPLE 'CERTIFICATE' PROGRAMS, WITH NO REGULATION OF THESE PROGRAMS AND NO MEANS TO MEASURE OUTCOMES ACROSS THE SPECTRUM.

The role of the asthma educator has increased over the past decade, as research has shown the importance of a well-educated, informed patient in the management of this chronic disease. Expertise in asthma education draws from many diverse areas and goes beyond factual content alone (*eg*, educational methods, factors affecting education).

Prior to the National Asthma Educator Certification Board's (NAECB) Asthma Educator Certification Examination, there were multiple "certificate" programs from a variety of sources (*eg*, local and state American Lung Association (ALA) chapters, universities, insurance and pharmaceutical companies, and organizations outside the US). There is no regulation of these programs and no means to measure outcomes across the spectrum.

Asthma specialists recognized the need for a standardized process to certify asthma educators and to evaluate their effectiveness in disease management. By providing a certification process, patients, providers, and health-care payers could be assured that information obtained from a Certified Asthma Educator (AE-C®) is based upon scientifically sound concepts of disease management.

DR. GENE L. COLICE, FCCP
Editor,
Pulmonary Perspectives

Background

In January 1999, representatives from over 50 stakeholder groups met in Washington, DC, to discuss the interest and need for the development of a standardized asthma educator certification process. The ALA served as the initial catalyst and convener of this consensus conference.

The National Asthma Educator Certification Board (NAECB) was incorporated in February 2001 as a private, nonprofit, tax-exempt, autonomous, voluntary credentialing organization. Officers were elected and bylaws were also approved at this time.

The board comprises 17 members who represent the multiple disciplines involved in asthma education, including allergy/immunology, behavioral science, emergency medicine, environmental health, health education, medicine, nursing, patient advocacy, pediatrics, pediatric and adult pulmonology, pharmacy, public health, pulmonary, and respiratory therapy. Representation is by discipline and competency, not by organizational membership. The Board also includes a public member and an at-large member.

The mission of the NAECB is to promote optimal asthma management and quality of life among individuals with asthma, their families, and communities by advancing excellence in asthma education through the Certified Asthma Educator process. In addition to offering national certification, one of the goals of this board is to secure third-party reimbursement for asthma education.

The NAECB developed and implemented qualifications and standards, as well as a certification examination, for asthma educators on a national level. The NAECB is the only US organization that has developed a national certification process. Collectively, the NAECB represents multiple stakeholders with an interest in asthma education.

The first examination for asthma educator certification was given September 19, 2002, with about 100 health-care professionals sitting for the test.

THE MISSION OF THE NAECB IS TO PROMOTE OPTIMAL ASTHMA MANAGEMENT AND QUALITY OF LIFE AMONG INDIVIDUALS WITH ASTHMA, THEIR FAMILIES, AND COMMUNITIES.

The Test

Like many other certification exams, the NAECB test is administered via computer through Applied Management Professionals. Candidates can take the test at any of 110 assessment centers located throughout the United States. There are no application deadlines, meaning that candidates can apply at any time throughout the year.

Recertification is required every 7 years via examination. For those wishing to receive assistance with the exam fees, two Dr. Linda B. Ford Scholarships are awarded yearly to qualified candidates.

The test itself has 175 questions. Twenty-five of these are pretest items—meaning they do not count against a person's final score. However, while taking the test, there is no way to differentiate between pretest items and those that count.

NAECB exam results are available onsite, meaning candidates know whether they have passed before even leaving the building. After a passing grade, a candidate will receive a certificate in the mail within 6 weeks. As of March 2007, 2,772 people (including repeaters) had taken the exam, with a total of 1,862 Certified Asthma Educators (AE-C®). The first time exam pass rate is 69.2%.

The Future

Just launched this spring, a self-assessment examination (SAE) is now available for purchase to provide additional resources for test preparation.

The SAE is composed of 75 questions, modeled on the type and style of questions found on the actual examination.

It is believed that candidates will find the SAE helpful in preparing for the certification exam.

Cognizant of the complex nature of asthma education/coordination/counseling, the NAECB is also actively working toward national coverage of Certified Asthma Educator services by third-party payers.

More information is available at www.naecb.org. ■

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Editor's Insight

Treatment of asthma requires a partnership between patient and health-care provider.

Components of this partnership include a comprehensive assessment of asthma severity, a multimodality approach to care, with agreement by the patient to fully adhere to the action plan, and asthma self-management education. Multiple health-care professionals should play a role in asthma self-management education.

The authors describe one process for training asthma educators. Although the ACCP does not endorse this particular plan or others, it is important for physicians treating patients with asthma to be aware of these approaches for developing skilled health-care professionals who can play a more integral role in asthma self-management education.

Asthma is a major problem in the United States today, and only with comprehensive management approaches will control of this difficult disease be attained.

—Editor

AMERICAN COLLEGE OF CHEST PHYSICIANS®

NEWS FROM THE COLLEGE

PRESIDENT'S REPORT

Patient-Focused Care: The Family's View

BY DR. MARK J. ROSEN, FCCP

In the last 2 months, I've hung up my stethoscope twice to be a "family member" for my 78-year-old mother and 19-year-old daughter, both of whom were hospitalized.

My mother had a stroke, a terrific recovery (all things considered), and went home after 5 days. Right now, I'm sitting in my daughter's hospital room, post-op day 5 following repair of a progressive scoliosis in a major New York referral center.

This month's message is simple: we need to organize our offices and our hospitals to have all of our patients treated the way we would want our mother or our daughter to be treated. Even if the care is great and the outcomes what we want, we need to treat people the way we want our families to be treated.

My mother had sudden onset change in mental status and weakness, and the ambulance took her to an outstanding hospital, where the stroke team was all over it. The CT and MRI were done right away, the diagnosis established, anticoagulation started, and she waited in the ED hallway for a bed in the stroke unit. And waited. It seemed that 4 hours later, the bed "wasn't ready." When I arrived, mother was on a stretcher in the ED hallway. I went to investigate the bed and saw hers not only "ready" but so clean I would have eaten dinner off the sheets.

"Can my Mom come up?"

"Not yet—we didn't get the report." I trot down to the ED, ask the nurse to give the report and was told that the report was given 2 hours ago. Meanwhile, my mother is parked on a stretcher in the ED and checked on rarely. She asks, "Mark, when will I go upstairs?" I shrug "soon," and my father is wondering why he supported me through medical school.

I return to the stroke unit, where it's now "change of shift," that mystical interval where time stands still. You know, like in "The Matrix": all motion stops, the planets stop, everything stops. No way Mom is going upstairs during this twice-daily aberration of cosmic time and space.

In her case, there was no bad outcome, just bad treatment, inconsiderate and unnecessary. I know that we do better, because I witnessed the Beth Israel MICU open and ready eight beds in ONE HOUR on the morning of 9/11.

Last Wednesday, my daughter had a wonderful, even artistic, procedure that converted her spine from a question mark to a straight line (with titanium rods and a lot of screws).

The surgeon and his office staff were unfailingly open, encouraging, informative, and honest. The registration and admission processes were swift and painless, the immediate pre-operative parade of nurses, anesthesiologists, and surgeons cordial and thorough. For safety, she was asked to identify herself and to spell her name and state her birthday often. Someone even marked her spine, just to make sure they were operating on the correct spine, I guess. They even started the surgery a half-hour early. The hospital is clean and modern.

Waiting outside the recovery room, my wife and I are told that they will keep my daughter overnight, and send her upstairs around 7:00 AM.

"Great, we'll be there."

"No, you can't see her until noon, when visiting hours start."

"Are you serious?"

"That's our policy."

"But she's only 19, and she's scared."

"Sorry sir, she's 19, she's an adult."

"Let me talk to your supervisor."

"I *am* the supervisor."

"Then let me talk to the administrator on-call."

"I don't have her beeper number."

I think the guy is lying. "Then, let's page her."

"I can't do that."

Now I *know* the guy is lying. He's not nasty, but it's his *job*, and it's their *policy*. "Are you saying that I need to start a scene, so you have to call Security, and then somebody will find the administrator?" I am not proud of making veiled threats that I would never carry out, but he's getting me angry.

"Wait, let me see what I can do."

A senior-looking nurse materialized a few minutes later, and we have a conversation. She looked annoyed. "Look," I say, "I can not believe what I am hearing. Is your policy that my wife and I can't see my daughter when she gets to her room from recovery?"

"That's our policy."

"I've been around hospitals, and I never heard of anything like this. [Here, I recite my biosketch, which I was trying hard to avoid doing.] We promise not to get in the way."

She relented. "OK, sure you can. Tell Security I told you it's OK."

The surgery was outstanding, but this episode was unpleasant and unnecessary. The "policy" is not about patients, and it's not about families. It's about the convenience of the staff.

We can fix this. I propose we start by eliminating "change of shift" delays in care. It put my mother through unnecessary discomfort, and it puts other mothers at more serious risk.

And let's change visiting hours to whenever the patient and family want them to be. It's what we would want for our families, and our patients and *their* families deserve the same treatment. ■

This Month in *CHEST*: Editor's Picks

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

▶ **Tight Blood Glucose Control With Insulin in the ICU: Facts and Controversies.** *By Dr. I. Vanhorebeek, et al*

▶ **Right Ventricular Diastolic Dysfunction and the Acute Effects of Sildenafil in Pulmonary Hypertension Patients.** *By Dr. C. Tji-Joong Gan, et al*

▶ **Contrast Echocardiography Grading Predicts Pulmonary Arteriovenous Malformations on CT.** *By Dr. K. Zukotynski, et al*

▶ **Prognostic Models for Selecting Patients With Acute Pulmonary Embolism for Initial Outpatient Therapy.** *By Dr. D. Jiménez, et al*

▶ **Transient Atrial Fibrillation Complicating Acute Inferior Myocardial Infarction: Implications for Future Risk of Ischemic Stroke.** *By Dr. C-W Siu, et al*

▶ **Stem Cells for Lung Disease.** *By Dr. M. R. Loebinger and Dr. S. M. Janes*

www.chestjournal.org

NEWS FROM THE COLLEGE

AMERICAN COLLEGE OF CHEST PHYSICIANS

9th Annual 'Making a Difference' Awards Dinner

The CHEST Foundation's 9th Annual Making a Difference Awards Dinner will encompass several celebrations this year. You won't want to miss a moment of it.

