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CHEST Physician

THE NEWSPAPER OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS

JIA LIU

MRI images identified structural damage in the lungs of individuals with high exposure to secondhand smoke, said Dr. Chengbo Wang.

MRI Shows Secondhand Smoke Damage

BY PATRICE WENDLING
Elsevier Global Medical News

CHICAGO — A novel magnetic resonance imaging technique may have provided the proverbial smoking gun in the secondhand smoking debate.

Using hyperpolarized helium-3 diffusion MRI, researchers at the University of Virginia in Charlottesville and the Children's Hospital of Philadelphia have for the first time identified structural damage in the lungs of individuals with high exposure to secondhand smoke.

Although it's known that exposure to secondhand cigarette smoke increases the risk of coronary heart disease and lung cancer, the evidence has not been sufficient to prove that secondhand smoke causes chronic obstructive pulmonary disease (COPD), which occurs in up to 30% of smokers, said lead investigator Chengbo Wang, Ph.D., at the annual meeting of the Radiological Society of North America. Prior methods such as shortness-of-breath tests or pulmonary function tests were not sensitive enough to detect early COPD in people with secondhand smoke exposure, and computed tomography exposes patients to ionizing radiation.

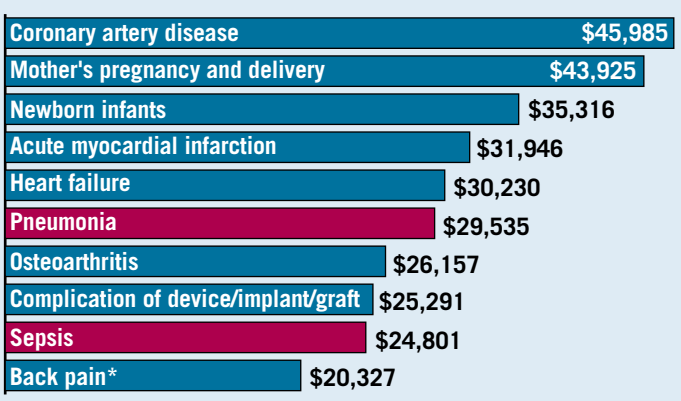
The technique used by Dr. Wang and his associates is similar to conventional MRI, except that the images are acquired after the patient inhales hyperpolarized helium.

See **Secondhand Damage** • *page 3*

VITAL SIGNS

10 Most Expensive Conditions Treated in Hospitals

(total national bill in millions of dollars)



*Includes spondylosis and intervertebral disc disorders.
Note: Based on data from the 2005 Nationwide Inpatient Sample.
Source: Healthcare Cost and Utilization Project

ELSEVIER GLOBAL MEDICAL NEWS

Barrier Protections Crucial in Pandemic Respiratory Disease

Simple steps will be 'highly effective.'

BY JONATHAN GARDNER
Elsevier Global Medical News

Hand-washing and wearing masks, gloves, and gowns could be more effective at interrupting the spread of a pandemic respiratory disease than the use of antibiotic or antiviral drugs, according to an analysis published online in BMJ.

In a meta-analysis of research into the means of reducing the spread of respiratory diseases, Cochrane Collaboration researchers found that "relatively cheap" personal hygiene measures significantly reduced the odds of developing the diseases (BMJ 2007 Nov. 28 [Epub doi: 10.1136/bmj.39393.510347.BE]).

The researchers said a meta-analysis of six case-control studies with comparable data, all of them analyzing the spread of severe acute respiratory syndrome, showed that wearing an N95 mask (OR 0.09), wearing a mask (OR 0.32), wearing a gown (OR 0.23), wearing gloves (OR 0.43), and hand-washing more than 10 times a day (OR 0.45) can reduce the incidence of respiratory diseases. When hand-washing and wearing masks, gloves, and gowns were combined, the odds ratio was 0.09.

The numbers needed to treat to avert a single case of respiratory disease were low: hand-washing (four), masks (six), N95 masks (three), gloves (five), gowns (five), and all measures combined (three).

"Simple public health measures seem to be highly effective at reducing the transmission of respiratory viruses, especially when they are part of a structured program including instruction and education and when they are delivered together," wrote the researchers, led by Dr. Tom Jefferson, coordinator at the Cochrane Disease Field in Allesandra, Italy. "Further large pragmatic trials are needed to evaluate the best

See **Pandemic** • *page 2*

INSIDE

Medicare May Expand CPAP Coverage

BY MARY ELLEN SCHNEIDER
Elsevier Global Medical News

Medicare may soon begin providing coverage for continuous positive airway pressure devices for beneficiaries who have been diagnosed with obstructive sleep apnea using unattended home monitoring.

The coverage proposal is an expansion of Medicare's current policy, which provides coverage for continuous positive airway pressure (CPAP) only when a diagnosis of obstructive sleep apnea (OSA) has been confirmed using polysomnography in a sleep laboratory.

"Our proposed policy to extend coverage for continuous positive airway pressure provides more options for Medicare beneficiaries and their treating physicians," Kerry Weems, acting administrator for the Centers for Medicare and Medicaid Services, said in a statement.

The CMS released the proposal in December, and officials at the agency plan to issue a final national coverage determination in March 2008. Medicare officials estimate that as many as 4 million Medicare beneficiaries suffer from OSA.

The CMS proposal would extend coverage in cases where the diagnosis was made as a result of a combination of a clinical evaluation and unattended home sleep monitoring using a type II, III, or IV device. In addition, Medicare is proposing to cover CPAP when the diagnosis of OSA is made through a clinical evaluation or another type of diagnostic test, as long as the

See **CPAP Coverage** • *page 10*

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More Guidelines Needed

Pandemic • *from page 1*

combinations. In the meantime, we recommend implementing the following interventions combined to reduce the transmission of respiratory viruses: frequent hand-washing (with or without antiseptics), barrier measures (gloves, gowns, and masks), and isolation of people with suspected respiratory tract infections.

In an accompanying editorial, Dr. Martin Dawes, family medicine chairman at McGill University, Toronto, criticized national and international public health officials for not helping physicians understand the most effective ways to reduce the spread of respiratory disease.

"Government and international Web sites such as the World Health Organization Web site on the status of pandemic flu are of some help in keeping health professionals up to date with the latest information," he wrote. "However, regularly updated evidence-based guidelines containing levels of recommendation and, where possible, measures of effectiveness such as [number needed to treat] would be very much more helpful to front line clinicians. Guidelines also highlight where the strength of the evidence is weak and more research is needed. We have an annually updated guideline on the management of hypertension, and it reflects badly on the consistency of knowledge translation that one is not available for influenza (doi 10/1136/bmj.39406.511817.BE).

The investigators searched medical library databases for papers in all languages describing randomized trials; cohort, case-control, and crossover studies; and before and after time series on measures to reduce the spread of respiratory diseases. They found 2,300 titles, but excluded 2,162 based on abstracts.

They retrieved 138 full papers, but found poor data quality and comparability in all but the six case-control studies analyzed. ■

Dr. Doreen Addrizzo-Harris, FCCP, comments: *This study emphasizes that simple, low-cost measures (hand-washing, masks, and gloves) can significantly impact the spread of respiratory disease. The key to success is in developing a structured program that educates medical and ancillary staff to make them aware of the benefits of employing these simple measures. This not only has to be applied in hospital settings, but also is important for ambulatory practices.*

Meet CHEST Physician's New Editorial Advisory Board Members

DR. NICOLA A. HANANIA, FCCP

Dr. Nicola (Nick) A. Hanania, FCCP, is an Associate Professor of Medicine in the Department of Medicine, Section of Pulmonary and Critical Care Medicine, and director of the Asthma Clinical Research Center at the Baylor College of Medicine in Houston, Tex. He is also director of the Asthma Adult Clinic and Pulmonary Diagnostic services at Ben Taub General Hospital in Houston. He is currently the chair of the ACCP Council of NetWorks. Dr. Hanania is a member of the editorial board of *Respiratory Medicine* and an ad-hoc reviewer for several peer-reviewed journals, including *CHEST* and *European Respiratory Medicine*. He is principal investigator for the American Lung Association Clinical Research Center at Baylor College of Medicine.

Dr. Philip Marcus, FCCP, is in pulmonary medicine private practice in Long Island, N.Y. He is also chief of the Division of Pulmonary Medicine at St. Francis Hospital in Roslyn, N.Y. He has been involved in education of medical students and is currently Clinical Professor of Medicine and Pharmacology at the New York College of Osteopathic Medicine, where he is the course director for the respiratory system course. His interests are in the area of obstructive lung diseases and pulmonary oncology. He has served as chair of the ACCP Practice Management Committee and is currently vice-chair of the Private Practice NetWork. He has also served as chair of the Fellows Asthma Course at CHEST 2006 and CHEST 2007.

DR. PHILIP MARCUS, FCCP

Dr. Mark L. Metersky, FCCP, is Professor of Medicine at the University of Connecticut School of Medicine, Farmington, in the Division of Pulmonary and Critical Care, and is director of the Pulmonary/Critical Care Fellowship Program. Dr. Metersky serves on the Technical Expert Panel for the Centers for Medicare and Medicaid Services National Pneumonia Project, the Quality Improvement Committee and the Health and Science Policy Committee of the ACCP, and the AMA Performance Measures Implementation and Evaluation Advisory Committee of the Physician Consortium for Performance Improvement. He is a reviewer for several peer-reviewed journals and serves on the editorial board for *CHEST*.

DR. MARK L. METERSKY, FCCP

Dr. W. Michael Alberts, FCCP, is Professor of Oncology and Medicine in the Department of Interdisciplinary Oncology at the University of South Florida College of Medicine in Tampa, Fla. He is the chief medical officer at the H. Lee Moffitt Cancer Center and Research Institute. His research and scholarly interests include the diagnosis and management of lung cancer, occupational airways disorders, and the business of medicine. He is an editorial board member for *CHEST* and serves on the editorial boards of several other journals. As an active ACCP Fellow since 1983, Dr. Alberts has served the ACCP in many leadership roles, including President, chair of the Continuing Education Committee and the Council of Governors, and serving on the Board of Regents and Executive Committee of the Board of Regents. ■

DR. W. MICHAEL ALBERTS, FCCP

IN THIS ISSUE

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CHEST PHYSICIAN

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Four Protein Markers May Predict Lung Cancer

BY JOHN R. BELL
Elsevier Global Medical News

Serum levels of four proteins showed a clinically useful predictive value for lung cancer, according to new findings from researchers at Duke University Medical Center, Durham, N.C.

Dr. Edward F. Patz Jr. and colleagues reported that their panel predicted cancer in patient serum samples with a sensitivity of 89.3% and a specificity of 84.7% (J. Clin. Oncol. 2007;25:5578-83).

Dr. Patz and colleagues first used two preliminary separate substudies to identify candidate proteins.

The first substudy used gel electrophoresis to compare levels of proteins in the blood of 10 newly diagnosed lung cancer patients and in 10 controls.

This substudy yielded four proteins: transferrin, retinol binding protein (RBP), haptoglobin, and fibrinogen beta chain. Fibrinogen beta chain was excluded, however, because of its potential to confound later test results.

The second substudy used matrix-assisted laser desorption/ionization time-of-flight mass spectrometry to assess blood samples from another group of patients with lung cancer and another control group. This step identified the protein alpha$_1$-antitrypsin (ATA).

The investigators also included two proteins previously identified by other researchers as having prognostic value when combined with other markers: carcinoembryonic antigen (CEA) and squamous cell carcinoma antigen (SCC).

Dr. Patz and colleagues next assessed levels of those six proteins in 100 sequential lung cancer patients and 100 age- and gender-matched controls via enzyme-linked immunosorbent assay (ELISA).

Within the patient group and the control group, 50 blood samples were assigned to a training phase and 48 and 49 samples to the test phase, respectively. The test phase used a tree-structured analysis algorithm called classification and regression tree analysis. This assigned each patient to one of seven groups, called nodes, based on the patient's levels of CEA, RBP, ATA, and SCC.

CLASSIFICATION INTO ONE OF THREE PARTICULAR NODES MEANT THAT A PATIENT HAD A 90% CHANCE OF HAVING LUNG CANCER.

The resulting classification tree correctly classified 44 of 50 samples (88%) from patients with lung cancer and 41 of 50 (82%) persons without cancer.

This translated to a sensitivity of 89.3% and a specificity of 84.7%.

These results were then subjected to independent, blinded validation. This confirmed the predictive value of the classification nodes.

Classification into one of three particular nodes meant that a patient had a 90% chance of having lung cancer, the investigators noted.

"The most immediate scenario in which this panel could be used is when an indeterminate pulmonary nodule is detected on imaging studies, whether detected in a screening trial or performed for other indications," the investigators wrote.

"Those patients with a low-risk clinical panel who do not fall into a malignant terminal node could be followed with imaging studies at intervals determined by the risk probability of the terminal node," the investigators added. ■

Effects Increased in Kids

Secondhand Damage • *from page 1*

The technique involves using a standard 1.5-tesla commercial scanner, which is modified by the addition of a multinuclear imaging package and a radiofrequency coil tuned to the helium frequency of 48.5 MHz. The intensity of the MR signal is enhanced by a factor of more than 100,000 on a 1.5-tesla scanner and by a factor of 1 million on a 0.15-tesla scanner. This translates into increased speed, signal-to-noise ratio, and sensitivity, thereby allowing for the evaluation of lung structures on a microscopic level, Dr. Wang explained.

It may be that having chronic irritation in the lungs interferes with new alveoli development.
DR. ALTES

The MR images show how far the helium atoms diffuse inside the lungs over 1.5 seconds. In some smokers, the alveoli become enlarged and develop holes, allowing the helium atoms to infiltrate the lung microstructure to a greater extent. This is reflected in higher apparent diffusion coefficient (ADC) values, which have been shown to be larger when measured in emphysematous lungs, compared with healthy lungs (Radiology 2006; 239:875-83).

Long-time scale ADC measurements are more sensitive to mild emphysematous changes than are the more conventional short-time scale ADC measurements, reported Dr. Wang, a magnetic resonance physicist in the department of radiology at Children's Hospital.

For the study, 60 individuals underwent helium diffusion MRI after inhalation of 50 cc of hyperpolarized helium diluted with nitrogen to a total volume of approximately one-third of their forced vital capacity, as measured by spirometry on the day of imaging.

In all, 23 individuals had low smoke exposure, defined as never having lived with a smoker nor worked in an occupation with high exposure to secondhand smoke; 22 had high exposure, defined as at least 10 years' exposure at home or work; and 15 were current or former smokers.

At baseline, their age ranged from 41 to 79 years, and the range of percent-predicted forced expiratory volume in 1 second values was 86%-112% (low-exposure group), 79%-120% (high-exposure group), and 49%-121% (current or former smokers). The threshold for an elevated ADC was set as 0.024 cm^2/sec or greater, which was two standard deviations above the mean ADC for all participants with low exposure to secondhand smoke.

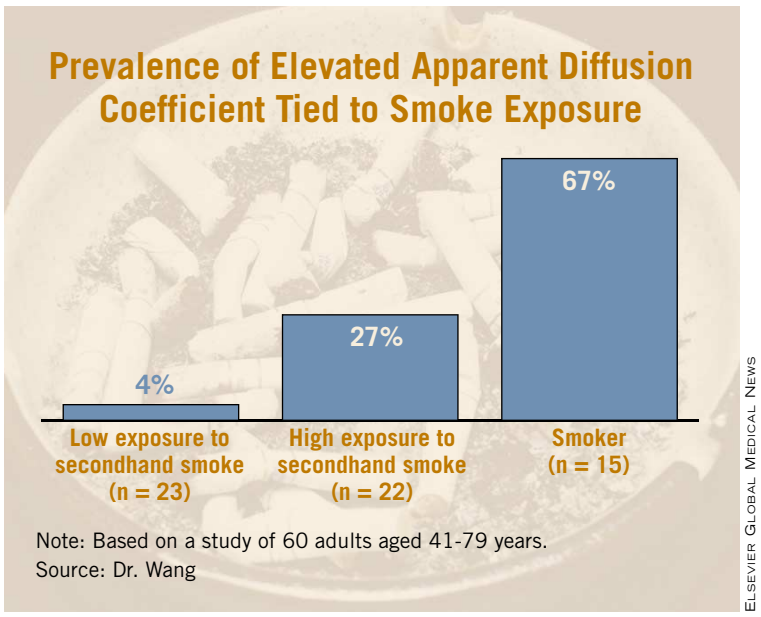
Only 1 (4%) of 23 participants with low exposure had an elevated ADC value, compared with 6 (27%) of 22 participants with high exposure and 10 (67%) of 15 smokers. The difference in ADC values was significant between smokers and the low-exposure group (P less than .001) and between the high- and low-exposure groups (P = .047).

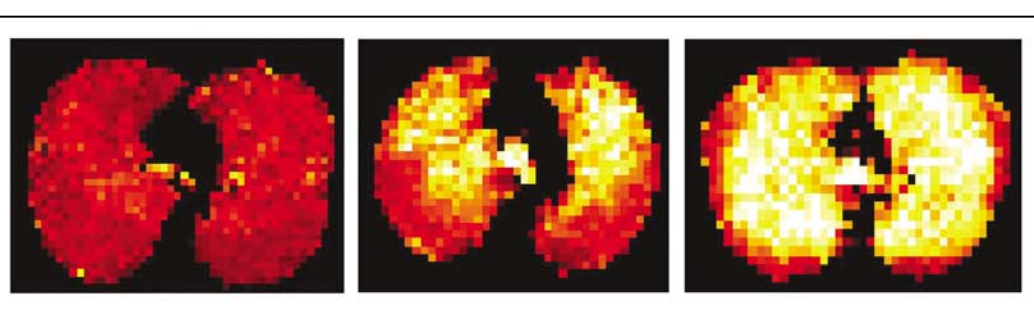
As for why some smokers had normal ADC values, Dr. Wang said that they may be genetically less susceptible to the harmful effects of smoking, while others are more sensitive and thus incur more lung damage.

