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SHERI MATTES/ELSEVIER GLOBAL MEDICAL NEWS

Smokers who were African American or Native Hawaiian were at significantly increased risk of developing lung cancer.

Lung Cancer Risk Higher Among Black Smokers

BY MARY ANN MOON
Elsevier Global Medical News

African American and Native Hawaiian smokers are more susceptible to lung cancer than are white, Hispanic, or Japanese American smokers, reported Dr. Christopher A. Haiman of the University of Southern California, Los Angeles, and his associates.

These groups' "striking" elevation in risk could not be attributed to differences between the populations in known or suspected risk factors such as diet, occupation, or socioeconomic status, so the underlying reason remains to be determined, the investigators said (N. Engl. J. Med. 2006;354:333-42).

Dr. Haiman and his associates examined the relationship between the incidence of lung cancer and smoking history using data from the Multiethnic Cohort Study.

That prospective study collected demographic and health data on 183,813 residents of California and Hawaii in the mid-1990s and updated the information again in 2003-2004.

During that interval, 1,979 of the study participants developed lung cancer.

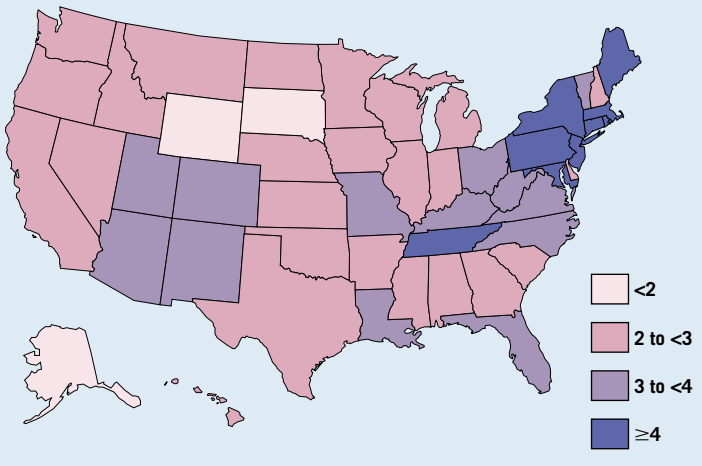
The risk of lung cancer differed sharply by racial/ethnic group among light smokers and moderate smokers.

African Americans and Native Hawaiians were at significantly increased risk of developing lung cancer. Compared with these

See **Lung Cancer** • *page 3*

VITAL SIGNS

Pulmonologists per 100,000 Population



RICHARD FRANKI/ELSEVIER GLOBAL MEDICAL NEWS

Sources: 2004 data, American Medical Association, U.S. Census Bureau

Benefits of LVRS Persisted 5 Years in Emphysema Cases

Surgery boosts survival, exercise capacity.

BY BRUCE K. DIXON
Elsevier Global Medical News

Survival, exercise, and quality of life advantages of lung volume reduction surgery in selected emphysema patients extend up to 5 years, according to follow-up data from the National Emphysema Treatment Trial.

"Lung volume reduction has been definitively demonstrated to affect long-term survival in patients with upper-lobe–predominant end-stage emphysema, and these findings make it easy to say that this subgroup of patients really ought to be referred for surgery," said Dr. Keith S. Naunheim, FCCP, of St. Louis University Hospital. "Now with 5 years of follow-up, we can see that the survival advantage enjoyed at 2 years persisted throughout, as did advantages in exercise and symptoms relief."

The National Emphysema Treatment Trial (NETT) accumulated 1,218 patients before recruitment was ended in 2002.

A 2003 published analysis of the prospective, multicenter, randomized trial had the following findings:

- ▶ Participants with mostly upper-lobe emphysema and low exercise capacity were more likely to live longer and to function better after lung volume reduction surgery (LVRS) than after medical treatment.
- ▶ Participants with mostly upper-lobe disease and high exercise capacity had no survival advantage over the medical group, but they did gain some exercise capacity.
- ▶ Those with mostly non–upper-lobe emphysema and with low exercise capacity continued to have similar survival and exercise ability after LVRS as after medical treatment, but had less dyspnea.
- ▶ Participants with mostly non–upper-lobe disease and with high exercise capacity had poorer survival after LVRS than after medical treatment.

See **LVRS** • *page 3*

Parents: More Asthma Information, Please

BY JOYCE FRIEDEN
Elsevier Global Medical News

WASHINGTON — Caregivers of inner-city children with asthma want better information about managing the side effects of asthma medications and practical ways to reduce asthma triggers, Beverley Russell, Ph.D., said at a meeting sponsored by the Office of Minority Health and the Department of Health and Human Services.

Dr. Russell, who is director of health professions education at the Center for Community Health Education, Research and Service, in Boston, conducted four focus groups, each with 12 participants. One group included caregivers of children with asthma, one included caregivers of children without asthma, one included physicians, and one included allied health professionals.

"In 2003, the asthma hospitalization rates for Latino and black children in Boston were five times that for whites and three times that for Asians," said Dr. Russell. "Our project wanted to know what experience folks in the community were having."

Three major themes emerged, she said.

One theme was that there was insufficient information given to caregivers to help them effectively manage children with asthma. Dr. Russell quoted one caregiver as saying, "I wish my provider would have looked more at side effects. … My child has a racing heart, hyperactivity, and [trouble sitting] still."

Focus group results also underlined that "providers need to

See **More Information** • *page 3*

INSIDE

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Updated Sleep Apnea Practice Parameters Outline Oral Appliances' Place in Therapy

BY JOYCE FRIEDEN
Elsevier Global Medical News

Oral appliances can be considered for therapy in certain patients with mild to moderate sleep apnea, according to new practice parameters from the American Academy of Sleep Medicine.

The academy first published practice guidelines on the use of oral appliances in 1995; but, since then, "the scientific literature regarding oral appliances has matured and expanded significantly," Dr. Clete Kushida of Stanford University and colleagues noted in the new practice parameters (Sleep 2006;29:240-3).

The parameters acknowledge that the continuous positive airway pressure (CPAP) device remains the preferred treatment for obstructive sleep apnea (OSA) in most patients. However, "although not as efficacious as CPAP, oral appliances are indicated for use in patients with mild to moderate OSA who prefer oral appliances to CPAP, or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP or treatment with behavioral measures such as weight loss or sleep-position change."

AASM President Dr. Lawrence J. Epstein, FCCP, said he hopes the new parameters will encourage more physicians to consider an oral appliance for their apnea patients.

"Anything we can do to help our patients get adequate treatment is beneficial," said Dr. Epstein, regional medical director for Sleep HealthCenters, in Boston. "Oral appliances can be very effective, particularly for people with mild to moderate sleep apnea. They have a success rate of 50%-70%, which is better than what you get with surgery."

He said that, with his own patients, he usually describes all the treatment options available and lets the patient choose. "Because of the higher effectiveness rate, we usually start with CPAP first, and then, if they can't tolerate it, we go to an oral appliance," Dr. Epstein said.

Dr. Kushida, director of Stanford's Center for Human Sleep Research, agreed that the patient's needs should come first. "If a patient has OSA and meets the indications described in [the practice parameters], the clinical literature provides evidence that oral appliances can help patients with OSA," he said.

But Dr. Epstein noted that there is another side to the reimbursement issue: what the patient's health insurance plan will pay for. "Some [plans] will require a trial of CPAP before they will reimburse for an oral appliance. People need to know what their insurance provides."

Dr. Kent Moore, D.D.S., president of the Academy of Dental Sleep Medicine, agreed. Oral appliances are "offering millions of people who are intolerant of CPAP an excellent, nonsurgical option," said Dr. Moore, an oral/maxillofacial surgeon in private practice in Charlotte, N.C.

Dr. Lionel Sadowsky, who has been making oral appliances for several years, said he was initially skeptical about the devices, but changed his mind once he saw some of the results.

"I think this appliance has a place, but it has to be done under medical supervision," said Dr. Sadowsky, chairman of orthodontics at the University of Alabama at Birmingham. "Since apnea can have potentially harmful consequences, I would hate to put in an oral appliance and mask someone's underlying or existing medical problems" without having the patient diagnosed via a sleep study and monitored by a physician with expertise in sleep apnea.

Oral appliances have advantages and disadvantages, compared with other treatment options, such as surgery, he said.