This year's highlights will feature:

- A special tribute to Dr. Thomas L. Petty, Master FCCP, celebrating his outstanding career and the establishment of the Thomas L. Petty, MD Master FCCP Endowment in Lung Research.
- Presentations to the Humanitarian Award recipients for their pro bono projects in communities all over the world.
- The ACCP Industry Advisory Council's presentation of support to this year's Community Outreach Event partner.
- The culmination of The CHEST Foundation's 10th anniversary celebration.

Join your ACCP colleagues and friends on Saturday, October 20, 2007, at the Chicago Cultural Center for the open reception from 7:00 to 7:45 PM in the G.A.R. Rotunda and Memorial Hall. The dinner and ceremonies will be held in the Sidney R. Yates Gallery and Exhibit Hall from 8:00 to 10:30 PM.

There will be a special Thomas L. Petty, MD, Master FCCP, VIP Reception, sponsored by Platinum Exclusive Sponsor Boehringer Ingelheim Pharmaceuticals, Inc. This reception is by invitation only and will take place from 6:00 to 7:00 PM in the Millennium Room. Those who have made a contribution to the Thomas L. Petty, MD Master FCCP Endowment in Lung Research, and Making a Difference Awards Dinner sponsors at the Bronze Sponsorship level, will receive tickets to this special reception.

Bus transportation to and from the Marriott Downtown and the Intercontinental Hotels will be provided. Buses will return guests to these two hotels at the end of the evening.

The CHEST Foundation's 9th Annual Making a Difference Awards Dinner is sponsored by Platinum Exclusive Sponsor: Boehringer Ingelheim Pharmaceuticals. Additional participating sponsors: AstraZeneca, LP, ALTANA Pharma US, Inc – a NYCOMED Company, Merck & Co., Inc., and Sepracor Inc.

Making a Difference Society members at the $1,000 level are entitled to two complimentary tickets.

Annual donors at the $500 level are entitled to one complimentary ticket.

Register online for the dinner at www.chestfoundation.org. For more information, contact Teri Ruiz at truiz@chestnet.org or (847) 498-8308. ■

The Dr. Petty Endowment In Lung Research

The CHEST Foundation, in partnership with Boehringer Ingelheim Pharmaceuticals, has established the **Thomas L. Petty, MD, Master FCCP Endowment in Lung Research**. This endowment was created to pay tribute to a leader in pulmonary and critical care medicine. Considered a "Father of Pulmonary Medicine," Dr. Petty's 40 years of dedicated service focused on lung research and improving the care of patients suffering with COPD.

As an expression of admiration and appreciation of Dr. Petty's outstanding work, The CHEST Foundation's Thomas L. Petty, MD, Master FCCP Endowment in Lung Research will support, in perpetuity, research in lung disease. Thus, this will continue his legacy and have an impact on ACCP members and friends far into the future.

Dr. Petty will also be honored at this year's 9th Annual Making a Difference Awards Dinner, where Platinum Exclusive Sponsor, Boehringer Ingelheim Pharmaceuticals, Inc., will host the Thomas L. Petty, MD, Master FCCP VIP Reception that same evening. This VIP Reception is by invitation only to contributors to the endowment at the $1,000+ level and the Making a Difference Awards Dinner sponsors at the Bronze Sponsorship level and up.

The CHEST Foundation asks you to consider making a contribution to honor Dr. Petty and support lung research.

Please contact Teri Ruiz at truiz@chestnet.org; (847) 498-8308; or visit www.chestfoundation.org for more information and to contribute. ■

ACCP's Online Career Service Offers New Tools

The College's online career service, ACCP Career Connection, has recently launched a new job seeker section with tools to help maximize your career in pulmonary, critical care, and sleep medicine.

The new "My Work Style" feature is a state-of-the-art self-evaluation tool that will help you identify optimal work environments and potential professional obstacles. Understanding your work style can help you identify and choose the right type of work environment where you will thrive, and ACCP Career Connection provides you with immediate, targeted access to local and national job opportunities.

Once you have identified a potential match, use the resumé builder to create and customize your professional resumé and the new "My Site" section to build a password-protected career Web site. Your personalized Web site can include a home page, photo, resumé, references, and the ability to upload articles you have written or published. Your site also will have a unique Web address that you can provide to potential employers.

All features on the ACCP Career Connection are free to job seekers and easy to use. To learn more, visit www.chestnet.org, and click on ACCP Career Connection at the bottom of the ACCP home page. Customer service is available for ACCP Career Connection at (888) 884-8242 or info@healthecareers.com.

ACCP Career Connection is a participating member of HEALTHeCAREERS Network, an integrated network of over 70 health-care association job banks. ■

Thomas L. Petty, MD, Master FCCP Endowment in Lung Research

A Legacy in Pulmonary Medicine

Considered a "Father of Pulmonary Medicine," Thomas L. Petty, MD, Master FCCP, is a recognized leader in chest medicine and outstanding contributor to the ACCP.

To honor Dr. Petty's accomplishments, The CHEST Foundation, in partnership with Boehringer Ingelheim, Inc., has established the Thomas L. Petty, MD, Master FCCP Endowment in Lung Research to support lung research and advances in patient care.

A Tribute to a Leader
Plan to attend The CHEST Foundation's Making a Difference Awards Dinner, where Dr. Petty will be honored.
Making a Difference Awards Dinner
Saturday, October 20, 2007
Chicago Cultural Center, Chicago, Illinois

Register online.
www.chestfoundation.org
Contact Teri Ruiz for more information.
truiz@chestnet.org or (847) 498-8308

Donate to this important fund today by contacting The CHEST Foundation.
www.chestfoundation.org
(800) 343-2227 or (847) 498-1400

THE CHEST FOUNDATION

AMERICAN COLLEGE OF CHEST PHYSICIANS®

NEWS FROM THE COLLEGE

NETWORKS

CHEST 2007 Plans Unfolding, Plus Clinical Research Survey

Cultural Diversity in Medicine

The NetWork is honored to have Dr. Alvin V. Thomas, Jr., FCCP, incoming ACCP President, as the featured speaker at the Cultural Diversity in Medicine Luncheon at CHEST 2007. Dr. Thomas will share his vision and goals for the ACCP to work toward resolving health-care disparities in the United States. The NetWork invites all CHEST 2007 attendees to hear Dr. Thomas's presentation, Health-Care Disparities: An Active ACCP Agenda. The luncheon will be held on Wednesday, October 24, from 11:30 AM to 12:45 PM.

The Cultural Diversity in Medicine NetWork has an important role in carrying out the ACCP's goals and shares Dr. Thomas's vision. The NetWork has developed sessions for CHEST 2007 to educate and provide strategies for overcoming disparities in health-care.

- Health-care Disparities and Factors Influencing Health: Monday, October 22, 10:45 to 11:45 AM
- Strategies To Reduce the Burden of COPD in the Minority Populations: Monday, October 22, 4:15 to 5:45 PM
- End-of-Life Issues Among Minority Patients: Tuesday, October 23, 4:00 to 5:30 PM

The steering committee also invites CHEST 2007 attendees to participate in the NetWork Open Meeting at CHEST 2007, scheduled for Tuesday, October 23, from 8:30 to 9:45 AM. In addition to the business discussion, Dr. Ravindra Mehta, FCCP, will present, Cultural Diversity in the Era of Expanding Medical Tourism. For more information about this NetWork, go to www.chestnet.org/networks/cultural_diversity/index.php or e-mail networks@chestnet.org.

Disaster Response

Simulation Station-CHEST 2007

The Disaster Response NetWork is excited to be a part of the CHEST 2007 Simulation Center. The newly expanded center will feature a variety of simulation exercises where participants can actively practice skills and apply knowledge in realistic scenarios.

The Disaster Response NetWork is developing a session that will focus on airway management of the patient during a toxic inhalation exposure or exposure to an infectious agent requiring personal protective equipment (PPE). The emphasis will be on intubation while wearing PPE, which has repeatedly been cited as a stressor to disaster response and management of the ICU patient. Participants in the session will gain an understanding of different PPE and improve their technique of airway management.

This rapid learning session will employ various instructional strategies, including task trainers, human patient simulators, and case-based discussion to reach our learning objectives. The course faculty includes instructors from the military and clinicians who have responded to multiple disaster situations globally.

Disaster in the Emergency Department is one of nine simulation exercises being offered at CHEST 2007. Online registration and a $30 fee are required. To learn more and register, go to www.chestnet.org.

Members in Industry

ACCP Survey on Clinical Trials

The Members in Industry (MII) NetWork is devoted to helping members of the College better understand the role of industry in medical education and clinical research.

The MII NetWork Steering Committee wanted to expand the knowledge available regarding the clinical research activities of the ACCP membership. In the spring of 2006, the NetWork implemented a survey of the ACCP membership regarding their clinical research activities with the following specific aims:

- To describe ACCP members' perception and activities regarding clinical research.
- To describe members' impression of industry-sponsored clinical research.
- To query the members' opinions regarding the ACCP's role in promoting clinical research.