There were not enough data to stratify the results by age at exposure, but the investigators believe that their data suggest that the effects of secondhand smoke may be even greater in those exposed during childhood when the lungs are in early stages of development.

"You are probably growing new alveoli up until age 8 or maybe even later, and so it may be that having this chronic irritation in the lungs would interfere with that process," said Dr. Talissa Altes, director of clinical research in the department of radiology at Children's Hospital and a senior author of the study. "It has been previously shown that children who have a high exposure to secondhand smoke have an increased risk of asthma, so it may be that inflammatory change would be detrimental to lung development."

The study was funded by the National Institutes of Health, the Flight Attendant Medical Research Institute, and the Commonwealth of Virginia Technology Research Fund. Siemens Medical Solutions provided the scanner. Neither Dr. Wang nor Dr. Altes disclosed any personal conflicts of interest. ■





RADIOLOGICAL SOCIETY OF NORTH AMERICA/DR. CHENGBO WANG

The hyperpolarized helium MRI images show the lungs of individuals with low exposure to secondhand smoke (left), high exposure to secondhand smoke (center), and those of smokers (right). The red color indicates normal alveoli, normal apparent diffusion coefficient (ADC) values, and healthy lungs, while yellow indicates enlarged alveoli, elevated ADC values, and lung damage.

Dr. Nicola Hanania, FCCP, comments: *Over the last few years, there has been a growing interest in novel radiological techniques to assess the anatomical changes that occur in the terminal airways and the lung parenchyma in patients with airway disease such as emphysema. This report describes the use of one such noninvasive technique that can reflect changes that occur in the distal lung as a result of secondhand exposure. The use of polarized He during MRI imaging permits the assessment of diffusion across the alveolar membrane, which is abnormal in patients with lung damage caused by smoking. This is a very promising research tool that permits early detection of lung damage caused by smoking. This is also a very promising research tool that permits early detection of lung disease, such as emphysema, in patients at risk, even before the onset of physiologic and clinical abnormalities.*

Fospropofol With Fentanyl Provides Adequate Sedation

BY PATRICE WENDLING
Elsevier Global Medical News

CHICAGO — A 6.5 mg/kg dose of the investigational sedative fospropofol disodium appears to be the best dosing regimen for patients undergoing flexible bronchoscopy, according to preliminary phase III data reported at CHEST 2007, the annual meeting of the American College of Chest Physicians.

Fospropofol disodium (Aquavan) is a prodrug of propofol, and has previously been shown to be effective in patients undergoing colonoscopy. Study sponsor MGI Pharma submitted a new drug application for Aquavan to the Food and Drug Administration in September 2007.

The average time to sedation for standard-dose patients was 6 minutes.
DR. SILVESTRI

The study, led by Dr. Brad D. Vincent and presented at the meeting by Dr. Gerald A. Silvestri, FCCP, both of the Medical University of South Carolina in Charleston, randomized 150 adults, age 18 years or older, to a standard dose of fospropofol disodium 6.5 mg/kg and 102 patients to a low dose of 2 mg/kg, both after receiving fentanyl citrate 50 mcg.

Based on the American Society of Anesthesiologists Physical Status Classification system, many of the patients (43%) were classified as having severe systemic disease or systemic disease that is a constant threat to life.

The primary end point of the industry-sponsored study was sedation success defined as a patient having three consecutive Modified Observer's Assessment of Alertness/Sedation (MOAA/S) scores of 4 or less after administration of the study drug and completion of the procedure without the use of alternative sedative medication and without manual or mechanical ventilation.

The secondary end point of treatment success was defined as completion of the procedure without use of alternative sedatives and without manual or mechanical ventilation.

Significantly more patients in the standard-dose group achieved sedation success than in the low-dose group (89% vs. 27.5%), the investigators reported. A MOAA/S score of less than 1 during the procedure was reported by 14% of the standard-dose group and 6% of the low-dose group.

The average time to sedation for standard-dose patients compared with low-dose patients was 6 minutes versus 14.5 minutes, respectively, and for patients to become fully alert it was 8 minutes versus 9 minutes, respectively.

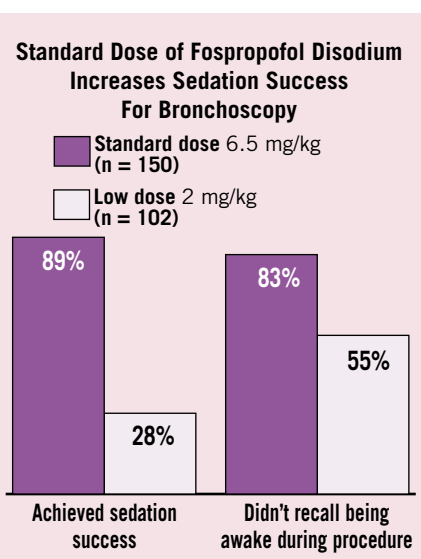
Treatment success was reported in significantly more patients in the standard-dose group than in the low-dose group (91% vs. 41%). Patients in the standard-dose group were also significantly more likely to report they didn't recall being awake during the procedure (83% vs. 55%), and to indicate they would be willing to use the same dosage again (95% vs. 78%).

Supplemental analgesics were used in 17% and 37% of patients, respectively.

Sedation-related adverse events occurred in 20% of standard-dose patients and 13% of low-dose patients; and included mild, transient perineal paresthesias (48%), pruritus (15%), and hypoxemia (9.9%). Eight patients who received 6.5 mg/kg fospropofol disodium experienced hypotension. No serious adverse events or deaths occurred, the investigators reported.

Dr. Silvestri reported that he is a consultant/speaker for MGI Pharma, while Dr. Vincent disclosed that he has received grant monies from "industry related sources." ■

Standard Dose of Fospropofol Disodium Increases Sedation Success For Bronchoscopy



Note: All patients first received 50 mcg of fentanyl citrate.
Source: Dr. Silvestri

ELSEVIER GLOBAL MEDICAL NEWS

Symptoms Portend Potential Smoking Relapse in Women

BY BETSY BATES
Elsevier Global Medical News

VANCOUVER, B.C. — Women appear to experience a 3- to 5-day period of heightened withdrawal and craving symptoms just prior to smoking relapse, offering what could be a golden opportunity for intervention, researchers reported at the annual meeting of the North American Primary Care Research Group.

The finding was a serendipitous discovery from a larger trial investigating associations between the menstrual cycle and smoking withdrawal, explained Dr. Bruce A. Center of the department of family practice and community health at the University of Minnesota, Minneapolis.

Participants included 137 female smokers aged 18-40 years who completed an intensive, month-long study as part of a larger, longitudinal smoking cessation trial sponsored by the National Institutes of Health. At baseline and for 30 days after an assigned quit date, they completed daily logs of specific symptoms of withdrawal, nicotine craving, and smoking urges, as well as negative affect.

Despite education, phone counseling, and monitoring, 111 enrollees relapsed over the course of the study.

The intensity of craving, withdrawal, and smoking urges rose quite precipitously during the 2-5 days prior to relapse, when it peaked. All of the symptoms declined after relapse occurred.

The next step will be to design and test an intervention that educates women in how to recognize and monitor their symptoms and take steps to prevent relapse once they recognize an escalation. Tools already exist for symptom monitoring, but these have not yet been widely introduced in the clinical setting, he said.

More work will be necessary to determine the most effective tools for staving off relapse when an uptick in symptoms is recognized, Dr. Center said. These tools might include a counseling session, telephone calls to a "quit line," an increase in the dose of smoking cessation medication, or a group therapy session. ■

Assessment Tool Helps Classify Pneumonia Severity

BY PATRICE WENDLING
Elsevier Global Medical News

CHICAGO — A simple severity-assessment tool for community-acquired pneumonia accurately identified patients needing intensive respiratory or inotropic support in a 7,464-patient, multicenter validation study.

SMART-COP was developed as part of the Australian Community-Acquired Pneumonia (CAP) study and measures eight features readily available at the time of initial assessment: low systolic blood pressure (less than 90 mm Hg), multilobar chest x-ray involvement, low albumin level (less than 3.5 g/dL), high respiratory rate (age-adjusted cutoffs), tachycardia (at least 125 beats per minute), confusion (new onset), poor oxygenation (age-adjusted cutoffs), and low arterial pH (less than 7.35).

A modified version for primary care physicians, called SMRT-CO, does not require the results of investigations such as serum albumin, arterial pH, and arterial oxygen tension.

For SMART-COP and SMRT-CO, the cutoff scores for increased risk of needing intensive respiratory or inotropic support (IRIS) are at least three points and at least two points, respectively, Dr. Patrick G.P. Charles of the department of infectious diseases, Austin Health, Heidelberg, Australia, and his associates reported in a late-breaking poster at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

The investigators calculated the area under the receiver operating characteristic (ROC) curve and the Hosemer-Lemeshow goodness-of-fit statistic to determine the ability of SMART-COP to predict the need for IRIS among 7,464 patients from five CAP databases, including 474 patients who needed IRIS. The patients' mean age was 65 years (range 18-100 years).

Sensitivity and specificity for SMART-COP in each of the five databases were 80% and 61%, 58% and 75.5%, 69% and 73%, 86% and 73%, and 89% and 46%, respectively. For SMRT-CO, those results were 86% and 51%, 71% and 59%, 81% and 58%, 85% and 55%, and 95% and 36%, respectively.

This high accuracy was found despite the fact that it wasn't possible in most cases to assess the lower cutoff values for respiratory rate and oxygenation in patients aged 50 years or younger, as proposed in the SMART-COP model, the investigators reported at the meeting sponsored by the American Society for Microbiology.

Sensitivity for SMART-COP in five databases was 80%, 58%, 69%, 86%, and 89%.
DR. CHARLES

The reason these data weren't available is that some databases didn't record actual values, but simply noted whether, for example, the respiratory rate was 30 breaths or more per minute. In the SMART-COP model, the cutoff is at least 25 breaths per minute for patients aged 50 years or less, and at least 30 breaths per minute for those older than 50 years.

Without the actual value for each test, the missing data were assumed to be normal, and no points could be assigned, Dr. Charles explained in an interview. He said it is difficult to know exactly how many data points were missing, but noted that albumin level was not recorded in about 4,500 patients and arterial blood gases were not recorded in about 4,500 patients.

"Based on this, it is very likely that the SMART-COP scores given to many patients were inappropriately low, making the sensitivity figures look lower than they probably should be if complete data were available," Dr. Charles said. "A prospective study is planned, which should answer this." ■

CMS Preventive Services Brochures

The Centers for Medicare and Medicaid Services has updated preventive services brochures for health professionals in the following areas: expanded benefits, diabetes-related services, cancer screenings, adult immunizations, bone mass measurements, glaucoma screenings, and smoking and tobacco-use cessation counseling.

To download the brochures, visit www.cms.hhs.gov/MLNProducts/MPUB/list.asp. ■

CT Pulmonary Angiography Deemed Safe, Effective

BY MARY ANN MOON
Elsevier Global Medical News

Computed tomographic pulmonary angiography was found "not inferior to" ventilation-perfusion lung scanning at identifying pulmonary embolism in the first direct comparison of the two approaches, researchers reported in the Dec. 19 issue of JAMA.

Even though the sensitivity of CT pulmonary angiography (CTPA) in detecting pulmonary embolism (PE) still is uncertain, the technology has been widely adopted and has largely supplanted ventilation-perfusion (V/Q) lung scanning as the standard method for assessing patients suspected to have PE.

To determine whether CTPA is at least as safe as V/Q, investigators conducted a randomized controlled trial of consecutive patients being assessed at five Canadian and American academic medical centers for suspected acute pulmonary embolism. The subjects had new or suddenly worsening shortness of breath, chest pain, hemoptysis, presyncope, or syncope, with or without signs of deep vein thrombosis (DVT), said Dr. David R. Anderson of Queen Elizabeth II Health Sciences Centre, Halifax, and his associates.

THE CRUCIAL QUESTION NOW IS WHETHER CT IS PRODUCING TOO MANY FALSE-POSITIVE RESULTS OR IS DETECTING 'CLINICALLY UNIMPORTANT' EMBOLISMS.

All 1,509 patients who met the eligibility criteria underwent clinical examination and D-dimer testing, and based on the results, were assigned a prescan probability of having pulmonary embolism. The 1,406 subjects still considered likely to have PE were then randomized to undergo either V/Q scanning (712 subjects) or CTPA (694 subjects). In some cases, leg ultrasonography also was done to clarify indeterminate results.

Based on these findings, subjects were diagnosed as having venous thromboembolism—a combination of PE and DVT—or that diagnosis was considered to be excluded. Patients in whom the diagnosis was excluded were not given anticoagulant therapy and were followed for 3 months to see if venous thromboembolism did develop.

The primary outcome measure of the study was the rate of symptomatic PE or proximal DVT events developing in the 3 months after a diagnosis of venous thromboembolism had been excluded. This rate was 0.4% in the group who had undergone CTPA, compared with 1.0% in the group who had undergone V/Q, a difference that was not significant.

These results indicate that CTPA is noninferior to V/Q scanning when the two techniques are combined with a consideration of clinical probability, D-dimer testing, and leg venous ultrasonography. Patients in whom the diagnosis is excluded by either CTPA or V/Q do not require anticoagulant therapy, the investigators said (JAMA 2007; 298:2743-53).

One unexpected finding that presents an important concern was that CTPA detected significantly more PE than did V/Q, yet the event rates and mortality rates were no different between the two groups.

This may be because CTPA produced more false-positive results than did V/Q, or it may be that CTPA detected embolisms that were clinically insignificant, Dr. Anderson and his associates said.

In an editorial comment accompanying this report, Dr. Jeffrey Glassroth, FCCP, of the Northwestern University Feinberg School of Medicine, Chicago, said the results were "comforting" because, until now, the sensitivity of CTPA in detecting PE has been much debated.

Given that this "unique head-to-head comparison" was "conducted in a manner that duplicated real-world best-practice conditions," the findings "can be confidently generalized," he said (JAMA 2007; 298:2788-9).

Dr. Glassroth concurred with Dr. Anderson and his associates that the crucial question now is whether CT pulmonary angiography is too sensitive and is either producing too many false-positive results or detecting pulmonary embolisms that are "clinically unimportant" and do not require treatment.

If so, this diagnostic method may expose some patients to unnecessary, costly, and potentially dangerous radiation and anticoagulation therapy, Dr. Glassroth noted. ■

Mortality Soars in Some Patients With ARDS

Nontrauma patients with respiratory distress in the surgical ICU have an unusually high mortality risk.

BY BRUCE JANCIN
Elsevier Global Medical News

COLORADO SPRINGS — Nontrauma surgical ICU patients who develop acute respiratory distress syndrome have a 10-fold greater 30-day mortality than those without this complication, Dr. Shirin Towfigh reported at the annual meeting of the Western Surgical Association.

This observation, derived from analysis of a large prospective single-center acute respiratory distress syndrome (ARDS) registry, stands in marked contrast to the situation prevailing among trauma surgical ICU patients. Multiple centers have reported that in contemporary practice, ARDS in trauma surgery patients in the ICU isn't an independent predictor of increased mortality, said Dr. Towfigh of the University of Southern California, Los Angeles.

Development of ARDS was associated with a 6.9-fold increased rate of mortality within the ICU.

DR. TOWFIGH

Although ARDS has historically been a major cause of mortality among the critically ill, the incidence of ARDS among surgical ICU patients has declined sharply during the past decade. However, nearly all prior studies of ARDS in surgical patients have come from trauma centers and been restricted to trauma patients. To round out the picture, Dr. Towfigh reported on 2,046 consecutive nontrauma surgical patients admitted to the ICU at USC during 2000-2005. All were evaluated daily for ARDS, as has been routine practice there since 2000.

The overall incidence of ARDS in the study population was 6.1%. But as has previously been reported in trauma surgery patients at USC and other trauma centers, the rate among these nontrauma surgical ICU patients declined sharply over time, from 12.2% in 2000 to 2.1% in 2005. That's an 83% drop in 5 years.

"The cause of this is unknown, but we do know that over the past decade or so in our ICU we have managed our patients differently, using lung-protective ventilation strategies, infection control measures, early extubation protocols, and judicious use of IV fluids, which may have improved the incidence of ARDS," Dr. Towfigh said.

Patients who developed ARDS were an average of 3.6 years older than those who didn't. They were also sicker upon ICU admission, as reflected in a mean APACHE-2 score of 23.8, compared with just 5.3 in nontrauma surgical patients without ARDS, and they had roughly a 50% greater prevalence of obesity. In a multivariate logistic regression analysis, risk factors for ARDS were obesity and evidence of sepsis, including tachycardia and use of pressors on admission.

Development of ARDS was associated with a 6.9-fold increased rate of mortality within the ICU, as well as with other major adverse outcomes.

Other independent predictors of ICU mortality included the use of pressors, which conferred a 2.9-fold increased risk, and a positive fluid balance, with a 2.3-fold greater risk.

Nontrauma patients were admitted to the ICU from virtually all general surgery divisions. Patients from two divisions had a disproportionate incidence of ARDS: those admitted from acute care surgery represented 23% of all nontrauma surgical ICU patients but accounted for 46% of those who developed ARDS; and colorectal surgery patients made up 8% of the total ICU population but 11% of those with ARDS.