"The disadvantage of the appliance is, it costs money and may not be paid for by insurance. The advantage is, it's reversible; if it doesn't work, you throw it away. Surgery isn't reversible." ■

Dr. Susan M. Harding, FCCP, comments: *Key points for implementation of these guidelines include (1) that an accurate diagnosis of OSA is made along with baseline assessment of potential complications of OSA, including excessive daytime sleepiness and cardiovascular comorbidities; (2) that the oral appliance is fitted by a qualified dental professional; (3) that the patient has a follow-up polysomnogram or an attended cardiorespiratory (Type 3) sleep study that shows normalization of the AHI and resolution of the clinical signs and symptoms of OSA; (4) that the patient also has follow-up with their dental professional every 6 months during the first year and at least yearly thereafter to evaluate device deterioration and oral structure health; (5) that the patient also has regular follow-up with their sleep physician to evaluate for oral appliance compliance and signs and symptoms of OSA. The dental professional and the sleep physician should work together as a team; and (6) oral appliance therapy appears to be most effective in patients with lower AHIs and in those patients with positional respiratory events (worse in the supine position), and in those with a lower BMI. CPAP continues to be first-line therapy for OSA, especially in patients with severe apnea.*

Correction

In the article "Sleep Center Success Doesn't Happen Overnight" (January 2006, p. 18), Dr. Steven H. Feinsilver, FCCP, should have been identified as an associate professor of clinical medicine at New York University and governor of the American College of Chest Physicians for New York state.

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Exercise Capacity Improved

LVRS • *from page 1*

"When the analysis was initially performed in 2002, the median follow-up was just 29 months, and only 60% of patients had undergone functional outcome testing at the 2-year mark," Dr. Naunheim explained. The NETT investigators set the threshold for significant clinical improvement at greater than 10 W on formal cycle ergometry testing.

In their extended analysis, Dr. Naunheim and his colleagues also assessed the dyspnea-related quality of life index as expressed by the St. George's respiratory questionnaire (SGRQ), an instrument administered at 6 months and annually at years 1-5.

'These patients still fare better than their medical counterparts who deteriorate from day one.'
DR. NAUNHEIM

The initial 2-year analysis of the entire cohort found no significant difference in survival between the LVRS and medical groups. On extended follow-up, however, "a previously unrecognized survival advantage emerged for LVRS at 5 years and overall throughout follow-up," Dr. Naunheim said at the annual meeting of the Society of Thoracic Surgeons.

LVRS significantly improved exercise capacity, but that benefit declined from 23% to 9% over 3 years. "However, even though mean exercise values in the LVRS group gradually decline and then drop below baseline at year 3, these patients still fare better than their medical counterparts who deteriorate from day one," he explained.

A similar trend was seen in quality of life: A greater than 8-unit improvement in SGRQ occurred in 40% of the LVRS patients, compared with 9% of the medical cohort at 1 year, and a similar advantage for LVRS remained throughout 4 years.

LVRS did not provide a permanent fix, however, and there was a gradual return toward baseline over time.

Although the results pertain to all 1,218 patients enrolled in NETT, the elimination of high-risk patients deemed to be poor candidates for LVRS brought to 1,078 the number of patients in whom independent predictors of prognosis could be identified.

Patients with upper-lobe–predominant emphysema and low exercise capacity continued to have improved survival out to 5 years. "With regard to maximal exercise capacity, this subgroup also benefited from LVRS with a greater than sevenfold chance for improvement at 1 year utilizing the 10-W threshold value," Dr. Naunheim said, noting once again that the improvement declines over time toward baseline.

The cumulative difference remained in the 12- to 13-W range throughout 3 years' follow-up, yielding a marked advantage for the LVRS patients, compared with their medical counterparts, he said. And this subgroup had a greater than 8-unit improvement in the SGRQ quotient that was significant out to year 5.

There was no survival advantage to LVRS in the upper-lobe–emphysema and high-exercise group. "However, once again, there was a fourfold increased chance of achieving the threshold value for exercise improvement following LVRS, and this continued out through year 3," Dr. Naunheim said. SGRQ scores favored the LVRS cohort both immediately and throughout year 5, with cumulative differences in the 12- to 15-unit range.

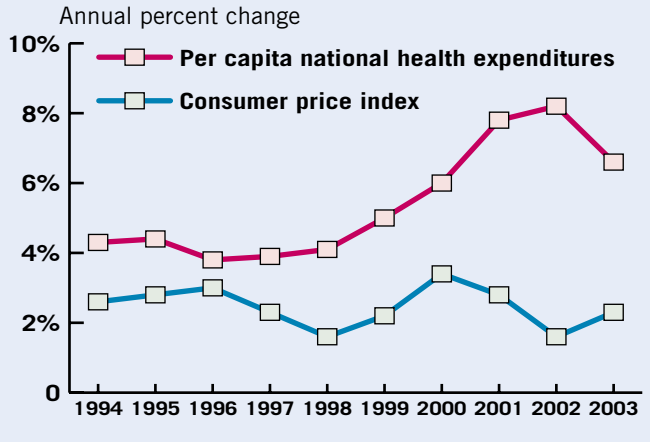
"In conclusion, lung volume reduction surgery yields improved chances for prolonged survival, increased exercise capacity, and improved quality of life. This is true both for the NETT population as a whole and for selected subgroups," Dr. Naunheim said. The improvements are durable for anywhere from 3 to 5 years, although patients do gradually return to baseline values.

Nevertheless, "we turn back the clock for these patients," Dr. Naunheim added in an interview. ■

Dr. Jeffrey W. Hawkins, FCCP, comments: *Follow-up of extended data from the National Emphysema Treatment Trial provides encouraging results for continued benefit in selected end-stage emphysema patients. Patient selection, of course, is the key determining factor of those patients who are most likely to benefit from LVRS as well as referral to surgeons/centers with appropriate expertise and experience.*

DATA WATCH

Rise in National Health Expenditures Slows



Source: The Henry J. Kaiser Family Foundation

KEVIN FOLEY/ELSEVIER GLOBAL MEDICAL NEWS

Behavior, Genetics May Play Roles

Lung Cancer • *from page 1*

two groups, whites had a relative risk of 0.45-0.57, while Hispanics and Japanese Americans had relative risks ranging from 0.21 to 0.39.

Among men who smoked at light or moderate levels, the incidence of lung cancer was 263.9 per 100,000 for both African Americans and Native Hawaiians, compared with 158.3 for whites, 121.4 for Japanese Americans, and 79.2 for Hispanics.

The pattern was slightly different among women, but the lung cancer incidence was still highest in African Americans, intermediate in whites, and lowest in Hispanics and Japanese Americans.

This pattern in racial/ethnic differences in risk occurred across all stages of disease, with African American and Native Hawaiian smokers at substantially higher risk than other groups.

African Americans also were at highest risk across all histologic types of lung cancer except for small-cell carcinoma, which was approximately twice as frequent among Native Hawaiians as among other groups.

Paradoxically, whites reported smoking the most cigarettes per day, and African Americans smoked the fewest, the investigators noted.

Differences among the groups in diet, occupation, and socioeconomic status did not explain these discrepancies in lung cancer susceptibility, they added.

Racial and ethnic differences in smoking behavior have been reported in previous studies and might play a role in these differences in susceptibility to lung cancer. For example, African Americans have shown higher circulating levels of nicotine and cotinine after smoking the same number of cigarettes as whites and Hispanics, which could be because they inhaled more deeply and more frequently when smoking.

If so, African Americans might have greater exposure to tobacco carcinogens than other groups, Dr. Haiman and his associates said. It also is possible that African Americans and Native Hawaiians are constitutionally more vulnerable to the effects of tobacco carcinogens.

Further study, particularly assessment of possible ethnic differences in the metabolism of nicotine and other carcinogens, "may help explain differences between populations in the susceptibility to smoking-related cancer," they said. ■

Dr. Gerard A. Silvestri, FCCP, comments: *This article has several important implications both for practicing chest physicians and researchers. For those studying lung cancer, this article presents yet further evidence that there are important genetic and racial determinants for those who will develop lung cancer. Perhaps as we unravel these genetic determinants, we will be able to identify those at ultra-high risk for developing lung cancer and those who will benefit from intensive early intervention aimed at smoking prevention and cessation. If screening is found to be efficacious, this high-risk group should be targeted, as the likelihood of finding disease will be higher. For now though, those practicing in areas where the population is predominantly Hawaiian or African American should do everything possible to get the word out to their patients and community groups about the increased risk of lung cancer among their population and the need for education regarding the ills of cigarette smoking.*

Caregivers Want Education

More Information • *from page 1*

know about the conditions people live in and the challenges they face," Dr. Russell said. "That would help providers be more realistic in devising treatment plans and interventions."

For instance, a provider suggested to one parent that she get a nonallergic mattress cover for her bed, and the woman replied, "The springs in my mattress keep popping out," Dr. Russell said. "Prescribing something like that just doesn't quite fit."