This online survey was sent to a random sample of 942 US physician members. There was a total of 211 respondents. The majority of respondents were between 45 and 55 years of age. Regarding primary practice, 51% were from academic and 43% were from private institutions, with the remainder from industry, insurance, etc.

When asked if they were actively involved in clinical research, 65% of the respondents answered yes. Regarding how much time they spent involved in clinical research, the respondents answered as follows: 41% spent less than 10% of their time; 63% spent 11 to 25% of their time; 12% spent 26 to 50% of their time; and 12% spent more than 50% of their time in clinical research activities.

Only 47% of respondents reported having received formal training in clinical research, and the majority of those trained during their specialty fellowship. Only 57% reported having access to a full-time study coordinator for their clinical research activities.

With respect to industry-sponsored clinical research, 76% of those surveyed reported they had participated. Those surveyed were asked about potential activities the College could explore to help support clinical research activities of the members; 81% answered that the College should actively encourage patients to participate in clinical research trials. In addition, 91% answered yes to the question of whether the College should create a clinical trial database for its members to create further awareness of possible research opportunities for themselves and their patients.

The MII NetWork hopes that this exercise is an important first step that will stimulate discussion regarding clinical research and lead to new projects to promote this critical part of medicine. Patient-focused care includes active participation in clinical research to ultimately improve individual patient outcomes.

For more information about this NetWork, go to www.chestnet.org/networks/accp_industry/index.php or e-mail networks@chestnet.org. ■

ACCP and The CHEST Foundation Antitobacco Efforts Ongoing

BY DR. D. ROBERT McCAFFREE, MASTER FCCP
Chair, The CHEST Foundation

The ACCP and The CHEST Foundation have distinguished themselves in efforts to battle the scourge of tobacco and its deadly effects on human health, effects that begin with the most vulnerable—children.

Some of these efforts are represented in the ACCP and CHEST Foundation educational programs for children, including *Make the Choice: Tobacco or Health* speakers kits, both for North American audiences, as well as an edition for Asian audiences; *The Evils of Tobacco,* created for Indian audiences; *Educational Guide on Lung Health for Elementary School Children*; *You Can't Run, You Can't Hide CD;* and many others.

A major aspect of our efforts to protect children has been our opposition to the immoral and inexcusable efforts of tobacco companies to market their deadly product to youth. One marketing ploy encouraged and supported by tobacco companies has been the positive presentation of smoking in the movies.

At recent meetings of the ACCP Board of Regents and The CHEST Foundation Board of Trustees, both groups unanimously supported the efforts of an organization based at the University of California San Francisco called Smoke Free Movies. One ultimate goal of this effort has been to ban smoking in any movies directed toward youth and assigning an R rating, in the future, to those movies depicting smoking. This effort has also been endorsed by a number of health organizations, including the American Medical Association, the American Heart Association, and the American Academy of Pediatrics.

Most recently, the Harvard School of Public Health made an invited presentation to the Motion Picture Association of America (MPAA) and presented their recommendation. The recommendation was for the MPAA to take "substantive and effective action to eliminate the depiction of tobacco smoking from films accessible to children and youth."

The MPAA, in response, adopted a very subjective policy calling for the Film Ratings Board to "consider smoking" in their ratings and stated that movies may receive a more adult rating because of pervasive or glamorized smoking. They did not commit to any actions that would reflect responsible actions to reduce the impact of smoking in movies on the initiation of smoking by children around the world.

We are disappointed that the MPAA did not elect to take a more responsible approach in this matter. The ACCP and The CHEST Foundation will continue to work for and support all efforts to eliminate all direct, indirect, and subliminal marketing of smoking to children.

To become more knowledgeable about this matter, go to www.smokefreemovies.ucsf.edu or www.hsph.harvard.edu/mpaa. Additionally, a recent meta-analysis of studies examining smoking in movies and its effect on children is available (Wellman et al. *Arch Pediatr Adolesc Med* 2006;160:1280).

To learn more about the ACCP and The CHEST Foundation antitobacco efforts, visit www.chestnet.org or www.chestfoundation.org. ■

NEWS FROM THE COLLEGE

AMERICAN COLLEGE OF CHEST PHYSICIANS

Creating Healthy Work Environments: Meaningful Recognition

BY GLADYS M. CAMPBELL, RN, MSN

(Last in a Series)

Employee recognition exists in all work environments, whether it is an annual merit increase, cost-of-living raise, token of appreciation during National Nurses Week, or employer-supported opportunity for education or advancement. However, are these activities truly meaningful to the professional employee? Is the recognition well thought out by the employer, peers, or colleagues? Is it distributed impersonally or begrudgingly as an organizational "gotta do?"

The business literature has revealed a shift in what employees view as meaningful recognition, job satisfaction, and motivation. In an era of extreme deprivation, where unions and federal regulations were the only source of equity and fair play in the workplace, higher wages were what employees most wanted. However, in recent times, salaries are no longer a primary source of satisfaction. Today's worker searches for meaning, the chance to contribute, and a sense of purposefulness, and wants to be recognized accordingly.

We need a sense of purpose. We care about our life's legacy and want to make a difference in the world. For this reason, we want to be productive, feel good about what we do, and feel we are making a contribution as part of a worthwhile enterprise.

AMERICAN ASSOCIATION of CRITICAL-CARE NURSES

Employers who simply go through the motions of recognizing employees tend to emphasize physical work conditions, salary, job security, or rote incentive and recognition programs. These employers may wonder why their efforts do not achieve employee satisfaction. How can an employer give recognition that will truly satisfy and potentially motivate staff?

Health care work is relationship-based. Relationships stem from knowing other people and being known. It is impossible to truly care for or respond to others unless we know their goals, fears, concerns, or individual needs. Health-care workers are motivated and encouraged by authentic and encouraging relationships. For this reason, staff satisfaction surveys show that employees remain committed to their place of employment because of their unit-based team relationships. Surveys additionally show that immediate supervisors and their relationship with staff have a significant impact on turnover and retention.

To feel recognized, our clinicians must believe that they are known and appreciated by others as individuals. They must have their professional goals and personal passions honored. They also need to work in an environment that is open, creative, and innovative and fosters their capabilities for doing good work.

In this type of environment, individuals are not only able to make contributions that are worthy of recognition at the local level, but also produce ideas and outcomes worthy of recognition within the larger professional community.

The ability to be creative, innovative, and produce noteworthy outcomes is satisfying and motivating and is a natural precursor to recognition.

Although it seems easier to reduce recognition to a singular gift or gesture, meaningful recognition cannot be "mechanically imposed." Meaningful recognition flows naturally from an environment of mutual trust and respect. It emanates from a culture where individual team member contributions are promoted, honored, valued, and recognized, and each individual is encouraged to make his or her optimal contribution.

For more information on AACN's Creating Healthy Work Environments initiative, visit www.aacn.org. ■

MS. CAMPBELL *is Executive Director, Northwest Organization of Nurse Executives/Nurse Leaders, Portland, OR.*

AMERICAN COLLEGE OF CHEST PHYSICIANS

NEWS FROM THE COLLEGE

SLEEP STRATEGIES

Training Pulmonary Fellows in Sleep Medicine: A Survey of Pulmonary Program Directors

The sleep medicine workforce has been growing exponentially for the last 20 years. However, despite this growth in the workforce of sleep medicine physicians, as the US population continues to age, and as sleep medicine care is sought by an increasing number of aging baby boomers, it is likely that the number of qualified sleep medicine specialists will be inadequate to meet this demand.

This has implications for sleep medicine training inside of pulmonary and critical care fellowship programs.

Typically, pulmonary physicians become interested in sleep medicine during a sleep laboratory rotation in their pulmonary fellowship. However, we know little about the content and scope of sleep medicine training in pulmonary fellowship programs.

For sleep medicine to thrive, we need an ongoing supply of physicians to gain interest during pulmonary fellowship training and then desire to spend an extra year in sleep medicine training. In response to this, the ACCP-Sleep Institute (ACCP-SI) conducted a survey of pulmonary training program directors. This article outlines the results of the survey.

ACCP-SI Survey

The survey was developed with input from the ACCP-SI steering committee and was sent in June and July 2006 to all the training directors of the pulmonary and critical care programs in the US. Pulmonary program directors answered an 18-question single-best-answer survey that assessed the availability of sleep training for pulmonary-critical care trainees at their institution. An online survey vendor, Survey Monkey (www.surveymonkey.com), was selected as the distribution platform, based on broad functionality and flexible architecture.

The survey was sent to 78 pulmonary and critical care programs in the United States. Forty-eight program directors completed the survey, which was considered to be a very good response rate.

Results

The survey found that most pulmonary training programs (87%) had an associated sleep disorder laboratory or center in which their fellows could gain experience. As expected, most of the sleep training is delivered by pulmonologists (95%), and 41.5% of the programs had at least one faculty member with board certification in sleep. A few programs had affiliations with other departments, typically neurology, for sleep laboratory rotations.

The survey also asked questions about how long the sleep medicine rotations lasted. Surprisingly, 43% of the programs surveyed reported that the pulmonary fellows spent less than 1 month during their fellowship learning sleep medicine.

On average, trainees received 17.5 ± 46 hours of formal instruction on obstructive sleep apnea, which forms the bulk of the clinical problem in this field, during their pulmonary and critical care fellowships. Program training directors estimated that the pulmonary fellows reviewed an average of 76 ± 93 polysomnographic recordings during their training, which is a reasonable number of studies to review. Nonetheless, 38% of the program directors were not confident that their trainees could accurately interpret polysomnographic recordings.

Sleep Institute
American College of Chest Physicians

Examining the question of breadth of sleep medicine training, one third of the programs provided no formal training to their trainees in behavioral sleep medicine. Finally, most programs reported that a low number of inpatient consults per month (8.5 ± 7.3) were related to sleep-disordered breathing.