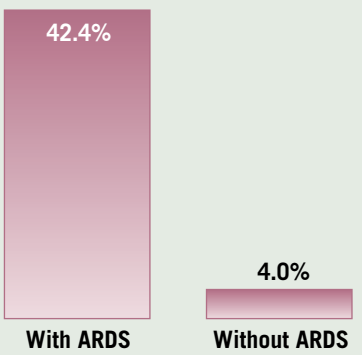
Discussant Dr. Christine S. Cocanour commented that the mortality rate associated with development of ARDS in nontrauma surgical patients in the ICU in this study is higher than typically seen in trauma surgical ICU patients with ARDS. It's closer to the mortality seen with ARDS in the medical ICU.

"I would not be surprised if most of these nontrauma surgical patients with ARDS have underlying chronic medical comorbidities, like those patients in the medical ICU—but they have surgical disease as well," said Dr. Cocanour of the University of California, Davis.

Dr. Towfigh replied that she and her coworkers plan to reanalyze their data to examine diabetes and other medical comorbidities as potential risk factors for ARDS among nontrauma surgical ICU patients.

As an aside, Dr. Cocanour said the high incidence of ARDS among acute care surgery patients in the USC study underscores the need to include training in surgical critical care for those pursuing a subspecialty in acute care surgery. ■

Acute Respiratory Distress Syndrome Affects 30-Day Mortality



Note: Based on data for 2,046 nontrauma surgical intensive care unit patients.
Source: Dr. Towfigh

ELSEVIER GLOBAL MEDICAL NEWS

To Fight MRSA, Focus On Surfaces Patients Touch

BY JONATHAN GARDNER
Elsevier Global Medical News

Rather than worrying about visible dirt, hospitals should focus on cleaning near-patient hand-touch sites to reduce the incidence of infections of methicillin-resistant *Staphylococcus aureus* and other health care–associated infections, according to a meta-analysis published online in the Lancet Infectious Diseases.

Cleaning crews in British hospitals "work to a set specification that encompasses and gives great emphasis to the cleaning of floors and toilets," wrote Dr. Stephanie Dancer of the department of microbiology at Southern General Hospital, Glasgow, Scotland (Lancet Infect. Dis. 2007 [Epub DOI:10.1016/S1473-3099(07)70241-4]).

Yet studies of the movement of microbes in a hospital suite over the course of a few days indicate that the most likely site from which MRSA, *Clostridium difficile*, and other pathogens reach a patient is nearby equipment that the patient or staff have touched, such as bed rails, door handles, and nurse call buttons. These surfaces "rarely feature in domestic cleaning specification," Dr. Dancer wrote.

Even hospitals that have instituted strong hand-hygiene programs cannot control infections when the bedside environment is contaminated, she added.

"These hand-touch sites, which might harbour and transmit microbial pathogens, are only poorly cleaned," wrote Dr. Dancer. "The responsibility for cleaning many hand-touch sites usually rests with the ward nurses, who are often very busy and almost permanently understaffed in many hospitals. Two recent studies in ICUs have shown an increased risk of infection after periods of inadequate nurse staffing or excessive workload. Concentration of available cleaning resources on high-risk hand-touch sites may be the most cost-effective cleaning strategy."

Dr. Dancer based her conclusions on an analysis of English-language papers in the last 50 years using search terms such as "hospital cleaning," "MRSA," and "staphylococci."

With hospital budgets tight, expanding the cleaning budget may not always be feasible, so changing the approach to cleanliness may be the best way to target infections, according to her review.

Notably, hand hygiene "is the single most beneficial intervention" in the control of pathogens, Dr. Dancer wrote, but it is hampered by behavior. "The problem with the cleaning of hands is that it is impossible to get everyone to do it at the most appropriate time," she wrote. "One study has already contrasted the success and relative ease of instituting and maintaining an environmental cleaning programme with the failure of a hand-hygiene initiative." ■

Risk of Hyperkalemia Raised by Red Blood Cell Transfusions

BY ROBERT FINN
Elsevier Global Medical News

SAN FRANCISCO — The more transfusions of packed red blood cells trauma patients receive, the higher their plasma potassium concentrations, according to a study of patients admitted to a combat support hospital in central Iraq.

Patients who received more than 7 U of packed RBCs were 4.8 times as likely to develop hyperkalemia as were those who received 7 U or fewer, according to the study by Dr. Matthew C. Aboudara and colleagues at Walter Reed Army Medical Center, Washington. Dr. Aboudara presented the study in a poster session at the annual meeting of the American Society of Nephrology.

The effect of massive transfusions on plasma potassium concentrations is controversial, with hypokalemia being reported at least as often as hyperkalemia.

Dr. Aboudara's study involved 131 patients admitted to the intensive care unit with trauma. The investigators excluded patients with a primary diagnosis of crush or burn injury, those with hyperkalemia or renal failure at the time of initial evaluation, those with a known history of chronic kidney disease, and those who had surgical management of their injury prior to being admitted.

Of the total cohort, 96 patients received at least 1 U of packed RBCs and 35 received none. In the transfused group, 38.5% of the patients developed hyperkalemia, compared with 2.9% in the nontransfused group, a significant difference. The investigators defined hyperkalemia as a potassium concentration of 5.5 mmol/L or more at any point during the study period. Five of the 131 patients died, all in the transfused group. All of those patients had severe hyperkalemia at the time of death.

In the multivariate analysis, only the number of units of transfused RBCs emerged as an independent predictor of hyperkalemia (relative risk 4.79). The results were adjusted for all factors that appeared to be associated with hyperkalemia in the univariate analysis, including baseline base deficit, baseline plasma bicarbonate, administration of vecuronium, fresh frozen plasma transfusion, platelet transfusion, cryoprecipitate transfusion, and transfusion of fresh whole blood.

The investigators attributed the hyperkalemia to the combination of hypovolemia and the rapid transfusion of old packed red blood cells into the central circulation. ■

Pages 8a—8d

Childhood Asthma Worsened by Traffic Exposure

BY KERRI WACHTER
Elsevier Global Medical News

Exposure to traffic pollution is associated with increased airway inflammation and decreased lung volume in children with asthma, according to a study of nearly 200 children in one Mexican town.

In the study, which was published in the American Journal of Respiratory and Critical Care Medicine, asthma measures such as exhaled nitric oxide and lung volumes were significantly associated with road density, a proxy for traffic exposure, wrote Dr. Fernando Holguin of Emory University in Atlanta and his colleagues. Exhaled nitric oxide (NO) is a biomarker for airway inflammation.

The investigation included 95 children with physician-diagnosed asthma and 99 children without asthma living in Ciudad Juárez, Mexico. The children were aged 6-12 years. Those children with asthma and those without asthma attended the same schools and were age- and sex-matched. The median distance between the children's homes and their respective schools was 397 m (Am. J. Respir. Crit. Care Med. 2007;176:1236-42).

At the baseline visit, children underwent spirometry and allergy skin testing; parents completed questionnaires about their child's medical history, use of asthma medications, respiratory symptoms, and environmental tobacco exposure. Participants were followed for 4 months. On a biweekly basis, participants were evaluated using exhaled NO measures, spirometry, and a daily respiratory symptom questionnaire. Parents administered the daily respiratory health questionnaires, which were then checked for consistency at the biweekly visits.

Children with asthma had higher levels of exhaled NO at baseline than did nonasthmatic children (5.6 parts per billion [ppb] vs. 3.1 ppb). They also had greater rates of respiratory symptoms, including coughing, wheezing, and phlegm. Of the children with asthma, 78% were classified as mild intermittent, 13% were mild persistent, 8% were moderate persistent and 1% were severe at baseline (based on Global Initiative for Asthma guidelines). Among children with asthma, 16% used a short-acting β-agonist, 9% used an inhaled corticosteroid, 3% used oral antihistamines, and 18% were prescribed antibiotics on at least one occasion during the study.

Air pollution was measured in the schools. The researchers measured 48-hour average particulate matter smaller than 2.5 mcm (PM), elemental carbon (EC), and weekly nitrogen dioxide. The average levels of PM, EC, and nitrogen dioxide were 17.5 mcg/m^3, 3.05 mcg/m^3, and 18.2 ppb.

Road density and traffic density were assessed. Road density was defined as the length of road in kilometers in each buffer area. Traffic density was defined as vehicle kilometers per hour within buffer areas around study schools and subjects' homes.

Models were adjusted for sex, age, body mass index, day of the week, season, total number of years of maternal and paternal education, and exposure to passive smoking.

Significant associations were observed between exhaled NO in children with asthma and the interquartile-range increase in road density in three different size buffer zones around participants' homes. In the 50-m buffer zone, there was a 28% increase in exhaled NO per interquartile range increment. In the 75-m buffer, there was a 27% increase per interquartile range increment. In the 200-m buffer, there was a 17% increase per interquartile range increment.

In addition, exposure to road density in these buffer areas was associated with reduced forced expiratory volume in one second (FEV_1): –0.091 L at 50 m, –0.071 L at 100 m, and –0.106 at 200 m. Exposure to nitrogen dioxide at school was only marginally associated with reduced FEV_1 (–0.020 L) in children with asthma. Exposure to the high road density in the 50-m buffer (of the child's home) was associated with a more than 50% increased risk of respiratory symptoms (odds ratio 1.53).

The researchers noted several study limitations. Traffic-related emissions were measured using only the surrogate marker, nitrogen dioxide. "Our inability to detect associations with elemental carbon and particulate matter exposure could be related to a lack of adequate exposure assessment," they wrote.

In addition, nitrogen dioxide, elemental carbon, and particulate matter were only measured at school, not at the children's homes.

Despite these limitations, "results from our study provide further evidence that traffic-related exposures are associated with increased airway inflammation and reduced lung function in children with asthma," the researchers concluded. ■

Flu Vaccine Rates Poor Among High-Risk Teens, Study Reveals

BY DOUG BRUNK
Elsevier Global Medical News

SAN DIEGO — The number of adolescents with asthma and other high-risk conditions who received the influenza vaccine increased between 1992 and 2002, but the coverage remains poor at about 15% overall, results from a large health maintenance organization study showed.

"About 85% of these kids who should have been getting the vaccine weren't getting it," Dr. Mari M. Nakamura said in an interview during a poster session at the annual meeting of the Infectious Diseases Society of America. "A risk-based approach to vaccination isn't working in this population. Universal vaccination in this age group may be warranted instead."

'About 85% of these kids who should have been getting the vaccine weren't getting it.'
DR. NAKAMURA

She and her mentor, Dr. Grace M. Lee, reviewed the medical records of 18,703 patients aged 11-17 years with high-risk conditions who were enrolled in Harvard Pilgrim Health Care, the largest nonprofit health maintenance organization in New England, for at least one influenza season and the preceding 1-year period, from 1992 to 2002.

High-risk conditions were indicated by ICD-9 diagnoses, and included asthma or other chronic pulmonary disease; chronic cardiac disease; immunosuppressive disorders or therapy; sickle cell anemia or other hemoglobinopathy; chronic renal dysfunction; or chronic metabolic disease. "The burden of influenza is especially high in children and adolescents with high-risk conditions, accounting for excess hospitalizations, outpatient visits, and antibiotic courses," the researchers wrote in their poster.

They evaluated the changes in influenza vaccination rates over the time period, as well as the number of missed opportunities for vaccination (defined as office visits during the first 4 months of influenza season at which an unvaccinated adolescent was not vaccinated).

The mean age of patients was 14 years, and 48% were female, reported Dr. Nakamura, a Harvard pediatric health services research fellow at Children's Hospital Boston. The majority of patients (90%) had asthma or other chronic pulmonary disease, whereas 2% had more than one type of high-risk condition.

Influenza vaccination rates improved significantly from 1992 to 1993 (from 8.3% to 12.8%, respectively), and then again from 1993 to 2002 (from 12.8% to 15.4%). Factors associated with a greater likelihood of vaccination included female gender, younger age, and the use of preventive care.

Adolescents with asthma or other chronic pulmonary disease were less likely to be vaccinated, compared with those who had other high-risk conditions.

The researchers also noted that from 1992 to 2002, about half of all unvaccinated patients had at least one missed opportunity for vaccination. "The main reasons they came in included preventive care and the need for other vaccinations," she said. "This tells us that providers are a group to target, to remind them that these patients should be getting flu vaccine every year."

The study was funded by Harvard Pilgrim Health Care and by the Agency for Healthcare Research and Quality. The researchers disclosed that they had no conflicts of interest. ■

Secondhand Smoke in Infancy Tied to Food, Inhalant Allergies

BY JONATHAN GARDNER
Elsevier Global Medical News

Swedish children exposed to secondhand tobacco smoke during infancy had a higher rate of indoor inhalant and food allergies than did children whose parents didn't smoke, according to a large study.

Previous research has linked wheezing in infants and exposure to environmental tobacco smoke, but had not firmly associated such exposure with risk of allergies.

Further, the study found a dose-response relationship between exposure to smoke and allergy, supporting possible causality and "indicating that exposure in early infancy to tobacco smoke may be associated with an increased risk of atopic sensitisation," wrote the authors, led by Eva Lannerö of the Institute of Environmental Medicine at the Karolinska Institute in Stockholm and the pediatrics department at Karolinska University Hospital.

The findings emerged from an ongoing prospective population-based study of more than 4,000 children born in Stockholm from 1994 to 1996, comprising 75% of the children born during that time and living in the area. The parents of the children were surveyed about environmental and general health factors when their children were a median age of 2 months old and again at ages 1, 2, and 4 years. Blood samples were obtained at age 4 years from 2,614 of the children and screened for IgE antibodies.

Of the 2,534 children whose parents answered all four questionnaires and underwent the blood test, 515 (20%) had at least one parent who smoked when the child was about 2 months old. Those children were more likely to be sensitized to food allergens (adjusted odds ratio 1.6) than inhalant allergens (1.1); sensitization was increased to such indoor inhalant allergens as cat (2.0), horse (2.1), and mold (3.2).

Children with one parent who reported smoking at the 2-month interviews were more likely than children of nonsmokers to be sensitized to inhaled indoor or food allergens (adjusted odds ratio 1.3) (Thorax 2007 Dec. 18 [Epub doi:10.1136/thx.2007.079053]). Sensitization was greater among children who had two parents who smoked (adjusted odds ratio 1.8) and whose parents smoked at least 10 cigarettes a day (2.0).

The researchers called the increased risk of food allergy sensitization "puzzling," although they said babies often aspirate food, which may trigger sensitization, and the aspiration may be encouraged by smoke. In addition, exposure of the pharynx to allergens and tobacco smoke at an early age may cause a "profound disturbance of the immune system," the investigators wrote.

The researchers said their findings may have been affected by recall bias, by survey avoidance among parents who smoke, and by a greater willingness to participate among parents of children with allergic diseases. ■

Watch for Recurrent Otitis Media in Children Who Snore

MINNEAPOLIS — Children with frequent, loud snoring are more likely to develop recurrent otitis media and to require tympanostomy tubes than are children who don't snore, based on data from more than 16,000 children aged 5-7 years.

Recurrent otitis media (ROM) and habitual snoring share many risk factors. To assess the relationship between these conditions, Dr. David Gozal, FCCP, of the University of Louisville (Ky.) and his colleagues compared the frequency of ROM and the need for tympanostomy tube placement in children who snored versus those who did not snore. The researchers presented their findings in a poster at the annual meeting of the Associated Professional Sleep Societies.

Parents of 16,321 children who attended public school in Jefferson County, Ky., completed questionnaires about their children's sleeping habits. Overall, 1,844 children (11%) had a history of habitual snoring (defined as snoring more than 3 nights per week). More than half (53%) of the habitual snorers were boys, and 26% of the habitual snorers were black. A total of 5,074 children had a history of ROM, and 2,604 children had tympanostomy tubes.

Nearly twice as many of the habitually snoring children had a history of ROM, compared with children who didn't snore (16% vs. 9%), even after controlling for known otitis media risk factors such as asthma, chronic rhinitis, allergies, and exposure to cigarette smoke.

Similarly, children with a history of habitual snoring were almost three times as likely as children without a history of snoring to have had tympanostomy tubes placed (24% vs. 9%, respectively), after controlling for the same risk factors.

Additional studies are needed to assess the prevalence of obstructive sleep apnea in children with ROM, the investigators wrote.

The study was supported by an NIH grant, The Children's Foundation Endowment for Sleep Research, and the Commonwealth of Kentucky Challenge for Excellence Trust Fund. Dr. Gozal had no financial conflicts to disclose related to the study.

—Heidi Splete

Sleep Disorders Linked to Heart, Psychiatric Risks

BY JOHN R. BELL
Elsevier Global Medical News

Patients diagnosed in the primary care setting with a sleep disorder were more likely than other patients to have previously been diagnosed with depression, anxiety, heart failure, or gastroesophageal reflux disease, according to findings of a large longitudinal cohort study.

Moreover, patients with sleep disorders were three times more likely than control patients to die within the year after the sleep disorder diagnosis was made and have a significantly higher rate of suicide.

The findings, published in the November 2007 issue of the Primary Care Companion to the Journal of Clinical Psychiatry, were derived from the General Practice Research Database, which contains data on 1.5 million British primary care patients. Mari-Ann Wallander, Ph.D., of Uppsala (Sweden) University and her colleagues analyzed data from patients who in 1996 were newly diagnosed with a sleep disorder, excluding those with sleep apnea, those with cancer before 1996, and those who were pregnant 1 year before or after the study began.

A total of 12,437 patients (61% women) were enrolled. Patients were aged 29-79 years, and the mean age at diagnosis was 52 years (Prim. Care Companion J. Clin. Psychiatry 2007;9:338-45).