Participants also talked about the environment of the inner city. "We are surrounded by the gas, the smell, the smoke from cars, and the pollution," she said. "Those living in public housing talked about carpets, dust, mold, insects, pets, cleaning materials the housing people use, and also tobacco smoke."

One mother lived next to an auto body shop and complained that whenever the shop was painting cars, her daughter asked for a treatment, because even with the windows closed, the fumes penetrated the home and triggered an asthma attack.

Caregivers suggested that providers put more emphasis on the difference between treating acute symptoms and controlling asthma over time.

Caregivers would prefer a provider who offers asthma education and ongoing monitoring, Dr. Russell noted. "One parent boasted that she had someone who did home visits, so the person could see where they live and come up with something that makes sense and fits for them in their environment."

In the two focus groups for health professionals, providers were aware of many of the caregivers' frustrations but said that they often didn't have as much time as they would like to deal with these issues, Dr. Russell said in an interview. ■

Dr. LeRoy M. Graham, FCCP, comments: *Providers should consider data from focus group studies. Increasingly, these studies provide perspectives of which we are often unaware. Such awareness may lead to more effective and efficient patient and family communication. Increased patient knowledge, empowerment, and enhanced therapeutic adherence are all potential benefits.*

Adult-Diagnosis Cystic Fibrosis May Be on the Rise

Adults with newly diagnosed CF reflect the fact that the phenotype can vary along a spectrum of severity.

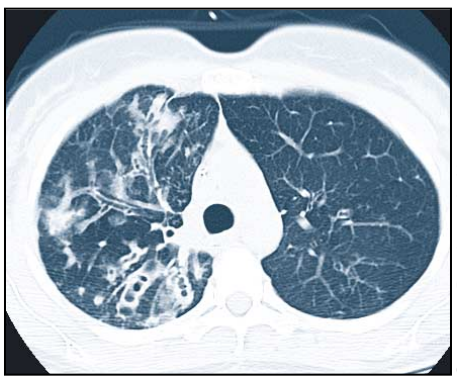
BY TIMOTHY F. KIRN
Elsevier Global Medical News

In his adult cystic fibrosis clinic in Denver, Dr. Jerry A. Nick has patients who were not diagnosed until they were 40 years of age or older.

These patients represent the tip of an iceberg of unrecognized patients, and clinicians need to be on the lookout for these individuals, Dr. Nick suggests.

His patients reflect the fact that the phenotype—or at least the clinical presentation—of cystic fibrosis can vary along a spectrum of severity. This has become clearer as more and more specific genetic mutations causing cystic fibrosis have been identified.

With that awareness, patients who were once just considered a curious aberration are now recognized as representing something significant, said Dr. Nick, director of the Adult Cystic Fibrosis Clinic of the National Jewish Medical and Research Center.



COURTESY DR. JERRY A. NICK

This chest CT scan shows severe bronchiectasis in a late-diagnosis CF case.

"These cases have shown up sporadically for years," he said in an interview.

Decades earlier, his predecessors at National Jewish collected a cohort of about 10 of these late-diagnosis patients, and tried to get a report published. They could not find a journal that was interested.

Dr. Nick recently published a paper on 27 of his late-diagnosis patients (Am. J. Respir. Crit. Care Med. 2005;171:621-6), comparing them with 28 patients diagnosed early who have survived into their 40s. He has also published a review article on long-term survival with cystic fibrosis (Curr. Opin. Pulm. Med. 2005;11:513-8).

Dr. Nick's patients are some of the oldest cystic fibrosis patients yet reported. The median age of his late-diagnosis patients is at present more than 52 years.

They may not be an exclusive group for long, however. Adult diagnosis is already becoming more common, Dr. Nick noted in his article.

In 1982, only 3% of patients enrolled in the Cystic Fibrosis Foundation patient registry had been diagnosed after the age of 18 years.

By 2002, patients diagnosed during adulthood composed 4% of the registry population, and 10% of the new patients added to the registry that year were diagnosed during adulthood.

Many of the late-diagnosis patients that Dr. Nick described in his article had been seeing physicians for years for recurrent and chronic lung infections, or similar symptoms.

They were thought to have asthma, or chronic obstructive pulmonary disease, or something else.

"We've seen a lot of these patients who were treated with course after course of antibiotics," he said.

But there is no question about their cystic fibrosis diagnosis, Dr. Nick said.

The patients all meet Cystic Fibrosis Foundation diagnostic criteria, and they have had genetic analysis, sweat chloride testing, and/or nasal potential difference testing.

European centers also have begun to take note of late-diagnosis patients, but most of the European patients have been diagnosed in their 20s and 30s.

The importance of Dr. Nick's older patients is that they may help to identify factors associated with long-term survival.

It is known that patients with the same genotype can have different phenotypes, and the median survival of patients with cystic fibrosis is still only 35 years of age, despite improvements in cystic fibrosis treatment.

SARA BRAYSHAW, MSN

Physicians who see a patient with a nontuberculous mycobacteria infection should have a strong suspicion of cystic fibrosis, explained Dr. Jerry A. Nick.

Dr. Nick has not uncovered any notable clues yet. But there are intriguing, observed differences between the early-diagnosed and late-diagnosed patients.

The late-diagnosed patients were less likely to have pancreatic insufficiency, so they tended to have better lung function and nutritional status.

They were also less likely to have cystic fibrosis–related diabetes, and they had somewhat better measurements of forced expiratory volume in 1 second.

One unexpected difference was that 74% of the late-diagnosis patients were women.

In the early-diagnosis group, the majority of older patients were male (64%), which is consistent with data in cystic fibrosis patient registries in general, Dr. Nick said.

Men also tend to have a longer median survival, by 3-5 years on average.

In addition, a large proportion of the late-diagnosis patients have positive cultures for nontuberculous mycobacteria.

These findings may be the most interesting, Dr. Nick explained, as they may indicate something about the airway environment that could be a clue to the patients' long-term survival.

Physicians who see a patient with a nontuberculous mycobacteria infection should have a strong suspicion of cystic fibrosis, he said.

The comparison study found that 4 of the 27 early-diagnosis patients had at least one positive culture for nontuberculous mycobacteria, compared with 14 of 28 late-diagnosis patients, Dr. Nick explained.

None of the early-diagnosis patients met criteria for an infection, while six of the late-diagnosis patients did.

In contrast, *Pseudomonas aeruginosa* was found less frequently in cultures from the late-diagnosis patients, although mucoid and nonmucoid strains were still found in more than 50% of cultures.

In general, the late-diagnosis patients had less severe manifestations, but not all had mild disease, Dr. Nick noted in the interview.

Four late-diagnosis patients have died, and two received a lung transplant.

Some had the same genotypes as early-diagnosis patients. ■

Therapy Horizon Brightens for Idiopathic Pulmonary Fibrosis

BY MARY ELLEN SCHNEIDER
Elsevier Global Medical News

NEW YORK — Physicians may be getting more options for the treatment of idiopathic pulmonary fibrosis as more therapies come down the research pipeline, Dr. Paul F. Simonelli said at a conference on pulmonary and critical care medicine sponsored by Columbia University.

Among the therapies under evaluation in recently completed or ongoing clinical trials for IPF are interferon-gamma-1b, *N*-acetylcysteine, bosentan, etanercept, and imatinib.

In addition, there are some molecules, such as pirfenidone, being tested that currently have no other approved uses, said Dr. Simonelli of Columbia University (New York).

The development of new therapies is critical because there are no approved treatments for idiopathic pulmonary fibrosis (IPF) and the standard approaches are not getting results, he said.

"IPF is a serious disease. It's a debilitating disease, and up to now we've had no effective therapy," Dr. Simonelli said.

The prevalence of the disease is about 83,000 cases in the United States with about 31,000 new cases each year.

And the disease has a mortality rate worse than that of almost any other major disease, except lung cancer.

Patients with IPF face a 5-year survivorship of less than 50%, Dr. Simonelli said.

INTERFERON-GAMMA-1B, *N*-ACETYLCYSTEINE, BOSENTAN, ETANERCEPT, AND IMATINIB ARE THERAPIES UNDER EVALUATION IN CLINICAL TRIALS.

The majority of available data relates to the use of interferon-gamma-1b in IPF.

An earlier phase III trial of about 330 patients showed no difference between the drug and placebo for the trial's primary end point of progression-free survival (N. Engl. J. Med. 2004;350:125-33).

However, a subgroup analysis indicated possible survival benefits with the drug.

A second phase III trial looking at survival as the primary end point is underway, and the drug maker InterMune is recruiting patients.