Comment

These survey results highlight some of the successes achieved in integrating sleep medicine into pulmonary training and some challenges ahead for sleep medicine in traditional pulmonary medicine fellowship programs.

On a faculty level, these data point out that there has been substantial growth of sleep medicine within pulmonary programs; almost all pulmonary divisions in teaching hospitals have a sleep medicine expert. This growth in sleep medicine in academic pulmonary programs has contributed to pulmonary medicine being the single largest specialty in the sleep medicine field; at present, approximately 60% of all board-certified sleep medicine physicians are also pulmonologists.

However, these data question how much of the expertise of the "sleep" faculty is imparted to the fellows. It appears from this survey that for a large percentage of programs (43%), fellows spend no more than 1 month on a sleep medicine rotation. Further, only 10% of programs surveyed have their fellows spend more than 4 months on a sleep medicine rotation.

Perhaps, not surprisingly, the survey suggests that 38% of pulmonary training directors are only "somewhat confident" in their fellows' abilities to interpret polysomnograms.

These data illustrate the disconnect between sleep medicine clinical work done by faculty and the training of pulmonary fellows in sleep medicine.

At present, sleep medicine is a rapidly growing field within pulmonary medicine and outside of it. Some informal estimates have suggested that approximately one third of patients now seen by pulmonary physicians are referred for a sleep disorder evaluation. Most of these patients will have some form of sleep-disordered breathing.

Another way to look at this, according other estimates, is that sleep apnea is in the top three diagnoses seen in pulmonary outpatient practices.

The disconnect between training and practice is this—how can you expect clinical competence from practitioners in sleep apnea management (we will leave out the other common sleep disorders for now) when they get a month of training in it? Sleep apnea is as common as asthma and COPD in the community and, yet, we are failing our fellows by not training them adequately to manage what may be one third of their future patients.

For sleep medicine to thrive within the pulmonary field, pulmonary medicine training programs need to improve their educational initiatives in sleep medicine.

Admittedly, this is hard. Pulmonary program directors have a lot of educational material to cover in this increasingly broad field. Also, the impact of a separate sleep board examination on pulmonary medicine is unknown.

Some program directors may view this as an opportunity to de-emphasize sleep medicine training in their programs, believing that interested fellows can get sleep training in a subsequent fellowship, if they want it. The problem with this approach is that the number of sleep medicine fellowships is low (only about 45), with a relatively low number of total positions. Pulmonary applicants must compete with a growing number of neurologists, psychiatrists, general internists, and pediatricians for positions in these fellowships.

Pulmonary medicine may no longer be the leading source of sleep medicine physicians in the future, if this approach prevails.

The Future

To improve the caliber of sleep medicine training in pulmonary fellowships, several changes need to occur in the current training of pulmonary and critical care fellows.

First, sleep medicine must have an adequate number of clinical faculty members willing and able to teach in the field. In institutions where sleep medicine laboratories are controlled by other specialties, appropriate partnerships need to be developed and nurtured in order for pulmonary fellows to get the training needed.

Second, there has to be a reasonable amount of time in the pulmonary curriculum for sleep medicine. "Reasonable" has not been defined, but it is certainly more than a 1-month rotation. More likely, 3 to 6 months is a "reasonable" amount. This curriculum time should combine both outpatient clinic assessments and time in the sleep laboratory learning how to interpret sleep studies.

The goal in a pulmonary medicine training program should be to have the trainee be able to recognize common and uncommon examples of sleep-disordered breathing. Trainees should also understand enough nonpulmonary sleep disorders medicine that they can "know what they do not know" and make appropriate referrals. This knowledge will only come from clinical experience supported by lectures or workshops.

The areas of discomfort in the sleep medicine field for many pulmonary physicians are neuroscience and behavioral medicine-based sleep medicine. This is understandable, since it is not part of their core medical training in most instances, yet it should not be an obstacle for pulmonary medicine training programs. Creative partnering with others in a medical center with this expertise can easily cover this content.

Sleep medicine is a rapidly growing part of the pulmonary medicine landscape. These survey results demonstrate that sleep medicine training in pulmonary fellowships is happening but could be a lot more robust. Improving this part of training will serve our fellows well and will serve the needs of their future patients. ■

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NEWS FROM THE COLLEGE

AMERICAN COLLEGE OF CHEST PHYSICIANS

Recognizing and Managing Sleep Disorders in Primary Care

BY JENNIFER PITTS, MA
Manager, Institute Development

In late 2006, the Institutes of Medicine reported that 50 to 70 million Americans suffer from a chronic sleep disorder, and the vast majority goes unrecognized, because physicians are not asking their patients about their sleep (Brief report. IOM, April 2006). Additional research confirms that sleep apnea, in particular, is significantly underrecognized in the primary care patient population and findings suggest expansion of clinician and patient education is key.

In response to this unmet need, the American College of Chest Physicians Sleep Institute (ACCP-SI) officially launched its first-ever educational initiative focused on increasing awareness, diagnosis, and treatment of sleep disorders in the primary care population (Ball et al, *Arch Intern Med* 1997;157:419; Chervin et al. *Rev Med Suisse* 2005; 1:2607).

ACCP Sleep NetWork members were invited to apply. From over 100 applicants, 21 sites were selected nationwide, which included accredited private sleep centers, academic medical centers, and community hospitals. The half-day program combines traditional didactic lectures, case-based presentations, and an interactive toolkit that emphasizes the consequences of not treating common sleep disorders, such as sleep apnea, insomnia, and restless legs syndrome.

As of June 2, 2007, 15 courses were completed and over 330 primary care providers had received this education. Attendees reported that improving patient education and offering new treatment options were the most important changes they wanted to make in their professional practice. All attendees reported that they would recommend the program to a colleague.

Dr. Jim Krainson, FCCP, a faculty member from one of the courses, said, "This was an very well thought out program that gave our lab a chance to provide the primary care providers in our community an educational experience that they can use to better serve their patients."

All 21 education programs will be completed by the end of July, and the ACCP-SI is currently working on plans to continue these programs in 2008. The ACCP-SI staff would like to thank the content development subcommittee and all of the faculty and program coordinators for their hard work and dedication to the success of this project. We also would like to recognize Dr. Lee K. Brown, FCCP, and Dr. Richard Castriotta, FCCP for their vision and leadership as chairs.

To learn more about the ACCP-SI ongoing education initiatives or future projects, visit www.chestnet.org/institutes or e-mail Jennifer Pitts at jpitts@chestnet.org. ■

What's Your Style? ACCP Presents CME in a New Way

New ACCP Learning Categories Offer More Options, More Focus

At CHEST 2007, the ACCP will introduce the ACCP Learning Categories. The categories are a new component of the overall ACCP education strategy that empowers medical professionals to obtain medical education through a variety of learning styles.

The ACCP Learning Categories (how you learn) complement the ACCP education curriculum (what you learn). Together, they provide a roadmap for CME that enables medical professionals to fulfill their professional and personal education goals.

"Physician continuing education is undergoing a transition from the traditional 'lecture style' presentation to more experiential learning modalities," said Dr. Brian W. Carlin, FCCP, Scientific Program Chair for CHEST 2007. "The new learning categories will help define the particular educational approach of the session and allow the attendees to better use their time and resources for the types of learning in which they are interested."

CHEST 2007 sessions will be assigned 1 of 36 clinically-focused education curriculum areas in pulmonary, critical care, and sleep medicine. Sessions also will be assigned one of six ACCP Learning Categories that clearly specify the type of instruction and methodology used. This new approach allows clinicians to choose sessions related to their clinical interests, education goals, and learning style.

Although the ACCP Learning Categories will premiere at CHEST 2007, all subsequent CME-related programs and ACCP educational activities will be designated to one of six learning categories:

- Learning Category I: Lecture-Based
- Learning Category II: Self-Directed
- Learning Category III: Evidence-Based
- Learning Category IV: Case- and Problem-Based
- Learning Category V: Simulation
- Learning Category VI: Quality Improvement

Also new at CHEST 2007, ACCP Learning Categories will be reflected automatically on the ACCP's online CME certificate, based on credit hours earned. Education credits applicable to state licensing requirements, such as medical ethics and end-of-life care, also will be indicated.

"ACCP has a strong history of delivering the most current and comprehensive continuing medical education for pulmonary, critical care, and sleep medicine," said Dr. Mark J. Rosen, FCCP, President of the ACCP. "The new ACCP Learning Categories further illustrate our commitment to education."

For more details on the ACCP education curriculum and the ACCP Learning Categories, visit www.chestnet.org. ■

CHEST 2007 in Chicago: Shop 'Til You Drop

In between sessions at CHEST 2007, you won't want to miss the shopping mecca that is Chicago.

Three streets within the downtown area reveal a shopper's paradise. Visit these streets! You'll find anything you desire, from designer duds to diamonds—and more.

- **The Magnificent Mile:** Located along Michigan Avenue, you'll find nearly 460 stores in eight city blocks, including four separate shopping centers! Be sure to stop in at The 900 Shops—complete with six levels of upscale retailers, and Water Tower Place, a Chicago favorite, featuring more than 100 popular stores.
- **Oak Street:** Here is where such names as Barney's, Jimmy Choo, Kate Spade, and Prada call home. Chic boutiques line this street, where only the most serious shoppers can get their fix. But beware—prices here are not for the faint-of-heart!
- **State Street:** That great street, known by Chicagoans as the retail historic district. Located just south of the river, this area is rich with landmark flagship department stores, such as Macy's and Sears. It's also where you'll find the Midwest's largest jewelry district, known by the locals as Jewelers' Row.

