VOL. 2 • NO. 4 • APRIL 2007

CHEST Physician

THE NEWSPAPER OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS

MARCIA WARD

A new class of tuberculosis tests, in vitro T-cell–based interferon-γ release assays, is on the horizon, said Dr. Charles Daley.

New Tests May Sharpen Detection of Latent TB

BY BRUCE K. DIXON
Elsevier Global Medical News

KEYSTONE, COLO. — New tests that detect latent tuberculosis infection by quantifying interferon-γ released from sensitized lymphocytes in whole blood may be a big step toward the elimination of TB, Dr. Charles Daley said at a meeting on allergy/clinical immunology, asthma, and pulmonary medicine.

This class of tests, called in vitro T-cell–based interferon-γ release assays (IGRAs), is the first replacement for the flawed tuberculin skin test, which has been in use in one form or another for a century.

"We absolutely can and must replace the tuberculin skin test, and the reason we can is because of these specific mycobacterium tuberculosis antigens, ESAT-6 and CFP-10," Dr. Daley said at the meeting, sponsored by the National Jewish Medical and Research Center.

The first replacement for the tuberculin skin test in a century, Quantiferon-TB (Cellestis), was approved by the Food and Drug Administration in 2001.

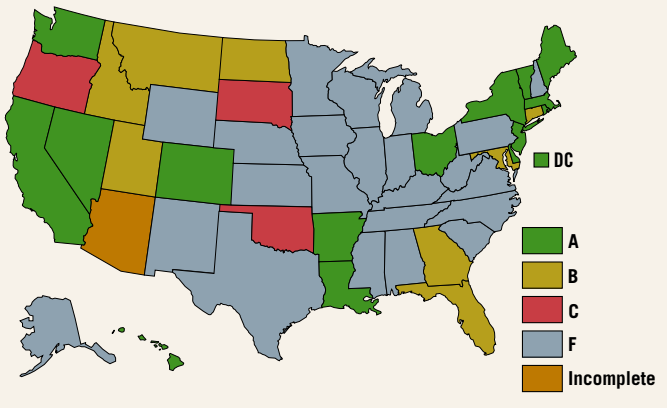
A version called Quantiferon-TB Gold In-Tube, which should be available this summer, will allow the drawing of blood directly into tubes containing the antigens, said Dr. Daley, who is head of mycobacterial and respiratory infections at National Jewish, Denver.

Another impending test is

See **TB Detection** • *page 3*

VITAL SIGNS

States Graded for Their Laws on Smoke-Free Air



Note: Scores based on points given for laws pertaining to government workplaces, private workplaces, schools, childcare facilities, restaurants, retail stores, recreational/cultural facilities, penalties, and enforcement.
Source: 2005-2006 data, American Lung Association

ELSEVIER GLOBAL MEDICAL NEWS

CT Screening for Lung Cancer Didn't Improve Mortality

Result is stark contrast to earlier study.

BY MARY ANN MOON
Elsevier Global Medical News

CT screening dramatically raised the rate of detecting small lung cancers and boosted the frequency of resections by a factor of 10 — but did not reduce mortality from the disease in a preliminary study.

These findings must be validated in larger randomized trials. Nevertheless, they "should raise doubts about the premise underpinning CT screening for lung cancer, and also raise concerns about its potential harms if pursued on a wide scale," the investigators wrote (JAMA 2007;297:953-61).

Such CT screening "should be considered an experimental procedure, based on an uncorroborated premise" that fatal tumors can be detected while they are still localized and potentially curable. This conclusion flies in the face of widespread but unfounded claims that lung CT screening "saves lives" and should be covered by Medicare and other payers, Dr. Peter B. Bach of Memorial Sloan-Kettering Cancer Center, New York, and his associates noted.

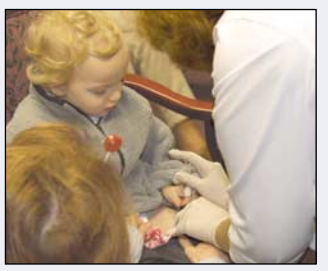
They assessed the effect of CT screening using data from three separate studies conducted at the Istituto Tumori in Milan; the Mayo Clinic in Rochester, Minn.; and the Moffitt Cancer Center in Tampa. All 3,246 subjects had a history of smoking. They were screened and then followed for a median of 3.9 years. The researchers calculated subjects' expected risks of a lung cancer diagnosis and of lung cancer death, based on statistical models widely used for that purpose.

"Far greater numbers" of subjects were diagnosed as having lung cancer by CT screening than would have been diagnosed without screening.

When the study researchers considered the data from all three studies, 144 cases were

See **CT Screening** • *page 2*

INSIDE



FDA Advises Against Actimmune for IPF

BY ELIZABETH MECHCATIE
Elsevier Global Medical News

Early termination of a study that found interferon gamma-1b didn't improve survival in patients with idiopathic pulmonary fibrosis has prompted the Food and Drug Administration to warn physicians about off-label use of the product for the disease.

The synthetic version of interferon gamma-1b, a biologic response modifier, is not approved for idiopathic pulmonary fibrosis (IPF), but is approved for other conditions. InterMune markets the agent as Actimmune.

"Doctors should carefully consider whether patients receiving Actimmune for IPF should continue to receive treatment," the FDA recommended in a public health advisory released last month. The agency also is advising physicians to discuss the results of the study with their IPF patients who have been treated with Actimmune.

The FDA advisory came just days after InterMune reported disappointing outcomes from an interim analysis of the phase III INSPIRE study.

That randomized, double-blind study of 826 patients with IPF showed that overall mortality was 14.5% among those receiving Actimmune injections and 12.7% among those receiving placebo injections. The difference was not statistically different. The total number of deaths was 115.

That overall survival result

See **Actimmune** • *page 2*

CHEST PHYSICIAN
5635 Fishers Lane, Suite 6000
Rockville, MD 20852
CHANGE SERVICE REQUESTED

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

Other IPF Trials in the Works

Actimmune • *from page 1*

"crossed the predefined stopping boundary for lack of benefit of Actimmune relative to placebo," according to a statement issued by the company.

Available since 1999, Actimmune is approved for reducing the frequency and severity of infections associated with chronic granulomatous disease and for delaying the time to disease progression in patients with severe, malignant osteopetrosis.

The biologic effects of interferon gamma include antifibrotic and antiproliferative effects, according to InterMune.

The IPF clinical trial's failure underscores the complexity of the disease and the need to conduct adequately powered trials to determine if a treatment is truly effective for IPF, said Dr. Clay Marsh, director of the Center for Critical Care and Respiratory Medicine at Ohio State University, Columbus, and division director of pulmonary, critical care, allergy, and sleep medicine.

The negative outcome was "particularly disappointing," he said in an interview, because phase II data were promising—and some phase III data suggested that the benefit may be greater in a subgroup of patients with less severe idiopathic pulmonary fibrosis.

Because no drugs have been shown to be effective treatments for IPF, "any type of study that provides some potential for benefit is received favorably" by physicians and patients, Dr. Marsh said. That led to the off-label use of Actimmune, he added.

One research challenge is to complete IPF treatment studies fast enough to provide answers for patients, Dr. Marsh explained, because the median survival after diagnosis is about 3 years.

"A lot of people are willing to try anything," he said.

There was evidence from an earlier study that patients with IPF who were deficient in gamma interferon might be more likely to respond to Actimmune, Dr. Marsh said.

But in the wake of the most recent findings, he predicted it was unlikely that possibility would be pursued.

The company will no longer pursue Actimmune for IPF, but InterMune will continue a phase III trial, CAPACITY, launched in April 2006 to study pirfenidone in patients with IPF.

An orally active small-molecule drug, pirfenidone has been shown to have positive effects on lung function in several phase II studies and in a phase III study of patients with IPF, according to InterMune.

Both Dr. Marsh and another IPF researcher, Dr. Naftali Kaminski, are hopeful about pirfenidone.

Dr. Marsh said that there are promising phase II study results with pirfenidone, with respect to reducing the worsening of the disease and protection against acute exacerbations.

Other treatments that are being studied in early trials include sildenafil (Viagra), bosentan (Tracleer), and iloprost (Ventavis), which address the pulmonary hypertension component of IPF, Dr. Marsh said.

But "pirfenidone is the one most people are excited about," he added.

On the positive side, the INSPIRE study increased awareness of the disease and showed that such a large study of idiopathic pulmonary fibrosis was possible, said Dr. Kaminski, director of the Dorothy and Richard P. Simmons Center for Interstitial Lung Disease, at the University of Pittsburgh.

"This is a disease that, although not as common as asthma or chronic obstructive lung disease, has captured the hearts of a lot of researchers around the country and around the world," added Dr. Marsh, who is hopeful that the current level of research and the growing number of clinical trials for IPF will identify effective therapies.

Neither Dr. Marsh nor Dr. Kaminski were INSPIRE investigators, but several patients from their centers were in the study. ■

The advisory is available on the FDA's MedWatch Web site at www.fda.gov/medwatch/safety/2007/safety07.htm#Actimmune.

Risk of Death Not Reduced

CT Screening • *from page 1*

diagnosed, whereas only 44 cases were predicted by the statistical model, raising the rate of cancer diagnoses by a factor of 3.2, Dr. Bach and his associates said.

Based on CT findings, 109 lung cancer resections were performed, when only 10.9 were predicted by the model, raising the rate of surgery 10-fold. However, "there was no evidence that CT screening reduced the risk of death due to lung cancer in any of the studies individually or combined."

"There appears to be neither a meaningful reduction in the number of advanced cancers being diagnosed nor a reduction in the number of individuals who die of lung cancer," the investigators said.

The 10-fold increase in resections apparently served only to excise tumors that were unlikely to cause clinically significant disease or death.

Such thoracic surgeries "may be insufficiently beneficial to justify the resulting morbidities," given that postoperative mortality after lung cancer resection averages 5% per year in the United States, "and the frequency of serious complications ranges from 20% to 44%," they added.

In an editorial comment accompanying this report, Dr. William C. Black of Dartmouth-Hitchcock Medical Center, Lebanon, N.H., and Dr. John A. Baron of Dartmouth Medical School, Hanover, N.H., said that these findings present a stark contrast to those of the I-ELCAP study (International Early Lung Cancer Action Program) published 6 months earlier (N. Engl. J. Med. 2006;355:1763-71).

Based on that study, the I-ELCAP investigators concluded from their findings that CT screening in populations at risk for lung cancer could prevent 80% of lung cancer deaths.

"Because of the presence of a simulated control group, the measurement of mortality, and the completeness of the outcome assessment, the study by Bach et al. more directly addresses the population effect of CT screening than does the ELCAP study," Dr. Black and Dr. Baron commented (JAMA 2007;297:995-7). ■

Dr. W. Michael Alberts, FCCP, comments: *When the patient asks his/her physician about lung cancer screening, it is often difficult to explain the pros and cons. A thorough understanding is crucial, however, to making an informed choice. When discussing this issue with patients, the phrase "fully informed" cannot be overstated.*

IN THIS ISSUE

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

CHEST PHYSICIAN

CHEST PHYSICIAN, the newspaper of the American College of Chest Physicians, provides cutting-edge reports from clinical meetings, FDA coverage, clinical trial results, expert commentary, and reporting on the business and politics of chest medicine. Each issue also provides material exclusive to the members of the American College of Chest Physicians. Content for CHEST PHYSICIAN is provided by the Elsevier Society News Group and Elsevier Global Medical News. Content for NEWS FROM THE COLLEGE is provided by the American College of Chest Physicians.

The statements and opinions expressed in CHEST PHYSICIAN do not necessarily reflect those of the American College of Chest Physicians, or of its officers, regents, members, and employees, or those of the Publisher. The American College of Chest Physicians, its officers, regents, members, and employees, and Elsevier Inc. do not assume responsibility for damages, loss, or claims of any kind arising from or related to the information contained in this publication, including any claims related to products, drugs, or services mentioned herein.

Address Changes: Send editorial correspondence and address changes to Circulation, CHEST PHYSICIAN, 5635 Fishers Lane, Suite 6000, Rockville, MD 20852.

POSTMASTER: Send change of address (with old mailing label) to CHEST PHYSICIAN, 5635 Fishers Lane, Suite 6000, Rockville, MD 20852.

CHEST PHYSICIAN (ISSN 1558-6200) is published monthly for the American College of Chest Physicians by Elsevier Inc., 60 Columbia Rd., Building B, Morristown, NJ 07960, 973-290-8200, fax 973-290-8250.

ELSEVIER SOCIETY NEWS GROUP
President, IMNG Alan J. Imhoff
Director, ESNG Mark Branca
Executive Director, Editorial Mary Jo M. Dales
Executive Editor, IMNG Denise Fulton
Executive Editor, EGMN Kathy Scarbeck
Publication Editor Terry Rudd
Publication Associate Editor Jay C. Cherniak
VP, Medical Education Sylvia H. Reitman
Senior Director, Marketing and Research Janice Theobald
Executive Director, Operations Jim Chicca
Director, Production and Manufacturing Yvonne Evans
Production Manager Judi Sheffer
Art Director Louise A. Koenig

Display Advertising Manager The Walchli Tauber Group: 443-512-8899, fax 443-512-8909, gary.walchli@wt-group.com, stephen.tauber@wt-group.com

Classified Sales Manager Rhonda Beamer, 443-512-8899, fax 443-512-8909, rhonda.beamer@wt-group.com

ADVERTISING OFFICES 60 Columbia Rd., Building B, Morristown, NJ 07960, 973-290-8200, fax 973-290-8250

CLASSIFIED ADVERTISING OFFICES The Walchli Tauber Group, 2225 Old Emmorton Rd., Suite 201, Bel Air, MD 21015, 443-512-8899

EDITORIAL OFFICES 5635 Fishers Lane, Suite 6000, Rockville, MD 20852, 240-221-4500, fax 240-221-2541

FDA Panel Selects Strains For 2007-2008 Flu Shot

BY ALICIA AULT
Elsevier Global Medical News

GAITHERSBURG, MD. — The 2007-2008 trivalent influenza vaccine should retain two strains from the current vaccine and change one strain, a Food and Drug Administration advisory panel voted on Feb. 28.

The Vaccines and Related Biological Products Advisory Committee followed the lead of the World Health Organization, which made its recommendations for a Northern Hemisphere winter vaccine a week earlier. The FDA usually follows its panels' advice.

IF THE COMMITTEE HAD CHOSEN DIFFERENT STRAINS, VACCINE MAKERS PROBABLY WOULD HAVE HAD TO REDUCE THEIR PRODUCTION BY 20%.

The decision gives the green light to manufacturers to go ahead with production. It generally takes until July or August for vaccine makers to complete testing, acquire FDA approval, and begin packaging their product. Distribution usually starts in September and ends by Nov. 1.

Based on surveillance reports, the availability of seed stock to grow viruses, and reagents to test potency, vaccine makers already had begun production of most of the strains that ultimately were selected, said Albert Thomas, a Sanofi Pasteur representative who spoke at the FDA meeting. The manufacturers take the early production risk in order to speed up the process, he explained.

If the FDA committee had chosen different strains, vaccine makers likely would have had to reduce their ultimate production by 20%, Mr. Thomas said.

That potential production loss pushed the committee to vote against changing one component, the influenza A (H3N2) strain, even though the most recent surveillance data suggest that a different H3 strain currently is emerging.

The WHO recommended keeping the current H3N2 strain, which is the A/Wisconsin/67/2005-like virus.

The 2006-2007 flu season had been dominated by influenza A (H1N1) strains, said Nancy J. Cox, Ph.D., director of the Centers for Disease Control and Prevention's influenza division. But in February, it appeared that H3N2 strains were starting to dominate. It wasn't clear yet which of those might be the predominant H3 strain, Dr. Cox said.

Although panelists were concerned about the emergence of a new H3N2 subtype, 11 of 13 members voted to keep the current H3 strain. "At this point, I feel like we don't have any choice," said Dr. Melinda Wharton, deputy director of the CDC's National Immunization Program and a temporary voting member of the committee. She noted that manufacturers already had begun production on the current H3 strain.

Two committee members said they wanted to defer a decision until more surveillance data were available.

The panel voted unanimously to change the current H1N1 strain from A/New Caledonia/20/99-like virus with A/Solomon Islands/3/2006. The WHO had recommended that change.

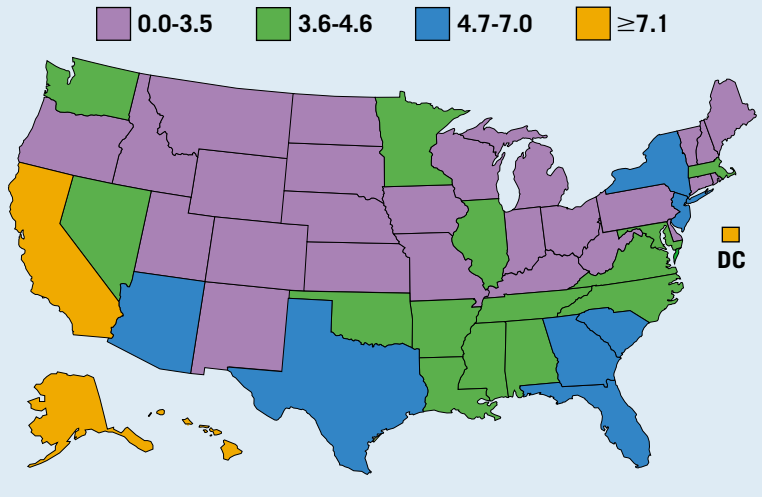
The FDA committee also voted unanimously to retain the current B strain—B/Malaysia/2506/2004-like virus—mirroring the WHO recommendation.

The 2006-2007 season has been fairly mild, Dr. Cox said. As of Feb. 17, widespread flu activity was reported in 24 states, 14 states reported regional activity, 10 reported local activity, and 2 reported sporadic activity.

For adults, the death rate from pneumonia and influenza—at 6.9%—was below the epidemic threshold of 7.9%. There were 3 pediatric deaths during that week, bringing the total to 15 deaths since the season began Oct. 1, 2006. ■

DATA WATCH

Rates of Tuberculosis in the United States
(per 100,000 population)



Source: Centers for Disease Control and Prevention

ELSEVIER GLOBAL MEDICAL NEWS

FDA Panel Backs Approval of 'Stopgap' Avian Flu Vaccine

BY ELIZABETH MECHCATIE
Elsevier Global Medical News

GAITHERSBURG, MD. — An inactivated H5N1 influenza virus vaccine that a federal advisory panel has recommended for approval would, if approved, become the first vaccine for avian influenza licensed in the United States.