Dr. Wallander, an employee of study sponsor AstraZeneca, and her colleagues compared these patients with a demographically similar group of 18,350 control patients, using regression analysis to determine odds ratios for various comorbidities.

They found that patients with sleep disorders were approximately three times as likely as a group of 18,350 control patients to have been diagnosed with anxiety (OR 3.7) or depression (OR 3.1).

They also were more likely to have had heart failure (OR 1.8), coronary heart disease (OR 1.4), gastroesophageal reflux disease (OR 1.4), irritable bowel syndrome (OR 1.5), and other ailments.

At the same time, there was a trend toward risk for sleep disorder diagnosis increasing with age.

The investigators also reported deaths occurring within the year following each sleep disorder diagnosis. They found that 16 of the 379 deaths (4.2%) in the sleep disorder group were due to suicide, versus 1 of the 157 deaths in the control group (0.6%). The suicides were primarily in patients with psychiatric diseases. ■

CPAP Changes Greeted Cautiously

CPAP Coverage • *from page 1*

patient is participating in a research study that meets CMS standards for clinical trial policy.

The CMS also plans to limit coverage for the CPAP devices to an initial 12-week period to gauge whether the patient will respond to the treatment. Medicare will continue to cover use of the CPAP in those patients who respond to the treatment.

In addition, the CMS is planning to eliminate the requirement for a minimum 2 hours of continuous recorded sleep during testing, because patients with severe OSA may not be able to meet the requirement. Some experts praised this aspect of the proposal, because some patients with severe disease and badly fragmented sleep never reach the sleep threshold quickly enough to conduct an air pressure titration on the same night.

The CMS based its decision on advice from the Medicare Evidence Development and Coverage Advisory Committee, external technology assessments from the Agency for Healthcare Research and Quality, a review of individual clinical studies, and public comments. Agency officials concluded that the evidence was sufficient to allow for coverage based on diagnosis with type II, III, and IV home sleep testing monitors in appropriately selected patients. ■

Dr. Charles W. Atwood, Jr., FCCP, former chair of the ACCP Sleep Institute, comments: *The CMS national coverage determination (NCD) about the use of portable sleep apnea testing for the prescribing of CPAP for OSA patients is likely to be a controversial decision and generate much discussion for the next few months while CMS receives comments from the field about it. Please remember that this is a preliminary decision—the final answer to this question will be revealed in about 3 months.*

The ACCP Sleep Institute's recommendation to CMS at the Sept. 12 meeting was basically pro-portable testing—but that we should proceed carefully with implementation of it. Based on this decision, it appears CMS is ready to jump in with both feet, essentially opening the gate to portable testing with any type of level II, level III, or level IV device (with a few notable exceptions).

In my opinion, at the heart of the decision are two important considerations. First, the CMS advisory committee could not say that in-laboratory polysomnography was the only reasonable test to make a diagnosis of sleep apnea. They rejected the idea of polysomnography as a "gold standard" for diagnosing obstructive sleep apnea. Second, and more importantly, they seem to be saying that results of CPAP therapy and clinical outcomes at a point in the future need to have more attention paid to them. This, I believe, is their rationale for having patients undergo a 12-week reassessment for patients to continue to qualify for CPAP therapy. CMS is emphasizing the treatment aspects of the continuum care more than they have previously. Finally, the NCD has virtually no details in it and provides no guidance about how such changes should be implemented.

Bottom line: This may be a positive decision for the field, but care needs to be exercised in implementation.

Electronic Connections With Patients Prove Productive

BY MICHELE G. SULLIVAN
Elsevier Global Medical News

NEW ORLEANS — Rather than unlocking a Pandora's box of nattering e-mails, an electronic patient portal that allows messaging and even access to test results can improve patient satisfaction and decrease patient visits.

"Many physicians think that this type of access is frightening," Dr. Gretchen P. Purcell said at the annual clinical congress of the American College of Surgeons. "They think they'll be barraged with messages, that patients will misinterpret their test results, and that physicians could even be held legally liable if they don't respond in time to an urgent message."

But health care providers, who are about 10 years behind the curve in the digital world, need to face up to the facts of the 21st century, said Dr. Purcell of the surgery department at the Children's Hospital at Vanderbilt in Nashville, Tenn. "Patients are demanding the same kind of online access to their medical information as they have for all other aspects of their lives."

Patient portals can be designed to suit the needs of different practices and to fulfill various functions. At a minimum, they allow patients to pay bills, schedule or change appointments, and request prescription refills. Other portals are more robust and give patients the ability to review medical records, view test results, and send messages to their health care provider, said Dr. Purcell, who is also with the biomedical informatics department at Vanderbilt Medical Center.

Among the most controversial topics are messaging and the ability to access test results, she said. "Messaging is probably the function physicians fear the most. Many think it's the equivalent of getting and sending personal e-mail, and this brings up all kinds of worries about security and privacy."

E-mail and messaging, however, are not the same things. Messages don't go to a personal e-mail account; instead, they go to a dedicated in-box. "This message box is routinely checked by an administrative assistant or nurse—someone who can often answer many of the questions, and who would involve the physician only when necessary—similar to phone call triage."

There also are concerns that these electronic exchanges aren't part of a patient's documented record. "Some portals can make messaging part of the medical record,' " Dr. Purcell said.

It's important to set clear expectations about response time and emergency issues. Most messaging systems tell patients that they may have to wait 2-3 business days for a personal reply and advise them to call 911 for a medical emergency.

It's not unreasonable to assume that electronic communication could allow patients to bombard offices with questions and requests. Although data are still limited, the studies that are out there suggest just the opposite, Dr. Purcell said.

Two studies published in 2005 indicate that messaging increases patient satisfaction without any corresponding increase in workload. The first study randomized 200 patients to secure messaging or usual care. Only 46% of the patients who were given access sent any messages at all; the average was just 1.5 messages per patient per year. And although messaging didn't reduce the number of telephone calls the office received, the number of office visits in the intervention group did go down (Int. J. Med. Inform. 2005;74:705-10).

The second study randomized 606 patients to a patient communication portal or to a Web site with general health information. Only 31% of the patients given access used the portal. The message box received only one message per day per 250 patients. Again, there was no difference in the number of office telephone calls between the groups, but the patients in the portal group reported better satisfaction with communication and overall care, even if they never used the portal (J. Med. Internet Res. 2005;7:e48).

Patients may even be willing to pay for the added convenience of messaging, the authors concluded. Of 341 patients surveyed, 162 (48%) were willing to pay for online correspondence with their physician, with $2 cited as the median payment they thought fair.

Patient access to test results is another area of clinician concern, she said. "Obtaining test results is probably the most commonly desired and most commonly used function of a patient portal, and one that makes physicians very nervous," Dr. Purcell said.

The MyHealthAtVanderbilt system (www.myhealthatvanderbilt.com) has three tiers of test results. "Some low-risk, high-value test results, such as cholesterol levels, are available immediately, and some results are available with a delay, such as tests that require interpretation in a specific clinical context," Dr. Purcell said. "But some results, such as cancer pathology and HIV tests, and others that require intensive patient counseling, are never available through the portal." ■

Hospitalized Patients Lead to Communication Breakdown

BY SHERRY BOSCHERT
Elsevier Global Medical News

SAN FRANCISCO — Both inpatient and outpatient physicians are dissatisfied with the level of communication between them when an older patient is hospitalized or discharged, but for different reasons, Dr. Alicia I. Arbaje reported.

She and her associates conducted 1-hour interviews with 18 physicians about communication during patient care transitions. Such transitions can be especially hazardous for older patients if important information is not communicated between physicians when the patient is discharged from the hospital, she said in a poster presentation at the annual meeting of the Gerontological Society of America.

The interviewees included seven physicians at one hospital, five physicians at one skilled nursing facility, and six physicians in five primary care practices.

Inpatient physicians complained that contact information for outpatient physicians was not readily available. They also complained that outpatient physicians were too busy to take their calls, and that it was difficult getting past the primary care office staff "gatekeepers" to reach the physicians. Outpatient physicians should consider talking to their staff about this and creating a mechanism for collecting information from inpatient physicians when they call, suggested Dr. Arbaje of Johns Hopkins University, Baltimore.

Outpatient physicians complained that inpatient physicians don't call to inform them about what's happening with their patients. "That side is a little more difficult" because it's harder for outpatient physicians to track down physicians in the hospital, as they typically don't stay in one place at a desk, she said. It might help if outpatient physicians gave their contact information to the emergency departments and inpatient wards of nearby hospitals to help facilitate communication, Dr. Arbaje suggested.

Outpatient physicians said that they expect early notification if one of their patients is hospitalized, and expect to be involved in major decisions made during the hospitalization. They acknowledged that they often are too busy to locate inpatient colleagues. Outpatient physicians also want notification prior to patient discharge and expect to receive discharge summaries in a timely fashion. They claimed ultimate responsibility for the patient.

Inpatient physicians varied in their perception of responsibility for the patient after discharge, but did feel responsible for transmitting urgent information to their outpatient colleagues.

Dr. Arbaje said she hopes to develop a rating system for communication during patient transfers to see if better communication correlates with better patient outcomes. "We say that it's important for a doctor on the inpatient side to call the outpatient physician, but does it really impact on patients' health?" she asked.

The investigators also plan further study on the best methods of communication (faxes, letters, phone calls, text pages, etc.) so that a strategy for good communication might be disseminated to inpatient and outpatient practices. ■

Pulmonary Perspectives

New Long-Acting β-Adrenergic Agents for Airways Disease

Formoterol and arformoterol are 12-h drugs but are the first LABAs available as nebulizer solutions.

Long-acting β-adrenergic bronchodilators (LABAs) were introduced in the United States more than a decade ago, and their precise role in clinical practice is still being debated.

The recent approval and launch of two new nebulizer formulations of formoterol, arformoterol (Brovana Inhalation Solution; Sepracor Inc.; Marlborough, MA) and formoterol (Perforomist Inhalation Solution; Dey, L.P.; Napa, CA), adds another dimension to their use. As with the previously approved LABAs, salmeterol inhalation powder (Serevent; GlaxoSmithKline; Philadelphia, PA) and formoterol inhalation powder (Foradil; Schering-Plough; Kenilworth, NJ), the two new formulations are 12-h drugs but are the first LABAs available as nebulizer solutions.

How might the new formulations be used? Both drugs have approval by the US Food and Drug Administration for the maintenance treatment of COPD, and this will be their major role. Guidelines for the management of COPD recommend the use of a LABA at stage II (moderate severity). As the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines state, "…long-acting bronchodilators are more effective and convenient …" than multiple doses of a short-acting bronchodilator (Guidelines and Resources. www.goldcopd.com. Accessed November 27, 2007). There already are two dry powder LABAs, but the availability of LABAs in nebulizer formulations fills a gap. A sizeable proportion of patients with COPD prefer to receive bronchodilator(s) by nebulization. Some feel that they derive more benefit from a nebulizer treatment. A recent review comparing the various methods of administration of inhaled therapies found that nebulization was as effective as any other method (Dolovich et al. *Chest* 2005; 127:335). Also, some patients have difficulty manipulating a dry powder inhaler because of poor manual dexterity, arthritis, previous strokes, or poor eyesight. A further consideration is that, for many patients, the cost of nebulizer treatments is reimbursed, whereas this may not be the case for dry powder treatments.

If a LABA in a nebulizer formulation is chosen as the long-acting bronchodilator in stage II COPD, either arformoterol or formoterol nebulizer formulations could be prescribed for twice-daily use. However, the patient will still require a rapid-acting agent for the relief of "breakthrough" bronchospasm occurring between LABA treatments.

No LABA is approved for as needed use for either COPD or asthma because of safety concerns. The safety issue is the "black box" warning that the US Food and Drug Administration gave to all LABAs. It stems from postmarketing safety studies with salmeterol, which showed a small, but statistically significant, increase in severe respiratory-related mortality in the salmeterol arm, amounting to one death for every 650 to 700 patient-years of treatment. Subgroup analysis showed that these events were concentrated in African-American patients (Nelson et al. *Chest* 2006; 129:15). Data on formoterol that have been routinely obtained during its development also showed a trend for a small increase in serious asthma-related events (Martinez. *N Engl J Med* 2006; 353: 2637).

The interpretation of these reports has been quite controversial (Nelson. *J Allergy Clin Immunol* 2006; 117:3). The events could be interpreted as happening due to the LABAs enabling asthmatics, who are starting an exacerbation, to avoid getting appropriate treatment until a crisis becomes inevitable. Nevertheless, the "black box" warning is attached to all LABAs, including the two new nebulizer formulations discussed in this article.

ALTHOUGH BOTH NEBULIZER LABA FORMULATIONS ARE ONLY APPROVED FOR MAINTENANCE THERAPY IN COPD, OTHER OFF-LABEL USES CAN BE CONSIDERED.

One conclusion that can be drawn about the risk, if any, from LABA use, is that available evidence does not suggest any risk of death or near-death from LABA use in patients with COPD. In fact, the very large 3-year study known as TORCH (Toward a Revolution in COPD Health) included two arms that exposed patients with COPD to ~8,000 patient-years of salmeterol treatment, either as monotherapy or as a component of the fluticasone-salmeterol combination (Calverley et al. *N Engl J Med* 2007; 356:775). No additional deaths were found in the salmeterol-treated groups. To the contrary, their mortality was actually lower than that of comparison groups. It is likely that long-term LABA use carries little, if any, risk in patients with COPD.

For patients with asthma, the opinion of asthma specialists is undecided but tends toward doubting that there is any risk (Nelson. *J Allergy Clin Immunol* 2006; 117:3) unless a higher than approved dose is used (Mann et al. *Chest* 2003; 124:70). It is unclear whether coadministration of an inhaled corticosteroid with a LABA reduces the possible risk. There is no reason to believe that a nebulizer formulation of formoterol would present a higher or lower risk than either of the dry powder LABA formulations that have been in use for years.

Although both nebulizer LABA formulations are only approved for maintenance therapy in COPD, other off-label uses can be considered. One can envision at least three such situations:

- Could a nebulized LABA play a role in the maintenance treatment of asthma?

Both dry powder LABA formulations, formoterol inhalation powder and salmeterol inhalation powder, have been approved as monotherapy and used by asthma patients for many years.

However, current asthma guidelines do not state any role for LABA monotherapy (The Global Initiative for Asthma. www.ginasthma.org. Accessed November 27, 2007). LABAs are only recommended in combination with antiinflammatory medications, which are usually inhaled corticosteroids.

There is no fixed combination of either of the new LABA solutions with a corticosteroid, so the only way to nebulize a LABA with an inhaled corticosteroid is to nebulize the two agents sequentially, which would be time-consuming and cumbersome, or to mix the LABA with a nebulized corticosteroid in the nebulizer cup. This raises the potential for unknown hazards, such as chemical interactions between the two molecules and a host of stability and compatibility issues that have not been explored. The nebulization of a mixture of formoterol and an inhaled corticosteroid in the same cup cannot be recommended without further study.

- Could a nebulized LABA be used as needed to relieve acute bronchospastic attacks, *ie*, for "rescue" purposes for patients with asthma or COPD?

In theory, and if the use was concomitant with appropriate antiinflammatory therapy in the asthmatic patient (not instead of it) and the number of such uses did not exceed the approved daily dose of maintenance therapy (two treatments per day), I see no objection. In practice, it would difficult to ensure that the use of any LABA met all of these provisos at all times. In Europe, several studies (McCormack et al. *Drugs 2007*; 67:2407) have suggested that a LABA-inhaled steroid combination can be used for both rescue and maintenance therapy in asthmatics, but even such combination use is unlikely to be approved for as needed use in the United States.

- Could a nebulized LABA have a role in the treatment of acute exacerbations of COPD or acute severe asthma in the hospital or ED?

Both conditions require frequent use of bronchodilators, particularly in the first few hours of therapy. For patients who are very dyspneic, nebulization is the preferred mode of administration. In both situations, a short course of corticosteroids will be given either orally or parenterally, removing the objection to LABA monotherapy previously raised.

Nebulizer treatments entail a significant amount of therapist time and cost, and there is the possibility that some treatments may be missed or late when a therapist's work load is heavy. A quick-acting bronchodilator, either a β-agonist alone, or in combination with ipratropium, should be the initial treatment, according to current guidelines for both asthma and COPD.

However, it is possible that follow-up treatments with a LABA might reduce the total number of treatments and time in the ED or hospital, thereby reducing the cost of these expensive events. The availability of nebulized LABAs makes this option more realistic. However, it should be restated that this use has not been fully explored for any LABA and would be off-label.

We also might consider whether there are differences between the two new nebulizer formulations, arformoterol and formoterol. Clinical experience with each is limited, as they have only very recently become generally available. Arformoterol is the (R,R)-enantiomer of formoterol, whereas formoterol is the racemic form of formoterol. The molar dose of arformoterol (nominally 15 g) is greater than that of formoterol (nominally 20 g) by 78%, which might imply greater efficacy and a smaller margin for safety for the former. Published data (Baumgartner et al. *Clin Ther* 2007; 29:261; Gross et al. *Clin Ther* 2008; in press) do not suggest a difference in either efficacy or safety between the two drugs. Both have an onset of action that is as rapid as that of albuterol, and a duration of action that is similar to that of salmeterol, at >12 h. Tachyphylaxis is expected with regular use of any agonist and has been seen with arformoterol, but not yet with nebulized formoterol in current dosages. The shelf life at ambient temperature after dispensing is 3 months for formoterol, and 6 weeks for arformoterol. In terms of retail cost, arformoterol is relatively expensive, with one report stating $380 per month. The retail cost of formoterol is unknown at the time of publication.