A European study showed potentially positive results for the addition of *N*-acetylcysteine to prednisone and azathioprine in treating IPF.

The drug showed improvement in vital capacity and diffusing capacity compared to treatment with prednisone and azathioprine (N. Engl. J. Med. 2005;353:2229-42). But Dr. Simonelli said the results are hard to interpret since the standard of care in Europe is the use of prednisone and azathioprine instead of a true placebo.

Another much-discussed possible treatment is pirfenidone.

Three trials have been conducted on the drug—an open-label phase II trial in North America, a Japanese trial that stopped early because patients on placebo were experiencing severe exacerbations, and a third trial ongoing in Europe.

Additional trials of the drug are expected to begin in the United States sometime this year. ■

What's New in Pulmonary Arterial Hypertension

BY BRUCE JANCIN
Elsevier Global Medical News

SNOWMASS, COLO. — Treatment options in pulmonary arterial hypertension have significantly improved in recent months with the marketing of two useful new agents: oral sildenafil and inhaled iloprost, Dr. Carole A. Warnes said at a conference sponsored by the Society for Cardiovascular Angiography and Interventions.

Iloprost (Ventavis), a prostacyclin analog, has several advantages over other available therapies. The inhaled route of administration makes iloprost a topical therapy that selectively causes vasodilation in the pulmonary circulation while minimizing systemic drug effects.

Inhaled therapy also promotes drug deposition in areas of the lung that are well ventilated, with resultant reduced ventilation/perfusion mismatch.

"This might be important in patients with associated parenchymal lung disease," noted Dr. Warnes, professor of medicine at the Mayo Medical School, Rochester, Minn.

A source of frustration for many physicians caring for patients with pulmonary arterial hypertension (PAH) is that iloprost, sildenafil, and the other drugs of proven efficacy result in only a modest, albeit clinically meaningful, improvement in 6-minute walk distance, the standard efficacy measure in clinical trials.

For example, in the pivotal randomized, placebo-controlled, double-blind crossover trial—Sildenafil Use in Pulmonary Arterial Hypertension (SUPER)—12 weeks of sildenafil (Revatio) at 20 mg t.i.d. resulted in a mean placebo-corrected 45-meter gain in 6-minute walk distance, compared with baseline (N. Engl. J. Med. 2005;353:2148-57). Twelve weeks of iloprost brought a 36-meter gain in another randomized trial. An ongoing major trial combining the two agents with their differing mechanisms of action aims to learn whether efficacy is enhanced.

'Perhaps we can regress pulmonary arterial hypertension, not just hemodynamically, but structurally.'
DR. WARNES

Recent developments in PAH involved a rat model of the disease, in which inhaled iloprost induced remodeling of the vascular structure of the pulmonary arteries (Am. J. Respir. Crit. Care Med. 2005;172:358-63). The prostacyclin analog resulted in reduced right ventricular systolic pressure, regression of right ventricular hypertrophy, attenuation of matrix metalloproteinase-2 and -9 expression, and decreases in the degree of muscularization and the medial wall thickness of the small pulmonary arteries in this German study.

That's a first for any drug. The animal data raise the possibility that damage to the pulmonary vascular circuit in patients with PAH may not be irreversible. "There is a structural change in the rat model. Perhaps we can regress PAH, not just hemodynamically, but structurally," Dr. Warnes said.

But inhaled iloprost is a complicated therapy. Patients self-administer it using a special device six to nine times per day, with each session taking about 10 minutes. Iloprost is approved for patients with New York Heart Association functional class III or IV PAH.

Sildenafil, however, is the first oral agent approved for early-stage PAH. In the SUPER trial, it not only improved 6-minute walk distance by 13% over baseline, it also lowered pulmonary artery pressure. Improvements were maintained at 12 months.

The near-term drug development pipeline includes more endothelin-receptor antagonists and prostanoids. But there is also an opportunity to test entirely new therapeutic approaches targeting abnormalities in PAH that have not yet been addressed, Dr. Warnes continued.

For example, PAH is associated with serotonin transporter-gene polymorphisms and increased circulating serotonin levels, raising the possibility that SSRIs might be beneficial. Potassium channels are downregulated on the pulmonary artery smooth muscle cells of patients with PAH, suggesting a therapeutic role for a potassium channel opener. The disease is also marked by increased circulating cytokines, autoantibodies, and chemokine expression, pointing to a potential application for immunosuppressive agents.

Patients with PAH have reduced vascular levels of vasoactive intestinal peptide; perhaps administration of vasoactive intestinal peptides would provide benefit. PAH is also marked by increased vascular endothelial growth factor activity, which could be addressed by antiangiogenesis agents. And even though warfarin has been standard therapy in PAH for decades, the effect of aspirin has never been studied, Dr. Warnes noted. ■

Think 'Bronchiectasis' in Frequent Antibiotic Users

High-resolution chest CT will show the permanently dilated, grossly distorted bronchi and bronchioles.

BY BRUCE JANCIN
Elsevier Global Medical News

KEYSTONE, COLO. — Anybody who needs two or more courses of antibiotics within a year for respiratory tract infections deserves to be evaluated for bronchiectasis, Dr. Gwen A. Huitt asserted at a meeting sponsored by the National Jewish Medical and Research Center.

"It's not normal for anyone to need any antibiotics during the year. By the time you get to somebody who needs two, three, or four courses of antibiotics for, say, a bronchitis or sinusitis—and remember, it's called the sinopulmonary tree—we need to think about underlying predisposing conditions," according to Dr. Huitt, director of the adult infectious disease care unit at the Denver center.

Bronchiectasis is far more common in primary care settings than most physicians realize.
DR. HUITT

She believes that bronchiectasis is far more common in primary care settings than most physicians realize. This conviction is based in part on the large number of telephone and e-mail consults she handles through National Jewish's "Lung Line" (800-222-5864 or lungline@njc.org) that turn out to involve previously undiagnosed bronchiectasis.

High-resolution chest CT is the diagnostic cornerstone. It will readily show the permanently dilated, grossly distorted bronchi and bronchioles that define bronchiectasis anatomically. The pathogenesis involves some sort of initial inflammatory process leading to a cytokine cascade, including tumor necrosis factor, interleukins, and elastases, along with accumulation of white blood cells. This inflammatory gunk predisposes to bacterial infection, which in turn damages mucociliary function. This process leads to a vicious cycle in which stagnant mucus attracts bacterial pathogens—*Pseudomonas aeruginosa* is the No. 1 infectious agent—further impairing the lungs' ability to clear mucus, resulting in more infections.

Although bronchiectasis is often thought of as a "wet" condition in which patients constantly hack up purulent phlegm, patients can in fact be "dry" and yet still have severe bronchiectasis, Dr. Huitt stressed.

Once it's determined that a patient has bronchiectasis, it's important to try to identify the etiology. Although bronchiectasis is the disease that defines cystic fibrosis, it has numerous other potential causes. These include α_1-antitrypsin (A1A) deficiency, Young's syndrome, allergic bronchopulmonary aspergillosis, autoimmune diseases, a severe pneumonia, and even gastroesophageal reflux disease (GERD).

Dr. Huitt routinely orders sputum cultures, a genetic screen for cystic fibrosis, an α_1-antitrypsin level and phenotype, an antinuclear antibody test, quantitative immunoglobulins, an esophagram, and pulmonary function tests to sift through the following causes of bronchiectasis:.

► **Cystic fibrosis.** At last count, roughly 1,300 genetic mutations have been identified that can contribute to the widely varied presentations of this disease. In patients with bronchiectasis, National Jewish physicians routinely order the Genzyme test that covers 97 of the most common ones. The traditional sweat chloride test isn't worth ordering in adults where cystic fibrosis is a possibility; the results are generally normal even in affected patients. "Go straight to genotyping," Dr. Huitt said.

► **Infection.** Worldwide, the No. 1 cause of bronchiectasis is undoubtedly tuberculosis. But other severe pulmonary infections—for example, pertussis or measles pneumonia—can also damage the mucociliary clearance mechanism and trigger the bronchiectatic process.

► **A1A deficiency.** Although it's classically an emphysematous condition, some affected patients instead present chiefly with recurrent pulmonary infections and bronchiectasis. Dr. Huitt orders both the A1A level and phenotype for screening because of recent data indicating not just homozygotes but phenotypic MZ heterozygotes may benefit from augmentation therapy.