When it comes to retail therapy, this city is a first-class, all-inclusive one-stop-shop. Whether you're in the mood to browse or buy, Chicago's got it in the bag, making it the perfect place for CHEST 2007.

For more information about Chicago, visit www.choosechicago.com/default.html.

Visit www.chestnet.org/CHEST for details about CHEST 2007. ■

ACCP Product of the Month: Prevention and Treatment of PE

A symposium presented at CHEST 2006 offered a look at the burden of venous thromboembolism (VTE).

The symposium addressed the evidence-based guidelines for the prevention and treatment of VTE, discussed treatment strategies for significant pulmonary embolism, examined catheter-based guidelines for prevention and treatment of VTE, and provided insight into pharmacologic therapy for the management of chronic thromboembolic pulmonary hypertension.

This monograph highlights the key educational points that were covered in each symposium presentation.

To view the monograph, please visit the ACCP online education site at www.chestnet.org/education/online/index.php, and click on the monograph link. ■

Severe Exacerbations Seen in Mild Pediatric Asthma

BY KATE JOHNSON
Elsevier Global Medical News

TORONTO — Current classifications of pediatric asthma fail to capture the potential for severe exacerbations in patients with mild disease, according to Dr. Christopher Carroll, FCCP, of Connecticut Children's Medical Center in Hartford.

In a study of nearly 300 asthmatic children, which Dr. Carroll presented in a poster at the annual meeting of the Pediatric Academic Societies, more than half of those admitted to the intensive care unit with severe exacerbations were classified as having "mild" asthma.

National Heart, Lung, and Blood Institute (NHLBI) guidelines classify pediatric asthma as either mild intermittent, mild persistent, moderate persistent, or severe persistent, based on the frequency of baseline symptoms, Dr. Carroll said in an interview at the meeting.

But this classification system fails to account for children in whom mild baseline disease can progress to severe exacerbations. "Kids with mild asthma can have severe life-threatening exacerbations where they need to be put on a ventilator or admitted to the ICU—and they can stay in the ICU for 8 days, some of them," he said.

Dr. Carroll and his associates reviewed the charts of 298 children aged 2 years or older who were admitted to the ICU with asthma exacerbation over a 9-year period. More than half (55%) of the children were classified as having mild asthma (defined as mild intermittent or mild persistent). In a comparison of children with mild asthma with those who had more severe disease, there were no differences in the severity of their exacerbations at admission, their hospital or ICU length of stay, or the therapies they received.

"This suggests that current classifications of chronic asthma do not necessarily predict asthma phenotypes during acute exacerbations," he noted.

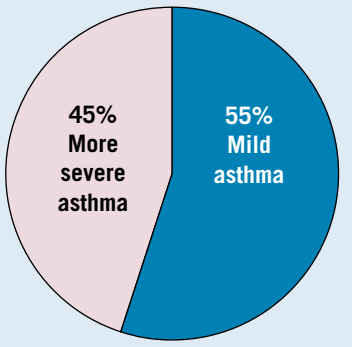
Compared with children who had more severe baseline disease, those with mild asthma were younger (7.6 vs. 9.8 years), less likely to have been admitted to hospital previously for asthma (42% vs. 77%), less likely to have been admitted to the ICU previously for asthma (11% vs. 41%), and less likely to have public insurance (46% vs. 65%).

There also were ethnic differences between the groups, with equal percentages of African Americans but fewer Hispanics in the milder group (30% vs. 47%) and more whites (42% vs. 24%).

"Our point here is to say that even kids with mild asthma are susceptible to severe exacerbations," said Dr. Carroll. "I was talking to some of my adult critical care colleagues who said that really, only severe asthmatics end up in the ICU. I said that's not true in kids. We see kids with 'mild asthma' who are in our ICU all the time."

Asked why he thought children with mild disease might be triggered into a severe exacerbation, Dr. Carroll said this is an important area of future research. "Asthma is a very heterogeneous disease; there are a lot of different types of asthma out there." He speculated that one possible reason could be that pediatric patients with mild disease might be less in tune with early symptoms of an exacerbation and less familiar with altering their medication regimen accordingly.

Children Admitted to ICU With Asthma Exacerbation Over a 9-Year Period



Note: Based on data from 298 children aged 2 years or older.
Source: Dr. Carroll

ELSEVIER GLOBAL MEDICAL NEWS

Cystic Fibrosis Diabetes Tamed By Tailored Insulin Treatment

BY BRUCE JANCIN
Elsevier Global Medical News

KEYSTONE, COLO. — Treatment of cystic fibrosis–related diabetes is essentially insulin adjusted to a largely unrestricted diet, Dr. Robert H. Slover said at a conference on the management of diabetes in youth.

"Never calorie-restrict these patients. High energy intake is necessary for their survival," he stressed. "These kids can eat 10,000 calories per day and still lose weight."

The oral medications used to treat type 2 diabetes can't be used in cystic fibrosis–related diabetes (CFRD). They carry unacceptable risks of liver damage in this population. Plus, the sulfonylureas interfere with the chloride transporter, added Dr. Slover of the Barbara Davis Center for Childhood Diabetes at the University of Colorado, Denver.

Basal/bolus insulin regimens can be employed, although some patients are able to maintain excellent glycemic control with mealtime injections only.

It's important to bear in mind, however, that glycosylated hemoglobin measurements may underestimate the degree of abnormal glucose metabolism in patients with CFRD. That's because they have higher red blood cell turnover, which dilutes the HbA_{1c}, he explained at the conference sponsored by the university and the Children's Diabetes Foundation at Denver.

Intermittent insulin is utilized during episodes of infection or corticosteroid administration. Insulin infusion may be necessary when enteral feeding is employed.

The dietary management principles operative in CFRD are markedly different than are those in type 1 diabetes. The recommended caloric energy intake in type 1 diabetes is 100% of the recommended daily allowance—and less if the patient is overweight. Patients with CFRD are encouraged to consume 120%-150% of the caloric RDA. They don't fuss over the glycemic index of foods, either.

Type 1 diabetic patients are encouraged to restrict intake of refined carbohydrates to less than 25 g/day while consuming a high-fiber, low-salt diet. In contrast, patients with CFRD are allowed to take in refined carbohydrates liberally throughout the day, although between-meal sugary drinks are discouraged. They are also advised to eat a high-salt diet and minimize intake of soluble and insoluble fiber because fiber promotes satiety, which has the unwanted effect of limiting energy intake.

The more than 22,000 Americans with CF receive much of their health care in the nation's 117 CF centers. Dr. Slover urged physicians with expertise in diabetes management to make themselves available at their nearby CF center. These centers traditionally have been staffed mainly by pulmonologists, who at times feel a bit out of their element in facing the growing epidemic of CFRD occurring as a result of the marked life span gains in the CF population.

As a diabetes specialist, working at a CF center is rewarding in several ways, according to Dr. Slover. For one, the CF Foundation is an outstanding example of evidence-based medicine in action; the group has been collecting outcomes data and using it to intelligently guide practice for many years. The payoff in terms of years of life expectancy gained has been most impressive, he said.

The other thing that's really gratifying to a diabetologist is how appreciative CF patients are. They are very well aware, for example, that the life expectancy of women with CFRD is 17 years less than in CF patients without diabetes, and they are hopeful that excellent diabetes management will give them back some of those years.

For physicians accustomed to butting heads with rebellious teenagers in an often-frustrating effort to get them to take their diabetes more seriously and lower their HbA_{1c} by a few tenths of a point, the eagerness of CF patients is truly refreshing, Dr. Slover said.

Universal Influenza Vaccination Would Strain Delivery

The 6- to 18-year-old age group would have to make 41.5 million extra visits to pediatricians.

BY KATE JOHNSON
Elsevier Global Medical News

TORONTO — Alternative settings, such as schools, should be considered if universal influenza vaccination is recommended for all U.S. school-age children, Dr. Cynthia Rand said in a poster presentation at the annual meeting of the Pediatric Academic Societies.

"Kids aged 6-18 years haven't yet had a recommendation for universal influenza vaccination, but we're expecting this recommendation in the flu season of 2008," Dr. Rand of the University of Rochester (N.Y.), said in an interview.

In the study, she calculated that more that 41.5 million extra visits to pediatric offices would be needed annually to meet the increased demand.

Although the emergency department has been suggested as a potential site for universal influenza vaccination (UIV), a related study found the added value of this delivery site would be "modest," at least from a public health perspective, her colleague Christina Albertin, also of the university, reported in another poster.

With data from the 2003-2004 Medical Expenditure Panel Survey (MEPS), Dr. Rand's study calculated the number of well-child and other primary care visits for 4,161 children. From this she estimated the number of extra visits between October and January that would be required for influenza vaccination.

It was assumed that children who are under 9 years of age would need two visits rather than one visit, if it was their first influenza vaccine.

There are new updated American Academy of Pediatric recommendations that first timers who failed to get their two flu shots should get two for the following year; this would boost the number of visits still further, she commented (Pediatrics 2007;119:846-51).

By focusing specifically on the 6- to 18-year-old age group that is expected to be captured in new UIV guidelines, the study found that for children under 9 years, 33% would need one extra visit and more than 50% would need two—accounting for 16 million additional visits.

For 9- to 18-year-old children and teens, 73% would need one extra visit, accounting for more than 25 million additional visits. In total, the 6- to 18-year-old age group would require 41.5 million extra visits to pediatricians during the influenza vaccination period, assuming no missed opportunities for vaccination and that 20% of the population had been vaccinated in a prior season.

Individuals who are black, Asian, uninsured, or living in poverty are more likely to need additional visits, Dr. Rand added.