The recent approval and availability of two new LABA formulations fills a gap in therapy by providing nebulizer versions of formoterol, a drug that uniquely combines a very rapid onset with a >12 h duration of action. Their main role is for the maintenance treatment of COPD, for which many patients with COPD prefer nebulizer therapies. ■

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Dr. Gross has disclosed no significant relationships with the companies/organizations whose products or services are discussed within this Perspective.

NEWS FROM THE COLLEGE

AMERICAN COLLEGE OF CHEST PHYSICIANS®

PRESIDENT'S REPORT

Growing Our Korean Alliance

BY DR. ALVIN V. THOMAS, JR., FCCP

The first month of my presidency was quite interesting. I participated in the meeting of the Korean Academy of Tuberculosis and Respiratory Diseases (KATRD) in Seoul, South Korea.

It was the first time that an ACCP President had been to Korea to participate in this scientific pulmonary meeting.

The meeting, held November 8-9, 2007, was the 105th meeting of the KATRD, which is the only academic pulmonary society in South Korea. It was founded in 1953, as the academic arm of the Korean National Tuberculosis Association (www.lungkorea.com/eng/).

The KATRD has two meetings each year (April and November). The November meeting had 684 attendees and over 192 oral and 176 poster presentations. My presentation was entitled, "Update in Venous Thromboembolism." Virtually all of the presentations were in the native language, but the slides were in English.

The KATRD wants to be more active internationally, and it is making a bid to sponsor the 2009 annual meeting of the Asian Pacific Respiratory Society (APSR). They are also interested in building a closer relationship with the ACCP.

The ACCP has a small but dynamic membership in South Korea (45 members). They are active members of the KATRD and were engaged in the academic programs of the meeting. Dr. Dong-Joon Lew, FCCP, is the ACCP International Regent and the active organizer of the ACCP chapter.

Seoul is an interesting city. The airport—Incheon International Airport—is one of the most modern I have experienced and is about an hour's drive from the center of the city. The city is quite large and has a population of 10 million with a population of 23 million in the entire metropolitan area. The Han River runs through the city and is crossed by many beautiful bridges.

Traffic volume in the city is substantial and marked by ever present and aggressive motorcyclists (who provide much of the small volume retail transportation in the city).

Dr. Younsuck Koh, director of the International Communication Committee of the KATRD and a pulmonary intensivist, was my primary contact for the meeting. Dr. Koh started the first critical care program in South Korea (in the mid-1980s). There are now 35 medical ICU programs in the country.

He is Director of a 28-bed medical ICU in Seoul's biggest hospital complex (including 2,000 beds and more than 200 critical care beds), ASAN Medical Center.

ASAN Medical Center is the primary hospital for the University of Ulsan College of Medicine.

After the meeting, Dr. Koh took my wife and me on a tour of the oldest city in South Korea, Gwangju, which is more than 1,800 years old.

The KATRD is a vibrant organization that is poised to be much more active in the international pulmonary/critical care medical community.

The ACCP chapter in Korea has the potential to grow substantially, and I look forward to an expanding relationship between the ACCP and the KATRD into the future. ■

AMERICAN COLLEGE OF CHEST PHYSICIANS

NEWS FROM THE COLLEGE

The ACCP Institutes Year in Review

The Critical Care Institute and the Sleep Institute pushed ahead with several key initiatives.

BY MICHAEL BOURISAW
Director of Institutes and Development Operations
AND JENNIFER PITTS, MA
Manager of Institute Development

In 2007, the ACCP Institutes continued to provide leadership for the ACCP in the areas of sleep and critical care medicine. Collaboration remains a hallmark of the Institutes and is apparent in the many projects in which we are engaged. Key projects and future areas of interest are presented below.

The American College of Chest Physicians Critical Care Institute (ACCP-CCI)

Chair Dr. Curtis Sessler, FCCP, completed his term at CHEST 2007, ending his 3-year stewardship for the ACCP-CCI. During his tenure, the Critical Care Institute grew from a concept to an active and important member of the critical care community.

Dr. Kay Guntupalli, FCCP, and newly named President-Designate of the ACCP, assumes the CCI leadership role for 2007-2008. Dr. Guntupalli brings her vast experience in critical care and a strong desire to accomplish projects that will have a positive impact on patient care in the ICU. Both Dr. Sessler and Dr. Guntupalli share the philosophy that a multidisciplinary approach to our projects makes our projects stronger and enhances the Critical Care Institute's relationship with other organizations in the arena of critical care medicine.

The most significant undertaking in 2007 was the formation of the *Task Force on Mass Casualty Critical Care*. In January, the CCI brought together a group comprising 37 experts from various fields, including bioethics; critical care; disaster preparedness and response; emergency medical services; emergency medicine; infectious diseases; hospital medicine; law; military medicine; nursing; pharmacy; respiratory care; and local, state, and federal government planning and response. The charge to this group was to review the current knowledge and level of preparedness and develop consensus suggestions offering guidance to the critical care community in the event of an overwhelming mass casualty scenario. Four documents have been produced and were submitted to *CHEST*. If accepted, they would become the basis for mass casualty critical care preparedness in this country.

In July, after the ACCP Board of Regents meeting, a team of experts in critical care, palliative care, and pain management came together in a continuing effort to address the issue of unmanaged pain in the ICU. This multidisciplinary team focused on developing an education and awareness plan. The goal is to help health care workers recognize the many incidents of unmanaged pain that occur daily in the lives of patients in the ICU. The committee currently is working on scholarly articles to bring light to different aspects of ICU pain management. An awareness campaign will follow, culminating in May during Critical Care Awareness Month.

An important focus of the ACCP-CCI in 2008 will be to work with the ACCP Educational Resources Division to develop a program devoted to expanding the knowledge and application skills of the ICU team. Such a program would incorporate adult learning theory, including simulation, into the education structure. By using knowledge, skills, and feedback, the hope is to increase the versatility of the ICU work force. Dr. Kay Guntupalli discussed how the CCI also could leverage the work she is already doing for her Eli Lilly Distinguished Scholar projects. This would include a focus on validating and disseminating the patient information booklets, ICU procedural video, and competencies to fellows.

A special thank you to outgoing committee members Dr. Loren Greenway, COL Harlan Patterson, MC, USA, FCCP, and Dr. Howard Corwin, FCCP, for their dedication and commitment to the vision and mission of the ACCP-CCI over the past several years.

The American College of Chest Physicians Sleep Institute (ACCP-SI)

Sleep medicine continues to grow and evolve in the United States, and the ACCP-SI provides a visible and active presence in the world of sleep medicine.

ACCP-SI Chair, Dr. Charles Atwood Jr., FCCP, completed his term at CHEST 2007, ending his 3-year stewardship for the ACCP-SI. Under Dr. Atwood's leadership, the ACCP-SI became a prominent voice in the field of sleep medicine through collaborative projects that had a positive impact on patient care. Dr. Barbara Phillips, FCCP, assumes the leadership role for 2007-2008. Dr. Phillips brings her vast experience in academic and clinical sleep medicine, as well as leadership experience as the Immediate Past President of the National Sleep Foundation. Her main goal during her tenure includes focusing on projects that advance the field towards the management of sleep disorders as a chronic illness.

The year 2007 proved to be exceptionally successful. The ACCP-SI launched its first-ever education initiative focused on increasing awareness, diagnosis, and treatment of sleep disorders in the primary care population. A series of 21 regional continuing medical education programs were held in select cities across the country. Each program included faculty participation from board-certified local and national sleep experts. Nearly 600 primary care providers, including internal medicine and family physicians, nurse practitioners, and physician assistants, attended these half-day Saturday programs.

Due to their overwhelming success and a continued perceived need for this type of educational opportunity, the Sleep Institute has secured additional grant funding to host another 20 programs in 2008. Improving upon the education course design of last year, courses for next year will include adult learning theory best practices that allow learners to walk away with more practical skills to apply to their practice. Formal faculty training sessions and a more robust outcome measurement process also will be implemented.

We will partner with The American Academy of Nurse Practitioners as an official cosponsor of the programs to ensure the appropriateness of course content, as well as strong attendance and participation. Applications to become a training site were e-mailed to NetWork members in mid-December. The programs are scheduled for April through November of 2008.

In addition to providing high-quality education programs, the ACCP-SI continues to play an important role in the national sleep advocacy effort as a founding member of the National Sleep Awareness Roundtable (www.nsart.org). Michael Bourisaw, Director of Institutes and Development Operations at the ACCP, was named to the steering committee to serve a 2-year term.

The main goal of the National Sleep Awareness Roundtable is to ensure that Americans understand the importance of healthy sleep through joint efforts in public awareness and improved organizational communication and collaboration.

The ACCP-SI will continue to reach out and collaborate with organizations interested in improving the care of patients suffering from sleep disorders, as we seek to serve our members, their patients, and the greater sleep community.

A special thank you to outgoing committee members Andrew DesRosiers, RRT, Dr. Lee Brooks, FCCP, and Dr. Aarunabh Talwar, FCCP, for their dedication and commitment to the vision and mission of the ACCP-SI over the past several years. ■

This Month in *CHEST*: Editor's Picks

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

- **On Writing Poetry.** *By Dr. M. Zack*
- **Simulation-Based Education Improves Quality of Care During Cardiac Arrest Team Responses at an Academic Teaching Hospital: A Case-Control Study.** *By Dr. D. B. Wayne, et al*
- **Systemic Inflammation and COPD: The Framingham Heart Study.** *By Dr. R. E. Walter, et al*
- **Peripheral Muscle Alterations in Non-COPD Smokers.** *By Dr. Maria Montes de Oca, et al*
- **Transparency and the "End Result Idea."** *By Dr. S. J. Swensen, and Dr. D. A. Cortese, FCCP*
- **Becoming the Journal of the Future.** *By Dr. R. S. Irwin, FCCP, and S. J. Welch*

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NEWS FROM THE COLLEGE

AMERICAN COLLEGE OF CHEST PHYSICIANS

Practice Management Update

Pay for Performance Initiatives are developed in nearly all sites of service to focus on the performance of quality medicine. On November 27, 2007, the Centers for Medicare & Medicaid Services (CMS) Physician Quality Reporting Initiative (PQRI) finalized the list of performance measures for their 2008 initiative that began January 1, 2008.

ACCP reviewed all 119 performance measures with Dr. Mark Metersky, FCCP, who has taken the lead for the ACCP on the development of performance measures with the AMA-hosted Physician Consortium. In addition to the eight measures in effect the last 6 months of 2007, there are a few additional performance measures that would be important to consider for a pulmonary practice. The specifications of these measures are detailed on the CMS Web site and are available at www.cms.hhs.gov/pqri.

If you have any PQRI questions, do not hesitate to contact the ACCP coding and reimbursement consultant, Diane Krier-Morrow, at (847) 677-9464 or dkriermorr@aol.com.

2007 and 2008 Performance Measures

#51 Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation
#52 Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy
#53 Asthma: Pharmacologic Therapy
#56 Vital Signs for Community-Acquired Bacterial Pneumonia
#57 Assessment of Oxygen Saturation for Community-Acquired Bacterial Pneumonia
#58 Assessment of Mental Status for Community-Acquired Bacterial Pneumonia
#59 Empiric Antibiotic for Community-Acquired Bacterial Pneumonia
#64 Asthma Assessment

New for 2008 for Pulmonary Medicine

#75 Prevention of Ventilator-Associated Pneumonia - Head Elevation
#76 Prevention of Catheter-Related Bloodstream Infections (CRBSI) - Central Venous Catheter Insertion Protocol
#114 Inquiry Regarding Tobacco Use
#115 Advising Smokers to Quit

General Clinical Performance Measures

#4 Screening for Future Fall Risk
#46 Medication Reconciliation (within 60 days of prior hospitalization)
#47 Advance Care Plan
#110 Influenza Vaccination for Patients ≥ 50 Years
#111 Pneumonia Vaccination for Patients 65 Years or Older
#129 Universal Influenza Vaccine Screening and Counseling

Structural Performance Measures

#124 HIT - Adoption/Use of Health Information Technology (Electronic Health Records)
#125 HIT - Adoption/Use of e-Prescribing

Make Your Voice Heard!

The Centers for Medicare & Medicaid Services (CMS) began its third annual Medicare Contractor Provider Satisfaction Survey (MCPSS) with a new sample of Medicare providers. The survey is designed to garner quantifiable data on provider satisfaction levels with key services performed by the Medicare fee-for-service contractors.

MCPSS offers providers an opportunity to contribute directly to CMS' understanding of contractor performance, as well as aid future process improvement efforts at the contractor level.

Specifically, the survey will be used by CMS as an additional measure to evaluate contractor performance. In fact, all Medicare Administrative Contractors (MACs) will be required to achieve performance targets on the MCPSS as part of their contract requirements by 2009.

CMS will contact approximately 35,000 randomly selected providers, including physicians and other healthcare practitioners, suppliers, and institutional facilities that serve Medicare beneficiaries across the country. If you are selected to participate in the survey, you will be notified by January 2008.

CMS urges all Medicare providers who are selected to participate in the MCPSS to complete and return their surveys upon receipt. CMS plans to make the survey results available in July 2008. The survey is designed so that it can be completed in about 15 minutes, and providers can submit their responses via a secure Web site, mail, fax, or by telephone. The full survey results and further information about the MCPSS are available at www.cms.hhs.gov/MCPSS.

ACCP and AMA Conducting Physician Practice Information Survey

For the first time in nearly a decade, the American College of Chest Physicians (ACCP), the American Medical Association (AMA), and more than 70 other medical specialty societies have worked together to coordinate a comprehensive multispecialty survey of America's physician practices. The purpose of the survey is to collect up-to-date information on physician practice characteristics in order to positively influence national decision makers. Thousands of practices will be surveyed in 2007 and 2008, from virtually all physician specialties to ensure accurate and fair representation for all physicians and their patients.

This project is unique because it explores both the clinical and business side of medical practice. This information is important for the nation's policymakers to learn what is truly involved in running a practice that provides expert patient care, while operating a business that is sustainable. A complete understanding of the landscape and the requirements for today's care is critical. These data will allow medicine to articulate practice concerns to national policy-makers that will lead to policy initiatives that not only help in the short-term but will allow future generations of doctors to continue providing superior care to their patients.

There is a small section in this study pertaining to practice expenses and the amounts that are attributable to you. Please encourage your staff to make these numbers available. The Centers for Medicare and Medicaid Services recently announced that the results of this study are considered critical to update physician payment. This is a vital part of the research, and we need to have accurate and complete data. This information remains confidential. The survey firm will not identify any individuals or entities participating in this research to any of the participating organizations.

Dmrkynetec has been retained to conduct the Physician Practice Information Survey among a representative random sample of practices in each of the participating specialties. The survey is an important and necessary vehicle for positive change. Please watch for this survey and do your part in completing it in a thorough and accurate manner if selected to represent our specialty. ■

Patient Information Organizations: COPD Foundation

The COPD Foundation is a nonprofit organization, active in supporting research and educating the general public in order to find the 12 million undiagnosed individuals living with COPD in the United States.

The COPD Foundation has partnered with the National Heart, Lung, and Blood Institute in the COPD *Learn More Breathe Better* Campaign by launching several new programs. The Mobile Spirometry Unit (MSU), a program that is a partnership with the American Association for Respiratory Care, traveled this past year with a team of respiratory therapists to 25 events across the nation, administering a total 10,152 spirometries, resulting in approximately 7 million media impressions. Another program is the C.O.P.D. Information Line—a toll-free support line where all sectors of the COPD community can access free educational materials, resources, and support from patient volunteers with COPD who staff the call line.

To support research on COPD, the COPD Foundation has conducted several research projects, including the Managing COPD and Comorbidities Survey, which revealed that comorbidities are common in the COPD population and add significant costs to COPD care; and the Primary Care Practitioners Needs Assessment Survey, which showed that almost half of surveyed primary care practitioners were not aware of clinical practice guidelines for COPD.

Most recently, the COPD Foundation launched the COPD Registry. The COPD Registry is leading the effort to collect the 10,500 names for the genetic epidemiology study of COPD—also known as the COPDGene study. The National Jewish Medical and Research Center in Colorado, and Brigham and Women's Hospital in Massachusetts, were recently awarded $37 million from the NHLBI to find the additional genes that predispose individuals to developing COPD. The COPD Registry will become the largest COPD patient database to accelerate recruitment for clinical research studies and clinical trials, and support the development of therapeutic solutions for COPD.

Enrolling individuals in the COPD Registry is crucial to the success of the COPDGene study. "We thank the many members of the ACCP for their dedication to the clinical management of individuals with COPD," says John W. Walsh, President of the COPD Foundation. "We'd like to invite you to partner with us in creating resources for clinical research. Help us find the individuals eligible to participate in the COPDGene study."

Individuals can sign up for the COPD Registry by calling the C.O.P.D. Information Line at (866) 316-COPD (2673), or visiting the Web site at www.copdfoundation.org. ■

AMERICAN COLLEGE OF CHEST PHYSICIANS

NEWS FROM THE COLLEGE

NETWORKS

Pneumonia Mortality Rates, Chronic Heart Failure

Chest Infections

Most pulmonologists are familiar with the Centers for Medicare & Medicaid Services (CMS) pneumonia performance measures. Indeed, many of us were probably drafted by our hospitals to help with issues such as the timing and appropriateness of antibiotic administration.

This spring, we will likely be called on again to help our hospitals respond to the report by CMS of 30-day risk-standardized hospital mortality rates for pneumonia admissions. This measure uses claims data but has been validated against a medical record-based mortality prediction tool. Hospitals will receive their performance results in April 2008, and CMS will publicly report these results in June 2008.