► **Autoimmune diseases.** Rheumatoid arthritis, scleroderma, Sjögren's syndrome, vasculitis, and mixed connective tissue diseases are very common in patients with bronchiectasis, and it's not at all unusual for the pulmonary manifestations to precede diagnosis of the autoimmune disease. It's for this reason Dr. Huitt advocates screening all bronchiectatic patients with an antinuclear antibody test. She also routinely orders separate serologies for anti-SSA and anti-SSB, because she finds a large number of bronchiectatic patients have previously undiagnosed Sjögren's syndrome.

► **HIV.** Although highly active antiretroviral therapy (HAART) effectively controls viral replication, there remains an ongoing inflammatory state affecting the pulmonary system. Expect to encounter a lot more cases of bronchiectasis due to underlying HIV in coming years as HAART-treated patients survive far longer than in the epidemic's early years.

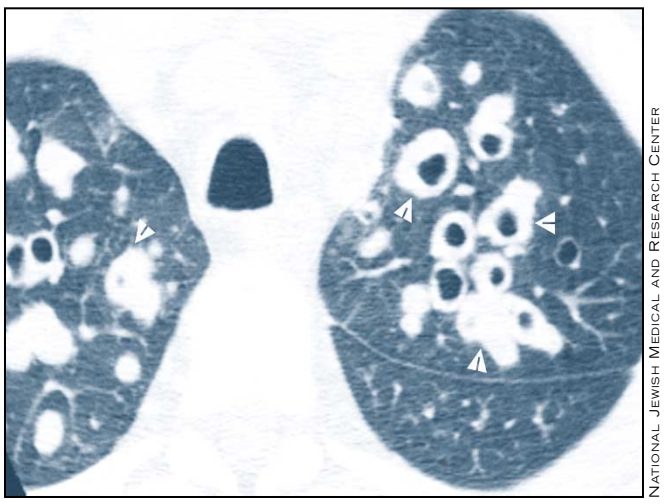
► **GERD.** Although it is considered controversial as a cause of bronchiectasis, Dr. Huitt believes that GERD is actually an important cause, and that the controversy exists only because of limitations in current methods of evaluating reflux. GERD can be clinically silent. Radiologists have taught Dr. Huitt two CT pearls that are indicators of esophageal hypertrophy secondary to reflux: an esophageal wall thickness in excess of 3 mm, or more than 15 mm of retained air in the esophageal lumen.

Sputum cultures should be obtained at baseline and every 6 months. Knowledge of the predominant chronic lung pathogen guides maintenance antimicrobial therapy aimed at preventing acute exacerbations of bronchiectasis that will require hospitalization and several weeks of intravenous antibiotics.

In the event sputum microbiology shows *P. aeruginosa*, it's essential that the laboratory describe whether the strain is mucoid or nonmucoid—something many large national laboratories are reluctant to do. "As soon as a patient acquires a mucoid strain as the predominant organism, the time to mortality definitely quickens," she said.

Periodic sputum analyses are also done to survey for the presence of a chronic nontuberculous mycobacterial infection. Antimicrobial susceptibility testing has been a controversial issue. New American Thoracic Society guidelines to come out later this year will for the first time call for routine susceptibility testing in individuals with nontuberculous mycobacterial lung infection, said Dr. Huitt, a member of the guidelines-writing committee.

Macrolide monotherapy is strongly discouraged in patients with chronic nontuberculous mycobacterial infection. The ATS recommends use of a three- or four-drug regimen involving clarithromycin, rifampin, ethambutol, and possibly streptomycin. ■



NATIONAL JEWISH MEDICAL AND RESEARCH CENTER

High-resolution chest CT, which is the diagnostic cornerstone of bronchiectasis, shows permanently dilated, grossly distorted bronchi and bronchioles.

TNF Blocker Registry Tracks Legionellosis, TB Risk

BY JANE SALODOF MACNEIL
Elsevier Global Medical News

VERSAILLES, FRANCE — A preliminary report from a French registry collecting severe reactions to anti–tumor necrosis factor–α therapy suggests that patients are at greater risk than realized of developing legionellosis and tuberculosis.

"What was most surprising was the 13 cases of legionellosis," Dr. Florence Tubach said at the 12th European Pediatric Rheumatology Congress. "[This] was quite unexpected."

Dr. Tubach of Hôpital Bichat in Paris reported on the first 137 cases in the multidisciplinary RATIO (Recherche Anti-TNF Infections Opportunist) registry, which began accepting cases on Feb. 1, 2004. In all, 486 French centers have agreed to report severe infections and lymphomas in patients on TNF-α antagonists to the project, which is soliciting information quarterly.

The patients recorded so far have had 60 severe bacterial infections and 63 opportunistic infections (including 20 TB, 15 virosis, and 13 legionellosis). They also had 13 cases of lymphoma, and 1 of myeloma. Rheumatoid arthritis was the most common underlying disease, occurring in 98 patients. The next most common underlying conditions were ankylosing spondylitis in 17 patients and Crohn's disease in 7 patients. Eight other diseases accounted for the remaining cases. Only two of the patients were children.

Dr. Tubach warned against making assumptions based on the number of patients who were taking infliximab, etanercept, or adalimumab. "We must be cautious with these numbers because we are in very small numbers, and infliximab has been available a long time, and adalimumab for only a short time," she said.

The median duration of anti-TNF therapy when patients presented with TB was 26 weeks, with a range of 2-173 weeks, Dr. Tubach reported in a presentation on the first 13 cases of TB. "TB is a persistent risk," she said. "TB may occur later than previously reported."

Before starting anti-TNF therapy, all but 2 of the 13 patients who became infected had intradermal tuberculin tests. The results were less than 5 mm in six patients, 5-10 mm in four patients, and more than 15 mm in one patient, Dr. Tubach said. Though five patients had a history of exposure to TB, she said none had a personal history of TB or had received any chemoprophylaxis against TB. All had normal chest x-rays.

Based on these findings, she said France has decided to modify guidelines for prevention "to include in the definition of latent TB patients with a history of TB exposure." Authorities have also lowered the cutoff for positivity on the intradermal tuberculin test to 5 mm, she said.

Dr. Tubach described the registry as "a good example of partnership between scientific societies, manufacturers, and the national authorities." It is supported by a grant from the three manufacturers of anti–TNF-α drugs: Abbott, Schering-Plough, and Wyeth. ■

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Triple-Drug Therapy Targets COPD Acute Exacerbations

'The principle here is if one drug is good, two are better, and three ... are best.'

BY BRUCE JANCIN
Elsevier Global Medical News

KEYSTONE, COLO. — Prevention of acute exacerbations has emerged as a major goal in chronic obstructive pulmonary disease—and the way to get there is with combination therapy, Dr. Barry Make, FCCP, said at a meeting sponsored by the National Jewish Medical and Research Center.

"The principle here is if one drug is good, two are better, and three—preferably from different medication classes—are best," according to Dr. Make, cohead of the COPD program at the Denver center.

Moreover, combining individually tailored pulmonary rehabilitation with drug therapy provides additive benefits in the domains of exercise capacity, health-related quality of life, and symptom reduction, he continued.

The traditional focus in COPD management and clinical trials has been heavily skewed toward preservation of lung function as reflected in forced expiratory volume in 1 second (FEV_1). But as is the case with other chronic incurable diseases, there has been in recent years a growing appreciation of additional outcomes, including quality of life, hospitalization costs, emergency department visits, and caregiver burden.

These COPD end points respond to treatment—as does the rate of exacerbations. Acute exacerbations are a particularly important outcome in COPD because of their substantial associated morbidity and the fact that they are a major driver of total cost of care.

The increased weight accorded of late to preventing acute exacerbations is reflected in a Department of Veterans Affairs multicenter double-blind clinical trial involving 1,829 patients with moderate to severe COPD randomized to 6 months of the long-acting inhaled anticholinergic bronchodilator tiotropium once daily or placebo. Of note, the coprimary end points in this large study were acute exacerbations and COPD-related hospitalizations.

One or more acute exacerbations were experienced by 27.9% of the tiotropium group and 32.3% on placebo. COPD-related hospitalizations occurred in 7% of the tiotropium group and 9.5% of controls. Moreover, frequency of hospitalization, days of antibiotic use, and unscheduled clinic visits were also significantly less with tiotropium, and time to first exacerbation was longer (Ann. Intern. Med. 2005;143:317-26).

Other studies have shown tiotropium to be superior to the short-acting anticholinergic bronchodilator ipratropium in terms of FEV_1 at 1 year, as well as in magnitude of improvements in health status, exercise capacity, and shortness of breath, Dr. Make noted.

The long-acting β-agonist bronchodilators have also been shown to reduce acute COPD exacerbations. These two classes of long-acting inhaled bronchodilators—the β-agonists and anticholinergics—are central to symptom management. And their combined effects are additive, as was shown recently in a study comparing formoterol b.i.d. to once-daily tiotropium to both drugs once daily (Eur. Respir. J. 2005;26:214-22).