At a meeting of the Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee, the panel agreed that there were sufficient data to support the safety and effectiveness of the investigational vaccine during an avian flu pandemic or in situations of potential high-risk exposure. The vaccine is based on an A/Vietnam strain of the H5N1 avian influenza virus.

The proposed indication for the vaccine, manufactured by Sanofi Pasteur, is for active immunization against influenza disease caused by the H5N1 A/Vietnam/1203/2004 influenza virus and for primary vaccination of healthy adults ages 18-64. Two 90-mcg doses of the vaccine would be administered intramuscularly, 28 days apart.

If approved, the vaccine would not be available commercially but would be part of the prepandemic vaccine stockpile in the United States.

Throughout the meeting, panelists and FDA officials referred to the vaccine as an "interim" or "stopgap" vaccine. Many other vaccines are being developed that are potentially better than this vaccine, said Dr. Norman Baylor, director of the FDA's office of vaccines research and review.

Panelist Robert Webster, Ph.D., chair of the department of virology and molecular biology at St. Jude Children's Research Hospital, Memphis, said it would not be clear how well the current vaccine works unless it were used in an actual pandemic. Nevertheless, if the H5N1 influenza virus does acquire human-to-human transmissibility, there will not be enough time to produce enough vaccine, so "we need this stockpile," he said.

Safety and efficacy data came from a prospective, multicenter randomized double-blind phase I/II trial launched in 2004 and conducted by the National Institute of Allergy and Infectious Diseases. Investigators measured hemagglutinin inhibition (HAI) immunogenicity in 452 adults, ages 18-64, who received two injections of different vaccine doses 28 days apart.

Among those who received the 90-mcg dose, the response rate (at least a fourfold increase in the HAI titer 28 days after the injection) was 23% after the first dose and 45% after the second dose, with a waning of the response rate to about 18% 6 months after the second dose, said Dr. Andrea James of the FDA's division of vaccines and related product applications. The immunogenicity in this study is less than that usually seen in studies of seasonal influenza vaccine, she pointed out.

Dose-related injection site reactions were the most common side effects, with 85% of those receiving 90-mcg doses having at least one such reaction.

The vaccine is also being investigated in a study of 259 elderly adults and a study of 125 children ages 2-9. Once the FDA makes a decision about licensing of the vaccine for people ages 18-64, the company will begin discussions about expanding the age range for approval, according to Sanofi Pasteur. ■

IGRAs Avoid False-Positive TB Results

TB Detection • *from page 1*

T-Spot.TB (Oxford Immunotec Ltd.), which detects or spots individual T cells, and can be used for the diagnosis of latent disease simply by detecting the presence of an effector T-cell response.

A major advantage of these new tests is that they avoid false-positive results caused by previous inoculation with the BCG vaccine, which is widely used outside the United States and is a critical factor in the screening of foreign-born individuals.

"Over time, this cross reactivity has led to a distrust of the skin test in vaccinated people, many of whom can't remember when or even if they received BCG," Dr. Daley said.

Dr. Daley, who consults for both companies, said that IGRAs are more sensitive and specific than the tuberculin skin test, and that the T-Spot.TB is more sensitive than Quantiferon-TB, while Quantiferon-TB is more specific. Both IGRAs correlate with exposure better than the tuberculin skin test, and may be more cost effective as well, he explained.

IGRAs also require only one patient visit, assess responses to multiple antigens simultaneously, do not boost anamnestic immune responses, provide results within a day, and greatly reduce interreader variability.

A prospective study of 393 consecutively enrolled patients with latent tuberculosis infection or suspected TB looked at agreement between the tuberculin skin test and both interferon-γ release assays, and found that indeterminate results were more common with Quantiferon-TB than with T-Spot.TB, particularly in young children and those who were immunocompromised (Lancet 2006;367:1328-34).

"We still need to study more populations to optimize sensitivity and specificity in these IGRA tests. I'm not convinced that the cut-points currently recommended by the companies are appropriate, and we need to know how these are going to work in the immunocompromised and in young children. There aren't enough data to guide us in these areas, so most people are kind of holding off on using these new assays," Dr. Daley said.

In addition, more needs to be learned about using IGRAs for serial testing. To that end, Dr. Daley and others are launching a four-center U.S. study of 3,000 health care workers who will be tested every 6 months with skin tests and both IGRAs.

Meanwhile, Dr. Daley and his colleagues at National Jewish are using Quantiferon-TB Gold and will begin using T-Spot.TB this summer. ■

Analysis Upholds Pulmonary Safety of Inhaled Insulin

BY NANCY WALSH
Elsevier Global Medical News

NEW YORK — The safety of inhaled insulin is holding up at 2 years in an ongoing study, with adverse pulmonary effects being small, occurring early, and proving reversible on cessation of the drug, Dr. Jay S. Skyler said at a meeting sponsored by the American Diabetes Association.

An interim analysis of a 5½-year multinational study that includes 441 patients with type 1 diabetes has found that declines in pulmonary function—most likely age related—were similar among patients randomized to receive either subcutaneous or inhaled insulin (Exubera, Pfizer) plus basal insulin.

The mean changes in forced expiratory volume in 1 second at 3 months for inhaled and subcutaneous insulin were –0.047 and –0.026, respectively, and at 24 months the mean changes from baseline were –0.104 and –0.082.

Only at the 3-month time point was the difference between the groups statistically significant.

Concerns that changes in pulmonary function would progress—which would have been a real worry—have not been borne out, explained Dr. Skyler, professor in the division of endocrinology, diabetes, and metabolism at the University of Miami, and the study's lead investigator.

CONCERNS THAT CHANGES IN PULMONARY FUNCTION WOULD PROGRESS—WHICH WOULD HAVE BEEN A REAL WORRY—HAVE NOT BEEN BORNE OUT.

There also have been concerns that repetitive inhalation of insulin particles could result in cumulative insults and the long-term development of fibrosis or tumors.

"But the statistical likelihood of a few drops of powder or liquid hitting the same spot on a repetitive basis is trivial to nonexistent," Dr. Skyler said.

He noted that the surface area of the adult human lung approximates that of a tennis court.

Among the 217 patients receiving inhaled insulin who completed the first 2 years of the trial, there also was a 33% reduction in risk of severe hypoglycemia compared with those receiving the drug subcutaneously (Diabetes Care 2007;30:579-85).

Patients receiving inhaled insulin did develop antibodies at an increased rate, said Dr. Skyler.

Mean insulin antibody levels at baseline were 4.50 and 4.15 mcU/mL in the inhaled and subcutaneous groups, respectively.

At 2 years, the respective levels were 64.5 and 3.85 mcU/mL.

"This was not surprising, because when a substance is taken in through the lung the immune system reacts in a Th2 fashion, favoring antibody formation," Dr. Skyler explained.

However, the antibodies do not appear to interfere with efficacy or to be associated with adverse effects, he added.

Researchers also looked at efficacy in the interim analysis, and found that glycemic control was sustained and similar in both groups.

Decreases in fasting glucose were greater among patients who were in the inhaled insulin group, and weight gain was significantly less.

"So one question that always comes up is, if it works and doesn't appear to have any major problems, and is priced not very differently from other insulins, why has it done so poorly in the marketplace?" Dr. Skyler said.

Since Exubera was approved in January 2006, marketing efforts for the inhaled insulin product have focused specifically on endocrinologists.

"I would submit that endocrinologists are the wrong target audience. We are not the ones who encounter the patients who are reluctant to use insulin," Dr. Skyler said.

"By the time patients reach us, with our team of nurse practitioners and educators, we can get people onto injected insulin with ease," Dr. Skyler continued.

Primary care physicians are more likely to see patients unwilling to go on injected insulin, he added.

Whether the use of inhaled insulin will increase when marketing efforts begin to target them remains to be seen, Dr. Skyler explained. ■

Controller Meds for Intermittent Asthma Cut ER Visits

BY DOUG BRUNK
Elsevier Global Medical News

SAN DIEGO — Targeting people who have severe intermittent asthma with control therapy could significantly cut down on the number of hospitalizations and trips to the emergency department, results from a large analysis of Southern California Kaiser Permanente enrollees suggest.

Intermittent asthmatics with a history of emergency hospital visits who were prescribed a controller medication in 2002 were 42% less likely to require emergency medical treatment in 2003, compared with those who did not receive a controller medication such as inhaled corticosteroids, inhaled long-acting β-agonists, inhaled cromolyn, or oral leukotriene modifiers.

The finding is important because during the measured year half of all patients who visited Southern California Kaiser Permanente emergency departments and hospitals for asthma had intermittent asthma.

"There is a group of intermittent asthmatics who we call severe intermittent asthmatics, who end up in the emergency room at the hospital a lot," Dr. Caroline C. Spagnola said in an interview during a poster session at the annual meeting of the American Academy of Allergy, Asthma, and Immunology. "We're trying to show that giving them inhaled controller medications helps prevent recurrences into the emergency room and the hospital."

She and her associates reviewed the pharmacy and diagnostic coding records of 109,682 asthma patients aged 5-56 years and classified them as having intermittent or persistent asthma. Intermittent asthma was defined having fewer than four dispensings of asthma controller and reliever medications in 2002, while persistent asthma was defined as having four or more dispensings of asthma controller and/or four or more reliever medications.

The primary outcome was asthma-related visits patients made to the emergency department or hospital in 2003.

Secondary outcomes included the percentage of patients prescribed controller medications and the mean number of combined hospitalizations and emergency department visits per patient in those who experienced emergency hospital use.

Receiving a prescription for controller meds reduced the risk of asthma-related emergency care.
DR. SPAGNOLA

The majority of patients studied (70%) had intermittent asthma, said Dr. Spagnola of the Southern California Permanente Medical Group, Los Angeles. Patients with intermittent asthma accounted for 2,022 (50%) of the 4,070 patients with primary outcome events and 2,341 (40%) of the 5,821 total outcome events identified.

The researchers also observed that patients who received a prescription for controller medications in 2002 had a 42% reduced risk of asthma-related emergency hospital care in 2003. This protective effect was seen in patients without a history of emergency hospital use in 2002 (odds ratio 0.79) but was more pronounced in patients who had such a history (odds ratio 0.68).

In their poster, the researchers acknowledged that a key limitation of the study is the fact that it measured medication dispensings, "which may not accurately reflect asthma medication use or clinical asthma status. Certainly, patients defined in our study as having intermittent asthma might have been judged to have persistent asthma if stratified by clinical guidelines rather than by administrative data."

Previous guidelines from the National Heart, Lung, and Blood Institute (NHLBI) have classified patients in either a mild intermittent, or a persistent category.

"We have long believed that there are differences within the 'intermittent' group and that not having asthma symptoms on an ongoing basis does not mean that patients have 'mild asthma.' This is borne out by our study results which showed that nearly half of all emergency department and/or hospital visits were made by patients we classified as 'intermittent.'

"These patients who we have termed 'severe intermittent' may correlate with 'low impairment, but high risk' in the new [NHLBI] guidelines," she noted.

No pharmaceutical industry research funding was used for the study, and Dr. Spagnola had no relevant conflicts of interest. ■

Advances in Diagnosis, Surgical Treatment Raise Physician Awareness of Tracheobronchomalacia

Nonsurgeons' interest in diagnosing the disorder grows as word spreads about the efficacy of surgery.

BY BRUCE JANCIN
Elsevier Global Medical News

SAN DIEGO — Think "tracheobronchomalacia" in the adult with progressive exertional dyspnea, a productive cough, and unremarkable spirometry findings, Dr. Simon K. Ashiku, FCCP, advised at the annual meeting of the Society of Thoracic Surgeons.

Tracheobronchomalacia (TBM) has historically been greatly underdiagnosed. But that's changing. The airway abnormality, which is often progressive and debilitating if not properly diagnosed and treated, is now on the radar screens of an increasing number of pulmonologists and internists. And thoracic surgeons anticipate a steady growth in referrals for membranous tracheobronchoplasty with polypropylene mesh, a highly effective, definitive therapy in carefully selected patients.

"There's more awareness of tracheobronchomalacia now in the pulmonary medicine community. We're going to be seeing a lot more cases," predicted Dr. Ashiku, a thoracic surgeon at Beth Israel Deaconess Medical Center, Boston.

TBM entails a softening of the trachea and mainstem bronchi, with flattening of the normally C-shaped tracheal rings. The result is an exaggeration of the physiologic narrowing and shortening of the large airway, which normally occurs during expiration when intrathoracic pressure exceeds intraluminal pressure. Common causes of TBM include chronic obstructive pulmonary disease (COPD), trauma, and congenital conditions.

The TBM patient's overcompliant airway collapses during expiration. The classic symptoms of TBM are progressive exertional dyspnea and a productive cough. The coughing fits are typically exacerbated by lying down. Recurrent pulmonary infections are also common.

Physician interest in TBM is increasing in part because of the availability of two reliable diagnostic studies: awake bronchoscopy under dynamic breathing conditions and dynamic airway CT. Plus, nonsurgeons are growing more interested in making the diagnosis as word gets around about the efficacy of surgery.

A STENTING TRIAL USING A REMOVABLE SILICONE STENT IS EXTREMELY HELPFUL IN DECIDING WHETHER TO OPERATE ON A PATIENT.

Continuous positive airway pressure and endobronchial stenting "are palliative, not definitive. Surgery is the only definitive therapy," Dr. Ashiku emphasized.

He said that a stenting trial using a removable silicone stent is extremely helpful in deciding whether to operate on a patient. That's because COPD is the etiology of TBM in roughly 60% of the patients he sees. In those patients, as well as some others, TBM symptoms may persist despite surgical restoration of normal airway anatomy. So if mechanical shoring up of the airway via a stenting trial of at least 2 weeks' duration doesn't improve symptoms, there's no point in subjecting a patient to major surgery.

"A stenting trial is the only way we've figured out so far to test COPD patients and see if their dyspnea is going to improve. You have to tease out what part of the patient's symptoms are due to small versus large airway disease," the surgeon continued.

When a patient improves with stenting but is a poor surgical candidate, Dr. Ashiku tries to leave the stent in place long term. However, one or more major complications—stent migration, mucosal damage, profound chest discomfort, intractable cough, infection—occur in 85% of stented patients.

"Stenting really isn't a good solution. The airways are huge. The stent sits in there and moves around a lot. It's just not natural to have anything in your airway," he explained.

Tracheobronchoplasty with propylene mesh is an attractive surgical solution because the mesh is placed outside of the airway, thus avoiding mucosal disruption.

Access is gained through a right posterolateral thoracotomy in order to apply mesh strips to the posterior membranous wall of the trachea and the right and left mainstem bronchi. The scaffolding must be extensive.

"If you leave any of the airway undone—and the distal left main is particularly hard to get to from a right thoracotomy—you'll have a choke point there and you'll get recurrent lower lobe infections and dyspnea," he said.

In Dr. Ashiku's experience, more than 90% of patients obtain complete or near-complete symptomatic relief. The average length of hospital stay is about 12 days, including 4 days in an intensive care unit. ■

Dr. Robert Cerfolio, FCCP, comments: *Dr. Ashiku and colleagues have presented an extremely important article on the undiagnosed problem of tracheobronchiomalacia. As obesity becomes an increasing problem in our society, as well as other societies around the globe, the incidence of this problem will increase. It already is relatively common and significantly undiagnosed. Although we agree that stenting leads to significant problems, surgery is risky as well and should be performed only in very carefully selected patients, and probably in specialized centers only. The key is patient selection. Patients should have airway mapping with videofluoroscopic spontaneous breathing studies first to ensure the problem is in the tracheal or main stem bronchi. Then patients should have trial with airway stenting with removable stents ONLY. If their symptoms resolve, then and only then should surgical mesh tracheobronchoplasty be considered. Although the earlier surgical results in a handful of patients are promising, the long-term results of these procedures are not known, and the word "curative" needs to be used with caution.*

Adult-Onset Asthma Boosts Cardiovascular Risk in Women

BY MITCHEL L. ZOLER
Elsevier Global Medical News

ORLANDO — Adult-onset asthma was linked to an almost twofold increased rate of coronary heart disease or stroke in women in a study with more than 15,000 people.

The mechanism behind this association is unknown but may be explained by an increased level of systemic inflammation in women with adult-onset asthma, Stephen Onufrak and associates reported in a poster at a conference on cardiovascular disease epidemiology and prevention sponsored by the American Heart Association. Prior findings from other studies also supported links between asthma and atherosclerotic events, and showed that the association was strongest in women, said Mr. Onufrak, an epidemiologist at Emory University, Atlanta.

The study used data collected from a total of 15,573 white and black persons who were enrolled in the Atherosclerosis Risk in Communities (ARIC) study from 1987 to 1989.

The study group included nearly 7,000 men, of whom 6,594 had no asthma, 227 had asthma that began during childhood, and 146 had adult-onset asthma. Also included were more than 8,600 women, with 8,093 who had no asthma, 214 who had childhood-onset asthma, and 299 whose asthma started after they became adults.

WOMEN WITH ADULT-ONSET ASTHMA WERE 70% MORE LIKELY TO DEVELOP CORONARY ARTERY DISEASE AND 79% MORE LIKELY TO HAVE STROKE.

For this analysis, the researchers defined childhood asthma as having its onset before age 21, and adult-onset asthma as appearing at age 21 or after.

The investigators then analyzed the rates of incident coronary heart disease or stroke during 12-14 years of follow-up based on the prevalence of asthma at baseline. The hazard ratios were adjusted to account for baseline differences in a number of demographic and clinical variables, including age, race, body mass index, smoking history, hypertension, serum lipid levels, and physical activity.