There is good rationale for the use of a mortality measure to complement the current process measures. There is a lack of high-quality evidence that improvements in the performance of the current process measures translate into improved outcomes. Also, the current process measures capture only a small fraction of the myriad of events that encompass the care for a patient hospitalized with pneumonia. This mortality measure should encourage hospitals to broaden the scope of quality improvement so that attention is paid to the entire hospital experience, including structural and organizational issues. Potential systems improvements include the adoption of pharmacy systems that help to avoid medication errors; avoidance of premature discharge; selection of the appropriate discharge destination; and improving communication between providers within the hospital and with those external to the hospital at the time of discharge.

Undoubtedly, the fact that hospitals will be judged, in part, based on what happens after discharge will cause consternation to some. However, the alternative use of in-hospital mortality as a performance measure could have the unintended consequence of encouraging hospitals to prematurely discharge patients who are likely to die. More importantly, we have all seen how poor communication at the time of discharge can result in poor outcomes. This measure will encourage hospitals to examine their discharge processes so that bad "hand-offs" can be prevented.

The primary goal of this effort is to encourage improvements in quality of care. We should continue to provide suggestions to CMS on how to improve this measure with that goal in mind.

Disclosure: This article was submitted by Dr. Mark Metersky, FCCP. Dr. Metersky is a paid consultant to CMS in the areas of patient safety and quality improvement.

Cardiovascular Medicine and Surgery

Hibernating Myocardium in Chronic Heart Failure

By Dr. Jun R. Chiong, FCCP

This is a summary of Dr. Mihai Gheorghiade's (Professor of Medicine, Northwestern University, Chicago, IL) lecture on current and future directions in the management of chronic heart failure that was presented during CHEST 2007 at the Cardiovascular Medicine and Surgery NetWork open meeting.

The presentation began with a review of the current state of the art of evidence-based treatment and was followed by a focus on identifying and treating reversible myocardial dysfunction, which is present in approximately 50% of patients with ischemic cardiomyopathy.

Cardiac tissue submitted to the stress of oxygen and substrate deprivation activates endogenous mechanisms of cell survival. This reversible dysfunctional tissue is commonly referred to as hibernating myocardium. These conditions result from a switch in gene and protein expression, which sustains cardiac cell survival in a context of oxygen deprivation and reperfusion stress. The basic mechanisms underlying stunning and hibernation research include neurohormonal activation, ischemia, cytokine activation, metabolic derangements, and hemodynamic alteration. Understanding the survival of the molecular adaptation of the cardiac myocyte during stress might help define novel mechanisms of endogenous myocardial salvage in order to expand the conditions of maintained cellular viability and functional salvage of the ischemic myocardium.

Hibernating myocardium is characterized by adaptive and degenerative features. Inotropic stimulation of the downregulated myocardium enhances regional function but at the cost of worsening its metabolic status. Functional methods used to determine the presence of hibernating myocardium appear more specific but less sensitive than the nuclear modalities, which assess perfusion and metabolic activity. Identification of viable, dysfunctional myocardium may be especially worthwhile. In some cases, recovery of contractility may occur upon revascularization.

Randomized, prospective trials (Surgical Treatment for Ischemic Heart Failure [STICH] Trial) evaluating outcomes after revascularization are ongoing. ■

CHEST Physician Deputy Editor Named

We are pleased to announce that Dr. Paul A. Selecky, FCCP, has been named the new Deputy Editor for *CHEST Physician*.

DR. PAUL A. SELECKY, FCCP

Dr. Selecky is a 2-year veteran of the Editorial Advisory Board and begins his term in January. He is currently Clinical Professor of Medicine, UCLA; and Medical Director of the Pulmonary Department, Sleep Disorders Center, and Palliative Medicine Service, Hoag Hospital, Newport Beach, CA.

Dr. Selecky is a past chair of the ACCP Continuing Education Committee and a past president of NAMDRC. He has participated in several ACCP committees, including Ethics, Government Relations, and Health and Science Policy, and he is a past chair of the Respiratory Care NetWork. ■

NEWS FROM THE COLLEGE

AMERICAN COLLEGE OF CHEST PHYSICIANS

SLEEP STRATEGIES

What's Up With the Sleep Institute?

The American College of Chest Physicians Sleep Institute (ACCP-SI) was founded in 2005. It was founded as a center of excellence, merging all sleep-related programs and resources of the ACCP into a central organizational unit in order to provide the ACCP an opportunity to become a strong voice in the future of sleep medicine. Its mission is to promote sleep health and the recognition, diagnosis, and treatment of sleep disorders through leadership, education, research, and communication.

The members of the ACCP and the SI emphasized, at the outset, that the ACCP-SI is the Sleep Institute, not the Sleep Apnea Institute. We view the entire field of sleep medicine as appropriate for our attention, not just the issues traditionally related to respiratory disease.

At the annual CHEST meeting in Chicago, Dr. Charles Atwood, FCCP, passed the Chair baton to Dr. Barbara Phillips, FCCP. Other members of the SI Committee are Drs. Richard Castriotta, FCCP; Peter Gay, FCCP; Paul Selecky, FCCP; Rochelle Goldberg, FCCP; Doug Puryear, FCCP; Teofilo Lee-Chiong, FCCP; Naresh Dewan, FCCP; Neil Freedman, FCCP; and Jim Parish, FCCP, as well as industry partners ResMed, Respironics, and Boehringer Ingelheim. Cephalon Pharmaceuticals is scheduled to become an industry partner in 2008.

Under the able leadership of Dr. Charles Atwood, FCCP, the SI got off to an excellent start. Some of the projects of the ACCP-SI are the following:

Regional Sleep Programs

These training sessions were conducted in 21 sites throughout the country, targeting the primary care community.

The SI committee members developed standardized curriculum, which focused on three main disease states, including obstructive sleep apnea, restless legs syndrome, and insomnia. Based on the extremely positive feedback from the nearly 600 primary care providers who participated in the courses, an additional 20 programs are planned for 2008.

Continuity of Care Conference

In the spring of 2007, the ACCP hosted a conference at its headquarters in Northbrook, IL, about management of sleep apnea as a chronic disease. The proceedings will be submitted to the journal *CHEST*. The next steps are a follow-up conference in the fall of 2008 and developing the concept of the sleep apnea educator.

National Sleep Awareness Week Echo Poll

This survey of ACCP members amplified knowledge, attitudes, and behaviors about sleep in women, the topic of the 2007 National Sleep Foundation poll.

A Visit With Health and Human Services Secretary

The ACCP visited Health and Human Services Secretary Mike Leavitt to talk about sleep and sleep disorders. This visit was organized through the National Sleep Awareness Roundtable (NSART); the ACCP-SI is a founding member of NSART. You can view the commemorative photograph of this event at www.nsart.org/site/c.gfLJJQOsHkE/b.2555499/k.BFEF/Home.htm.

Testimony to the Centers for Medicare & Medicaid Services

Dr. Charles Atwood, FCCP, from the University of Pittsburgh Medical Center, provided testimony on behalf of the ACCP at the national coverage determination meeting of the Centers for Medicare & Medicaid Services in Baltimore, MD, on September 12, 2007. The testimony focused on ambulatory monitoring for sleep-disordered breathing.

Sleep Medicine Board Review Course

The first Sleep Medicine Board Review Course was offered in August 2006. The 2007 course attracted over 600 participants.

What lies ahead for the Sleep Institute? We have many plans in the works. Here is a sample of a few of the plans:

1. Development of the concept of a sleep educator, modeled after the very successful asthma educator and diabetes educator programs. This idea grew out of the Continuity of Care Conference, when we realized that follow-up care for patients with sleep apnea is not always optimal, and that we do not always excel in management of sleep disorders as chronic illnesses. Here is the current working definition of a sleep educator, courtesy of Dr. Neil Freedman, FCCP:

Sleep educators are health-care professionals and/or members of various health-care disciplines who, as part of a multidisciplinary team, provide health care to persons with or at risk for various sleep disorders. To attain these goals, sleep educators achieve a core body of knowledge, skills, experience, and expertise in the diagnosis and management of the spectrum of common sleep disorders, including, but not limited to, insomnia, sleep-disordered breathing, and other conditions associated with excessive daytime sleepiness.

We will hold a planning meeting for the sleep educator course in the spring of 2008, and we will hopefully roll out a training course in early 2009.

2. Development of an echo poll designed after the very successful Sleep in America poll of the National Sleep Foundation. This project will be ably chaired by Dr. Rochelle Goldberg. The theme of this year's Sleep in America poll is "Sleep and Performance." We will include many of the same questions in an echo poll of ACCP members to see how our membership compares with the population at large. Watch for publication of these results in an upcoming issue of *CHEST Physician*!

3. Continued participation in the NSART, which is likely to focus on secondary analysis of existing data sets, such as the NHANES and the Behavioral Risk Factor Surveillance System.

4. Expansion of our regional sleep meetings, which is made possible through educational grants from Boehringer Ingelheim, Sepracor, ResMed, and Respironics.

The program design for 2008 will use a more integrated adult-learning format and will include a faculty-training component.

In summary, the Sleep Institute is working hard on behalf of the College. We are doing very good work—work that is unique and distinguishes us from other professional societies or advocacy groups in the sleep medicine field.

In the past 3 years, we have made our mark on the field. The next few years will see maturation of our efforts and growth into some newer areas. Stay tuned!

Your Sleep Institute wants to hear from you! Please feel free to contact me at bphil95@aol.com and check out our Web site at www.chestnet.org/institutes/si/index.php. ■

Dr. Barbara Phillips, MSPH, FCCP
Chair, ACCP Sleep Institute

Michael Bourisaw
Director, ACCP Sleep Institute

Calling All Chest Physicians of Indian Origin

BY NAMITA SOOD, MB, BCH, FCCP

The Chest Physicians of Indian Origin (CPIO) exists as part of the American College of Chest Physicians (ACCP).

It was created in 1998 as a forum for communication for physicians of Indian origin within the ACCP. However, it has evolved into an interdisciplinary group of ACCP members in the United States and India.

The purpose of the CPIO is to enhance communication and interaction between ACCP members in the United States and India and to develop collaborative projects focused on improving cardiopulmonary health across the continents.

The membership meets each year during the annual CHEST meeting. The CPIO is led by a steering committee of ACCP members and an ACCP staff liaison.

Recent projects have included the Evils of Tobacco CD in seven languages, the Ant E Tobacco cartoon CD/book in four languages including English, Telugu, Urdu, and Spanish, and a handbook for asthma care for patients.

The CPIO also aims to facilitate faculty exchange scholarships and attendance at ACCP-sponsored meetings.

These projects are supported by CPIO membership dues, which are collected as voluntary donations. These funds are separate from ACCP membership dues and from donations to The CHEST Foundation.

I would encourage you to become a member and to actively participate in this group.

Any ACCP member of Indian origin living in the United States or Canada or any other interested ACCP member who would like to join the CPIO can e-mail Christine Derbes at cderbes@chestnet.org.

More information about the CPIO, membership and the project proposal process is available at www.chestnet.org/networks/CPIO/index.php, or you can contact me at Namita.sood@osumc.edu. ■

AMERICAN COLLEGE OF CHEST PHYSICIANS

CHEST 2007 WRAP-UP

Ninth Annual Foundation Dinner Honors Dr. Petty

The Chicago Cultural Center was an elegant background for The CHEST Foundation's Ninth Annual Making a Difference Awards Dinner that featured a tribute to Thomas L. Petty, MD, Master FCCP, and recognized 16 ACCP members for their outstanding pro bono work.

Antonio Mora, coanchor of CBS 2 Chicago's 6:00 PM newscast, was the guest emcee. Friends and colleagues of Dr. Petty, including Drs. Dick Briggs, Dennis Doherty, Leonard Hudson, and Richard Matthay, shared personal stories of the relationships that developed from working with Dr. Petty during the years of their own medical careers. Boehringer Ingelheim Pharmaceutics was the platinum sponsor of the dinner and host of the VIP Reception for Dr. Petty. Kathryn Lucas, Director of Professional Relations and Education for BI, related her professional experiences with Dr. Petty over the past 30 years.

A video featuring Dr. Petty's extensive contributions to pulmonary medicine and noteworthy career was shown to the 400 dinner guests and is available for viewing at www.chestfoundation.org.

The CHEST Foundation continues to receive generous donations to the Thomas L. Petty, MD, Master FCCP Endowment in Lung Research. If you are interested in making a tax-deductible gift that will support the important advances Dr. Petty has made in lung research and patient care, please contribute online at www.chestfoundation.org or contact Teri Ruiz at truiz@chestnet.org.

CHEST Foundation Chair and Trustee, Dr. D. Robert McCaffree, Master FCCP, did the honors of introducing and presenting crystal awards to the five Humanitarian Project Development Grant recipients for their pro bono work in Arkansas, Connecticut, Louisiana, Texas, and Romania. Dr. Paul A. Kvale, FCCP, Chair of The CHEST Foundation Pro Bono Committee, recognized nine ACCP members who received The CHEST Foundation Humanitarian Recognition Awards for projects in Arkansas, Connecticut, Indiana, Oregon, Bahamas, India, Italy, and Uganda. Mrs. Cindy Johnson, Ambassadors Group Chair, presented Dr. Archana Mishra, FCCP, with a crystal award as the Ambassadors Group Humanitarian Recognition Award recipient for her work in India.

ACCP

Dr. Thomas L. Petty (right) greets Zorita Thomas and Dr. Alvin V. Thomas, Jr., at the dinner.

The evening's program concluded with the presentation of a CHEST Foundation Honorary Humanitarian Award to Mrs. Lucy Lehman. The CHEST Foundation confers an Honorary Humanitarian Award to a person who is not an ACCP member but helps to further The CHEST Foundation's mission through an outstanding effort that exceeds ordinary contributions of time, expertise, vision, and financial support.

Mrs. Lehman was honored for her extensive work in giving of her time and financial resources to many philanthropic causes, particularly in the area of improving global health. For the past 7 years, she has assisted The CHEST Foundation to help ensure that families have equal access to health information and health care.

The ACCP and The CHEST Foundation leadership and staff congratulate all those who were honored. Log on to www.chestfoundation.org/humanitarianAwards/2007.php to meet the 2007 recipients of The CHEST Foundation's Humanitarian Awards. ■

The ACCP International Physician Mentoring Program

BY DR. C. SOLA OLOPADE, FCCP
Professor and ACCP Governor for Illinois

Earlier this year, I received an interesting telephone call from Tracy Goode, ACCP Vice President, Member Activities, who asked if I would be interested in developing a week-long program at the University of Illinois for 16 young physicians chosen from several countries. They were to participate in the ACCP International Physician Mentoring Program, a 2-week educational program, which included attending CHEST 2007.

As the new ACCP Governor for Illinois and 2006 recipient of a Humanitarian Project Development Award from The CHEST Foundation, I quickly accepted the challenge before having time to think about what the opportunity would entail. As it turned out, it was one of the most exciting activities I have undertaken in a long time.

Now in its fourth year, the 2007 ACCP International Physician Mentoring Program was sponsored by Nycomed International Management GmbH. This year's diverse group came from 14 countries: Argentina, Australia, Brazil, Germany, Greece, Hungary, Mexico, the Netherlands, Poland, Romania, Slovakia, South Africa, Switzerland, and the United Kingdom.

The first week of the program at the University of Illinois involved daylong sessions that covered essential areas of interest in pulmonary, critical care, and sleep medicine. The young physicians toured the clinical and research facilities, participated in clinical rounds in the ICUs, attended clinical and research conferences, and joined journal club sessions and a proposal and grant writing workshop.

Highlights of the program were the team interaction with the staff and faculty during rounds and sharing different strategies for managing clinical cases, as well as dealing with ethical issues in end-of-life care. Clearly, cultural sensitivity and differing health-care resources require pragmatic approaches to patient management, especially in the ICU—where, during a terminal illness, a patient spends the most health-care dollars in his or her lifetime.

The outstanding collegiality among the participants promoted an atmosphere of productive exchanges and development of collaborative initiatives, which I hope will last beyond the mentoring program. The first week ended with an evening dinner and a unique opportunity to interact with the ACCP leadership and program faculty before the start of CHEST 2007.

The International Physician Mentoring Program is worthy of continuation, and I hope to see more participants from Africa and Asia in the future. ■

CHEST 2007 WRAP-UP

Simulation Stimulation at CHEST 2007

BY VIVA JO SIDDALL
Assistant Vice President, Educational Resources

The simulation center at CHEST 2007 was a learning experience … for the learners, the faculty, and, especially, the ACCP.

The ACCP is in a period of educational change. You may have noticed the addition of different types of hands-on workshops, enhanced with various combinations of simulation, including problem-based learning (PBL); standardized patients (SP); human models; task trainers; computer simulations; high-fidelity human patient simulators outfitted with all the environmental trimmings, monitors, ventilators, bronchoscopes, and IV access for medication administration.

More than all these educational enhancements, the ACCP has made the commitment to challenge learners through the use of a pretest/posttest, checklist for assessment of skills and to be used as a guide to self-directed learning.

Approximately 800 learners visited the simulation center over 4 days to participate in 1 of 13 closed sessions covering nine separate clinical domains: emergency medicine, difficult airway, pediatric airway, critical care, bronchoscopy, pulmonary function testing, polysomnography, ultrasound in the critical care unit, and health systems management.