The third drug class with efficacy for preventing acute COPD exacerbations is the inhaled corticosteroids. In a meta-analysis of six clinical trials, this therapy reduced the relative risk by 30% (Am. J. Med. 2002;113:59-65).

The highly regarded 2004 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommend adding inhaled steroids to prevent exacerbations in patients with stage III or IV (severe to very severe) COPD who are experiencing acute exacerbations despite being treated with other therapies.

This is, however, an off-label indication in the view of the Food and Drug Administration, which has approved the use of inhaled steroids in COPD only for added bronchodilation in patients already on a long-acting β-agonist.

And the sole combination approved for this more limited purpose is fluticasone/salmeterol 250/50.

"We have dueling recommendations here," Dr. Make observed. ■

Lymph Node Status Correlated With Lung Tumor Size on Screening CT

BY MARY ANN MOON
Elsevier Global Medical News

Lymph node status correlates strongly with tumor diameter in both non–small cell and small cell lung cancer found in asymptomatic people on screening CT scans, reported Dr. Claudia I. Henschke, FCCP, and her associates in the International Early Lung Cancer Action Program.

Previous studies of data collected for cancer registries have not shown such a strong correlation between tumor size and lymph node metastases for these types of cancer. Now for the first time, "we have ... demonstrated the prognostic significance of tumor size directly," said Dr. Henschke of New York Presbyterian Hospital–Weill Cornell Medical Center, New York, and her associates.

Given that most lung cancers without lymph node metastases are highly curable, the findings suggest that tumor size on CT scanning is also a prognostic indicator for curability, the researchers noted (Arch. Intern. Med. 2006;166:321-5).

The I-ELCAP study followed 28,689 men and women screened with low-dose, noncontrast CT scans at 38 medical centers around the world between 1993 and 2004. The median age was 61 years at enrollment in the study, and subjects reported a median of 30 pack-years of smoking.

A total of 464 cases of lung cancer were diagnosed; there were 436 cases of non–small cell carcinoma and 28 of small cell carcinoma.

For non–small cell lung cancer, lymph nodes were negative in 91% of cases with the smallest tumors (15 mm or less in diameter), 83% of cases with 16-mm–25-mm tumors, 68% of cases with 26-mm–35-mm tumors, and 55% of cases in which tumors were 36 mm or more in diameter.

This correlation was strong for solid nodules but only suggestive for part-solid nodules, and was not present at all for fully nonsolid nodules. Cancers that present as nonsolid nodules are either noninvasive adenocarcinomas or mixed subtypes with a small invasive component, Dr. Henschke and her associates explained.

The findings were similar for the few small cell lung cancers that were detected, all of which were solid nodules. Lymph nodes were negative in 67% of the cases in which the tumor was 25 mm or less in diameter, compared with 23% of cases in which the tumor was larger than 25 mm.

These results highlight "the usefulness of finding latent cancers at small sizes," the investigators said. ■

Liver Toxicity Reported With Telithromycin

The Food and Drug Administration is recommending that physicians monitor patients taking telithromycin (Ketek) for signs and symptoms of liver problems in response to reports of liver toxicity in three patients taking the drug.

Telithromycin is the first of the ketolide class of antibiotics to be approved, and is indicated for adults for the treatment of serious bacterial infections, such as community-acquired pneumonia, acute bacterial sinusitis, and acute exacerbation of chronic bronchitis. The drug is marketed by Aventis Pharmaceuticals Inc.

All three patients developed jaundice and abnormal liver function. One patient recovered, one required a transplant, and one died. The patients previously had been healthy and were not using other prescription drugs. Examination of the livers of two of the patients revealed massive tissue death. The cases were reported online as an early-release article in the Annals of Internal Medicine (www.acponline.org/journals/annals/hepatotoxicity.htm).

The FDA recommends that telithromycin should be stopped in patients who develop signs or symptoms of liver problems. Patients who have been prescribed the drug and who are not experiencing side effects such as jaundice should continue taking their medicine. Patients who notice any yellowing of their eyes or skin, or other problems such as blurry vision, should call their health care provider immediately. Telithromycin should be used only for infections caused by a susceptible microorganism. These include *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Staphylococcus aureus*, *Chlamydophila pneumoniae,* and *Mycoplasma pneumoniae*.

The FDA is continuing to investigate the issue of liver problems in association with the use of telithromycin in order to determine if labeling changes or other actions are warranted.

—Kerri Wachter

Rapid Avian Influenza Test Is Approved by the FDA

A rapid test to detect human infection with avian influenza provides preliminary results in just 4 hours instead of the standard 2-3 days, according to officials with the Food and Drug Administration and the Centers for Disease Control and Prevention.

The test is being made available to the World Health Organization and individual countries including the United States.

The test, developed by the CDC and rushed through the FDA approval process, is intended to detect H5 viral strains from respiratory secretions in patients suspected of being infected. Further testing is then required to identify specific subtypes such as the H5N1 subtype, which so far has been responsible for 166 human infections and 88 deaths worldwide.

"This provides a presumptive positive result, not a definitive result," Dr. Steve Gutman of the FDA said in a teleconference sponsored by that agency. "And a negative result does not conclusively rule out infection." He said the test is not intended as a screening tool but rather to investigate signs and symptoms of avian influenza in people who have possibly been exposed to the virus.

Within the United States, the test, which is known as the Influenza A/H5 (Asian Lineage) Virus Real-Time RT-PCR Primer and Probe Set, is being distributed to about 140 designated laboratories in the Laboratory Response Network. About 87% of the country's population lives within 1 hour of such a lab, said the CDC's Steve Monroe, Ph.D.

Physicians wishing to test a patient should send their samples directly to the closest Laboratory Response Network lab.

—Kate Johnson

Study: Leukotriene Modifiers, Vasculitis Not Linked

Patients' use of the drugs in the previous 2-6 months was not associated with Churg-Strauss syndrome.

BY NANCY WALSH
Elsevier Global Medical News

SAN DIEGO — The use of leukotriene modifiers to treat patients with asthma was not associated with the development of Churg-Strauss syndrome in a population-based, nested, case-control study.

Shortly after leukotriene modifiers were introduced in the mid-1990s, there were reports of more cases of this rare vasculitis than would be expected, suggesting there might be a link, Dr. Leslie R. Harrold said at the annual meeting of the American College of Rheumatology.

Subsequently, an investigation of reports of the syndrome to the Adverse Event Reporting System (AERS) database, maintained by the Food and Drug Administration, found a strong association with zafirlukast and montelukast, though not with zileuton (Clin. Ther. 2004;26:1092-104).

Several possible explanations for leukotriene modifiers being related to Churg-Strauss syndrome have been suggested, such as an increased awareness of the condition, and reductions in corticosteroid doses resulting in the unmasking of an underlying eosinophilic syndrome (J. Rheumatol. 2005;32:1076-80).

It also is possible that patients receiving leukotriene modifiers tend to have more severe asthma, which may predispose them to Churg-Strauss syndrome.

"To investigate this relationship, we assembled a cohort of 382,377 adults who received three or more dispensings of an asthma drug during any calendar year between Jan. 1, 1996, and Dec. 31, 2002," said Dr. Harrold of the University of Massachusetts, Worcester. The study was funded by GlaxoSmithKline.

The cohort came from a national health plan and three managed care plans, with a combined patient population of 13.9 million.

Information on patient age, gender, drugs dispensed, diagnoses, and procedures was obtained from automated databases, and cases of Churg-Strauss syndrome were identified through the databases and confirmed through chart reviews.

Each patient with Churg-Strauss syndrome was then matched with 100 controls for age, sex, health plan region, and year of cohort entry.

Dispensing information for the patients before they were diagnosed with Churg-Strauss syndrome also was obtained.

A total of 47 possible, probable, or definite cases of Churg-Strauss syndrome and their 4,700 matched controls were identified and analyzed by the investigators, Dr. Harrold explained.

IT IS ALSO POSSIBLE THAT PATIENTS RECEIVING LEUKOTRIENE MODIFIERS TEND TO HAVE MORE SEVERE ASTHMA.

Compared with controls, patients were significantly more likely to have received a greater number of asthma drug classes overall, and to have been given prescriptions for oral steroids, inhaled steroids, and leukotriene modifiers.

On multivariate analysis, the number of asthma drug classes used within the previous 6 months and the use of leukotriene modifiers in the previous 2-6 months were not associated with Churg-Strauss syndrome.