The numbers are overwhelming, underscoring the need for new delivery systems, said Dr. Rand. "School-based systems would require a lot of coordination because school nurses would also be overwhelmed. They would need help from the public health infrastructure."

The numbers of visits needed are overwhelming, underscoring the need for new delivery systems.
DR. RAND

Emergency departments have been discussed as another possible vaccination delivery site.

However, the benefits of implementing an ED delivery system are unclear, Ms. Albertin said in an interview.

With data from the MEPS (2002-2004), her study analyzed the number of ED visits from a sample of 10,073 children aged 6 months to 18 years between October and December, and calculated how many of them had also had a primary care visit during that period.

"Overall 3.7% of the children had an ED visit, and about half of them had no primary care visit during that time period, and therefore might have benefited from being vaccinated in the ED," she said.

While it's a small percentage of the population, this number represents half of the pediatric ED population, which suggests that the benefits of an ED vaccine delivery system may be debatable, she said.

"Of course, EDs are busy places, and vaccination probably won't happen consistently, but is 1.9%—that's the percentage who didn't have a primary care visit—enough to start pushing for vaccination in the ED or not?" she asked.

While many pediatricians have been strong supporters of primary care vaccination, without reliance on the ED, Dr. Rand's study suggests perhaps multiple options will be needed.

In the meantime, "we need to avoid missed opportunities in primary care; give vaccines early—in time to deliver a second dose before outbreaks occur; [and] continue vaccinating until the vaccine supply runs out to allow a wider vaccination interval. … Black, Asian, uninsured, and impoverished patients may need focused outreach," she said. ■

Dr. LeRoy Graham, FCCP, comments: *While the benefits of universal pediatric influenza vaccine have been well described, Dr. Rand correctly cites the need for pragmatic health care planning to achieve this goal!*

Bronchopulmonary Dysplasia Clinic Streamlines Outpatient Care

BY KATE JOHNSON
Elsevier Global Medical News

TORONTO — The establishment of an interdisciplinary outpatient clinic for patients with bronchopulmonary dysplasia can significantly improve care and decrease hospital readmissions, reported Dr. Stephen Welty of Columbus Children's Hospital.

Before the establishment of his hospital's outpatient clinic, an analysis of 269 children with bronchopulmonary dysplasia (BPD) discharged to their general follow-up clinic in 2003 revealed that 29% were readmitted within 1 month of discharge, Dr. Welty said at the annual meeting of the Pediatric Academic Societies.

"When we first saw that number, we were horrified," he said. "And for two of those patients their stay [after readmission] was about 6 months, which was quite alarming."

Staff felt that factors contributing to the high readmission rate included family anxiety and lack of education about caring for their child at home, medical conditions such as reactive airway disease, and resource issues such as living remotely. In addition, BPD patients have complex, multidisciplinary needs that require social, nutritional, and developmental specialists, said Dr. Welty.

READMISSIONS WITHIN 30 DAYS OF DISCHARGE WENT FROM 29% BEFORE THE ESTABLISHMENT OF THE CLINIC TO 3% THE FIRST YEAR AFTER ITS ESTABLISHMENT.

"Our hypothesis was that by seeing children at regular scheduled intervals in an interdisciplinary BPD clinic, we would reduce readmission rates," he said.

The BPD clinic staff saw all patients before discharge to assess the adequacy of oxygenation and whether discharge was realistic, and then saw them again 2 weeks after discharge to reevaluate. A study comparing outcomes within 30 days of discharge found that readmissions went from 29% before the establishment of the BPD clinic to 3% the first year after its establishment, 6% the second year, and 5% the third year. Dr. Welty suggested this reduction in readmissions was mostly due to the prevention of pulmonary exacerbations.

The study estimated that the BPD clinic resulted in a cost saving of between 2.5 and 3 million dollars per year based on the fact that the average length of stay on readmission was 19 days, with an average cost of $53,600 per patient. The average cost of a BPD clinic visit is $533.

"We believe other potential benefits of the clinic are improved family satisfaction; improved feeding, nutrition, and growth; and improved developmental outcomes," he added. ■

Dr. LeRoy Graham, FCCP, comments: *Well-planned interdisciplinary care clinics for chronic diseases such as BDP improve outcomes and are thereby clearly cost effective.*

Infant Age May Affect Asthma Risk in Virus Season

SAN FRANCISCO — Infants who are 4 months old at the peak of the winter virus season have a 15% increased risk of developing asthma, Pingsheng Wu, Ph.D., reported in a poster presentation at the International Conference of the American Thoracic Society.

This suggests that there is a critical susceptibility period for the development of asthma, wrote Dr. Wu and associates of Vanderbilt University, Nashville, Tenn.

They conducted a study involving 95,310 children who were enrolled in the State of Tennessee's Medicaid program between 1995 and 2000, and who were followed until the age of 5 years.

The researchers correlated these records with records for the peak date of winter virus circulation each year as determined by the frequency of hospitalization for bronchiolitis caused by respiratory syncytial virus (RSV). Earlier studies established that hospitalization for RSV bronchiolitis during infancy is associated with a significantly higher risk of childhood asthma.

During the six winter seasons included in the study, the peak date of virus circulation ranged from Dec. 23 at the earliest to Feb. 10 at the latest.

Of all the children in the cohort, 14% developed asthma.

The investigators determined that children who were 120 days old on the peak day of virus circulation were most likely to develop asthma by 5 years of age, and children 337 days old on the peak day were least likely to develop asthma, after adjustment for a number of factors, including maternal smoking, gender, whether the child had siblings, race, rural versus urban residency, marital status, maternal education, birth weight, and birth term.

The difference in risk of developing asthma between the children at the peak and trough of susceptibility was 15%.

Among the implications of this finding is the possibility that the rate of childhood asthma could be lowered if efforts at preventing respiratory syncytial virus infection were targeted at infants during their critical susceptibility period, Dr. Wu and associates said.

—Robert Finn

‘Transplant Tourists’ Present Ethical Dilemma

U.S. physicians are often asked to provide follow-up care for patients who received organs abroad.

BY SHERRY BOSCHERT
Elsevier Global Medical News

SAN FRANCISCO — A patient comes to you with a new kidney, or lung, or heart, but he didn’t get it under your supervision. He’s a “transplant tourist,” who decided that being on an organ waiting list in the United States wasn’t good enough and traveled to another country to buy an organ and have it transplanted.

By U.S. standards, what he did was unethical. Now he’s back and in your office, asking for follow-up care. What do you do?

U.S. physicians “are all over the map in their views on what should be done here,” James DuBois, Ph.D., said at the annual meeting of the International Society for Heart and Lung Transplantation. As the chair of health care ethics at St. Louis University, he has interviewed physicians about this and other ethical questions in transplant care.

Some say it’s obvious that the patient should be accepted for treatment. Others believe that providing follow-up care to transplant tourists enables an unethical system that shouldn’t be supported. Yet other physicians find a work-around, sending these patients to a colleague who does not share their objections to transplant tourism, he noted.

The dilemma has become more common in recent years, Dr. DuBois added. The World Health Organization estimates that 1 in every 10 organ transplants worldwide now happens through transplant tourism. Despite a general medical consensus that paying for organs is unethical, organ sales and transplant tourism are thriving in countries like China, Pakistan, and Iran, where desperate patients with failing organs from more affluent countries including the United States seek help.

“Just as we speak different languages, we very often speak different moral languages,” Dr. DuBois said. In Iran, for example, the transaction is not discussed as organ sales but as “incentivized gifting” to living donors or to families of the deceased donor. “Would a funeral payment constitute a payment for an organ?”

Statements opposing payments for organs have been issued by the United Network for Organ Sharing, the Institute of Medicine, the World Health Organization, the Transplantation Society, and others based on concerns that poor or vulnerable donors could be exploited. In Iran, 85% of donors are poor or unemployed, and most have no health care or follow-up care, he noted. Dr. DuBois also cited allegations that Chinese prisoners have been killed to harvest organs for transplant tourists.

WHO estimates that 1 in 10 organ transplants worldwide now happens through transplant tourism.
DR. DUBOIS

The consensus against organ sales is far from unanimous, however. Sales (or the equivalent) exist in many countries, either legally or through the black market. The transplantation literature features a growing number of proposals to allow organ sales, he said.

He served on an Institute of Medicine task force that came out against payments for organs, but the panel could not agree on why sales should be opposed. In the end, it issued a conditional prohibition against sales, saying it would be premature to offer payments, assuming that rates of organ donations would continue to rise, he said.

In the United States, medical policies are “fairly silent” about what to do with returning transplant tourists, Dr. DuBois noted. A position statement issued by the American Society of Transplantation in March 2007 expressed concerns about the sources and quality of organs in transplant tourism, the risk of infectious disease transmission, and ethical issues, but said that optimal follow-up care should not be withheld.

One way to parse the issue ethically is to think of the difference between refusing to provide a kind of medical service and refusing care to a kind of patient, Dr. DuBois said. The former (such as refusing to perform an abortion yourself) typically is more acceptable socially and legally than the latter (such as refusing care to a minority group).

Rejecting transplant tourists “more resembles refusing to treat a certain kind of patient,” he said. “The kind of services you’re providing are routine follow-up services.”

Physicians who want to avoid facing transplant tourists can try to discourage patients from going abroad for organs, he suggested, and collaborate to form policies that discourage transplant tourism. ■

Respiratory Complications Rise After Surgery in 1989-2004

BY BRUCE JANCIN
Elsevier Global Medical News

DALLAS — The incidence of pulmonary complications after major abdominal surgery climbed nationally by 21% overall between 1989 and 2004, with the biggest increases occurring in respiratory failure and adult respiratory distress syndrome, Dr. Carlos H. Orces reported at the annual meeting of the Society of Hospital Medicine.