The 2-hour closed sessions began with a demographic survey given to help the ACCP to define the learner populations interested in these types of expanded educational offerings. Next, a self-assessment survey was administered to be used for a needs assessment driving future offerings. Finally, there was a pretest. After a brief "story" about what the learner would find at the preassigned stations, the learners were met by a team of multidisciplinary faculty members who attended an 8-hour faculty development session prior to the opening of the simulation center. The instruction and simulations, many including checklists to gauge performance, continued for 90 min. During the wrap-up, a posttest was administered to assess the transfer of facts (cognitive assessment), followed by a post self-assessment given to establish whether or not the learner was exposed to all stated learning objectives. Finally, there were course evaluations and a call for the learners input on courses offered by the ACCP.

The ACCP has obtained institutional review board (IRB) approval to report the findings of its education sessions. The data from the CHEST 2007 simulation center are being reviewed and will be reported in the near future. The future educational offerings in development for the ACCP participants built on the sampling of stations from the CHEST 2007 simulation center include ultrasound fundamentals and advanced, advanced airway, pediatric airway, critical care, and bronchoscopy. As these courses are finalized, information will be available on the ACCP Web site at www.chestnet.org/simulation/index.php. Many of these courses will be offered at the ACCP Northbrook, Ill., headquarters in the simulation center that is now being equipped and will be ready for use sometime during the first quarter of 2008.


ACCP

Approximately 800 learners visited the simulation center over 4 days to participate in 1 of 13 closed sessions.

The ACCP wishes to thank the approximately 100 faculty for their enormous teaching effort and for taking time during CHEST 2007 to support this event. The success of this event was accomplished with the participation of the ACCP members, volunteer faculty, industry supporters, and ACCP staff. ■

Annual Outreach Event Reaches Chicago Kids

Over 40 ACCP members and Ambassadors Group members participated in the annual ACCP Industry Advisory Council and The CHEST Foundation Community Outreach Event on Monday, October 22.

This year, the volunteers presented the Lung Lessons℠ program to 125 fifth graders at Kinzie Elementary School, which is a member of the Math/Science Midway Cluster of the Chicago Public School system. Volunteers presented facts about good lung health, living with asthma, and the dangers of smoking to five groups of children. Children in one of the groups were hearing-impaired and enthusiastically participated in the lesson with the aid of their interpreters.


ACCP

At the 2007 Outreach Event, Zorita Thomas shows the "jar of tar" to Chicago fifth graders.

All children received a Puffree small, stuffed dog key chain, a Love Your Lungs™ wristband, and signed a giant poster under the words "I Will Never Smoke" that was posted in each of the five classrooms. Dr. Sean Egan, principal of Kinzie School, presented The CHEST Foundation with a framed picture of one of the groups of children holding a sign, "Thank You ACCP," which is now proudly displayed in The CHEST Foundation's office.

The CHEST Foundation and the ACCP Industry Advisory Council presented the Kinzie School Parent's Club with a donation of $10,000 to support educational efforts. ■

AMERICAN COLLEGE OF CHEST PHYSICIANS

CHEST 2007 WRAP-UP

ACCP Applauds CHEST 2007 Award Winners

The College is proud to salute the outstanding individuals who received awards in 2007.

ACCP Honor and Memorial Lecturers and Awardees

College Medalist Award
Dr. Bartolome R. Celli, FCCP
Honorary Fellow Award
Dr. Jean-Louis Teboul, FCCP (Hon)
Presidential Citation Honor Lecture
Dr. John E. Heffner, FCCP
Roger C. Bone Memorial Lecture
Dr. Alan H. Morris
Murray Kornfeld Memorial Founders Lecture
Dr. Mark H. Sanders, FCCP
Margaret Pfrommer Memorial Lecture in Long-term Mechanical Ventilation
Dr. Dudley Childress
Pasquale Ciaglia Memorial Lecture in Interventional Medicine
Dr. Armin Ernst, FCCP
Distinguished Fellow Award
Dr. Richard S. Irwin, FCCP
Edward C. Rosenow III, MD, Master FCCP, Honor Lecture
Dr. Richard W. Light, FCCP
Distinguished Scientist Honor Lecture
Dr. Brian J. Whipp
Master Fellows Award
Dr. Gerald L. Baum, Master FCCP
Dr. Susan K. Pingleton, Master FCCP
Master Teacher Award in Continuing Medical Education
Dr. Edward C. Rosenow III, Master FCCP
Alfred Soffer Award for Editorial Excellence
J. Patrick Barron
Distinguished Service Awards—Pro Bono Faculty
Dr. W. Michael Alberts, FCCP
Dr. Carlos M. Alvarado-Galvez, FCCP
Dr. Antonio R. Anzueto
Dr. V. Theodore Barnett, FCCP
Dr. Sidney S. Braman, FCCP
Dr. John D. Buckley, FCCP
Dr. Bart Chernow, Master FCCP
Dr. Mark Cohen
Dr. Vera A. De Palo, FCCP
Dr. Naresh A. Dewan, FCCP
Dr. William F. Dunn, FCCP
Dr. Rafael Espada
Dr. Marco V. Flores, FCCP
Dr. Johnny C. Galina, FCCP
Dr. W. Brendle Glomb, FCCP
Dr. Allen I. Goldberg, Master FCCP
Dr. Kalpalatha K. Guntupalli, FCCP
Dr. Jay Guntupalli
Dr. Richard S. Irwin, FCCP
Dr. Paul A. Kvale, FCCP
Dr. Carla R. Lamb, FCCP
Dr. Michael J. Light, FCCP
Dr. D. Robert McCaffree, Master FCCP
Dr. Mary Anne McCaffree, FCCP
Dr. Atul C. Mehta, FCCP
Dr. Ian J. Morales
Dr. Rodolfo C. Morice, FCCP
Dr. James M. Parish, FCCP
Dr. Jorge M. S. Pascual, FCCP
COL Harlan S. Patterson, MC, USA, FCCP
Dr. Luis F. Perez-Martini, FCCP
Dr. Vlasis S. Polychronopoulos, FCCP
Dr. Udaya B. S. Prakash, FCCP
Dr. Aymarah M. Robles, FCCP
Dr. Mark J. Rosen, FCCP
Alan Roth, RRT
Dr. Carlos Salazar-Vargas, FCCP
Dr. Mihaela Sescioreanu
Dr. Curtis N. Sessler, FCCP
Dr. Deborah Shure, Master FCCP
Dr. Jorge E. Sinclair Avila, FCCP
Dr. Alan Smith
Dr. Charlie Strange, FCCP
Dr. Roberto Vargas, FCCP
Dr. Luiz A. Vasquez
Dr. Sandra K. Willsie, FCCP
Dr. Stephen M. Winter, FCCP
Dr. Mark E. Wylam
Alton Ochsner Award Relating Smoking and Health
Dr. Caryn Lerman
Dr. Rachel Tyndale
Canadian Thoracic Society Christie Memorial Lecture
Dr. Peter Warren
Canadian Thoracic Society/Institute of Circulatory and Respiratory Health Distinguished Lecture in the Respiratory Sciences
Dr. Gregory P. Downey, FCCP
International Partnering for World Health Award
John L. Kirkwood
Archie Turnbull
Carl C. Booberg

The CHEST Foundation Awards

Roger C. Bone Advances in End-of-Life Care Award
Dr. James A. Avery, FCCP
The Association of Specialty Professors and The CHEST Foundation of the ACCP Geriatric Development Research Award
Dr. Harold R. Collard, FCCP
Dr. Carlos A. V. Fragoso, FCCP
The CHEST Foundation and the LUNGevity Foundation Clinical Research Award in Lung Cancer
Dr. Patrick Nana-Sinkam, FCCP
The CHEST Foundation Clinical Research Award in Lung Transplantation
Dr. James D. Maloney
The Second GlaxoSmithKline Distinguished Scholar in Respiratory Health
Dr. Sidney S. Braman, FCCP
The American Lung Association and The CHEST Foundation Career Investigator Award
Dr. Lin Zhang
The CHEST Foundation Clinical Research Award in Women's Health
Dr. Thirumagel Anandhi Murugan

Clinical Research Trainee Awards

The CHEST Foundation and ALTANA Pharma US for Clinical Research in COPD
Dr. Christina Kao
Dr. Jennifer D. Possick

A list of The CHEST Foundation **2007 Humanitarian Award winners** can be found at www.chestfoundation.org/humanitarianAwards/2007.php. ■

And More CHEST 2007 Winners ...

Alfred Soffer Research Awards

This award is named in honor of Dr. Alfred Soffer, Master Fellow of the College, Editor in Chief of the *CHEST* journal from 1968 to 1993, and Executive Director for the ACCP from 1969 to 1992.

Two $1,500 awards were granted to the winners, and four $1,000 awards from The CHEST Foundation were granted to the finalists.

- Dr. Christopher Carroll (Winner)
- Dr. Carmen Rosario (Winner)
- Dr. Anthony Castleberry (Finalist)
- Dr. Kelly Chin (Finalist)
- Dr. Denis Hadjiliadis (Finalist)
- Dr. Jayasimha Murthy (Finalist)

Young Investigator Awards

A total of $12,250 was granted to 10 abstract finalists at CHEST 2007. The top three winners received $2,275, and the remaining seven were awarded $775. Finalists were evaluated on the basis of their written abstract and their presentations at CHEST 2007.

- Dr. Jose Barrera (Winner)
- Dr. Adnan Majid (Winner)
- Dr. Robert Updaw (Winner)
- Dr. Morohunfolu Akinnusi (Finalist)
- Dr. Ashraf Gohar (Finalist)
- Dr. Elzbieta Grabczak (Finalist)
- Dr. Jason McKinney (Finalist)
- Dr. Christina Migliore (Finalist)
- Dr. Fares Mouchantaf (Finalist)
- Dr. Andreas Zierer (Finalist)

Top Five Best Posters Award Winners

Each of these five poster winners received $200. Finalists were evaluated on their written abstract and quality of their poster presentation during CHEST 2007. All categories were eligible.

- Dr. Rodrigo Cartin-Ceba
- Dr. Lindsay Chaney
- Dr. William Kuo
- Dr. Jinesh Mehta
- Dr. Lisa Wolfe

Case Report Awards

This year, there were over 367 submissions. From those 367, 144 were selected for presentation in 24 different categories. The winner from each category received $100. Based on those presentations, the 24 best cases were selected.

Category:

- Airway Disorders: Dr. Neelam Patel
- Bronchoscopy: Dr. Johann Brandes
- Cancer Cases I: Dr. Timothy Quast
- Cancer Cases II: Dr. Carrie Samiec
- Cancer Cases III: Dr. Hima B. Kona
- Cardiovascular: Dr. Wissam B. Abouzgheib
- Critical Care Conundrums: Dr. Akram Khan
- Drug-Related Cases: Dr. Sachin Pendharkar
- Fungal/Parasitic Disease: Dr. Anita Reddy
- Iatrogenic and Diagnostic Critical Care Dilemmas: Dr. Nathan Sandbo
- ICU Curiosities: Dr. Jorge Guerrero
- ICU Dilemmas: Dr. Ching Fei Chang
- Infectious Disease Cases: Dr. Tim Lahm
- Interstitial Lung Disease I: Dr. Fabien Maldonado
- Mycobacterial Disease: Dr. Muhammad Rehman
- Organ Transplant: Dr. Stephen Clum
- Pleural Disease: Dr. Nisha Rathi
- Pulmonary Conundrums: Dr. Jennifer Fulton
- Pulmonary Hypertension: Dr. Alicia Gerke
- Pulmonary Puzzles: Dr. Negin Hajizadeh
- Pulmonary Vascular Disease: Dr. Alberto Colomer
- Surgical Successes: Dr. Twinkle Chandak
- Unusual Infections: Dr. Justin Gisel
- Vasculitis: Dr. Damian Compa

CHEST 2007 WRAP-UP

New Session at CHEST a Resounding Success

The first ever Youth Tobacco Prevention Health Education "Train-the-Trainer" session was presented during CHEST 2007.

Ambassadors Group members, Monir Almassi, Susan Kvale, and Kathy Wilder, taught the Lung Lessons℠ program to 10 children from Chicago's Happiness Club. Using a variety of audiovisuals that each use when they bring the Lung Lessons℠ curriculum to their local elementary schools, the lesson was interesting, creative, and interactive.

More than 30 people saw the Lung Lessons℠ presentation being demonstrated and taught at the same time. The children participated with enthusiasm and interest with comments and questions that went well over the 1-hour lesson that was planned. The CHEST Foundation extends their appreciation to Monir, Susan, and Kathy, and head chaperone, Anne Callaghan from The Happiness Club, for their organization and participation.

Plans are in progress to make the videotape of this session available on The CHEST Foundation's Web site. ■

Exhibit Hall Bingo

Attendees at the annual CHEST meeting in Chicago had the opportunity to play disease state bingo in the Exhibit Hall and complete the terms "Asthma," "COPD," and "PAH" on their game cards to win various prizes. The following three attendees were winners:

▶ **Asthma Bingo—Monday, October 22**
Prize: laptop computer
Karen Mella, RRT, Miami, FL

▶ **COPD Bingo—Tuesday, October 23**
Prize: TV/DVD combination
Wendi R. Mason, MSN, Nashville, TN

▶ **PAH Bingo—Wednesday, October 24**
Prize: iPod® mobile digital device
Dr. Jennifer Martinelli, Duluth, MN

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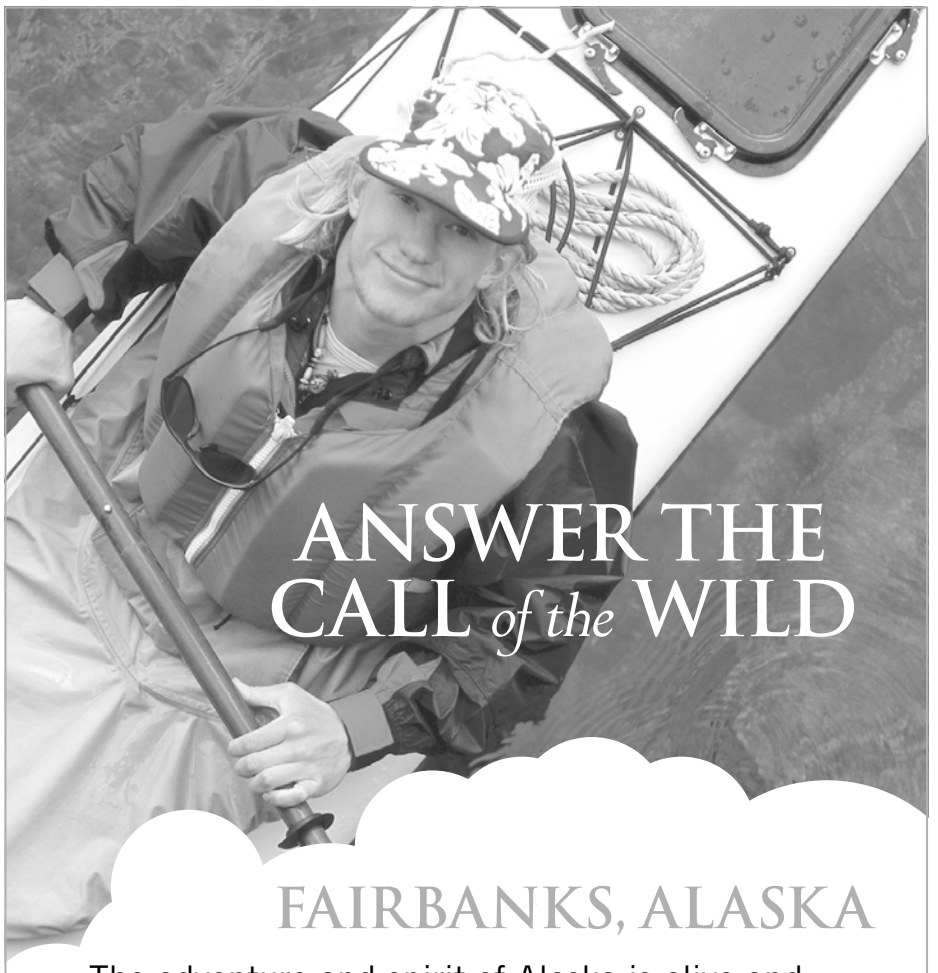
PROFESSIONAL OPPORTUNITIES



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Shannon@wefinddocs.com

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BC/BE Pulmonologist. Multispecialty community hospital in midcoast region seeks full-time physician. Safe, smog-free, and rapidly growing city with excellent schools and year-round recreation. Ideal family environment. Contact: Mark Biscone, Executive Director, Waldo County General Hospital, PO Box 287, Belfast, ME 04915. 207-338-9302; ceo@wchi.com www.wchi.com

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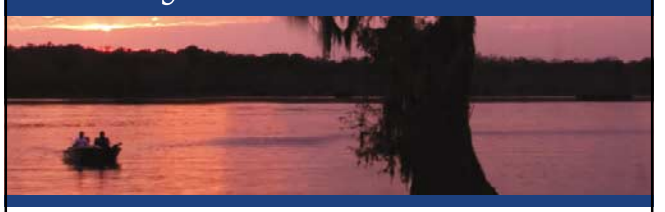

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AMERICAN COLLEGE OF CHEST PHYSICIANS

CHEST 2007 WRAP-UP

CHEST Challenge 2007

Competing from around the country, the semifinalists attended CHEST 2007 for play-offs, and the exciting competition ended Wednesday evening when the final three teams vied for the top spot. And, here are the winners:

Semifinalists:

Coney Island Hospital
Dr. Kona Hima
Dr. Muhammad Rehman
Dr. Julian Williams

University of Connecticut Health Center
Dr. Binusha Moitheennazima
Dr. Wassim Shwaika
Dr. Aydin Uzunpinar

University of Miami Jackson Memorial Hospital
Dr. Saleh Alazemi
Dr. Sau Yin Wan

University of Oklahoma Health Science Center
Dr. Nadim Daher
Dr. Jijo John
Dr. Hussein Youness

University of Toronto
Dr. Terry Baker-Ivey
Dr. Jakov Moric
Dr. Parisi Rahimi

University of Washington
Dr. Colin Cooke
Dr. Timothy Watkins

ACCP

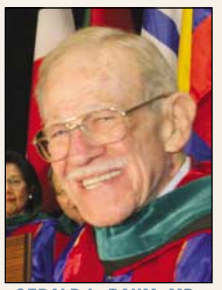
The first-place winners celebrate their victory.