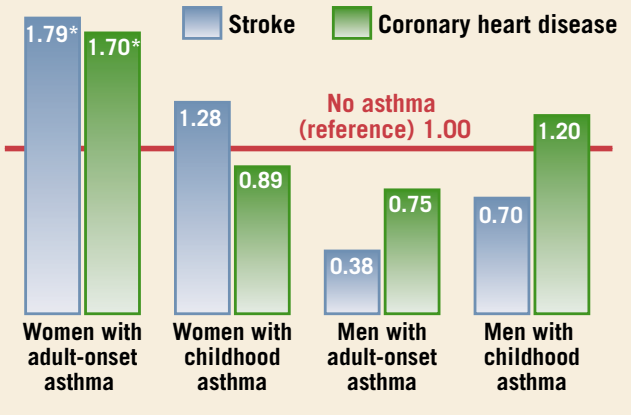
The analyses showed that women with adult-onset asthma were 70% more likely to develop coronary artery disease and 79% more likely to have stroke, compared with women without asthma. Both of these differences were statistically significant.

No significant change was seen in the hazard ratios for coronary heart disease or stroke, compared with people with no asthma, among women who had childhood asthma or among men with either adult-onset or childhood asthma (see box).

The investigators performed another analysis that focused just on the men and women who had never smoked.

Again, women with adult asthma had a statistically significant twofold increased risk of coronary heart disease or stroke, compared with women without asthma. No significant differences in outcome rates were seen in women with childhood asthma or among men, the researchers reported. ■

Hazard Ratios for Coronary Heart Disease And Stroke With Asthma



*Significant difference from reference level.
Note: Based on data from 15,573 people enrolled in ARIC study.
Source: Mr. Onufrak

ELSEVIER GLOBAL MEDICAL NEWS

Newly Vaccinated May Need Two-Dose Flu Follow-Up

BY MIRIAM E. TUCKER
Elsevier Global Medical News

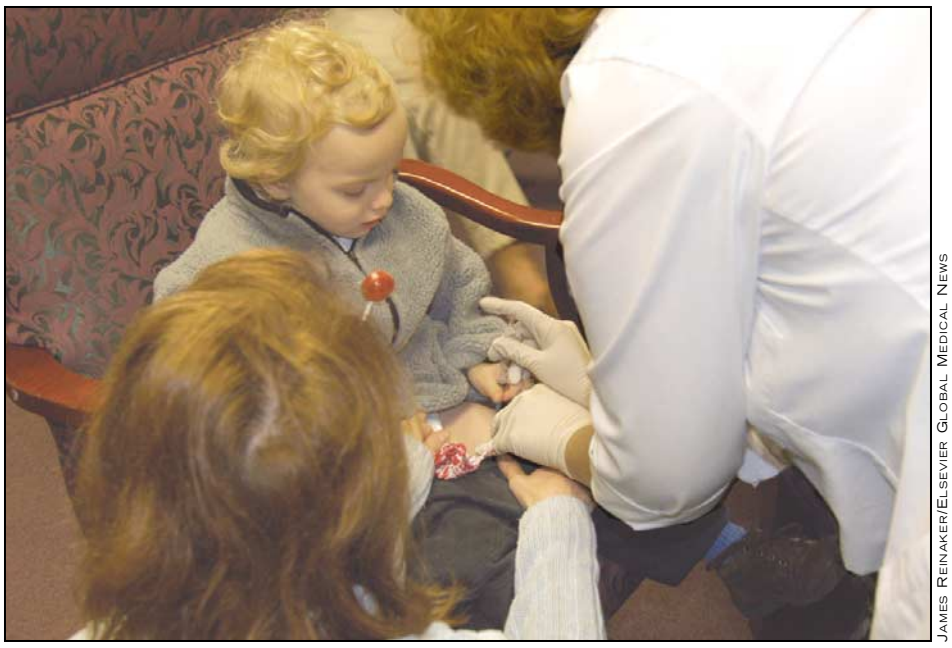
ATLANTA — Children aged 6 months to 9 years who did not receive two doses of vaccine the first time they were immunized against influenza should receive two doses the following season, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recommended at its winter meeting.

For an adequate immune response, children aged 6 months through 9 years receiving influenza vaccine for the first time are supposed to receive two doses given at least a month apart. But for a variety of reasons, some children receive only one dose. Two studies published in 2006 suggest that these children would be better protected against influenza if they receive two doses the following year, Dr. Anthony Fiore of the CDC's National Center for Immunization and Respiratory Diseases, told the committee.

In one study, when the influenza B antigen was changed for the second season, children who received only one dose in their first season of being vaccinated and one dose in their second season had less immunologic response to the influenza B antigen than children who received two doses (Pediatrics 2006;118:e579-85).

The other study showed that, in consecutive seasons when the influenza vaccine antigens were unchanged, effectiveness against influenza-like illness in the second season was less for 6- to 21-month-olds being vaccinated for the first time who received one dose in both seasons, than for 6- to 21-month-olds who received one dose in their first season and two doses in their second season (J. Pediatr. 2006;149:755-62).

The ACIP recommendation brings it in line with the American Academy of Pediatrics, which issued the same guideline in October 2006. The American Academy of Family Physicians, which usually follows ACIP's recommendations, will likely change its advice as well, AAFP coliaison Dr. Doug Campos-Outcalt said in an interview.



JAMES REINAKER/ELSEVIER GLOBAL MEDICAL NEWS

Studies suggest that children being vaccinated for the first time who receive only one dose of flu vaccine are better protected if they receive two doses the next year.

That recommendation was the only major change that will appear in the ACIP's 2007 influenza statement, which does not add any new age or risk groups for routine immunization, compared with 2006. The statement will continue last season's advice against the use of amantadine and rimantadine for treating or preventing influenza because resistance to the antivirals among H3N1 strains in the United States was more than 30% this season, Dr. Fiore noted.

The statement will, however, contain some new language. More direct wording will address the lack of scientifically conclusive evidence demonstrating harm from exposure to vaccine containing thimerosal preservative, and the recommendation that any age- and risk-factor–appropriate preparation is acceptable depending on availability. Prior to its vote on the influenza immunization statement, the ACIP heard a presentation summarizing available data on thimerosal.

Reinforcement of the need for health care workers to be immunized against influenza will be included in the statement, which also will mention new recommendations from several professional societies that all facilities employing health care workers offer the vaccine and require a written declination for those who chose not to be vaccinated.

New language on the timing of influenza immunization will note that although the ideal time is late September and October, immunization efforts should continue through January and beyond. Peak influenza activity occurs in February or March in most seasons, Dr. Fiore commented.

Pediatricians and family physicians who treat children should be aware that the ACIP is gearing up to expand its influenza vaccination recommendations beyond the current ages 6 months to 5 years to include all children aged 5-18 years. A meeting is planned for this summer to consider the scientific and implementation issues, with the goal of implementation for the 2008-2009 flu season, Dr. Ban Mishu Allos, the ACIP's influenza immunization task force chair, told the committee.

Indeed, universal annual childhood immunization against influenza is already a stated goal of several national, state, and regional professional health care organizations, Dr. Deborah Wexler, chief of the Immunization Action Coalition, informed the committee at the meeting.

Those groups include the American Academy of Physician Assistants, the American College Health Association, the American College of Obstetricians and Gynecologists, the American College of Preventive Medicine, and the American Hospital Association. Other supporters include the American Lung Association, the American Nurses Association, the American Osteopathic Association, the American Pharmacists Association, the National Medical Association, the National Hispanic Medical Association, the Society for Adolescent Medicine, and the Society of Teachers of Family Medicine. ■

Dr. LeRoy Graham, FCCP, comments: *Mounting evidence continues to support the concept of universal annual influenza vaccination in children age 6 months to 18 years. It also appears that two doses of vaccine in the initial year of immunization provide the greatest protective benefit.*

Physicians Petition FDA About Kids' OTC Cough and Cold Meds

BY ELIZABETH MECHCATIE
Elsevier Global Medical News

A citizen's petition filed by a group of Maryland pediatricians calls on the Food and Drug Administration to ban the marketing of over-the-counter antitussive, expectorant, nasal decongestant, antihistamine, and combination cough and cold products to children younger than 6 years.

The petition, filed with the FDA last month, also asks the agency to issue a public statement explaining that these products "have not been shown to be safe and effective for the treatment of cough and cold in children under six years of age."

The petition notes that in 2004, about 900 children in Maryland under age 5 overdosed on these products and, over the last 5 years, the medical examiner has linked at least four deaths in children under age 4 years in Baltimore "to unintentional overdoses of OTC cough and cold combination drug products."

The petition is signed by 14 pediatricians, including Dr. Joshua Sharfstein, commissioner of the Baltimore City Health Department, and the heads of pediatric departments at medical institutions in the city.

"Everyone agrees that infants and young children are fragile and we should be very confident that if medications are given to infants and young children, we do everything possible to ensure that the medications will be effective and that they are administered safely," Dr. Stephen Czinn, chair of pediatrics at University of Maryland Medical Center, Baltimore, and a signatory to the petition, said in an interview.

The manufacturers of these products should conduct well-designed studies in children aged 5 years and under to determine whether the medications are effective, said Dr. Czinn.

The petition cites studies that have not found these products to be effective, but that their availability in pharmacies has given the public the sense "that they have proven effectiveness and can and should be used," he added.

"For the sake of our children, it is important for parents to be educated and realize that very few of these medications have actually undergone rigorous testing to demonstrate they are effective," Dr. Czinn said, also referring to the exorbitant amount of money spent on these medications for young children.

During a press briefing March 2, FDA officials confirmed that the agency was reevaluating the safety and efficacy of OTC cough and cold products in children. Dr. Charles Ganley, director of the FDA's office of nonprescription drug products, said that the agency is examining questions that include how efficacy was determined for these products and how adult data are extrapolated to children.

The review was started last year—after deaths were reported in children who took prescription cold products containing the sedating antihistamine carbinoxamine—to determine if approved OTC cough and cold products were associated with similar cases, Dr. Ganley said.

In June 2006, the FDA announced that it had ordered manufacturers of unapproved products containing carbinoxamine to stop marketing the products, some of which were being promoted for use in infants and children under age 2. In a statement issued at that time, the FDA had received 21 reports of deaths in children that age that were associated with drugs containing carbinoxamine.

Historically, efficacy in children has been based on efficacy in adults, and extrapolating that data to children, generally with pediatric pharmacokinetic data to determine the dose—a process that is also under review, Dr. Ganley said.

He pointed out that millions of OTC doses of cough and cold products are used weekly in the United States "very safely," but parents need to strictly adhere to dosing instructions, and should consult with their physicians when so instructed on the package. ■

Dr. LeRoy Graham, FCCP, comments: *Complications due to misuse of OTC cold preparations in children seem to be infrequent. However, the fact that they do occur at all with the use of medications without proven efficacy in a population targeted by aggressive marketing is deplorable. In the absence of appropriate clinical trials to explore efficacy in this population, their continued use should be strongly discouraged.*

Quality Measures Crafted for Palliative, Hospice Medicine; Evidence-Based Indicators to Come

BY BRUCE K. DIXON
Elsevier Global Medical News

The National Quality Forum has published a comprehensive quality measurement and reporting system for the new subspecialty of hospice and palliative medicine.

"A National Framework and Preferred Practices for Palliative and Hospice Care Quality" crosses all health care settings and establishes minimum preferred practices. Published in December by the National Quality Forum (NQF), the framework is intended to be the first step in a process through which rigorous, quantifiable internal and external quality indicators are developed. The document is based on an extensive set of clinical practice guidelines published in 2004 by the National Consensus Project for Quality Palliative Care (NCP).

The NQF is a private, not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting. NQF was assisted in this project by the Robert Wood Johnson Foundation.

The NCP is a consortium of the American Academy of Hospice and Palliative Medicine, the Center to Advance Palliative Care, the Hospice and Palliative Nurses Association, and the National Hospice and Palliative Care Organization.

"Together, these two documents define the state of the art in palliative care practices," according to the NQF report. Of particular importance, palliative care services are indicated across the entire trajectory of a patient's illness; their provision should not be restricted to the end-of-life phase.

The field of palliative care "is escalating dramatically in response to an aging population and an overburdened health system. People are eager for direction in terms of palliative care," said NCP chair Betty R. Ferrell, Ph.D., of the City of Hope National Medical Center in Duarte, Calif.

More than 2,000 U.S. hospitals have palliative care programs of some kind, but the interdisciplinary care outlined in the NCP guidelines remains confined mostly to large, metropolitan hospitals, Dr. Ferrell said in an interview.

"What we have to do now is catch up the practice. A family practice doctor may say he takes care of dying patients, but now we have to make sure that that doctor knows what to do, that he's competent in pain management, knows how to break bad news, and holds family conferences in the ICU. The culture has changed, but there's still an enormous amount of work to be done to translate this change in attitude into action," she said.

According to the NCP, palliative care should be integrated into all health care for debilitating and life-threatening illnesses. The NCP framework for quality assessment emphasizes these goals:

- Address pain and symptom control, psychosocial distress, spiritual issues, and practical needs with patient and family throughout the continuum of care.
- Offer patients and families the information they need in an ongoing and understandable manner, so they may grasp their condition and treatment options. Elicit their values and goals over time; regularly reassess the benefits and burdens of treatment; and remain sensitive to changes in the patient's condition during the decision-making processes about the care plan.
- Ensure genuine coordination of care across settings with regular, high-quality communication, particularly at times of transition or changing needs. Use case management techniques to provide effective continuity of care.
- Prepare both the patient and family for the dying process and for death, when it is anticipated. Explore hospice options; allow opportunities for personal growth; and offer bereavement support for the family.

"These quality indicators will advance palliative care in all disciplines to improve the quality of life of people facing life-threatening and chronic, debilitating diseases," said Judy Lenz, R.N., who is chief executive officer of the Hospice and Palliative Nurses Association.

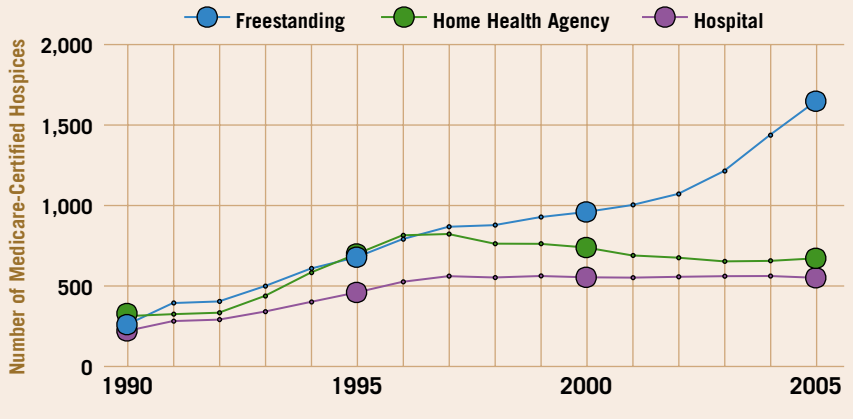
The NQF preferred practices will assist in laying the foundation for all hospice and palliative care services as well as to maximize the quality of care in a cost-effective manner, said Dr. Ronald S. Schonwetter, executive vice president and chief medical officer of LifePath Hospice and Palliative Care in Tampa. Medicare reimbursement for hospice and palliative care will likely be influenced by pay-for-performance quality measures at some point, said Dr. Schonwetter in an interview.

A technical report to identify appropriate evidence-based quality indicators for the specialty is being worked on by researchers at the University of North Carolina, at Chapel Hill. They will turn over the findings of their report to the Centers for Medicare and Medicaid Services in the next year.

"The NQF and the development of preferred practices are crucial steps in that process," explained Dr. Schonwetter, who is the immediate past president of the American Academy of Hospice and Palliative Medicine. ■

DATA WATCH

Number of Freestanding Medicare-Certified Hospices Rapidly Increasing



Notes: Based on data from the Centers for Medicare and Medicaid Services.
Source: Hospice Association of America

ELSEVIER GLOBAL MEDICAL NEWS

Medical Groups Support Subspecialty Certification

BY BRUCE K. DIXON
Elsevier Global Medical News

SALT LAKE CITY — The new subspecialty of hospice and palliative medicine will be open to osteopathic as well as allopathic physicians, following a decision by the American Osteopathic Association's Bureau of Osteopathic Specialists to approve certification in the discipline.

The Feb. 16 action complements a decision by the American Board of Medical Specialties last September to move forward with plans to allow allopathic physicians to become certified in the new subspecialty. ABMS-recognized certification will be offered to physicians in 10 specialties: anesthesiology, emergency medicine, family medicine, internal medicine, pediatrics, physical medicine and rehabilitation, psychiatry and neurology, radiology, surgery, and obstetrics and gynecology.

Osteopathic certification in the new field will be offered to osteopathic physicians in four specialties: family medicine, internal medicine, neurology and psychiatry, and physical medicine and rehabilitation.

Sponsorship of a subspecialty by such a large number of specialty boards is unprecedented, according to Dale E. Lupu, Ph.D., chief executive officer of the American Board of Hospice and Palliative Medicine (ABHPM), in Silver Spring, Md. "Having 10 specialties working together is completely new," she said at the annual meeting of the American Academy of Hospice and Palliative Medicine.

It took the ABHPM 10 years to persuade the ABMS to recognize hospice and palliative medicine as a medical subspecialty, Dr. Lupu said. From 1996 through 2006, the ABHPM certified more than 2,800 physicians in hospice and palliative medicine, she added.

The effort to achieve ABMS-recognized subspecialty status also involves accreditation of graduate medical education by the Accreditation Council of Graduate Medical Education (ACGME). "Successful completion of an accredited educational program usually is a prerequisite to admission to an ABMS board examination," Dr. Lupu noted.

Starting in 2008, a new certification exam will be available, and will be administered by the cosponsoring ABMS member boards.

During a 5-year grandfather period (2008-2012), physicians from the 10 ABMS specialties can sit for the board exam in hospice and palliative medicine without completing fellowship training, said Dr. Ronald S. Schonwetter, executive vice president and chief medical officer of LifePath Hospice and Palliative Care in Tampa.

During this period, applicants must qualify for the exam by having cared for at least 50 terminally ill patients and by meeting other criteria. (Eligibility requirements can be viewed at www.abhpm.org, and other information is available at the American Academy of Hospice and Palliative Medicine Web site, www.aahpm.org.)

After the initial 5-year period, "it will be necessary for [applicants] to take a year-long fellowship training before they can sit for the board and be certified in hospice and palliative medicine," Dr. Schonwetter, a former chairman of the ABHPM, said in an interview.

There's much work to be done, he added, including the development of programs in unique settings, such as psychiatry, neurology, radiology, and anesthesiology.