BUCKING THE OVERALL UPWARD TREND IN PULMONARY COMPLICATIONS FOLLOWING SURGERY WERE ATELECTASIS AND PLEURAL EFFUSION.

Bucking this overall upward trend in pulmonary complications after surgery were atelectasis and pleural effusion. The risks of those particular pulmonary complications declined over the study period, said Dr. Orces, of Laredo (Tex.) Medical Center.

He used data from the National Center for Health Statistics’ National Hospital Discharge Survey to determine the number of adults who had major abdominal surgery during 1989-2004. In that period, just under 12,900,000 adults underwent total colectomy, partial excision of the large intestine, cholecystectomy, appendectomy, vagotomy, gastrectomy, splenectomy, radical pancreaticoduodenectomy, exploratory laparotomy, or abdominal perineal resection of the rectum.

Postoperative pulmonary complications were significantly more frequent in men, with an incidence of 7.8%, compared with 5.7% in women.

These pulmonary complications prolonged hospital stays by an average of 10 extra days over the mean 6-day length of stay for abdominal surgery patients who did not experience a pulmonary complication.

Postoperative pulmonary complications increased with age. For example, among men who underwent major abdominal surgery in the period from 2001 through 2004, the incidence was 4% in those less than 45 years, 6% in 45- to 64-year-olds, 12.1% in those aged 65-84, and 15.6% in men aged 85 or older, Dr. Orces said.

The incidence of postoperative adult respiratory distress syndrome jumped 2.56-fold between 1989-1992 and 2001-2004.

The incidence of respiratory failure climbed 2.24-fold, while the incidence of pneumonia increased by a more modest yet statistically significant 13%.

In contrast to the increase in respiratory distress syndrome, respiratory failure, and pneumonia, the incidence of postoperative pleural effusion plunged by 42% over the study period, and atelectasis declined by 15%. ■

Follow-Up on Thoracic Stent-Grafts Encouraging

BY SHERRY BOSCHERT
Elsevier Global Medical News

SEATTLE — Follow-up data on 190 patients who underwent endovascular treatment for thoracic aortic disease between 1997 and 2006 showed generally good results, Dr. John F. Reidy said at the annual meeting of the Society for Interventional Radiology.

The procedure was technically successful in all but one case. The mortality 30 days after the procedure was 8%, and later mortality was 9%, rates which "would compare very favorably with surgery in such patients, " said Dr. Reidy of Guy's and St. Thomas' Hospital Trust, London.

Many of the patients were very sick and were poor candidates for surgery, "or as we would say, 'Not fit for a haircut,' " he added. Patients were treated acutely in 62 cases and had an elective procedure for chronic disease in 128 cases.

The most feared complication, paraplegia, developed in 4% (seven patients). After cerebrospinal fluid [CSF] drainage, four recovered fully, one recovered partially, and one had permanent paraplegia. One of the seven died.

Strokes occurred in 4% of patients, all during the endovascular procedure. Three of these patients recovered fully, and one partially recovered. Two died, and one showed no recovery.

The predominant indication for treatment was degenerative aneurysm in 106 patients. Other indications included acute dissection, chronic dissection, mycotic aneurysm, trauma, coarctation, or Takayasu's arteritis.

"All in all, this is very encouraging and shows that the endografts are here to stay," Dr. David M. Williams of the University of Michigan, Ann Arbor, said in formal commentary after Dr. Reidy's presentation. "About the only conditions in which it's really uncertain what role [endografts will] play would be the patient with marginal anatomy and in patients with acute uncomplicated dissection."

The single-institution results from Dr. Reidy's series fairly closely match results from a multicenter, controlled study of 142 patients treated with thoracic stent-grafts, Dr. Williams noted (J. Vasc. Surg. 2005;41:1-9). The study admitted only patients with degenerative aneurysm who had 2-cm landing zones on either side of the aneurysm, and did not include patients with active leaks, acute or chronic dissections, or mycotic aneurysms. "In general, the patients in Dr. Reidy's group are much sicker," he said.

The technical success rate in that series was 98%. Procedure times were 150 minutes in the multicenter study and 113 minutes in the single-center series. Patients lost 506 cc and 500 cc of blood in the multicenter and single-center cohorts, respectively. Hospital stays were 7.6 days and 7.4 days, respectively.

As in Dr. Reidy's series, the stroke rate was 4% in the multicenter study. Paraplegia occurred in 3%, compared with 4% in Dr. Reidy's series. The 30-day mortality was lower (2%) in the multicenter study than in the single-center series (8%), probably because the former did not include patients with acute disease, Dr. Williams suggested.

The similarity in results "points out that this is going to be a very durable procedure worldwide," he said.

Early in the series, the procedure was done under general anesthesia, "but our routine now is to do regional and an epidural anesthetic," Dr. Reidy said. "We think this has advantages in detecting paraplegia earlier" so that CSF drainage can begin.

The surgeons at Dr. Reidy's institution did not routinely transpose the subclavian artery. "If there are concerns about the landing zone where we're going to cover the subclavian, and we're not going to be in an ideal position, we would do a right-to-left carotid-to-carotid bypass 1 week earlier," he said.

Carotid-to-carotid bypass was the most common additional procedure required; it was done in 16 patients. Seven patients with severe arterial disease needed repair of an access artery. Other additional procedures included embolectomy, stent-grafts for abdominal aortic aneurysm, aorto-iliac conduit, and dissection of bare stents. ■

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Medical Records Technology Can Promote Patient Safety

Ideally, hospitals, pharmacies, and insurers will use technology to integrate information and coordinate their systems.

BY HEIDI SPLETE
Elsevier Global Medical News

WASHINGTON — Health information technology's greatest potential contribution to patient safety lies in areas related to record keeping and record retrieval, David N. Gans said at a conference sponsored by the National Patient Safety Foundation.

"Adding technology gives you the opportunity to improve patient safety," but the technology must be used properly for there to be an impact, said Mr. Gans of the Medical Group Management Association.

Medical groups that reorganize their work flow will see the greatest benefits from health information technology.

Ideally, hospitals, pharmacies, and insurers will be able to use the technology to integrate information and coordinate their systems, he said.

But many medical practices have not fully embraced electronic health records (EHRs) or other types of health information technology as a way to improve patient safety.

To find the extent to which medical groups implement safety practices with and without technology, Mr. Gans and his colleagues surveyed 3,629 medical groups that had completed the Physician Practice Patient Safety Assessment (PPPSA) (Health Affairs 2005;24:1323-33).

The goal of the PPPSA is to provide information that medical groups can incorporate into procedures that will improve patient safety.

The PPPSA was developed by the Medical Group Management Association's center for research, the Health Research and Educational Trust, and the Institute for Safe Medication Practices.

The assessment consists of 79 questions related to patient safety in six areas:

- Medications (17 questions).
- Handoffs and transitions (11 questions).
- Surgery and invasive procedures, sedation, and anesthesia (6 questions).
- Personnel qualifications and competency (10 questions).
- Practice management and culture (22 questions).
- Patient education and communication (13 questions).

For each question in these six safety domains, respondents can choose from among five answer choices ranging from "unaware or aware but no activity to implement" to "fully implemented everywhere."

Overall, more than 70% of the groups surveyed used paper medical records, while the others used a scanned-image system, a relational database, or other methods.

But practices that have electronic health records still use paper forms for certain functions, primarily for laboratory orders, he said.

"Even among practices with EHRs, 30% used paper lab forms," he said.

In addition, 16% of the practices with EHRs used manual methods to order prescriptions and 13% used manual methods to assess drug interactions.

To illustrate one practice's experience with patient safety self-assessment, Christine A. Schon of the Dartmouth-Hitchcock Medical Center in New Hampshire shared her group's experience with the PPPSA.

The data came from the Nashua branch of the medical center and included 62 providers in five locations that serve about 250,000 patients.

The medical director of the Nashua division initiated the group's assessment as part of an ongoing goal to improve patient safety.

"We are almost paper chartless," Ms. Schon said.

"But what we want to do is make sure we are managing our patient population effectively," she said.

The Dartmouth-Hitchcock group used the PPPSA as a tool to evaluate how well the group was meeting the National Patient Safety Goals. The PPPSA took about 3 hours to complete, although the time will vary according to the size of your practice, she noted.

As a result of taking the PPPSA, the Dartmouth-Hitchcock group learned that technology isn't everything.

"Our biggest 'aha' moment, as I called it, was [when we realized] that we have a tendency to rely very heavily on electronic medical records, and so we found that if we can't do it electronically, we aren't thinking about doing it," Ms. Schon said.

"We predominantly had good electronic systems in place to make sure that we were doing safe practices and engaged with the patient," she said.

But the group did find that, although physicians were focused on entering information into the EHR and checking for interactions, they weren't really making sure that patients understood their medications.

"That's an area where you still have to rely on a piece of paper and a conversation," Ms. Schon noted.

Patients themselves are not always reliable if doctors ask what medications the patients are taking, she added.

As a result of the assessment process, Ms. Schon's group is considering the use of a checklist to review with patients before they leave the hospital. The sheet would explain what medications the patients are taking and why.

In addition, the group plans to stop using medication samples because they can confuse patients who take generic versions of the brands. "We are the health care safety net for our community," Ms. Schon said. ■

For more information about the PPPSA or about how to order PPPSA materials, visit www.physiciansafetytool.org.

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Cigna, Aetna Top List Of Insurance Payers

BY ALICIA AULT
Elsevier Global Medical News

In 2006, Cigna Healthcare moved from fifth place to top ranking among national payers, and Aetna moved from fourth place to second, according to the second annual assessment of overall payment performance conducted by one of the nation's largest physician revenue management companies.

Not surprisingly, state Medicaid programs ranked near the bottom.