First Place:
University of Tennessee Health Science Center
Dr. Mehrdad Ghaffari
Dr. Kanchan Koirala
Dr. Qurrat-Ul-Ain Nawab

Second Place:
Drexel University College of Medicine, Hahnemann University Hospital
Dr. Anas Hadeh
Dr. Naeem Malik
Dr. Justin Sebastian

Third Place:
National Capital Consortium Pulmonary and Critical Care Fellowship Training Program
CAPT Christopher King, MC, USA
CAPT Sean MacDermott, MC, USAF
LCDR Robert Walter, MC, USN

ACCP Honors Two New Master Fellows


GERALD L. BAUM, MD, MASTER FCCP


SUSAN K. PINGLETON, MD, MASTER FCCP

The title of Master Fellow was established in 1980 to honor Fellows of the ACCP who achieved national or international professional prominence due to their personal character, leadership, eminence in clinical practice, contributions to medical research, or years of outstanding service to the College. The title of Master Fellow is conferred by a majority vote of the ACCP Board of Regents.

Gerald L. Baum, MD, Master FCCP, is Medical Director (Emeritus), Israel Lung Association and Emeritus Professor of Medicine, Sackler School of Medicine, Tel Aviv University. He previously served as Chief of Pulmonary at Chaim Sheba Medical Center, Tel Hashomer, Israel. Dr. Baum's current interests are focused on TB control, rehabilitation of patients with COPD, smoking cessation and education, occupational lung diseases, and alternative approaches to pulmonary diseases, with an emphasis on public health education in these areas. Dr. Baum was the ACCP College Medalist in 1989 and has served on the Ethics Committee, *CHEST* Editorial Board, and the Palliative and End-of-Life Care NetWork.

Susan K. Pingleton, MD, Master FCCP, is the Petersdorf Scholar in Residence, American Association of Medical Colleges, Washington, DC. She has held the positions of Pulmonary and Critical Care Division Director at the University of Kansas for 10 years and Chair of the Department of Internal Medicine for more than 5 years. Among her other positions held at the University are medical director of Critical Care Services and chair of the ICU Committee. Dr. Pingleton currently is a reviewer for the journal *CHEST*. Her commitments to the ACCP are remarkable, and she has held numerous leadership positions, including serving as ACCP President from 1999 to 2000. ■

Master Fellows

2007 Dr. Gerald L. Baum, Master FCCP
2007 Dr. Susan K. Pingleton, Master FCCP
2006 Dr. Om P. Sharma, Master FCCP
2004 Dr. Allen I. Goldberg, Master FCCP
2004 Dr. Paul D. Stein, Master FCCP
2003 Dr. D. Robert McCaffree, Master FCCP
2002 Dr. John G. Weg, Master FCCP
2001 Dr. Dick D. Briggs, Jr., Master FCCP
2001 Dr. Ronald B. George, Master FCCP
2000 Dr. A. Jay Block, Master FCCP
2000 Dr. James E. Dalen, Master FCCP
2000 Dr. Deborah Shure, Master FCCP
1999 Dr. Bart Chernow, Master FCCP
1997 Dr. Farokh E. Udwadia, Master FCCP
1997 Dr. Max Harry Weil, Master FCCP
1996 Dr. Marvin I. Dunn, Master FCCP
1996 *Dr. Shigeto Ikeda, Master FCCP
1996 Dr. Edward C. Rosenow III, Master FCCP
1995 *Dr. Roger C. Bone, Master FCCP
1995 Dr. Thomas L. Petty, Master FCCP
1995 *Dr. Aquiles J. Roncoroni, Master FCCP
1993 *Dr. Antonio Blasi, Master FCCP
1992 Dr. Alfred Soffer, Master FCCP
1980 *Dr. Arthur M. Olsen, Master FCCP

* = deceased

INDEX OF ADVERTISERS

DORIBAX™
(doripenem for injection)
for Intravenous Infusion

Brief Summary: The following is a brief summary only. Before prescribing, see complete Prescribing Information in DORIBAX™ (doripenem for injection) labeling.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of DORIBAX™ and other antibacterial drugs, DORIBAX™ should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting and modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CONTRAINDICATIONS
DORIBAX™ is contraindicated in patients with known serious hypersensitivity to doripenem or to other drugs in the same class or in patients who have demonstrated anaphylactic reactions to beta-lactams.

WARNINGS AND PRECAUTIONS:
Hypersensitivity Reactions: Serious and occasionally fatal hypersensitivity (anaphylactic) and serious skin reactions have been reported in patients receiving beta-lactam antibiotics. These reactions are more likely to occur in individuals with a history of sensitivity to multiple allergens. Before therapy with DORIBAX™ is instituted, careful inquiry should be made to determine whether the patient has had a previous hypersensitivity reaction to other carbapenems, cephalosporins, penicillins or other allergens. If this product is to be given to a penicillin- or other beta-lactam-allergic patient, caution should be exercised because cross-hyperreactivity among beta-lactam antibiotics has been clearly documented.

If an allergic reaction to DORIBAX™ occurs, discontinue the drug. Serious acute hypersensitivity (anaphylactic) reactions require emergency treatment with epinephrine and other emergency measures, including oxygen, IV fluids, IV antihistamines, corticosteroids, pressor amines and airway management, as clinically indicated.

Interaction with Sodium Valproate: Carbapenems may reduce serum valproic acid concentrations to subtherapeutic levels, resulting in loss of seizure control. Serum valproic acid concentrations should be monitored frequently after initiating carbapenem therapy. Alternative antibacterial or anticonvulsant therapy should be considered if serum valproic acid concentrations cannot be maintained in the therapeutic range or seizures occur. *[see Drug Interactions]*

***Clostridium difficile*-Associated Diarrhea:** *Clostridium difficile*-associated diarrhea (CDAD) has been reported with nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile,* and surgical evaluation should be instituted as clinically indicated. *[see Adverse Reactions]*

Development of Drug-Resistant Bacteria: Prescribing DORIBAX™ in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Pneumonitis with Inhalational Use: When DORIBAX™ has been used investigationally via inhalation, pneumonitis has occurred. DORIBAX™ should not be administered by this route.

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

- Anaphylaxis and serious hypersensitivity reactions *[see Warnings and Precautions]*
- Interaction with sodium valproate *[see Warnings and Precautions* and *Drug Interactions]*
- *Clostridium difficile*-associated diarrhea *[see Warnings and Precautions]*
- Development of drug-resistant bacteria *[see Warnings and Precautions]*
- Pneumonitis with inhalational use *[see Warnings and Precautions]*

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

During clinical investigations, 853 adult patients were treated with DORIBAX™ IV (500 mg administered over 1 hour q8h) in the three comparative phase 3 clinical studies; in some patients, parenteral therapy was followed by a switch to an oral antimicrobial. *[see Clinical Studies (14)* in full Prescribing Information*]* The median age of patients treated with DORIBAX™ was 54 years (range 18-90) in the comparative cUTI study and 46 years (range 18-94) in the pooled comparative cIAI studies. There was a female predominance (62%) in the comparative cUTI study and a male predominance (63%) in the pooled cIAI studies. The patients treated with DORIBAX™ were predominantly Caucasian (77%) in the three pooled phase 3 studies.

The most common adverse reactions (≥ 5%) observed in the DORIBAX™ phase 3 clinical trials were headache, nausea, diarrhea, rash and phlebitis. During clinical trials, adverse drug reactions that led to DORIBAX™ discontinuation were nausea (0.2%), vulvomycotic infection (0.1%) and rash (0.1%).

Adverse reactions due to DORIBAX™ 500 mg q8h that occurred at a rate ≥1 % in either indication are listed in Table 1. Hypersensitivity reactions related to intravenous study drug and *C. difficile* colitis occurred at a rate of less than 1% in the three controlled phase 3 clinical trials.

Table 1: Adverse Reactions† with Incidence Rates (%) of ≥1% and Adverse Events†† Having Clinically Important Differences in Frequency by Indication in the Three Controlled, Comparative DORIBAX™ Phase 3 Clinical Trials

	Complicated Urinary Tract Infections (one trial)		Complicated Intra-Abdominal Infections (two trials)	
System organ class	DORIBAX™ 500 mg q8h (n =376)	Levofloxacin 250 mg IV q24h (n = 372)	DORIBAX™ 500 mg q8h (n = 477)	Meropenem 1 g q8h (n = 469)
Nervous system disorders				
Headache	16	15	4	5
Vascular disorders				
Phlebitis	4	4	8	6
Gastro-intestinal disorders				
Nausea	4	6	12	9
Diarrhea	6	10	11	11
Blood and Lymphatic System Disorders				
Anemia††	2	1	10	5
Renal and Urinary Disorders				
Renal impairment/ Renal failure††	<1	0	1	<1

Table 1: Adverse Reactions† with Incidence Rates (%) of ≥1% and Adverse Events†† Having Clinically Important Differences in Frequency by Indication in the Three Controlled, Comparative DORIBAX™ Phase 3 Clinical Trials *(continued)*

	Complicated Urinary Tract Infections (one trial)		Complicated Intra-Abdominal Infections (two trials)	
System organ class	DORIBAX™ 500 mg q8h (n =376)	Levofloxacin 250 mg IV q24h (n = 372)	DORIBAX™ 500 mg q8h (n = 477)	Meropenem 1 g q8h (n = 469)
Skin and subcutaneous disorders				
Pruritus	<1	1	3	2
Rash*	1	1	5	2
Investigations				
Hepatic enzyme elevation**	2	3	1	3
Infection and Infestations				
Oral candidiasis	1	0	1	2
Vulvomycotic infection	2	1	1	<1

* includes reactions reported as allergic and bullous dermatitis, erythema, macular/papular eruptions, urticaria and erythema multiforme
** includes reactions reported as alanine aminotransferase increased, aspartate aminotransferase increased, hepatic enzyme increased, and transaminases increased
† An adverse drug reaction was defined as an undesirable effect, reasonably associated with the use of DORIBAX™ that may occur as part of its pharmacological action or may be unpredictable in its occurrence.
†† An adverse event refers to any untoward medical event associated with the use of the drug in humans, whether or not considered drug-related.

Postmarketing Experience: The following adverse reaction has been identified during post-approval use of doripenem outside of the U.S. Because this reaction was reported voluntarily from a population of uncertain size, it is not possible to reliably estimate its frequency or establish a causal relationship to drug exposure.

Anaphylaxis

The following treatment-emergent adverse events (known to occur with beta-lactams including carbapenems) have been reported voluntarily during post-approval use of DORIBAX™ outside of the U.S. They are included due to their seriousness, although it is not possible to estimate their frequency and causality has not been established:

Stevens Johnson Syndrome
Toxic epidermal necrolysis
Interstitial pneumonia
Seizure

DRUG INTERACTIONS
Valproic Acid: A clinically significant reduction in serum valproic acid concentrations has been reported in patients receiving carbapenem antibiotics and may result in loss of seizure control. Although the mechanism of this interaction is not fully understood, data from *in vitro* and animal studies suggest that carbapenem antibiotics may inhibit valproic acid glucuronide hydrolysis. Serum valproic acid concentrations should be monitored frequently after initiating carbapenem therapy. Alternative antibacterial or anticonvulsant therapy should be considered if serum valproic acid concentrations cannot be maintained in the therapeutic range or a seizure occurs. *[see Warnings and Precautions]*

Probenecid: Probenecid interferes with the active tubular secretion of doripenem, resulting in increased plasma concentrations of doripenem. *[see Clinical Pharmacology (12.3)* in full Prescribing Information*]* Coadministration of probenecid with DORIBAX™ is not recommended.

USE IN SPECIFIC POPULATIONS
Pregnancy: Category B: Doripenem was not teratogenic and did not produce effects on ossification, developmental delays or fetal weight following intravenous administration during organogenesis at doses as high as 1 g/kg/day in rats and 50 mg/kg/day in rabbits (based on AUC, at least 2.4 and 0.8 times the exposure to humans dosed at 500 mg q8h, respectively). There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when DORIBAX™ is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Of the total number of subjects in clinical studies of DORIBAX™, 28% were 65 and over, while 12% were 75 and over. Clinical cure rates in complicated intra-abdominal and complicated urinary tract infections were slightly lower in patients ≥65 years of age and also in the subgroup of patients ≥75 years of age versus patients <65. These results were similar between doripenem and comparator treatment groups.

No overall differences in safety were observed between older and younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

Elderly subjects had greater doripenem exposure relative to non-elderly subjects; however, this increase in exposure was mainly attributed to age-related changes in renal function. *[see Clinical Pharmacology (12.3)* in full Prescribing Information*]*

This drug is known to be excreted substantially by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function or pre-renal azotemia. Because elderly patients are more likely to have decreased renal function or pre-renal azotemia, care should be taken in dose selection, and it may be useful to monitor renal function.

Patients with Renal Impairment: Dosage adjustment is required in patients with moderately or severely impaired renal function. *[see Dosage and Administration (2.2)* and *Clinical Pharmacology (12.3)* in full Prescribing Information*]* In such patients, renal function should be monitored.

PATIENT COUNSELING INFORMATION

- Patients should be advised that allergic reactions, including serious allergic reactions, could occur and that serious reactions require immediate treatment. They should report any previous hypersensitivity reactions to DORIBAX™, other carbapenems, beta-lactams or other allergens.
- Patients should be counseled that anti-bacterial drugs including DORIBAX™ should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When DORIBAX™ is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by DORIBAX™ or other antibacterial drugs in the future.
- Keep out of the reach of children.

MINI-BAG Plus is a trademark of Baxter International Inc.

Manufactured by:
Shionogi & Co. Ltd.
Osaka 541-0045, Japan

Distributed by:
Ortho-McNeil Pharmaceutical, Inc.
Raritan, NJ 08869

10157600B 10/2007

INTRODUCING DORIBAX

- Clinical efficacy proven in complicated intra-abdominal infections* and complicated urinary tract infections, including pyelonephritis†
- Demonstrated safety and tolerability profiles—no seizures reported in 4 large Phase III clinical trials

Carbapenem potency that breaks through today's gram-negative pathogens‡[1-3]

- Proven in vitro activity vs *P aeruginosa*, Enterobacteriaceae, and *A baumannii*[1-3]

‡ In vitro activity does not necessarily correlate with clinical results.

Please see brief summary of full Prescribing Information on following pages.

NEW DORIBAX™
doripenem for injection

TOUGH TO RESIST

* DORIBAX is indicated as a single agent for the treatment of complicated intra-abdominal infections caused by susceptible strains of *E coli, K pneumoniae, P aeruginosa, B caccae, B fragilis, B thetaiotaomicron, B uniformis, B vulgatus, S intermedius, S constellatus,* or *P micros.*

† DORIBAX is indicated as a single agent for the treatment of complicated urinary tract infections caused by susceptible strains of *E coli,* including cases with concurrent bacteremia, *K pneumoniae, P mirabilis, P aeruginosa,* or *A baumannii.*

To reduce the development of drug-resistant bacteria and maintain the effectiveness of DORIBAX and other antibacterial drugs, DORIBAX should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting and modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Important Safety Information

DORIBAX is contraindicated in patients with known serious hypersensitivity to doripenem or other carbapenems, or in patients who have demonstrated anaphylactic reactions to beta lactams.

Serious and occasionally fatal hypersensitivity (anaphylactic) and serious skin reactions have been reported in patients receiving beta-lactam antibiotics. These reactions are more likely to occur in individuals with a history of sensitivity to multiple allergens. If an allergic reaction to DORIBAX occurs, discontinue the drug.
Serious acute anaphylactic reactions require emergency treatment with epinephrine and other emergency measures, including oxygen, IV fluids, IV antihistamines, corticosteroids, pressor amines and airway management, as clinically indicated.

Carbapenems may reduce serum valproic acid concentrations to subtherapeutic levels, resulting in loss of seizure control. Serum valproic acid concentrations should be monitored frequently after initiating carbapenem therapy. Alternative antibacterial or anticonvulsant therapy should be considered if serum valproic acid concentrations cannot be maintained in the therapeutic range or seizures occur.

Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over 2 months after administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C difficile* may need to be discontinued.

When doripenem has been used investigationally via inhalation, pneumonitis has occurred. DORIBAX should not be administered by this route.

Safety and effectiveness in pediatric patients have not been established.

The most common adverse reactions (≥5%) observed in clinical trials were headache, nausea, diarrhea, rash, and phlebitis.

REFERENCES: 1. Evangelista AT, Yee C, Pillar CM, Aranza-Torres MK, Sahm DF, Thornsberry C. Surveillance profiling of doripenem activity against *Pseudomonas aeruginosa* isolated from inpatients and ICU patients: results of the TRUST surveillance initiative. Presented at the 45th Annual Meeting of the Infectious Diseases Society of America (IDSA); 2007: San Diego, CA. **2.** Data on file, Ortho-McNeil, Inc. **3.** Jones ME, Draghi DC, Brown NP, Aranza MK, Thornsberry C, Sahm DF, et al. Baseline surveillance profile of Doripenem (DOR) against key gram-negative pathogens encountered in the United States. Presented at the 46th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC); 2006:San Francisco, CA.

For more information, visit us at www.doribax.com

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