"We need to expand our services among hospitals, nursing homes, and assisted living facilities, and we need to educate and understand the needs of physicians from the multiple disciplines" who wish to become palliative care specialists, Dr. Schonwetter said.

"Approval of hospice and palliative medicine by 10 ABMS specialties shows the desire for this type of care by our colleagues, who see on a first-hand basis what hospice and palliative medicine can do for their patients," he added.

Fast-Track Lobectomy Protocol Delivers Cost Savings

BY BRUCE JANCIN
Elsevier Global Medical News

SAN DIEGO — A fast-track protocol following lobectomy that eliminates numerous time-honored but apparently unnecessary practices markedly reduces hospital length of stay while maintaining high-quality clinical outcomes, Dr. Robert J. McKenna Jr. said at the annual meeting of the Society of Thoracic Surgeons.

This accelerated management protocol is the product of the sort of critical self-examination required of thoracic surgeons if their specialty is to thrive in the face of increasingly stiff competition, added Dr. McKenna, surgical director of the Cedars-Sinai Center for Chest Diseases and professor of thoracic surgery at the University of California, Los Angeles.

"Thoracic surgery is being attacked by minimally invasive procedures. We need to make sure that what we do is as cost effective as possible," he explained.

For example, in 2007 most surgeons still consider the presence of a chest tube postoperatively to be an indication for chest x-rays. It's a long-standing tradition. But it's a practice that adds cost and lengthens hospital stays while providing negligible clinical value—and so it has been discarded in the Cedars-Sinai fast-track protocol.

Other elements of the fast-track protocol include no routine postoperative laboratory tests, no routine ICU stay, the use of hydrocodone (Vicodin) and subcutaneous hydromorphone (Dilaudid) for pain rather than epidural analgesia, and discontinuation of chest tubes when output drops below 300 cc in 24 hours provided no air leak is present. If there is an air leak, the patient is discharged with a Heimlich valve once chest tube output is less than 300 cc in 24 hours.

With the fast-track protocol, 46% of patients went home 1 or 2 days after the procedure.
DR. McKENNA

Dr. McKenna reported on 282 consecutive patients who had video-assisted thoracoscopic (VATS) lobectomy at Cedars-Sinai under the fast-track protocol. Mean and median lengths of stay (LOS) were 3.26 and 3.0 days, and 46% of patients went home on postoperative day 1 or 2.

The mortality rate was 0.4%, air leaks lasting more than 1 week occurred in 2.8% of patients, 3.9% received blood transfusions, and 1.8% developed postoperative atrial fibrillation. One patient had deep vein thrombosis. In 89.3% of cases, no complications occurred after the procedure. Only two patients were readmitted: one due to a transient ischemic attack, and one who had a prolonged air leak and could not tolerate an outpatient chest tube.

The institutional payoff of such a fast-track policy is sizable. Under the Diagnosis-Related Groups system, Medicare pays roughly $24,000 per lobectomy, unless a patient is a major outlier. "Whether your patient is in the ICU for 3 days and in the hospital for 10, or just overnight, the hospital gets the same money," Dr. McKenna said.

At Cedars-Sinai, the average direct costs entailed in a VATS lobectomy with a 2-day LOS come to $5,838, compared with $8,548 for the 7-day LOS more typical elsewhere. Another way to look at the financial side is to determine how many lobectomies can be done per hospital bed in a year. At Cedars-Sinai, which is always filled to capacity, the profit per lobectomy-dedicated bed per year is $776,100 with a 7-day LOS but $2,254,000 with a 2-day LOS.

While VATS lobectomy is the norm at Cedars-Sinai, the fast-track protocol should be equally applicable to the open procedures that constitute the vast majority of lobectomies performed worldwide, Dr. McKenna added.

His report of markedly shortened LOS turned heads. "Eighty-nine percent of patients had no complications. What do you say to those results? They're just incredible," said Dr. Robert J. Cerfolio, FCCP, professor of surgery and chief of thoracic surgery at the University of Alabama, Birmingham.

"Pretty amazing," added Dr. Joe B. Putnam, professor of surgery and chair of the department of thoracic surgery at Vanderbilt University, Nashville, Tenn. But Dr. Cerfolio also sounded a cautionary note: "I've noticed that since I've hired somebody in my practice to do a better job of follow-up, I've become a much worse surgeon. More people are coming into the emergency room than I was aware of in the past. Our 90-day mortality has gone up because we weren't previously aware of problems at home."

Dr. McKenna conceded his follow-up data aren't comprehensive. "Our patients fly in from all over the country and around the world, but I do see them the day before they leave to make sure they're doing well," he said. Moreover, he noted, his Southern California patients return 1 week postdischarge and again 1 month later—and 90% of them have complication-free recoveries. ■

Aspiration Risk Overlooked After Pulmonary Resection

The incidence of dysphagia with aspiration after thoracotomy was 17%, or roughly one in six.

BY BRUCE JANCIN
Elsevier Global Medical News

SAN DIEGO — Aspiration following major pulmonary resection is a surprisingly common and underrecognized problem, Dr. W. Brent Keeling reported at the annual meeting of the Society of Thoracic Surgeons.

His prospective study of carefully screened patients showed the incidence of dysphagia with aspiration after thoracotomy for pulmonary resection was 17%, or roughly one in six.

The number is far greater than most surgeons would guess, but that's because they don't systematically look for it, and the thoracic surgery literature gives this postoperative complication short shrift, according to Dr. Keeling of the University of South Florida, Tampa.

Dr. Keeling reported on 176 consecutive patients who underwent a bedside clinical swallowing evaluation by a speech pathologist and surgeon on postoperative day 1 after thoracotomy for pulmonary resection. Thirty-seven (20.9%) failed the clinical exam, which included observed swallowing of thin liquids and pureed and solid foods. They were referred for a diagnostic videofluoroscopic esophagram, which demonstrated evidence of dysphagia with aspiration in 30 of 37 patients, or 16.9% of the total population.

The diet of patients without evidence of aspiration was advanced as tolerated. In contrast, patients with positive radiographic findings were maintained without liquids or solid food, with insertion of an enteral feeding tube as indicated.

Impaired swallowing with aspiration is typically transient, however, and none of the patients in this series was discharged with a temporary or permanent enteral feeding tube in place, the thoracic surgeon continued.

Only one patient experienced aspiration following a negative clinical screening exam.

His study also identified several potential risk factors for aspiration following major pulmonary resection. These included advanced age, a non–muscle-sparing posterolateral thoracotomy, mediastinal lymphadenectomy, neoadjuvant chemotherapy, and prior or current head and neck cancer.

But whether increased awareness of an individual's aspiration risk coupled with initiation of preventive measures will reduce the incidence of postoperative pneumonia remains to be seen.

Dr. Keeling noted that an increased risk of pulmonary complications in head and neck cancer patients after pulmonary resection was also reported in a recent study from the M.D. Anderson Cancer Center, Houston.

In that study, the malignancy was independently associated with a 17.5-fold increased risk of aspiration pneumonia (Ann.Thorac. Surg. 2006;82:1982-7).

"Our study is clearly influencing our practice in that all patients now receive a clinical evaluation of swallowing on postoperative day 1, and we go on from there," Dr. Keeling said in an interview.

In the subgroup with a history of head and neck cancer—which often is associated with non–small cell lung cancer—he and his colleagues are even more proactive. Those patients get a swallowing evaluation prior to undergoing lung resection.

He and his coinvestigators are still accruing patients and haven't yet done a cost-benefit analysis of routine screening for aspiration early after major lung resection, but Dr. Keeling believes the practice is likely to be highly cost effective. The hospital charge for a speech pathology evaluation is a couple of hundred dollars, and a videofluoroscopic exam is twice that. But a single episode of aspiration pneumonia typically entails more than $60,000 in hospital charges. ■

Dr. Robert Cerfolio, FCCP, comments: *Aspiration, both silent and clinically apparent, is the number one morbidity in general thoracic surgery. It is exceedingly common in patients who undergo pulmonary resection as well as esophagogastrectomy, and the use of a double-lumen tube is an underappreciated culprit of this problem. The keys to avoiding serious postoperative aspiration from occurring are to educate the patient and to take strict aspiration precautions postoperatively. Since we have done this and just assume that all patients aspirate, we have reduced our morbidity from this vexing problem, but have not eliminated it.*

Lung Cancer Resection Mortality Lower at Teaching Hospitals

BY BRUCE JANCIN
Elsevier Global Medical News

SAN DIEGO — Lobectomy for lung cancer is associated with significantly lower in-hospital mortality when performed at teaching, as compared with nonteaching, hospitals, Dr. Robert A. Meguid reported at the annual meeting of the Society of Thoracic Surgeons.

"There's a public perception that teaching hospitals can be dangerous places because of training issues, and concerns are frequently voiced by patients and echoed in the lay press regarding a fear of physicians-in-training practicing upon them," he noted. "The data from our study refute these fears."

His study, which reviewed 50,576 lung resections performed in 37 states during 1998-2003, earned the J. Maxwell Chamberlain Memorial Award for the top general thoracic surgery study presented at the meeting.

Of the resections, 75% were lobectomies, 15% segmentectomies, and 10% pneumonectomies. Just over half of the procedures were done at teaching hospitals.

The study data came from the Nationwide Inpatient Sample, a large retrospective administrative database, explained Dr. Meguid of Johns Hopkins University, Baltimore.

In-hospital mortality occurred in 3.6% of patients at teaching hospitals and 4.0% at nonteaching hospitals, a statistically significant difference. The rates were 2.9% and 3.6% for lobectomy, respectively, whereas there was no significant difference for the other resection types in postop mortality based on hospital type.

Mortality in this study proved to be independent of hospital case volume. That is in contrast with earlier studies showing better outcomes for esophageal and pulmonary resection, carotid endarterectomy, coronary artery bypass graft, and several other operations when they are done at high-volume centers

In a multivariate logistic regression analysis controlling for potential confounders including patient demographics, comorbidities, and hospital case volume, lobectomy at a teaching hospital was independently associated with a 19% reduction in the risk of mortality.

It's high time to get the word out to patients and physicians that teaching hospitals are safe places to undergo lung resection, Dr. Meguid said.

He added that the next step in the research will be to try to pin down the specific factors contributing to better outcomes at teaching hospitals and disseminate those measures, to whatever extent possible, to nonteaching hospitals to raise the overall standard of care.

"We suspect that many of the factors contributing to the observed differences are due to differences in the processes of care that exist between teaching and nonteaching hospitals," he continued.

These include the presence of subspecialty-trained surgeons; care from in-house residents, fellows, and physician extenders; access to dedicated surgical ICUs; comprehensive safety initiatives; and clinical care protocols for postop management.

Discussant Dr. Carolyn E. Reed, FCCP, urged caution in interpreting the results.

She noted that word of a 19% relative risk reduction in mortality could trigger a media circus and a major shift in referral patterns among cancer patients, reactions that would be premature. "The absolute mortality difference in the study is small," Dr. Reed said, and could be due to differing institutional case mixes.

Moreover, the data's validity is called into question by the finding that pneumonectomy mortality didn't differ by hospital type.

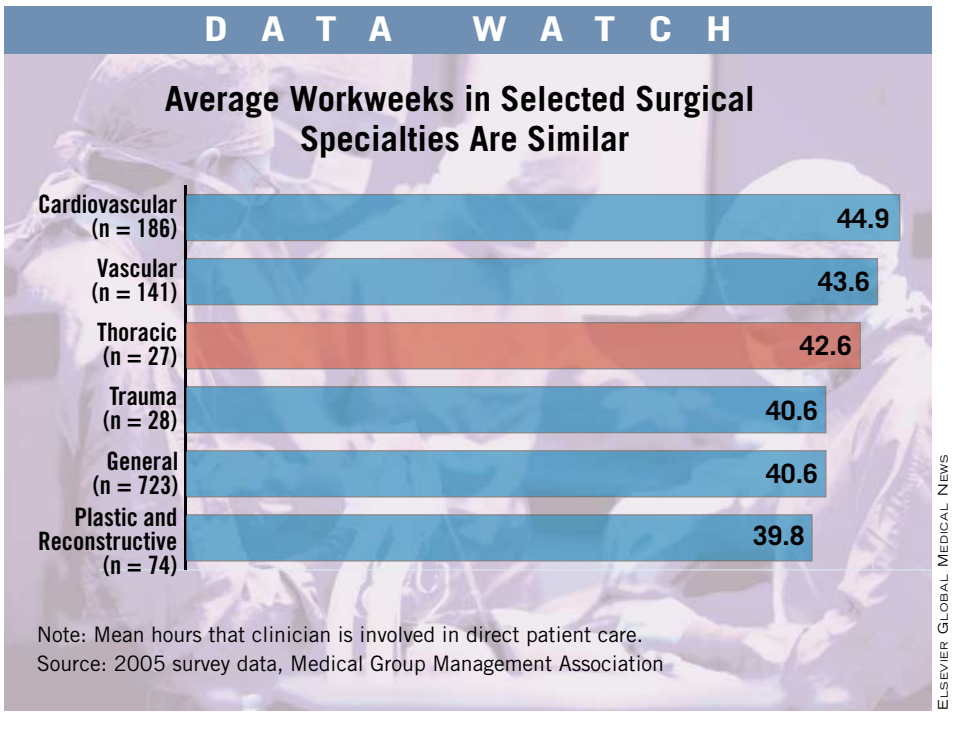
This operation is typically reserved for the most complex cases, and the associated mortality difference would be expected to be even larger than for lobectomy, said Dr. Reed, professor of surgery and chief of general thoracic surgery at the Medical University of South Carolina, Charleston.

"We must be very careful about outcome data because the public, policy makers, and payers are eager to manipulate this information to their own ends," Dr. Reed said.

With such low national in-hospital mortality, perhaps a more meaningful study end point would be 30-day mortality, 6-month disease-free survival, or a functional performance measure, she added. ■

Dr. Robert Cerfolio, FCCP, comments: *It has been long recognized that teams who perform more operations than teams who do not will over time fare better. This is in part a reflection of a surgeon who does 3-4 procedures a day, compared with one who does 1-2 a month. However, even more important may be the team that surrounds the surgeons, who know just how to care for that type of patient. It is the team that makes the difference.*

DATA WATCH



ELSEVIER GLOBAL MEDICAL NEWS

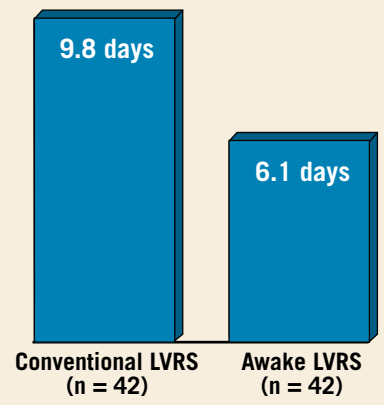
Novel Lung-Volume Reduction Surgery Cut Hospital Stay

BY BRUCE JANCIN
Elsevier Global Medical News

SAN DIEGO — Awake thorascopic nonresectional lung-volume reduction surgery in patients with disabling emphysema results in a survival benefit similar to that of conventional resectional surgery, but with substantially shorter hospital stays and lower costs, Dr. Eugenio Pompeo said at the annual meeting of the Society of Thoracic Surgeons.

He compared outcomes in 42 consecutive patients who underwent the novel procedure, which was developed by Dr. Pompeo and colleagues at the University of Rome Tor Vergata, with a control group consisting of the 42 patients who most recently underwent conventional resectional lung-volume reduction surgery (LVRS) under general anesthesia and single-lung ventilation at the university.

Mean Hospital Stay Shorter In Awake Nonresectional LVRS



Source: Dr. Pompeo

Survival at 2 years was similar in the awake surgery group (87%) and in controls (91%). Fewer than one-quarter of patients in each study arm underwent LVRS for disabling emphysema symptoms in the contralateral lung within 2 years.

The BODE index—a composite of body mass index; obstruction of airflow as assessed by spirometry; dyspnea grade as assessed by modified Medical Research Council criteria; and exercise capacity as reflected in the distance covered in a 6-minute walk, a test that's widely utilized in following patients with chronic obstructive pulmonary disease—showed an average 2.24-point improvement at 2 years in the awake surgery group and a comparable 1.9-point improvement in controls.

The mean hospital stay was 6.1 days in the awake surgery group, compared with 9.8 days with conventional LVRS. Procedure-related costs averaged 5,460 euros in the awake group and 9,591 euros in controls, the surgeon said.

The novel awake nonresectional form of LVRS relies upon thoracic epidural anesthesia delivered by a catheter inserted at T4 in order to achieve its effects at the T1-T8 levels. One of its major purposes is to achieve motor block of the intercostal muscles while preserving diaphragmatic breathing.

The thorascopic surgical technique entails introflexion of the most emphysematous areas of the upper lung lobe with a cotton swab, grasping the redundant lung edges with forceps, and using a 45-mm no-knife endostapler with a 3.5-mm cartridge to plicate a suture line starting at the apex of the upper lobe and continuing along the ventral and dorsal sides.

The result is roughly a 50% reduction in upper-lobe volume achieved without any loss of lung tissue. A comparable decrease in volume was accomplished via resection in the 42 controls, Dr. Pompeo said.

Session cochair Dr. Michael S. Mulligan, FCCP, expressed concern about the possibility of an awake patient experiencing decompensation, which would mandate urgent intubation and isolation of the lung.

"It's a little intimidating for some of us to think about these critically ill patients being wide awake while we're making holes in their chest and operating on them," added Dr. Mulligan, a thoracic surgeon at the University of Washington, Seattle.

Dr. Pompeo replied that urgent conversion to conventional LVRS was required twice in the 42-patient series and was accomplished without a hitch.

Elsewhere at the meeting, Dr. Malcolm M. DeCamp, FCCP, noted what he termed the drastic underutilization of LVRS for severe emphysema. Although the Centers for Medicare and Medicaid Services approved payment for LVRS at authorized centers, based on the results of the landmark 1,200-patient National Emphysema Treatment Trial (NETT), the agency paid for a mere 225 or so of the operations in 2005.

"We know that the estimated number of patients out there suffering is in the millions," said Dr. DeCamp, chief of cardiothoracic surgery at Beth Israel Deaconess Medical Center, Boston.