The performance rankings were compiled for the second year in a row by AthenaHealth, a Watertown, Mass.–based company that collects about $2 billion a year for medical providers.

AthenaHealth used claims data from 8,000 providers, representing 28 million "charge lines," or line items. The medical services were billed in a total of 33 states.

The ranking included national payers that had at least 120,000 charge lines and regional payers with at least 20,000 charge lines.

In 2005, Humana was the top-ranked payer, followed by Medicare. A year later, Medicare held the third position, while Humana dropped to fourth.

Rounding out the top eight national payers were UnitedHealth Group, WellPoint, Coventry Health Care, and CHAMPUS/Tricare.

According to AthenaHealth, there were several trends observed from year to year. In 2006, days in accounts receivable (DAR) dropped by 5%, from 36.2 days to 34.4 days. Blue Cross & Blue Shield of Rhode Island had the lowest DAR at 16.8 days. New York's Medicaid plan had the highest, at 111 days.

Payers are also asking patients to pay more up front, which places a greater collections burden on physicians.

During 2006, there was a 19% increase in the amount of billed charges that were transferred to patients, according to AthenaHealth.

The overall ranking was based on how often claims were resolved on the first pass, denial rate, denial transparency, percentage noncompliance with national coding standards, and percentage of claims requiring medical documentation.

Denial rates ranged from a low of 4% at Cigna's southern plan to a high of 48% at Louisiana's Medicaid program.

The Medicaid programs were laggards on all performance measures. The Illinois Medicaid program paid medical claims on the first attempt only about 30% of the time, and was the second slowest payer overall, with an average 103 days to pay a claim. In Texas, physicians resubmitted denied claims at least twice 47% of the time, according to AthenaHealth.

"We are seeing disturbing administrative process breakdowns with some state Medicaid plans that are resulting in a growing number of physicians no longer accepting new Medicaid patients," said Jonathan Bush, chairman and CEO of AthenaHealth.

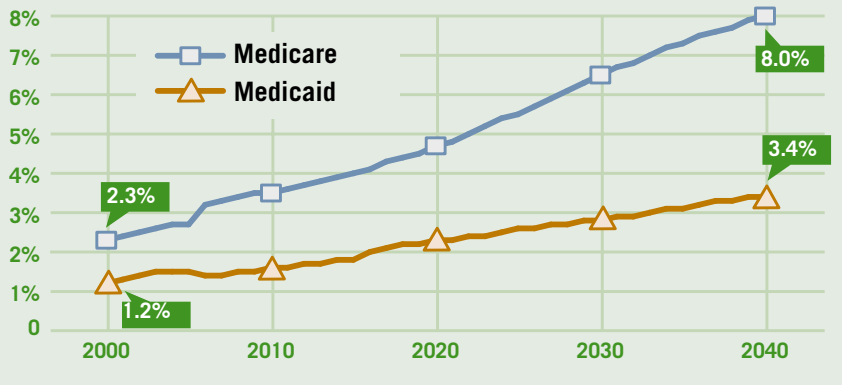
The company said that some states have experimented with managed care as a solution to Medicaid's administrative difficulties.

But in Georgia, that may have backfired. A year after patients were moved into managed care, the Medical Association of Georgia "has had to troubleshoot more than 500 complaints from physicians, most of which should have been eliminated by the Care Management Organizations shortly after the start-up," said Dr. S. William Clark III.

The performance rankings have been posted on the Web at www.athenapayerview.com. ■

DATA WATCH

Medicare Expected to Increase at a Faster Rate Than Medicaid as Percent of GDP



Notes: Based on 2005 and 2006 data. GDP is gross domestic product.
Source: Government Accountability Office

ELSEVIER GLOBAL MEDICAL NEWS

Family Conference Benefits Relatives of Dying Patients

BY ROBERT FINN
Elsevier Global Medical News

SAN FRANCISCO — A proactively scheduled and structured end-of-life conference for relatives of intensive care unit patients reduces stress, anxiety, and depression in family members, according to a randomized controlled trial reported by Dr. Élie Azoulay at the International Conference of the American Thoracic Society.

The trial, conducted with family members of 126 patients dying at 22 ICUs in France, compared the structured conference to the usual practice at each ICU, which rarely involved a formal conference scheduled in advance, said Dr. Azoulay of the Saint-Louis Hospital, Paris.

The structured conferences were significantly longer in the intervention group (a median of 30 minutes vs. 20 minutes), more physicians were present (a median of two vs. one), and family members spoke for far longer (a median of 13.5 minutes vs. 5 minutes).

An end-of-life conference helps family members voice concerns and reduce feelings of guilt.
DR. AZOULAY

Patients whose families were in the intervention group also underwent significantly fewer unnecessary interventions such as the use of mechanical ventilation, vasopressors, or dialysis (N. Engl. J. Med. 2007;356:469-78).

Contacted by telephone 90 days later, family members in the intervention group scored significantly lower on the Impact of Event Scale (IES), a measure of symptoms related to posttraumatic stress disorder. In the control group, 69% of the respondents had IES scores above 30, compared with only 45% in the intervention group.

Similarly, control group respondents had significantly higher scores on the Hospital Anxiety and Depression Scale, including higher scores on both the anxiety and depression subscales, compared with respondents from the intervention group.

More than twice as many family members in the control group reported receiving newly prescribed psychotropic drugs after the death of the patient (23% vs. 11%).

The structured interview was based on the mnemonic VALUE (see box), which emphasizes the role of the caregiver in eliciting information and questions from the family members and listening to their responses. Family members also received a bereavement-support leaflet.

The leaflet describes the organization of an intensive care unit, includes a glossary of terms such as "sedation" and "palliative care," discusses practical matters such as paperwork and the disposition of the patient's body, and prepares family members for the emotions associated with bereavement.

Dr. Azoulay said in an interview that in his view the most important part of the leaflet is the first two sentences, which read, in English translation, "You have come to see a loved one in the intensive care unit. The doctor has just told you that none of the treatments can prevent your loved one from dying." In his experience, many physicians never come right out and say this in a way that family members can understand, and as a result family members are often surprised at the patient's death, believing that recovery is still possible.

With the use of the VALUE structure, a scheduled end-of-life conference helps family members express the patient's wishes, helps them voice concerns and reduce feelings of guilt, enables more physicians and family members to be present, and increases the amount of time provided for end-of-life information.

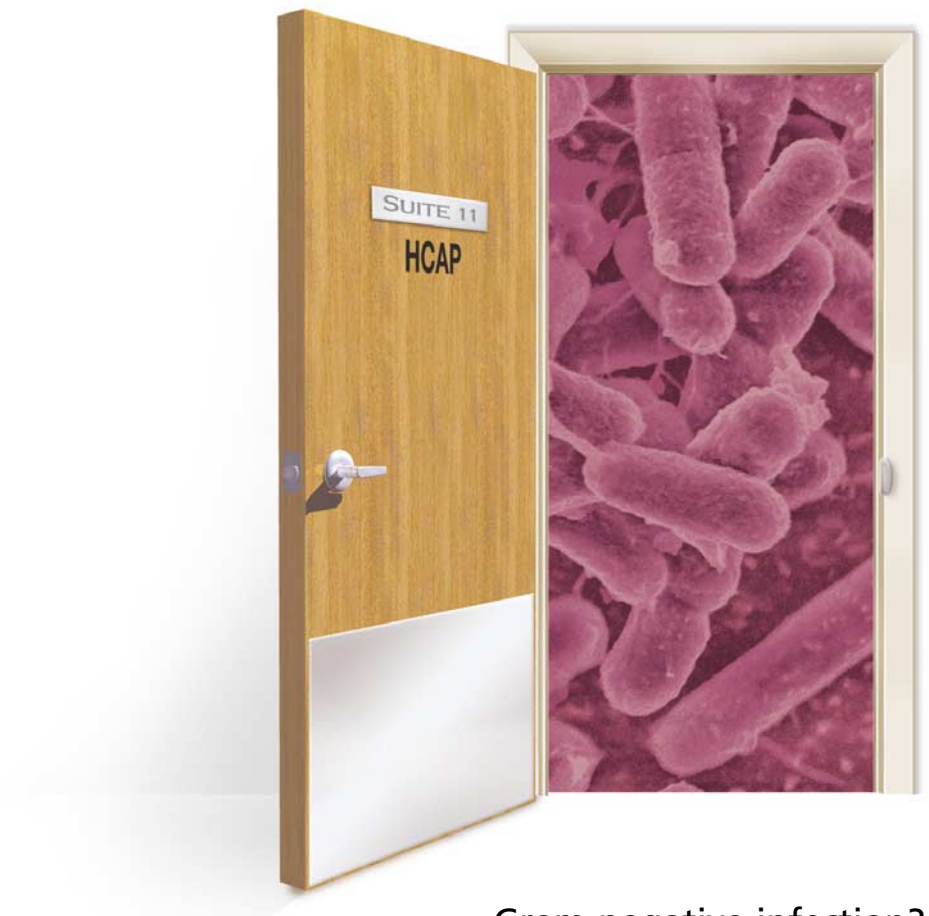
While acknowledging that the longer, structured end-of-life conferences place more of a burden on physicians, Dr. Azoulay compared this burden with others that are routine in critical care, such as frequent hand washing and donning gowns. ■

VALUE Mnemonic

V: Value and appreciate what the family members say.
A: Acknowledge the family members' emotions.
L: Listen.
U: Ask questions to allow the caregiver to **U**nderstand who the patient was as a person.
E: Elicit questions from family members.

Source: Dr. Azoulay

knock, knock.



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HCAP defined as: healthcare-associated pneumonia.

Please see brief summary of prescribing information on adjacent page.