Only oral and inhaled steroids were associated with the syndrome, with odds ratios of 5.1 and 4.4, respectively.

When asked about the difference in her findings from those in the AERS report, Dr. Harrold explained that her study was population based.

The AERS reporting system "is best used for signal detection and hypothesis generation, but the data lack true denominators of exposed and unexposed individuals eligible for the drug of interest. These study differences [probably] account for the observed differences in results," she said.

The estimated annual incidence of Churg-Strauss syndrome, which is characterized by eosinophilia, sinusitis, asthma, and allergic rhinoconjunctivitis, is between 0.5 and 3.1 cases per million people, but is higher among asthmatics, at approximately 60 per million, she said.

"Most likely, exposure to leukotriene modifiers is indicative of severe asthma, which is strongly associated with Churg-Strauss syndrome," Dr. Harrold said. ■

Pulmonary Artery Banding Didn't Impede Later Repair

BY DIANA MAHONEY
Elsevier Global Medical News

ORLANDO — Pulmonary artery banding for up to 8 months does not compromise subsequent Damus-Kaye-Stansel connection, nor does it impede successful Fontan repair in neonates with univentricular heart and excessive pulmonary blood flow, Dr. Andrew C. Fiore said at the annual meeting of the Southern Thoracic Surgical Association.

"This is a challenging group of patients, and there continues to be much controversy about how best to manage them," said Dr. Fiore, a professor of surgery at St. Louis University. Pulmonary artery banding (PAB), with or without any associated aortic arch reconstruction, is the preliminary component of one of two staged management strategies. As part of the approach, the banding is followed by a Damus-Kaye-Stansel (DKS) connection with concomitant bidirectional Glenn anastomosis, hemi-Fontan, or modified Blalock-Taussig shunt to improve pulmonary blood flow and subsequent total cavopulmonary connection (TCPC) Fontan surgery. The second strategy involves a Norwood operation with a systemic outflow reconstruction from the heart, followed by a similar staged palliation sequence, according to Dr. Fiore.

The use of PAB to limit pulmonary overcirculation has been shown to be an effective preliminary palliative component, as it prevents the development of congestive heart failure and pulmonary hypertension. However, the procedure may create pulmonary insufficiency, induce ventricular hypertrophy, and cause dysplastic changes of the pulmonary valve, which could compromise the function of the later DKS connection and subsequent TCPC Fontan surgery.

To determine whether PAB was associated with such consequences in the clinical experience of surgeons at St. Louis University Health Sciences Center and Indiana University in Indianapolis, Dr. Fiore and his colleagues reviewed the outcomes of 27 infants with single-ventricle physiology who underwent the procedure between January 1994 and March 2004 at both institutions.

"We wanted to answer three questions," said Dr. Fiore. "Does pulmonary artery banding followed by DKS alter semilunar valve function? What is the optimal source of pulmonary flow? And, does the [PAB] staged approach preclude successful Fontan connection?"

The mean age at the time of banding in the 27 patients (74% male) was 22 days. With respect to morphology, 12 of the infants had double-inlet left ventricle/L-transposition of the great vessels, 5 had unbalanced atrioventricular canal, 5 had mitral stenosis/atresia, 4 had tricuspid atresia/D-transposition of the great vessels, and 1 had single ventricle/dextrocardia.

In most of the infants, PAB was performed using a thoracotomy approach. "The placement of the pulmonary band is critical in order to preserve function of the pulmonary valve and to not impede upon the pulmonary arteries," said Dr. Fiore. Pulmonary artery pressure was adjusted to one-third to one-half systemic pressure, with oxygen saturation between 80% and 85%, he noted. Approximately 60% of the infants underwent associated aortic arch reconstruction—either coarctation or interrupted aortic arch repair—at the time of banding.

All of the infants in the review underwent debanding and DKS at a mean of 10.2 months after the initial banding. To establish pulmonary blood flow, 16 of the infants received a Glenn anastomosis or hemi-Fontan connection, 6 received a modified Blalock-Taussig shunt, and 5 received both. Associated procedures at the time of DKS included atrial septectomy in 17 patients, pulmonary artery augmentation in 15, arch augmentation in 2, permanent pacemaker insertion in 2, and tricuspid valve replacement in 1.

Following the DKS procedure, "there were six early deaths secondary to low cardiac output—all in patients who had central shunts," said Dr. Fiore. Four of the deaths occurred in infants who had modified Blalock-Taussig alone, and two were in patients who had the modified Blalock-Taussig along with bidirectional Glenn or hemi-Fontan procedures, he said.

Of the surviving infants, 16 (including 12 who had bidirectional Glenn or hemi-Fontan, 2 with modified Blalock-Taussig, and 2 with both) underwent Fontan connection at 28 months post DKS. There were no early deaths in any of the infants, but there were three late deaths among five infants in the Glenn/hemi-Fontan only group who required systemic shunt placement at the time of the Fontan procedure because of borderline oxygen saturation, Dr. Fiore said.

Echocardiographic studies in the infants before they underwent DKS and at a median of 4.7 years' follow-up revealed no significant aortic or pulmonary insufficiency. At follow-up, the mean left ventricular outflow tract pressure gradient was 5 mm Hg. ■

Legionnaires' Disease Rare But Real in Pediatric Cases

BY MIRIAM E. TUCKER
Elsevier Global Medical News

WASHINGTON — Consider the diagnosis of legionnaires' disease in any child with pneumonia who doesn't respond to β-lactam antibiotic therapy, Dr. David Greenberg and his associates advised in a poster presented at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

Legionnaires' disease is considered a rare cause of community-acquired pneumonia in children. Most of the published literature on the subject is in the form of case reports, and nearly all have used serologic tests, for which sensitivity and specificity are uncertain. Awareness of *Legionella* as a potential cause of pediatric pneumonia is important because the disease doesn't respond to standard empiric therapy and may be quite severe and life-threatening, said Dr. Greenberg of Soroka University Medical Center, Beer-Sheva, Israel.

A Medline search identified 76 reported cases of legionnaires' disease in children. Of those, 33 (43%) came from the United States, possibly because of a higher index of suspicion for the disease among U.S. physicians and the availability of specific diagnostic tests for *Legionella*. Spain was second, with 10 cases, followed by Italy with 7. None were reported from developing countries, probably because diagnostic tests are not available there, the investigators noted at the meeting, sponsored by the American Society for Microbiology.

Patients ranged in age from 5 days to 19 years, with a mean of 24 months. Symptoms and signs were nonspecific, including fever in nearly all the patients. Cough, tachypnea, and hypoxia also were common.

Results of laboratory tests, including culture, serology, direct fluorescent antibody, urine antigen, and polymerase chain reaction, also were nonspecific and not helpful in making the diagnosis.

Of 63 patients with chest radiographs, pulmonary infiltrates were seen in 97% and pleural effusion in 30%. Forty-one (54%) of the 76 cases were classified as hospital acquired. These patients were more likely to be newborns and to have underlying diseases. The 35 patients with community-acquired legionnaires' disease were less likely to be immunosuppressed (37% vs. 90%).

Mortality was 41% in the hospital-acquired cases and 23% in the community-acquired cases. Compared with the 51 who survived, the 25 who died were younger and were more likely to have underlying diseases. Children who received inappropriate antibiotics were three times more likely to die than were those appropriately treated (76% vs. 24%), Dr. Greenberg and his associates said.

Environmental links to *Legionella* were identified in 23 (88%) of the hospital-acquired cases, compared with just 3 (33%) of those acquired in the community. Tap water, hot water tanks, showerheads, respiratory therapy equipment, and humidifiers were the most common sites of colonization. These findings suggest that all hospitals—including children's hospitals—should routinely culture their water supply for *Legionella*, they advised. ■

Intensive Insulin Therapy Didn't Cut ICU Mortality

In patients who stayed in the ICU more than 3 days, however, in-hospital mortality was reduced.

BY MIRIAM E. TUCKER
Elsevier Global Medical News

Targeting blood glucose levels to below 110 mg/dL with insulin therapy prevented morbidity but did not significantly reduce mortality among patients in a medical intensive care unit, said Dr. Greet Van den Berghe and her associates, of Catholic University of Leuven, Belgium.

A total of 1,200 adult patients who were predicted to require medical intensive care for at least 3 days were randomized to either strict normalization of glucose levels (80-110 mg/dL) with the use of infused insulin, or to conventional therapy in which insulin was given only when the blood glucose level exceeded 215 mg/dL and stopped below 180 mg/dL (N. Engl. J. Med. 2006;354:449-61).