He blamed the situation on patients' lack of awareness of LVRS and on apathy in the general medical community. Many physicians, he said, are unaware that the mature 5-year NETT results showed a significant overall 14% relative risk reduction in mortality with LVRS, compared with best medical therapy, and a 37% reduction in the subgroup with upper-lobe–predominant disease and low exercise capacity. Perhaps more important to patients, LVRS also conferred substantial, durable improvements in exercise capacity and quality of life (Ann. Thorac. Surg. Aug. 2006;82:431-43).

"Based on a tremendous collaborative effort [among pulmonary medicine, surgery, and the government], we've conducted a 1,200-patient trial that has to be considered by almost any standard a positive one, yet we're unfortunately not seeing very many cases," Dr. DeCamp said. ■

New Data Demonstrate Decline in Ocular Infection After Transplant

Opportunistic ocular infections in heart, lung, and heart-lung transplant recipients may not be as common as once thought, a prospective study indicates.

In 115 patients followed for a median 43 weeks, only one developed an ocular infective complication—*Aspergillus* endophthalmitis—after surgery, reported Toks Akerele and Dr. Susan Lightman of Moorfields Eye Hospital, London.

Regular ophthalmic screening of asymptomatic patients for complications can be forgone, the investigators concluded, but physicians need to maintain a "high index of suspicion" and act promptly when a problem is identified (Br. J. Ophthalmol. 2007;91:310-2).

Ocular examinations were performed at time points ranging from immediately after transplantation to 25 years after the procedure (median 43 weeks). The median age of the transplant recipients was 51 years.

Of 115 heart, lung, and heart-lung transplant recipients at a post-transplantation outpatient clinic at Harefield Hospital in London, 54% had complications at follow-up. The most common findings were cataracts (17%), hypertensive change (8%), chorioretinal scarring (5%), and diabetic retinopathy (3%), the investigators wrote.

The study found that 18 patients (16%) were symptomatic at examination; blurred vision was the most common symptom.

Compared with 43% of symptomatic patients, only 14% of asymptomatic patients had ocular findings that may be associated with transplantation. "Transplant patients should be encouraged to report promptly if they have ocular symptoms and symptoms should prompt further investigation," they advised.

The investigators cited previous studies showing that as many as 16% of patients with ocular complications after solid organ transplants had opportunistic infections. However, surgical technique improvements; immunosuppressive regimes, which are required long-term; and "increasingly effective" forms of antimicrobial treatment and prophylaxis have "changed the natural history of opportunistic infection following transplantation," they wrote.

In addition to those gains, the investigators also attributed the low incidence of diabetic and hypertensive retinopathy and the mild signs to "the good control and high patient motivation that is required before embarking on transplant surgery."

—Lorinda Bullock

Pulmonary Perspectives

The Legislative Path to Differential Reimbursement

Recent federal legislation has authorized the Centers for Medicare and Medicaid Services (CMS) to implement a nationwide pay-for-performance (P4P) program for physicians.

This approach is not a new concept in the world of manufacturing or even in health care. Currently, more than 35 health plans representing 30 million members offer P4P programs. At least 80 private health plans are expected to have similar programs in place in the near future. The United Kingdom has implemented a comprehensive program within its National Health System.

Background

The US Congress became alarmed when Medicare spending on physician services began to accelerate in the 1980s. In response, the Omnibus Budget Reconciliation Act of 1989 reformed the way Medicare paid for physician services.

This legislation required the establishment of a physician fee schedule and a system of spending growth targets, the Medicare Volume Performance System. On January 1, 1996, with the assistance of the AMA, Medicare carriers implemented a system of automatic denials of certain physician charges within their claim processing under the Correct Coding Initiative. In 1998, the Sustainable Growth Rate (SGR) system of spending targets replaced the Medicare Volume Performance Standard. While the resource-based relative value scale (RBRVS) fee schedule was carried forward, Congress established a new formula for determining the annual update for Medicare payment rates for physicians' services. Despite these legislative revisions, Medicare spending on physician services continued to accelerate. In 1980, Medicare spending for physician services totaled $7.5 billion; by 2003, Medicare spending on these services totaled $47.9 billion. With the publication of the Institute of Medicine's report on medical errors and needless deaths, policy makers flocked to the idea of a new reimbursement system based on physician reporting of specific practice information and backed up by public reporting of physician compliance.

Recent Legislation

As a prelude to implementing this system, CMS developed a voluntary reporting program with no financial consequences in early 2005. This became operational in 2006 as the Physician Voluntary Reporting Program.

Legislation was required, however, to allow CMS to introduce differential reimbursement of physicians for their services. Legislation had been introduced in both the House and Senate in mid-2005 under the rubric of "value purchasing." These bills stalled in committee; however, there was extensive P4P language inserted in the Senate version of the Deficit Reduction Act of 2005 by Senators Grassley and Baucus. This language was removed from the final bill by House Conferees. With the passage of HR 6111 in late December 2006, CMS was given the authority to begin a differential reimbursement system based on physician reporting of specified data. The bill provides for an additional 1.5% reimbursement for data reporting beginning on July 1, 2007. The program, as outlined in the bill, would cover the period from July 1, 2007, through December 31, 2007. Modifications in the initial program will be developed for 2008. While some have celebrated this as a 1.5% bonus, this could only be considered a bonus if you feel that the current reimbursement for E&M services minus the expenses of operating a practice, which have risen from an overhead of 30 to 45% and more in recent years, is equitable and that no extra work will be involved in the reporting process.

IMPROVEMENT IN QUALITY AND COST WILL ONLY OCCUR WHEN POLICY MAKERS ARE WILLING TO CONFRONT OUR TECHNOLOGICALLY ADVANCED, FOR-PROFIT HEALTH-CARE SYSTEM.

Challenges

There are a number of unanswered questions about the program authorized in HR 6111, and it has been left to CMS to develop the rules and regulations. It is not entirely clear what the base amount eligible for the additional 1.5% will be, and the legislation has included a formula that will limit the extra payment amount. Since there will be a 2-month window in the beginning of 2008 to complete claims submission for 2007, and an unspecified time for CMS to review and verify the data, I would expect the additional reimbursement for 2007 no earlier than the summer of 2008. Important questions include:

- How will the base reimbursement level be established in the future?
- From where will the additional P4P funds come?
- Will the money for the new system be taken out of the current pot or will there be additional monies for compliance with performance measures?
- Will the "bonus" money be paid annually or semiannually?

Conceivably, services rendered in January of one year may not be paid in full until March of the following year. Public reporting of physician compliance will be part of the program. How rapidly and how publicly this will take place has not been defined.

The initial reporting of data will probably be direct submission on the CMS claim form. CMS has been instructed to explore a mechanism for physicians to provide data on quality measures through a medical registry, such as the Society of Thoracic Surgeons National Database. Measures that qualify for additional reimbursement at this time are the measures of the 2007 Physician Voluntary Reporting Program, which did not include any pulmonary indicators. The current list is not final, and additions may be implemented by CMS. CMS has been asked to publish a proposed set of quality measures appropriate for use in 2008 by August 15, 2007, in the *Federal Register*.

In their attempt to find a solution to escalating costs, politicians are making the mistake of believing that cost and quality issues are directly linked. Advocates are creating the impression that this additional micromanagement of physicians will promote market competition, control costs, and improve the quality of health care. They have not paid attention to the results of the P4P system in the United Kingdom. With the emphasis on preventive care health care and increased frequency of laboratory testing, expenditures have increased.

Going Forward

In the short term, the government's metric for success of this P4P program will be financial. The additional layer of regulatory control over physician behavior is likely to fail just as badly as the Volume Performance Standard and the Sustainable Growth Rate legislation.

If the intent is true quality improvement, the process measures being implemented should be replaced by outcome measures. When this plan does not meet expectations, I anticipate further attempts to clamp down on expenditures through disease management programs for the common chronic diseases, including COPD. Improvement in quality and cost will only occur when federal policy makers are willing to frankly confront our technologically advanced, for-profit health-care system in which there is expanding consumer demand driven by an increasing consumer base.

Where might the solutions lie?

While P4P could help focus clinicians' attention somewhat on evidence-based medicine and may improve outcomes in the long term, medical school and training program education should be focused more on patient care and the natural history of common diseases.

Patient expectations need to be grounded in reality through better public education and realistic media reporting on medical issues.

The cloud of unreasonable medical liability should be lifted by establishing medical review panels and following other's steps that have been outlined in the proposals of the American Medical Association.

While some legislators have taken the position that the malpractice premium is a small component of physician overhead, they underestimate the effect of the current system on the overall cost of care from duplicative care, futile care, and excessive radiographic and laboratory testing.

Fortunately, for those of us in practice, the American College of Chest Physicians will continue to develop educational programs that promote effective and efficient patient-focused care. ■

James A. L. Mathers, MD, FCCP
Pulmonary Associates of Richmond
Richmond, Virginia

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

Editor's Insight

Dr. Mathers nicely summarizes many of the issues that led Congress and CMS (and many HMOs nationwide) to implement P4P. He is also justified in expressing skepticism about the underlying assumption that this initiative will actually brake the steady increase in health-care expenditures.

A recent review of public reporting and P4P in hospital quality improvement (*N Engl J Med* 2007; 356:486) suggested that modest improvements in the process of care (*eg*, more frequent use of aspirin in patients with myocardial infarction) might be achieved with the promise of financial gain but did not provide insights into the costs of these activities and the impact on outcomes (*eg*, survival for patients with myocardial infarction).

The editorialist for this article stated that P4P is at the tipping point (*N Engl J Med* 2007; 356:515) and, I agree, but for different reasons than most might expect. The momentum behind P4P is insurmountable; that tipping point has been passed. Whether data will confirm that this social experiment of financially reimbursing compliance with processes of care will both improve outcomes and reduce costs is the tipping point still in balance.

—Editor

NEWS FROM THE COLLEGE

AMERICAN COLLEGE OF CHEST PHYSICIANS

PRESIDENT'S REPORT

Capitol Hill Caucus: What Are the American People Thinking?

From March 5-7, ACCP members and staff went to Washington, DC, for the 14th annual ACCP Capitol Hill Caucus. The primary purpose of the Caucus is for our members to meet with members of Congress and staffers to lobby for legislation that is important to our patients and our profession. It is also a unique educational opportunity to learn, at close range, about how our political system works and how to be most effective in making it work for us.

BY DR. MARK J. ROSEN, FCCP

This year, 19 ACCP Governors and members from 33 states plus the District of Columbia and Puerto Rico, along with 2 Canadian ACCP members participated in this 3-day event, which also included a 3-hour meeting of the ACCP Government Relations Committee.

The Caucus was planned and executed adroitly by Dr. Lawrence C. Mohr, Jr., FCCP, Chair of the ACCP Government Relations Committee; Dr. Paul D. Banick, FCCP, Vice Chair; Lynne Marcus, ACCP Vice President for Health Affairs; Michael M. Gaba, Esq., of Holland & Knight, LLP, our Washington legal counsel; and several of the ACCP staff.

It was structured to give us an overview of the issues, to hear from some congressmen about their views on the problems and solutions, to instruct us on how to interact with members of Congress and their staffs—both in Washington and at home, and to set us loose with new or improved lobbying skills in the congressional office buildings to meet with our representatives about the issues … and all in less than 3 days.

Everyone understands that it is very important to our elected leaders that they get re-elected. To that end, they retain consultants to help them get re-elected. Pollsters find out what constituents are thinking and what will drive constituents' voting behavior in the next election.

On Monday evening, we heard presentations from two big-league pollsters, one Republican and one Democrat, on the results of their studies about these issues. These people are experts in framing questions to get answers that would please their sponsors, but, in this exercise, both sides agreed almost completely about the country's concerns and opinions about its leaders.

It was no surprise that across the wide range of the American public (rich/poor, Republican/Democrat, and any other variable), people agree that the war in Iraq is the most important issue and that the President and Congress are not handling it well. This led to the 2006 Democratic Congressional takeover and will determine the outcome of the next election if there is no significant progress (this is not me talking—this was the Republican pollster.)

What *was* surprising is that, by far, the most important domestic issues on the minds of the voters involve health care: Americans are far more concerned about the rising costs and declining access to quality health care than they are about terrorism, immigration reform, education, and a raft of other issues.

This concern is shared by poor and middle-class voters alike. The 46 million uninsured who we *know* about (we can only estimate the numbers of uninsured and undocumented residents who will access the health-care system), together with insurance premiums that rise in double digits annually at the same time that benefits are scaled back, are a major concern to most voters.

There seems to be general agreement that a comprehensive solution like "universal" health care is a long way off, not only because it is unaffordable while funding a war and servicing an exploding national debt, but also because a significant fraction of the public believes that the beneficiaries of a universal access policy are somehow "undeserving." Interim solutions, like state-sponsored programs with basic benefits for all, and perhaps a federal program that covers all children, would be achievable first steps.

Dr. Mohr framed the question that this country must eventually confront: "In America, is health care a right or a privilege?"

We clinicians know that universal access to health care in this country is already a right, at least to the extent that we do not turn people away from emergency rooms when they present with a life-threatening illness. Rather, they get admitted and have necessary surgery and other treatments. If you work in a teaching hospital like me, when uninsured patients are admitted to the hospital, we may be their attending physicians. The expenses are covered by the hospital, perhaps supplemented by emergency Medicaid and other coverage if and when it is secured.

Let's go back to pollsters, who can elicit seemingly contradictory answers to questions, depending upon how the questions are framed. When asked, "Does America spend too much on illegal immigrants?", most respond, "Yes." When asked, "Would you favor a policy where an illegal immigrant with a heart attack is refused admission to a hospital?", almost all would say "Of course not!" We are too decent to take that position, and besides, it's against the law.

So, we agree that we *must* provide universal coverage in certain situations. In our current system, the costs of care are shouldered by the hospitals, because the Federal government passes the bill to the states, and the states to the hospitals where the patients show up for treatment.

Our problem is that we cannot craft an acceptable system to make care available to all people before they become sick enough to need emergency treatment.

Other countries seem to have figured this out. In Canada and many European countries, coverage for all is not only a benevolent social policy, but it is less expensive than ours, and people do just as well.

But the United States is not, for example, Sweden. Expanding access to care needs to be tied to programs to use it appropriately, and that means setting limits, and that sounds kind of un-American. The pollsters agreed that the American people demand lots of care, even if it's unnecessary care. They just don't want to pay for it: the *government* should pay for it. Here, the weight of public opinion is not going make finding a solution easier.

If not for the war in Iraq, health care would be the dominant issue in the country today. Critical care is a major factor in health-care costs, and the critical care workforce shortage is a looming issue as the population ages. In next month's column, I will discuss our Capitol Hill Caucus meetings with members of Congress and their staffs about these issues. ■

Chicago: The Windy City Welcomes You!

Chicago—home of the Sears Tower, deep-dish pizza, and CHEST 2007! Bordered by Lake Michigan and with a skyline all its own, Chicago boasts a metropolitan ambience that combines big-city living with small-town hospitality. Pair this amazing city with the annual meeting's amazing reputation, and you can't go wrong. But first, here are just a few fun things to know before making your way to Chicago.

Let's start with a well-known myth. While Chicagoans have experienced some pretty gusty days, the nickname "The Windy City" actually has nothing to do with the weather. It was coined in 1893 by the editor of the now defunct New York Sun newspaper, in commenting on Chicago's politicians.

Oh, and Navy Pier's Ferris Wheel is a replica of the first one ever created, which made its debut in Chicago at the 1893 World's Columbian Exposition. And did you know that some of the world's most famous faces are from Chicago? Harrison Ford, Bill Murray, Robin Williams, and Oprah Winfrey are just a few from the big and little screen. And legendary musicians include Muddy Waters and Miles Davis. Also, perhaps the world's most famous cartoonist, Walt Disney, himself, called Chicago home.

The city's rich history and fun facts are just a few of the reasons why Chicago is our kind of town and the perfect place for CHEST 2007!

For Chicago information, visit www.choosechicago.com/default.html. Stay tuned for more details about CHEST 2007, October 20-25! ■

This Month in *CHEST*: Editor's Picks

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

▶ **Methylprednisolone Infusion in Early Severe ARDS: Results of a Randomized Controlled Trial.** *By Dr. G. Meduri, et al*

▶ **Atrial Septostomy in Treatment of End-Stage Right Heart Failure in Patients With Pulmonary Hypertension.** *By Dr. M. Kurzyna, et al*

▶ **Significance of Extranodal Extension of Regional Lymph Nodes in Surgically Resected Non-small Cell Lung Cancer.** *By Dr. Y-C Lee, et al*

▶ **Influenza and COPD Mortality Protection as Pleiotropic, Dose-Dependent Effects of Statins.** *By Dr. F. J. Frost*

▶ **Chest Ultrasonography for the Diagnosis and Monitoring of High-Altitude Pulmonary Edema.** *By Dr. P. J. Fagenholz, et al*

www.chestjournal.org

AMERICAN COLLEGE OF CHEST PHYSICIANS

NEWS FROM THE COLLEGE

CRITICAL CARE COMMENTARY

Preventing Nosocomial Infections: The Value of a Systematic Evidence-Based Approach

Nosocomial infections are among the most important, preventable complications in critical care medicine. These infections are associated with longer hospitalization, greater costs, added morbidity, and, in some instances, additional attributable mortality.

Various individual interventions have been demonstrated to reduce infection rates; however, the systematic application of multiple interventions combined into a logical approach may be particularly effective. Recent reports illustrate the feasibility of applying these structured approaches across many ICUs and highlight the power of these strategies when measured in cumulative serious infections avoided. Systematic approaches for reducing catheter-related bloodstream infection (CRBSI), ventilator-associated pneumonia (VAP), catheter-associated urinary tract infection (CAUTI), and the important challenge of hand hygiene are briefly reviewed.

Critical Care Institute
American College of Chest Physicians

Catheter-Related Bloodstream Infection

Approximately 5 million central venous catheters (CVCs) are placed in the United States annually, and bloodstream infection (BSI) accompanies 3 to 5% of these placements (Bearman et al. *Semin Respir Crit Care Med* 2006; 27:310). The strongest independent risk factor for nosocomial BSI is intravascular catheterization (Rojo et al. *J Hosp Infect* 1999; 42:135). Importantly, these infections carry an attributable mortality rate of as high as 35% (Pittet et al. *JAMA* 1994; 25:1598). Primary mechanisms include colonization of both the external surface and the lumen of the catheter during insertion and subsequent manipulations. The incidence of clinically significant infection increases with each ICU day. Thus, strategies to create a sterile environment during insertion, promote good catheter care, and minimize duration are crucial.

Guidelines for preventing intravascular catheter-related infections published by the Centers for Disease Control and Prevention (CDC) in 2002 emphasize the following: (1) educating and training health-care providers who insert and maintain catheters; (2) using maximal sterile barrier precautions during CVC insertion; (3) using a 2% chlorhexidine preparation for skin antisepsis; (4) avoiding routine replacement of CVCs as a strategy to prevent infection; and (5) using antiseptic/antibiotic impregnated short-term CVCs if the rate of infection is high despite adherence to other strategies (O'Grady et al. *MMWR Recomm Rep* 2002; 51:1).

Reduced CRBSI rates have been demonstrated by applying these and other infection control principles (Eggimann et al. *Lancet* 2000; 355:1864; Sheretz et al. *Ann Intern Med* 2000; 132:641; Coopersmith et al. *Crit Care Med* 2002; 30:59; Berenholtz et al. *Crit Care Med* 2004; 32:2014; Wall et al. *Qual Saf Health Care* 2005; 14:295). However, recent work highlights the impact of applying a systematic approach to multiple hospitals, such as throughout the states of Pennsylvania (*MMWR Morb Mortal Wkly Rep* 2005; 54:1013) and Michigan (Pronovost et al. *N Engl J Med* 2006; 355:2725). In the latter project, implementing a program that emphasized five evidence-based recommendations to reduce CRBSI (hand washing, full barrier precautions for line insertion, skin cleaning with chlorhexidine, avoiding femoral line insertion, and removing unnecessary catheters) at 103 ICUs in Michigan led to a significant ($p < 0.002$) reduction in nosocomial BSI, from 7.7 per 1,000 catheter days to 1.4 per 1,000 catheter days at about 18 months of follow-up. Optimizing compliance with these strategies, through staff education, the use of a central line cart with all necessary supplies, the use of checklists to ensure adherence to standard of care practices, and "policing" by nurses and other observers to stop procedures if these practices were not being followed, is a key step for success (Pronovost et al. *N Engl J Med* 2006; 355:2725).

Ventilator-Associated Pneumonia

VAP develops 48 h after intubation and is estimated to occur in 10 to 20% of mechanically ventilated patients (Safdar et al. *Crit Care Med* 2005; 33:2184). Most cases of VAP develop as a result of colonization of gastric and/or oropharyngeal secretions with pathogenic microorganisms, followed by aspiration of infected material into the lower respiratory tract. Accordingly, interventions designed to reduce VAP generally focus on preventing these events, and many have been tested in clinical trials (Kollef et al. *Crit Care Med* 2004; 32:1396). The CDC (Tablan et al. *MMWR Recomm Rep* 2004; 53:1) lists the following interventions as having sufficient evidence for widespread implementation: perform surveillance; adhere to published guidelines for care of respiratory equipment; maintain backrest elevation at 30 to 45°; avoid nasotracheal intubation; remove subglottic secretions by suctioning; remove secretions prior to endotracheal tube removal; and use chlorhexidine oral rinse for adult cardiac surgery patients. Structured application of these and other interventions, with emphasis on education of health-care workers, has led to reduced VAP rates (Salahuddin et al. *J Hosp Infect* 2004; 57:223; Lai et al. *Infect Control Hosp Epidemiol* 2003; 24:859). Broad application to multiple ICUs, such as the nationwide implementation in Germany's ICUs (Gastmeier et al. *J Hosp Infect* 2006; 64:16), can improve adherence to desired processes and lead to better outcomes (Resar et al. *Jt Comm J Qual Patient Saf* 2005; 31:243).

Urinary Tract Infections

Nosocomial CAUTI is an important ICU problem, accounting for 31% of nosocomial infections in US medical ICUs (Richards et al. *Crit Care Med* 1999; 27:887). The risk of bacteriuria associated with indwelling urinary catheterization is 3 to 10% per day, and bacteremia is found in 4% of patients with catheter-related bacteriuria (Saint et al. *Arch Intern Med* 1999; 159:800).

Microorganisms causing CAUTI are usually from the patient's own colonic or perineal flora or from the hands of health-care workers during insertion of the catheter or collection from the drainage system (Maki et al. *Emerg Infect Dis* 2001; 7:342). Risk factors for CAUTIs include prolonged catheterization, female gender, urinary catheter insertion outside of the operating room, diabetes mellitus, malnutrition, and other distant sites of infection (Bearman et al. *Semin Respir Crit Care Med* 2006; 27:310).

Strategies to decrease the incidence of CAUTI include education, good hand hygiene, proper sterile insertion technique, limited manipulation of the catheter and drainage system, and proper patient selection. Most sources agree that catheters should be limited to use in critically ill patients; postoperative patients requiring urine output measurement; patients with significant perineal wounds or sacral decubitus; and debilitated, paralyzed, or comatose patients. Daily assessment for the continued necessity of indwelling urinary catheters and removal when they are no longer indicated are important but often forgotten.

Hand Hygiene

Hand hygiene (hand washing, antiseptic hand wash/rub, or surgical hand antisepsis) is an important preventive measure for limiting transmission of pathogens in ICUs. Hand hygiene should be performed before and after each patient encounter. Various studies have reported poor observed compliance with hand hygiene by health-care workers, with observed rates of compliance ranging from only 9 to 63%. A report from the Infectious Disease Society of America Hand Hygiene Task Force listed the following observed risk factors for poor adherence to recommended hand hygiene practices: being a physician (as opposed to a nurse), male sex, understaffing, working in an ICU, high number of opportunities for hand hygiene per hour of patient care, and working during weekdays (as opposed to weekends) (Boyce et al. *Infect Control Hosp Epidemiol* 2002; 23:S3). Successful programs to increase compliance with hand hygiene have been multifaceted, emphasizing patient education, health-care worker education, and increased availability/accessibility of hand hygiene products.

Alcohol-based products are superior to antimicrobial soaps for reducing bacterial counts on hands—including multidrug resistant pathogens (Boyce et al. *Infect Control Hosp Epidemiol* 2002; 23:S3). None of the currently available hand antisepsis agents is reliably sporicidal against clostridium or bacillus species; hand washing with soap and water is recommended to help physically remove spores from the hands of health-care workers when exposed to these organisms (Boyce et al. *Infect Control Hosp Epidemiol* 2002; 23:S3). Regardless of choice of hand antisepsis, at least 30 s of hand rubbing is recommended.

What You Can Do

The systematic application of evidence-based approaches for preventing nosocomial infections in the ICU setting is crucial for reducing the incidence of these important complications.

Recent reports indicate that widespread implementation of these measures in an organized strategy is both feasible and effective.

Accordingly, ICU caregivers and administrators must embrace the mandate for eliminating nosocomial infections through use of bundled evidence-based interventions and multidisciplinary attention to achieve consistent long-term compliance. ■

Catherine E. Grossman, MD
Assistant Professor of Medicine
and
Curtis N. Sessler, MD, FCCP
Orhan Muren Professor of Medicine
Medical Director of Critical Care

Division of Pulmonary and
Critical Care Medicine
Virginia Commonwealth
University Health System
Richmond, VA

NEWS FROM THE COLLEGE

AMERICAN COLLEGE OF CHEST PHYSICIANS

HEALTH AFFAIRS

Contact Your Senators To Back New Legislation

BY LYNNE MARCUS
Vice President, ACCP Health Affairs

The bipartisan **Patient-Focused Critical Care Enhancement Act,** introduced on February 28, 2007, in the US Senate by Senator Richard Durbin (D-IL) and Senator Mike Crapo (R-ID), is based on the May 2006 Department of Health & Human Services, Health Resources and Services Administration (HRSA) report that confirms the increased demand for current and future critical care services will be exacerbated by an imminent shortage of critical care providers.

"Whether caring for an aging parent or anticipating your own health-care issues, the need for critical care spans all ages and all generations," said Mark J. Rosen, MD, FCCP, President of the American College of Chest Physicians. "The introduction of this bill is an initial step that will help the American College of Chest Physicians and other critical care societies ultimately achieve the goal of ensuring quality patient-focused critical care today and for years to come."

In Senator Durbin's introductory comments, he stated that "the growing shortage of critical care physicians undermines the quality and availability of health-care services in the United States. This shortage can be expected to disproportionately impact rural and other areas of the United States that already often suffer from a suboptimal level of critical care services.

"The **Patient-Focused Critical Care Enhancement Act** authorizes a series of modest and sensible measures that — if enacted now instead of waiting for this shortage to worsen — can help to obviate the problem," Senator Durbin added.

The **Patient-Focused Critical Care Enhancement Act** is strongly endorsed by the key medical specialty societies and patient groups involved in critical care medicine, including the American College of Chest Physicians, the American Thoracic Society, the Society for Critical Care Medicine, the Association of Critical-Care Nurses, the Acute Respiratory Distress Syndrome Foundation, and The Sepsis Alliance.

Please join the ACCP in showing your support for optimizing the delivery of critical care medicine.

Contact your Senators and urge them to address the critical care workforce shortage by cosponsoring this important legislation, **S. 718**, the **Patient-Focused Critical Care Enhancement Act**.

Go to www.chestnet.org/practice/gr/CCWorkforce.php to learn more about the legislation and to e-mail your Senators. ■

Forum of International Respiratory Societies Meets

BY DR. W. MICHAEL ALBERTS, FCCP

The Forum of International Respiratory Societies (FIRS) is an organization of international medical societies that has respiratory disease as its primary interest.

The member societies are the American College of Chest Physicians, Asian Pacific Society of Respirology, American Thoracic Society, European Respiratory Society, Latin American Thoracic Society, and International Union Against Tuberculosis and Lung Disease.

The Forum meets at each of the member societies' annual meetings and once yearly at a stand-alone meeting.

The most recent stand-alone meeting was hosted by the ACCP and held in Miami, FL, January 22-23. Dr. W. Michael Alberts, FCCP, Immediate Past President of the ACCP, is the current Chair of the Forum and convened the meeting. Dr. Mark J. Rosen, FCCP, President of the ACCP, and Alvin Lever, FCCP(Hon), Executive Vice-President and CEO of the ACCP, completed the College's delegation.

This meeting was primarily devoted to strategic planning and provided an opportunity for the Forum to review the body of work produced since its inception in 2003 and to create policies and procedures for the future.

Tracy Goode, ACCP Vice-President of Member Activities, and Rich Waters, ACCP Vice-President of Marketing, expertly facilitated the strategic planning session. A new mission statement was crafted, and the process of amending the Forum Constitution to better reflect the new structure was initiated.

With the growing burden of respiratory disease throughout the world, it is important that the world's leading respiratory societies actively communicate and join forces where and when it is beneficial.

The Forum, through informal communication enabled by the development of relationships and in the context of formal meetings, provides that opportunity and achieves its mission by providing an opportunity to discuss mutual issues, launch initiatives, and learn from each other. ■

FIRS New Mission Statement

To promote lung health worldwide through a partnership of international respiratory societies and organizations that share and coordinate their collective knowledge, expertise, and resources.

The ACCP Industry Advisory Council: The Medical Information Section of an Exhibit Booth

BY KATHRYN B. LUCAS
Director, Professional Relations and Education, Boehringer Ingelheim Pharmaceuticals, Inc.

It was recently brought to the attention of the ACCP Industry Advisory Council that not all convention attendees understand the purpose of the medical information section of a promotional exhibit.

Therefore, we have taken the opportunity to outline the purpose and value of this educational tool.

In their commitment to the free exchange of scientific information between health-care professionals, pharmaceutical companies deploy medical information teams to leading medical conferences in order to respond to unsolicited inquiries from health-care professionals.

The medical information staff consists of trained health-care professionals who uphold the highest professional standards of rigor and integrity in addressing the health-care community and in disseminating nonpromotional medical information upon request. When a query cannot be fully addressed at the medical information booth, the staff conducts follow-up research and responds in writing to the health-care professional, citing currently available medical literature and/or clinical data.

Through the medical information booths at conferences, the pharmaceutical companies invite, encourage, and sustain the free exchange of scientific information between health-care professionals—a cornerstone of medical research, innovation, and progress. ■

ACCP Industry Advisory Council Mission:

To serve as the vehicle for interaction between the ACCP and the corporate community, with the goals of enhancing the resources available for the professional development of ACCP programs and members, and receiving and providing consultation on issues that may impact industry and medicine.

CHEST Challenge 2007—Let the Games Begin!

Fellows-in-training can compete NOW to win a free trip to CHEST 2007 and cash prizes by playing the 6th annual CHEST Challenge. It starts with the multiple-choice online test of pulmonary and critical care medicine knowledge at www.chestchallenge.org.

▶ Three fellows each from the nine highest scoring training programs will receive free transportation, housing accommodations, and registration to CHEST 2007.

▶ During CHEST 2007, these teams will compete in live game-show-style final rounds.

There is nothing to lose, as scores are confidential and never reported.

For more information about CHEST Challenge, e-mail jnemkovich@chestnet.org.

CHEST Challenge is supported by AstraZeneca LP (Play-offs) and ALTANA Pharma US, Inc – a NYCOMED Company (Championship). ■

May Is Asthma Awareness Month!

For more information, go to www.chestnet.org.

AMERICAN COLLEGE OF CHEST PHYSICIANS®

NEWS FROM THE COLLEGE

NETWORKS

Projects, Surveys, Careers, and More

Thoracic Oncology

The year 2007 is very important for thoracic oncology at the ACCP, as several important products will be unveiled:

- *Diagnosis and Management of Lung Cancer: ACCP Evidence-Based Clinical Practice Guidelines (Second Edition)*: rigorously developed guidelines cover the span from prevention to end-of-life care, with new chapters on BAC and integrative oncology.
- *Lung Cancer: ACCP Clinical Resource*: tool kit containing a Quick Reference Guide for Physicians, sets of slides, and patient education materials.
- *Treating Tobacco Dependence: American College of Chest Physicians Tool Kit (Third Edition)*: new edition with new sections on the role for pediatricians, coding and reimbursement, advocating for smoke-free communities, performance measures, and an updated pharmacotherapy guide.

Members of the Thoracic Oncology NetWork participated in the development and/or review of these publications and products. Watch this publication and www.chestnet.org for more information. NetWork information is available from Sandra Zelman Lewis, PhD, Staff Liaison, at slewis@chestnet.org.

Women's Health

During CHEST 2006, the Women's Health NetWork, along with The CHEST Foundation, continued its mission of community outreach, interacting with students at North Star Elementary School and medical students at the University of Utah Medical School discussing lung health and tobacco use in young adults.

Continued outreach and program development is clearly needed. Multiple survey results have demonstrated that there has been an increase in tobacco use among young adults ages 18-24 on college campuses, especially the use of smokeless tobacco and cigars.[1] Another phenomenon that has been noted is the increase in tobacco use described as "social smoking," or smoking mainly with others rather than alone.[2]

Previous research demonstrated that undergraduate medical education relating to tobacco cessation and prevention strategies and health risks was often inadequate.[3] Although there has been some subsequent progress, there is continued need to integrate culturally relevant tobacco dependence education throughout curricula, including specific training in smokeless tobacco intervention and tobacco use prevention.[4,5] Training of future physicians to ensure competency in tobacco control and treatment is crucial.

The Network and The CHEST Foundation continue to produce and enhance educational tools relating to tobacco use, prevention, and cessation. The 4th edition of the speakers kit, Make the Choice: Tobacco or Health?, was released in late 2006 and is available on the ACCP Web site at http://speakerskit.chestnet.org/. The kit contains slides and resources for creating effective tobacco prevention presentations.

We would like to encourage ACCP Affiliate members to participate in the CHEST 2007 outreach event on Monday, October 22, at Kinzie School in Chicago. To volunteer, contact Sue Ciezadlo at sciezadlo@chestnet.org.

1. *Rigotti NA, Lee JE, Wechsler H. US college students' use of tobacco products: results of a national survey.* JAMA *2000; 284:699-705*
2. *McBurney PG, Moran CM, Ector WL, et al. Time in continuity clinic as a predictor of continuity of care for pediatric residents.* Pediatrics *2004; 114: 1028*
3. *Ferry LH, Grissino LM, Runfola PS. Tobacco dependence curricula in US undergraduate medical education.* JAMA *1999; 282:825-829*
4. *Spangler JG, Richmond R, George G, et al. Tobacco intervention training: current efforts and gaps in US medical schools.* JAMA *2002; 288:1102-1109*
5. *Powers CA, Zapka JG, Bognar B. Evaluation of current tobacco curriculum at 12 US medial schools.* J Cancer Education *2004; 19:212-219*

Members in Industry

Have you ever wondered where you could learn more about alternative career opportunities for pulmonary physicians, in addition to traditional patient care or academic roles?

Your colleagues in the Members in Industry NetWork look forward to sharing their experiences with you. Join us at CHEST 2007 in Chicago for a session entitled "Contemplating a Career Change: Alternative Careers in Industry." Dr. Dawn Carlson, the Vice Chair of this NetWork, will chair this session.

Dr. Carlson worked for 5 years in academic medicine. She then made a career transition to work for a Chicago-based pharmaceutical company, first in pharmacovigilance, then in two different clinical development teams.

The NetWork aims to promote cooperation between the ACCP and industry and to foster advances in clinical research and medical education. It strives to fulfill its goals of integrating the NetWork within the greater chest medicine community and serving as a resource to the ACCP members. Watch your CHEST 2007 programs for presentations from our NetWork.

Presentations from CHEST 2006 are available online at accp.chestnet.org/memresources/downloads/networks/2006/industry.pdf.

Practice Administration

The NetWork, along with other ACCP leaders, is working diligently toward providing physician and administrative members with information and resources to help operate and manage the practice of pulmonary, critical care, and sleep medicine.

The group has embarked on a 5-year survey project, and, more recently, partnered with the Medical Group Management Association (MGMA) to provide practice managers with an excellent tool to assess the health of their practice, identify specific traits and measures that are pertinent to successful practice management, and enhance understanding of critical performance indicators.

The success of the project and of ongoing efforts relies on member involvement in the survey process.

The College is currently recruiting practices to participate in the "ACCP Practice Profiles" surveys. Participating practices will receive a complimentary report comparing their practice to others in chest medicine, and copies of the MGMA's *Cost Survey Report and/or Physician Compensation and Production Survey Report* in print format.

Participation empowers practices by providing quality information about issues most important to the efficiency of practice operations.

Practices that take part in this project will be asked to complete the monthly online *Practice Management Survey*, which will take less than 2 minutes to complete each month. In addition, they will be asked to participate in two MGMA surveys: *Physician Compensation and Production Survey* and *Practice Cost Survey*.

This is a great opportunity to see just how your practice "measures up" to better performing practices. If you are interested or would like to nominate a representative from your practice to participate, contact Joyce Bruno by e-mail (jbruno@chestnet.org) or fax (847) 498-5460.

Respiratory Care

The Respiratory Care NetWork steering committee is charged with recommending, to the ACCP President, qualified and interested ACCP members for appointment as representatives to several external respiratory care organizations.

The ACCP has been one of the long-standing main sponsors, along with the American Society of Anesthesiologists (ASA) and the American Thoracic Society (ATS), of the American Association for Respiratory Care, Inc (AARC).

Physicians are appointed to the AARC's Board of Medical Advisors (BOMA), which has additional representation from the Society of Critical Care Medicine (SCCM), American Academy of Pediatrics (AAP), American College of Allergy and Immunology (ACAI), and NAMDRC. BOMA advises AARC on respiratory care issues involving physicians and supports AARC's efforts in the socioeconomic and political domains.

The ACCP, AARC, ASA, and ATS are sponsors of CoARC, the Committee on Accreditation for Respiratory Care. CoARC is responsible for reviewing and recommending accreditation of all the respiratory care educational programs in the United States.

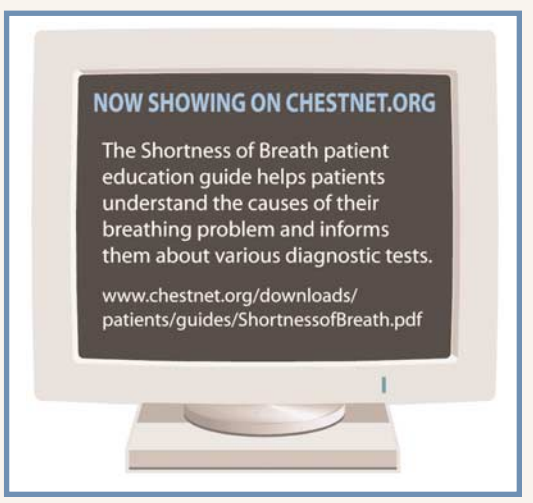
CoARC is presently seeking individual physicians to serve alongside a respiratory care educator as site visitors for programs undergoing evaluation. Training is available, followed by observer experience, to promote comfort in performing this very vital role.

Finally, The National Board for Respiratory Care, Inc (NBRC) also is sponsored by ACCP, AARC, ASA, and ATS, each of which appoint members to the Board of Trustees.

NBRC credentials individual respiratory care practitioners and pulmonary function technologists.

Further information about these organizations can be obtained as follows:

- **For AARC and BOMA:** Toni L Rodriguez, EdD, RRT, AARC President (rodriguez@gatewaycc.edu) or Sam P Giordano, MBA, RRT, AARC CEO (giordano@aarc.org).
- **For CoARC:** David W Chang, EdD, RRT, CoARC Chairman (dchang@athenstech.edu) or William W Goding, MEd, RRT, CoARC Interim Executive Director (bill@heasc.org).
- **For NBRC:** Theodore Oslick, MD, NBRC President (toslick@comcast.net or Gary A Smith, NBRC CEO and Executive Director (gsmith@nbrc.org). ■



NEWS FROM THE COLLEGE

AMERICAN COLLEGE OF CHEST PHYSICIANS

EDUCATION INSIGHTS

Is Continuing Medical Education Really Effective?

BY ED DELLERT, RN, MBA
ACCP Vice President, Educational Resources

Continuing medical education (CME) is a system that encourages and embraces the goal of physicians to always pursue the acquisition of the most up-to-date clinical information. However, literature suggests that there is a discrepancy between the evidence and clinical practice.

Reducing this gap is a goal of the ACCP Continuing Education Committee. The Committee continues to research and determine what CME tools and techniques are most effective in disseminating and retaining medical knowledge for those who participate in ACCP educational courses and products. Identification of the most effective CME tools is critical to improving not only CME but decreasing the gap between evidence and practice.

The ACCP nominated a topic to the Agency for Healthcare Research and Quality (AHRQ) to comprehensively and systematically synthesize the evidence regarding the effectiveness of CME and differing instructional designs in terms of knowledge, attitudes, skills, practice behavior, and clinical practice outcomes. The report was prepared by AHRQ's Johns Hopkins University Evidence-Based Practice Center in Baltimore, MD. The results of this project were released by AHRQ in February 2007 and are available at www.ahrq.gov/clinic/tp/cmetp.htm.

The evidence was gathered using specific eligibility criteria and handsearching of selected journals and electronic databases, including MEDLINE®, EMBASE®, the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane Database of Abstracts of Reviews of Effects (DARE), PsycINFO®, and the Educational Resource Information Center (ERIC®). Of the 68,000 citations identified by literature searching, 136 articles and 9 systematic reviews ultimately met our eligibility criteria.

AHRQ's new evidence report suggests that CME does improve and maintain the knowledge, skills, and performance of physicians. Common themes included the following: live media was more effective than print, multimedia was more effective than single media teaching interventions, and multiple exposures to content were more effective than a single exposure. The number of articles that addressed internal and/or external characteristics of CME activities was too small and the studies too heterogeneous to determine if any of these are crucial for CME success. Evidence was limited on the reliability and validity of the tools that have been used to assess CME effectiveness. The evidence indicates that simulation methods in medical education are effective in the dissemination of psychomotor and procedural skills. It could not be determined if physician characteristics (*eg*, age or gender) and/or other factors (*eg*, specialty or years in practice) influence the impact of CME.

The ACCP is reviewing the report to develop a nonclinical ACCP evidence-based guideline. Under the direction of LTC(P) Lisa Moores, MC, USA, FCCP, and Dr. Michael Baumann, FCCP, and the guidance of leaders in CME and evidence-based guideline development, a group met in March 2007 to determine what recommendations could be concluded from the AHRQ report. More research is needed to determine which types of media, techniques, and exposure volumes, as well as what internal and external audience characteristics, are associated with improvements in outcomes. ■

AMERICAN COLLEGE OF CHEST PHYSICIANS

NEWS FROM THE COLLEGE

Creating Healthy Work Environments: Appropriate Staffing

BY KARLENE M. KERFOOT, PHD, RN, CNAA, FAAN; RENEE GARRICK, MD; AND MICHAEL ISRAEL, MPH

Creating excellence in patient care outcomes can happen only within the context of a healthy working environment. Toxic environments in which there are poor communication and collaboration, an absence of mutual respect, demoralizing conflict, and unsafe staffing will lead to errors, higher complication and mortality rates, staff turnover, decreases in hospital profitability, and intense patient and family dissatisfaction.

In an effort to intervene and build a roadmap to the development of healthy work environments, the American Association of Critical-Care Nurses (AACN) developed six standards for establishing and sustaining healthy work environments.

One of these standards, appropriate staffing, is the keystone to building healthy work environments. A mounting body of evidence shows that inappropriate staffing can adversely impact patient care outcomes. The challenge is to implement this evidence into the everyday task of creating appropriate staffing in our hospitals. We must hold ourselves as accountable to staffing by evidence as we hold clinicians accountable to providing clinical care based on evidence.

Unfortunately, nurse staffing is too often seen as merely staffing to ratios, which ignores the tremendous variation in patient acuity and needs and in nurse competencies. In reality, the process is more complicated if we are to create safe passage for patients through the health-care system. Despite reasonable ratios, patients can continue to have poor outcomes if the environment is not healthy and the needs of the patient are not matched with the skills of the nurse.

Appropriate staffing means that staffing must ensure the effective match between the patient's needs and the competencies of the nurse. To further describe the pathway to meet this standard, the following critical elements must be in place:

- The health-care organization has staffing policies in place that are solidly grounded in ethical principles and support the professional obligation of nurses to provide high quality care.
- Nurses participate in all phases of the staffing process.
- There is a system in place to evaluate the effect of staffing decisions on patient and system outcomes.
- There is a system in place that facilitates team members' use of staffing and outcomes data to develop more effective staffing models.
- Support services at every level of activity are available to ensure the nurse can focus on the requirements of the patient and the family.
- The health-care organization adopts technologies that increase the effectiveness of nursing care delivery.

With the mounting evidence about the positive effect of healthy work environments on patient care outcomes and retention of and engagement of staff, it is imperative that everyone in health care rise to the occasion and make a commitment to implementing these standards.

The standards provide an excellent opportunity for the development of collegial projects between physicians, CEOs, other administrative staff, and nurses to collectively adopt the standards as the operating framework of the hospital and to incorporate the standards and critical elements of appropriate staffing as the first foundational step to adopt the standards.

For more information, go to www.aacn.org/hwe. ■

Bibliography

AACN Standards for Establishing and Sustaining Healthy Work Environments. Aliso Viejo, CA: American Association of Critical-Care Nurses (AACN), 2005

Aiken L, Clarke S, Sloane DM, et al. Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. JAMA 2002; 288:1987-1993

Foley BJ, Jennings BM, Kee CC, et al. Characteristics of nurse and hospital work environments that foster satisfaction and clinical experience. J Nurs Adm 2002; 325:273-282

Needleman J, Buerhaus P, Mattke S, et al. Nursing staffing levels and quality of care in hospitals. N Engl J Med 2002; 346:1715-1720

Thornby D, Sessler C. Creating healthy work environments: introduction. CHEST Physician. January, 2007:18

DR. KERFOOT *is Interim Chief Nursing Officer,* DR. GARRICK *is Chief Medical Officer, and* MR. ISRAEL *is President and Chief Executive Officer, Westchester Medical Center, Valhalla, NY.*

May Is Critical Care Awareness & Recognition Month

For more information, go to www.chestnet.org.

Attend The CHEST Foundation's Making a Difference Awards Dinner!

The CHEST Foundation's Making a Difference Awards Dinner will be held Saturday evening, October 20, 2007, at the historic Chicago Cultural Center.

The Making a Difference Awards Dinner allows colleagues and friends an opportunity to network and enjoy themselves before the pace of the CHEST meeting accelerates. The evening's ceremonies will highlight the outstanding pro bono service of ACCP members from around the world. Presentation of the 2007 Humanitarian Project Development Grants and the Humanitarian Recognition and Ambassadors Group award winners will be honored. Additionally, there will be the ACCP Industry Advisory Council's presentation of annual support for the community outreach event, which will be awarded to this year's outreach event partner, Kinzie Elementary School, in Chicago.

Price per ticket is $150, and registration will be available on The CHEST Foundation's Web site at www.chestfoundation.org, beginning July 1, 2007. Making a Difference Society members are entitled to two tickets, and annual donors at the $500 level are entitled to one ticket. For more information, please contact Teri Ruiz, at truiz@chestnet.org. ■

Enter Ambassadors Group's Poster Contest!

Do you have a child, grandchild, niece, or nephew who is between 8 and 14 years old and loves to draw? Have them create a design showing how to Love Your Lungs™.

The winning design will be used on posters displayed at CHEST 2007. Often, the winning design is also displayed on the T-shirts worn by those participating in the annual 5K Lung Health Walk/Run. The CHEST Foundation's Ambassadors Group sponsors this poster contest each year.

ACCP

The 2006 winning design by Rachel Like, age 10.

Magic markers create the most colorful and bright design, and entries with 12 words or less give the most effective message.

So get those entries submitted! For rules and a submission form, go to www.chestfoundation.org/specialInitiatives/ambassadorsGroup.php, and click on "CHEST 2007 Poster Contest."

Contact Sue Ciezadlo, at (847) 498-8363 or sciezadlo@chestnet.org, if you have any questions. **Deadline for all entries is June 1, 2007.** ■

Wisconsin Students Run for Lung Health

You're never too young to get involved in promoting lung health—a notion that was proven last spring when students from Wisconsin Hills Middle School in Brookfield, WI, put on their running shoes for the "3K Walk/Run For Kids Lung Health," supported by The CHEST Foundation.

The event, which was created by Ambassador Group member Monir Almassi, began with a presentation about the ill effects of smoking and how to maintain good lung health. Then, nearly 200 students, parents, and staff participated in a 3K walk/run. Afterwards, all participants were given Love Your Lungs wristbands and booklets about teens and smoking. Wisconsin Hills Middle School will repeat the "3K Walk/Run for Kids Lung Health" again this May.

Mrs. Almassi spearheaded this event to support the work and commitment of The CHEST Foundation. As The Foundation celebrates its 10th Anniversary, consider ways you can promote and commemorate its philanthropic spirit. To find out how you can organize an outreach event in your community, visit www.chestfoundation.org. ■

Ex-Smokers' Arterial Stiffness Resolved After 10 Years

BY LESLIE SABBAGH
Elsevier Global Medical News

Former smokers who have quit for at least 10 years have arterial stiffness comparable with that of people who never smoked, according to a large cross-sectional Irish study.

Dr. Noor A. Jatoi of the department of pharmacology and therapeutics, Trinity College, Dublin, and coauthors compared arterial stiffness and smoking status in 554 hypertensive patients who had no cardiac or renal disease and who were not on vasoactive medications (DOI:10.1161/HYPERTENSIONAHA.107.087338).

Among the 554 patients, 150 currently smoked, 136 were former smokers, and 268 never smoked. The patients' mean age was 47.8 years. Former smokers were placed into one of three groups: those who had quit cigarettes for less than a year, those who had quit for 1-10 years, and those who had stopped for longer than 10 years.

At baseline, there was no significant difference among the groups in body mass index (BMI), and significantly more men than women had stopped smoking. The researchers evaluated aortic stiffness using pulse-wave velocity (PWV), transit time, and wave reflection measurements.

Compared with current and former smokers, patients who never smoked had significantly lower brachial and aortic systolic blood pressure. Smoking status and transit time, wave reflection, and PWV had a "direct linear relationship" that placed former smokers at levels between current smokers and nonsmokers.

The investigators found statistically significant direct relationships between the duration of smoking cessation and PWV, wave reflection, and transit time in ex-smokers, after adjusting for age, sex, BMI, and mean arterial pressure.

Current smokers and those patients who stopped smoking for less than 1 year had similar arterial stiffness. Subjects who had quit smoking between 1 and 10 years earlier had "intermediate levels" of stiffness, and those who had quit for more than 10 years had arterial stiffness not significantly different from that of those who had never smoked, the authors reported in the May issue of Hypertension.

Diabetes Linked to Diminished Lung Power in Heart Disease

BY HEIDI SPLETE
Elsevier Global Medical News

CHARLESTON, W.VA. — Ischemic heart disease patients with comorbid diabetes start cardiac rehabilitation programs at a disadvantage: They have less lung power than nondiabetic heart disease patients do, according to a poster presented at the annual meeting of the American Association of Cardiovascular and Pulmonary Rehabilitation.

To identify possible deficits in oxygen consumption among diabetic heart disease patients, Bradly Chapman, an exercise physiologist at the University of Toledo, Ohio, and his colleagues measured peak oxygen consumption in 76 diabetic and 114 nondiabetic adults at the start of a standard cardiac rehabilitation program.

The researchers assessed the patients using a motorized treadmill and determined peak oxygen consumption (Vo_2) by using the highest recorded measurement based on an average of every 5-7 breaths.

The diabetic and nondiabetic groups were matched for age and weight, and the heart disease diagnoses were not significantly different between the two groups.

The mean peak Vo_2 of the diabetic patients was found to be 17.2 mL/kg per minute, compared with 20.2 mL/kg per minute for the nondiabetic patients, a significant difference.

Previous studies have shown that exercise training should be encouraged in cardiac patients with diabetes because it not only improves aerobic capacity but also promotes better diabetes management, the researchers wrote.

The findings that the diabetic patients had a lower oxygen capacity suggest that exercise training could have an even greater clinical benefit for diabetic coronary patients than it does for nondiabetic patients, they said.

The researchers did not reassess the patients at the end of the rehabilitation program.

But the study supports previous findings that peak oxygen consumption tends to be lower in diabetic heart disease patients than in nondiabetic patients, the researchers said.

FDA Warns on Linezolid for Catheter-Related Infections

Mortality was higher in those treated with linezolid who were infected with gram-negative organisms.

BY ELIZABETH MECHCATIE
Elsevier Global Medical News

The Food and Drug Administration has issued an alert about a higher rate of deaths associated with the antibiotic linezolid in a recent study of patients with catheter-related bloodstream infections.

For patients infected with gram-positive organisms, there was no difference in death rates between patients on linezolid (Zyvox) and patients on a comparator antibiotic.

"In contrast, mortality was higher in patients treated with linezolid who were infected with gram-negative organisms alone, with both gram-positive and gram-negative organisms, or who had no infection when they entered the study," according to the FDA advisory, posted on the agency's MedWatch site last month.

Health care professionals should remember that linezolid is not approved for treating catheter-related bloodstream infections, catheter-site infections, or for treating infections caused by gram-negative bacteria, the FDA cautioned.

The open-label trial enrolled 726 seriously ill patients aged 13 years and older with intravascular catheter-related bloodstream infections, including those with catheter-site infections. Almost half the patients were in an intensive care unit, and 26% were intubated.

Patients were randomized to either linezolid 600 mg intravenously or orally every 12 hours, or to 1 g of vancomycin administered every 12 hours for 7-28 days. Those on vancomycin could be switched to oxacillin or dicloxacillin if the pathogen was methicillin susceptible and could also receive concomitant therapy for gram-negative infections.

Up to 84 days after receiving the first dose of the drug, mortality among patients taking linezolid was 21.5%, compared with 16% among patients on a comparator antibiotic. Among patients with gram-positive infections only, mortality was roughly equal for patients on linezolid and those on a comparator (16.7% vs. 17.2%, respectively).

But among those with gram-negative organisms only, 27% of patients taking linezolid died, compared with 9% of those on a comparator. Among patients with gram-positive and gram-negative pathogens, 35% of those on linezolid died, compared with 18% of those on a comparator. Among those patients with no infection at baseline, 26% of those on linezolid died, compared with 13% of those on a comparator.

The FDA cautioned that the advisory is based on a preliminary analysis of these data, and that the agency has not come to any final conclusions about the implications of this new study. ■

The notice for health care professionals is available at www.fda.gov/medwatch/safety/2007/safety07.htm#Zyvox. Serious adverse reactions can be reported to FDA's MedWatch program at 800-332-1088 or www.fda.gov/medwatch.

Glycemic Control Protocol Reduced Errors, Saved Time

BY MARY ELLEN SCHNEIDER
Elsevier Global Medical News

ORLANDO — The use of a computer protocol to achieve tight glycemic control dramatically lowered insulin administration errors, compared with a paper-based protocol, according to a study of simulated patients in an intensive care unit conducted at the University of Maryland, Baltimore.

Converting an existing paper-based insulin protocol to an easy-to-use computer format reduced dosing errors, saved time, and improved satisfaction among ICU nurses, Dr. Anthony Y. Lee of Columbus Children's Hospital in Ohio said at the annual congress of the Society of Critical Care Medicine.

Paper-based protocols can be cumbersome and time consuming for ICU nurses, Dr. Lee said. "These protocols can be lengthy and complex, and that can lead to errors in protocol interpretation resulting in insulin dosing errors," he said.

Dr. Lee and colleagues at the University of Maryland Medical Center, Baltimore, recruited 51 medical ICU nurses to complete seven simulated patient scenarios using both the standard paper-based insulin protocol and a computer version of the protocol.

The simulated scenarios included a clinical case description, a current insulin dose, and new and prior blood glucose level. The nurses were given standardized instructions on how to use both paper and computer versions of the protocol. The nurses were required to indicate the new insulin dose and the time of the next blood glucose check. The researchers analyzed the data using Wilcoxon's test and t tests.

The simulated situations produced 357 paper responses and 357 computer responses showing a significant reduction in errors using the computer format.

Use of the paper protocol resulted in 82 insulin-dosing errors, compared with 4 errors using the computer system. It appeared that the same study participant committed all four errors using the computer protocol, Dr. Lee said.

The number of errors in the timing of the next blood glucose check declined from 47 with the paper-based protocol to 8 with the computer format.

The time to completion also dropped, from about 9 minutes using the paper-based protocol to 6 minutes using the computer program.

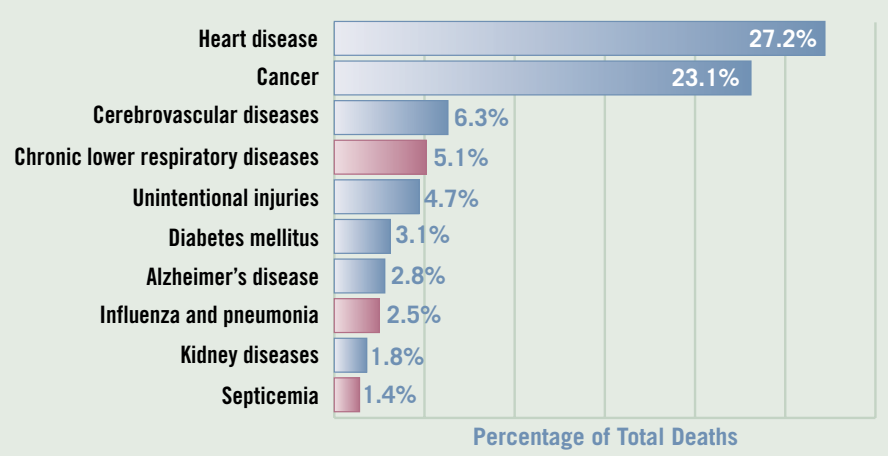
In addition, the researchers found that the nurses preferred the computer version of the insulin protocol. All of the results reached statistical significance.

There were some limitations to the study, particularly the use of simulated patients, Dr. Lee said. The researchers also did not distinguish whether the dosing errors were clinically significant.

The dosing was considered incorrect if it was off by 0.5 U/hour. However, about 80% of the dosing errors were off by 1 U/hour or more, Dr. Lee said. ■

DATA WATCH

Top 10 Causes of Death



Note: Based on 2004 U.S. data from the National Center for Health Statistics.
Source: CA Cancer J. Clin. 2007;57:43-66

ELSEVIER GLOBAL MEDICAL NEWS

Warnings Added to Sleep Drugs' Labels

BY ELIZABETH MECHCATIE
Elsevier Global Medical News

Warnings about the risks of complex sleep-related behaviors such as driving while asleep and about serious allergic reactions that have recently been associated with sleep drugs, are being added to their labels, at the request of the Food and Drug Administration.

The FDA announced last month that the manufacturers of the 13 approved sedative hypnotics, which include older drugs such as Dalmane and newer drugs such as Ambien and Lunesta, had been asked to describe cases of anaphylaxis and angioedema, and cases of complex sleep-related behaviors in their labels. In addition, the drugmakers have begun sending out "Dear Health Care Provider" letters describing these adverse events and the label changes.

The need for these changes are based on postmarketing reports of these events, "which we believe are serious and about which practitioners and patients need to know," Dr. Russell Katz, director of the FDA's division of neurology products, said during an FDA teleconference last month.

After receiving postmarketing reports of angioedema and anaphylaxis in people on the most recently approved hypnotic, ramelteon (Rozerem), the FDA reviewed the entire class for this effect and found similar cases. The review of complex sleep-related behaviors—which include driving, making phone calls, preparing and eating food, and having sex, all while asleep—began after such cases were publicized about 1 year ago.

Although such cases can be difficult to interpret, "we believe the entire class is capable of producing those events as well," Dr. Katz said. Physicians should advise patients that the complex sleep behaviors are more likely to occur when people take higher than normal doses, and when they take these drugs with other drugs that can affect the nervous system or with alcohol, he added.

Dr. Katz described both types of events as "relatively rare," based on the information available. He added that no deaths have been reported in association with any of the events reported to the FDA.

After the teleconference, an FDA spokesperson said that the agency had received a "couple of dozen" reports of complex sleep behaviors but emphasized that these events are likely to be underreported, and that the decision to strengthen labeling was not based on numbers but on the serious nature of these adverse effects. There were more cases of allergic reactions, but no specific numbers were provided.

Manufacturers also have been asked to develop "Patient Medication Guides" to directly inform patients about the risks and about what they can do to minimize their risks of experiencing these events. Medication guides are leaflets that are required for certain drugs with particular risks, which are distributed with each new prescription or refill.

These will not be available soon, however, since the companies have until May to submit their versions of the guides, which will then need to be reviewed by the agency.

But the events also are being added to the "information for patients" section of the drug labels, which physicians can use to counsel patients. "Patients should be aware that there are behaviors that they can engage in that can decrease the risk of these events occurring, namely, to refrain from alcohol [and] other drugs that depress the nervous system and to make sure they take the right dose," Dr. Katz emphasized.

The FDA also has requested that the manufacturers conduct clinical trials to determine whether the complex sleep behaviors are more common with some of the drugs and not others. Dr. Katz said that none of the companies had approached the agency yet with plans for such studies and acknowledged that getting them to do studies would be more difficult than making the labeling changes.

The label change affects drugs including Zolpidem, marketed as Ambien/Ambien CR by Sanofi-Aventis; butabarbital, marketed as Butisol Sodium by Medpointe Pharmaceuticals HLC; flurazepam, marketed as Dalmane by Valeant Pharmaceuticals; quazepam, marketed as Doral by Questcor Pharmaceuticals; triazolam, marketed as Halcion by Pharmacia & Upjohn Inc.; eszopiclone, marketed as Lunesta by Sepracor Inc.; estazolam, marketed as Prosom by Abbott; temazepam, marketed as Restoril by Tyco Healthcare Group; ramelteon, marketed as Rozerem by Takeda Pharmaceutical Inc.; secobarbital, marketed as Seconal by Ranbaxy Pharmaceuticals Inc.; and zaleplon, marketed as Sonata by King Pharmaceuticals Inc. ■

CPAP Success Undermined by Poor Acceptance

MONTREAL — Only 65% of sleep apnea patients agree to begin continuous positive airway pressure, and there is a 5% annual dropout rate, according to an 8-year follow-up study.

"Only one-third of those who accepted were still using the therapy at the end of our study," Dr. Per-Olle Haraldsson reported at the Eighth World Congress on Sleep Apnea. And among the patients still using continuous positive airway pressure (CPAP), only 40% were fully compliant—meaning they used it for 90% of their time asleep.

The study included 221 patients for whom CPAP therapy was recommended. A total of 144 patients initiated the therapy and 59 of these discontinued at some point during the study, reported Dr. Haraldsson of the department of otorhinolaryngology, head, and neck surgery at the Karolinska Institute in Stockholm. A further 18 subjects died during the study period, leaving 67 patients still using CPAP at the end of the study. Compliance data from 48 of these patients revealed that only 19 of them used the therapy optimally, he said.

"The most crucial thing about prescribing CPAP therapy is that you must select the patients very carefully," Dr. Haraldsson said in an interview. "We found that patients with an ODI [oxygen desaturation index] above 30 were more likely to accept CPAP and were more compliant because they were usually more symptomatic." Patients with less-severe symptoms are likely better candidates for mandibular appliances, and roughly 25% of patients are candidates for surgery.

In both groups, cumbersome equipment topped the list of reported reasons for declining or dropping out of CPAP therapy. Nonacceptors also said they could not face the treatment for the rest of their lives and were worried they would not be able to sleep, while those who dropped out of therapy cited noisy equipment and the lifelong nature of therapy.

—Kate Johnson

Could Serum Testosterone Be a Marker for OSA?

BY DOUG BRUNK
Elsevier Global Medical News

CARMEL, CALIF. — If preliminary results from an ongoing study are accurate, low baseline total serum testosterone levels could be a marker for obstructive sleep apnea in older men, Yao Schmidt reported at the Western regional meeting of the American Federation for Medical Research.

The issue is important because 20%-60% of men aged 60-80 years have borderline hypogonadism, said Ms. Schmidt, who is a second-year medical student at the University of Colorado Health Sciences Center, Denver.

As part of a larger ongoing study regarding the effects of exercise on the elderly, she and her associates at the university's Center on Aging evaluated 28 men aged 60-80 years. They recorded each man's apnea-hypopnea index (AHI), baseline total serum testosterone level, age, body mass index (BMI), neck size, and LDL cholesterol level.

The mean age of the men in both groups was 67 years, mean BMI was 29 kg/m^2, mean serum testosterone level was 288 ng/dL, mean neck diameter was 16 inches, and mean LDL cholesterol level was 103 mg/dL.

The researchers then divided the patients into two groups: 14 with obstructive sleep apnea, defined as having an AHI of 10 or greater, and 14 without obstructive sleep apnea, defined as having an AHI of less than 10.

The mean baseline serum testosterone level in the men with obstructive sleep apnea was 262 ng/dL, compared with a mean of 315 ng/dL in the men who did not have obstructive sleep apnea, a difference that was statistically significant. However, there were no significant differences between the two groups in terms of age, BMI, neck diameter, and LDL cholesterol level.

"Does obstructive sleep apnea cause lower testosterone levels, or do lower testosterone levels cause obstructive sleep apnea?" Ms. Schmidt asked. "It's unclear. It's possible both ways. Chronic hypoxemia could cause some brief atrophy, which could possibly [affect] the hypothalamus-pituitary axis."

Before Prescribing Drugs, Think 'S.E.L.F.' for Hypersomnia in Kids

BY ROBERT FINN
Elsevier Global Medical News

RANCHO MIRAGE, CALIF. — Behavioral treatments should be the first line of defense when treating children with hypersomnia, Dr. Raphael Pelayo said at a meeting on sleep disorders in infants and childhood.

Dr. Pelayo developed the mnemonic S.E.L.F. to help children, parents, and physicians remember some of the best ways to regulate sleep: with Social interactions, Exercise, Light, and Food.

"This really works," said Dr. Pelayo of Stanford (Calif.) University. "It sounds too simple, and you may not believe it, but this really, really works."

When children exhibit excessive daytime sleepiness, many parents' first impulse is to put them to bed earlier. This is often exactly the wrong thing to do, in part because the children fall asleep with light and wake up with darkness, the reverse of what nature intended.

Similarly, many teenagers skip breakfast but snack just before bedtime, have trouble sleeping, and are sleepy the following day. Before prescribing modafinil, have the parents restrict the teen's access to food in the evening.

Often parents will drag a hypersomnolent child to the doctor, and point out during the visit that he or she spends the entire evening watching television or playing computer games. "The parents want you to be the heavy and take away their computer time, their TV time," Dr. Pelayo said. "Instead I flip things around. I say, 'You can watch TV all you like—first thing in the morning. You can play computer games—first thing in the morning.' "

"Behavior before drugs" is the slogan Dr. Pelayo uses even with children with narcolepsy. "With narcoleptics, it cannot be overemphasized that it's got to be naps before drugs," he said at the meeting sponsored by the Annenberg Center for Health Sciences. "I always tell them that it's kind of like diabetes. It's a chronic condition, and you can lead a normal life, but you've got to watch your diet. The same thing is going to have happen with narcolepsy. For the rest of your life you've got to be conscious of your sleep hours. Your friends in college may cram and stay up late, but that's not what you're going to do."

Don't Expect Quick Fixes for Medicare Fee Crisis

BY JOEL B. FINKELSTEIN
Elsevier Global Medical News

WASHINGTON — It won't be cheap to fix Medicare's problematic physician pay formula, but lawmakers aren't saving any money by waiting to replace it either, experts testified at a hearing of the Senate Finance Committee.

"We have been kicking this can down the road for the past 5 years. This committee, and certainly Congress, understands it's not going to get any easier," said Dr. Cecil Wilson, board of trustees chairman for the American Medical Association.

The rising cost of health care is one of the biggest problems facing the government. At the current rate of growth, federal spending on Medicare and Medicaid will eventually consume 20% of the U.S. economy, according to Peter Orszag, Ph.D., director of the Congressional Budget Office.

"In health care, we get what we provide incentives for. We currently provide lots of incentives for advanced technologies and high-end treatment, and we get a lot of that. We provide very little incentive for preventive medicine and get very little of that," testified Dr. Orszag.

Early in 2006, lawmakers asked the Medicare Physician Advisory Commission (MedPAC) to examine ways to shift those incentives. Their findings were presented to the committee a few days before MedPAC members presented the commission's annual report to Congress.

While the report represents the consensus of the commission, commissioners were unable to forge a consensus on what should be done to replace the Sustainable Growth Rate (SGR) system, MedPAC Chairman Glenn Hackbarth testified.

Instead, the commission offered lawmakers two alternative approaches—one that doesn't include an SGR-like spending target and one that does.

Eliminating spending targets altogether would require Congress to create a whole new system with incentives to physicians to provide high-quality and low-cost care, Mr. Hackbarth said.

Choosing to keep spending targets would simplify payment reform but still would require changes to make the system more equitable.

While doctors account for a small portion of increasing premiums, they are the only group that has spending targets imposed on them, Dr. Wilson said.

"The AMA asks that Congress ensure that physicians are treated like hospitals and other providers by repealing the SGR and enacting a payment system that provides updates that keep pace with increases in medical practice costs," he said.

In cooperation with several other physician groups, the AMA brought to the hearing a list of recommendations to achieve those goals.

No matter whose plan is embraced, fixing the SGR system is unlikely to come cheap.

The Congressional Budget Office has estimated that current proposals will cost anywhere between $22 billion and $330 billion over 10 years.

"There are lots of steps, including [health information technology] and comparative effectiveness, that offer at least the potential to bend that curve over the long term, but the cost savings may not show up in the next 10 years. That is just the way it is," testified Dr. Orszag.

He added that it will take time and resources to build a system in which Medicare pays for high-value instead of high-cost services.

"Given the scale of the problems that we face, we need to be trying lots of different things and recalibrating all the time," he said.

There are good ideas out there, testified Mr. Hackbarth, but the Centers for Medicare and Medicaid Services is the bottleneck.

"We've got some very promising demonstrations under way, but it takes us forever to get them developed, in place, gather results, and translate them into policy," he testified. The agency doesn't have the staff or information systems to move forward expeditiously. ■

INDEX OF ADVERTISERS

ZLB Behring

Zemaira® — The next generation in purity for Alpha-1 augmentation therapy

- **Pure** — The only Alpha-1 augmentation therapy approved by the FDA as highly purified (lot release specification, ≥94% purity)*[,1-3]
- **Effective** — **Three times fewer** COPD exacerbations than with Prolastin®†
- **Well tolerated** — **Six times fewer** infusion-related adverse events than with Prolastin®‡
- **Fast** — **Half or less** the infusion time of other augmentation therapies§[,1-3]

Zemaira® is indicated for chronic augmentation and maintenance therapy for adults with alpha$_1$-proteinase inhibitor (A_1-PI) deficiency and emphysema.

Clinical data demonstrating the long-term effects of chronic augmentation therapy with Zemaira® are not available.

As with other Alpha-1 therapies, Zemaira® may not be appropriate for the following adult individuals as they may experience severe reactions, including anaphylaxis: individuals with a known hypersensitivity and/or history of anaphylaxis or severe systemic reaction to A_1-PI products or their components and individuals with selective IgA deficiencies who have known antibodies against IgA.

In clinical studies, the following treatment-related adverse events were reported in 1% of subjects: asthenia, injection-site pain, dizziness, headache, paresthesia, and pruritus.

Zemaira® is derived from human plasma. As with all plasma-derived products, the risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, cannot be completely eliminated.

For more information, call **1-866-ZEMAIRA (1-866-936-2472),** or visit **www.Zemaira.com.**

Zemaira®
alpha$_1$-proteinase inhibitor (Human)
Unmatched purity. Uncompromised care.

Please see brief summary of full prescribing information on following page.

* Shelf life purity specification is ≥90%

† In a retrospective analysis in the pivotal clinical trial, Zemaira® patients were three times less likely to experience exacerbations of their COPD than Prolastin® patients

‡ No clinically significant differences were detected between the treatment groups

§ Based on recommended dosage as stated in the product package inserts of 60 mg/kg body weight at the infusion rate of 0.08 mL/kg/min