The intensive treatment group experienced significantly fewer newly acquired kidney injuries than did the conventionally treated patients (9% vs. 6%), were weaned earlier from mechanical ventilation (hazard ratio 1.21), and were discharged earlier from both the ICU (1.15) and from the hospital (1.16). There was no significant effect on bacteriemia, the researchers reported.

Among the 1,200 patients in the intention-to-treat analysis, ICU and in-hospital mortality were not significantly reduced by intensive insulin therapy. At day 3, mortality was 2.8% of the 605 patients randomized to conventional treatment, compared with 3.9% of the 595 in the intensive treatment group. Total in-hospital deaths occurred in 40% and 37%, respectively.

THE INTENSIVE INSULIN THERAPY GROUP EXPERIENCED FEWER KIDNEY INJURIES AND WERE WEANED EARLIER FROM MECHANICAL VENTILATION.

However, when the 767 patients who stayed in the ICU for more than 3 days were examined separately, the in-hospital mortality was reduced significantly, from 53% of the 381 conventionally treated patients to 43% of the 386 in the intensive treatment group, Dr. Van den Berghe and her associates reported.

In contrast, among the 433 patients who stayed in the ICU less than 3 days, mortality was slightly—but not significantly—higher in the intensive treatment group. After censoring 65 patients for whom intensive care had been limited or withdrawn within 72 hours after ICU admission, the in-hospital mortality was 15% for the conventional treatment group and 17% with intensive treatment.

The most likely explanation for the difference in the effect of insulin therapy in the group as a whole compared with those staying in the ICU at least 3 days is that benefits from intensive insulin therapy take time to be realized. Because the intervention is aimed at preventing complications that occur during—and perhaps as a result of—intensive care, it wouldn't be expected to work if the patient has a high risk of death from the disease that prompted the ICU admission, the investigators pointed out.

The mortality findings from these medical ICU patients differ from what the authors reported previously in a study of 1,548 surgical ICU patients, for whom mortality at 12 months was 8% with conventional treatment versus 4.6% with intensive insulin therapy (N. Engl. J. Med. 2001;345:1359-67).

When complications resulting from intensive care contribute to an adverse outcome, a preventive strategy such as intensive glucose control is likely to be effective. This would explain why patients with long stays in the medical ICU benefit more than those with short stays, as was shown in the surgical ICU, they said.

Hypoglycemia (defined as blood glucose levels at or below 40 mg/dL) was more common among the intensively treated patients and was also identified as an independent risk factor for death. However, among those who had hypoglycemia, the intensively treated patients were less likely to die in the ICU than were the conventional treatment patients (46% vs. 67%). ■

Contributing writer Giancarlo La Giorgia assisted with this report.

Hypercapnic Acidosis May Protect in Acute Lung Injury

BY MARY ANN MOON
Elsevier Global Medical News

Hypercapnic acidosis appears to be protective in patients with acute lung injury who are on mechanical ventilation, "rather than simply a tolerated side effect" of their treatment, according to Dr. David A. Kregenow, FCCP, of the University of Washington, Seattle, and his associates.

Hypercapnic acidosis, also known as "permissive hypercapnia," traditionally has been viewed as an acceptable side effect of mechanical ventilation "that can be tolerated in an effort to avoid ventilator-associated lung injury," the investigators said (Crit. Care Med. 2006;34:1-7).

HYPERCAPNIC ACIDOSIS WAS LINKED TO REDUCED MORTALITY IN THOSE WHO RECEIVED 12 ML/KG TIDAL VOLUMES, BUT NOT IN 6 ML/KG TIDAL VOLUMES.

However, recent evidence indicates that the condition may itself have favorable anti-inflammatory and antioxidative effects.

Dr. Kregenow and his associates conducted a secondary analysis of the data collected in a randomized clinical trial done by the National Institutes of Health's Acute Respiratory Distress Syndrome (ARDS) Network and published in 2000.

That trial showed that hypercapnic acidosis was associated with reduced mortality at 1 month post injury.

Dr. Kregenow's group reexamined the data with the aim of separating the beneficial effects of hypercapnic acidosis from those of the mechanical ventilation itself.

The trial involved 861 patients with acute lung injury and acute respiratory distress syndrome who were treated with mechanical ventilation at 10 university centers. Dr. Kregenow and his associates separated the subjects who developed hypercapnic acidosis from those who did not and calculated the 1-month mortality rates.

Hypercapnic acidosis was linked to reduced mortality in those who received 12 mL/kg tidal volumes but not in those who received 6 mL/kg tidal volumes.

"These findings are consistent with the theory that ventilator-associated lung injury is occurring to a greater extent in the 12 mL/kg tidal volume group and that [hypercapnic acidosis] mitigates this injury," they said.

The exact mechanism by which hypercapnic acidosis might limit lung injury remains unknown, but there are several possible mechanisms because it is known to suppress many potentially harmful cellular and molecular processes.

For example, acidosis reduces the release of tumor necrosis factor–α, decreases neutrophil-endothelial cell adhesion, reduces the generation of free radicals, decreases interleukin-8 production, and suppresses nitric oxide production.

Further studies are needed to confirm that hypercapnic acidosis is truly beneficial for patients with acute lung injury, as well as to determine which dose, duration, and type of acidosis is optimal, they noted. ■

Of Tennis Balls and Backpacks: Sleep Apnea Tx Pearls

BY BRUCE JANCIN
Elsevier Global Medical News

KEYSTONE, COLO. — Because oral appliances and surgery don't cut the mustard as broadly applicable alternatives to nasal continuous positive airway pressure for treatment of obstructive sleep apnea, what clinically useful options remain for the patient who flat-out doesn't want to wear a face mask to bed every night?

Postural therapy is one effective measure. "I use it a lot," Dr. Robert D. Ballard said at a meeting that was sponsored by the National Jewish Medical and Research Center.

"When I get a patient who doesn't want to use CPAP even after we've spent a lot of time on all of our tricks to improve compliance, that's when I resort to postural therapy," explained Dr. Ballard, director of the sleep disorders program at the center, located in Denver.

The idea is simple: Keep patients with obstructive sleep apnea (OSA) off their back. When they're sleeping on their back, gravity pulls the tongue and palate against the posterior pharyngeal wall, creating a predisposition to obstruction.

WHEN A PATIENT 'DOESN'T WANT TO USE CPAP EVEN AFTER WE'VE SPENT A LOT OF TIME ON ... COMPLIANCE, THAT'S WHEN I RESORT TO POSTURAL THERAPY.'

That's why the apnea-hypopnea index—the prime indicator of OSA severity—is always worse when a patient sleeps in the supine as opposed to a lateral position. In fact, some patients experience OSA only while supine.

One method of keeping patients off their back during slumber is to have them sew a tube sock from shoulder to shoulder across the back of their pajamas, then fill the sock with tennis balls.

"That'll keep a relatively thin patient off their back, but some of these people are pretty big—and the bigger the patient, the less likely postural therapy will work. I'll have heavy patients put a backpack on and fill it up with stuff," Dr. Ballard said.

"A couple of my male patients have taken this one step further. They've gotten women's bras. They're very comfortable, apparently, and you can fill up the cups, put the bra on backwards, and it'll do a really nice job of keeping patients off their back," he continued.

Obese patients often ask if weight loss is likely to cure their OSA.

The answer is no.

Extremely obese individuals who lose a massive amount of weight through bariatric surgery often experience a significant reduction in OSA severity; however, the vast majority still have the sleep disorder, albeit in milder form.

"When obese patients come to me to talk about weight reduction, I'm pretty up front with them. I tell them that in my career I've seen maybe five patients in my clinic who have totally controlled their sleep apnea with weight reduction," Dr. Ballard said.

Interestingly, none of these five individuals were extremely obese prior to the weight loss.

All of the five individuals were classified as either overweight or mildly obese before they reduced their body mass index by 10%-20% with resultant complete freedom from OSA.

"I think weight loss has real utility in the population that's overweight to stage I obese. That's the group where I would most stringently recommend weight loss, because they can make big changes in their sleep apnea in response," the physician said.

Bilevel positive airway pressure, or BiPAP, is useful in patients who can't tolerate standard continuous positive airway pressure (CPAP) because of expiratory discomfort.

That's the case for many patients with comorbid asthma or chronic obstructive pulmonary disease, because such individuals' lungs are thought to be hyperinflated to begin with.

BiPAP features separately adjustable inspiratory and expiratory pressures, making expiration more comfortable for such patients.

BiPAP isn't for unselected OSA patients, though. Comparative studies have shown that in unselected OSA patients, BiPAP has no compliance advantage over CPAP. And it is more expensive, although the price differential has been shrinking, Dr. Ballard noted. ■

Pulmonary Perspectives

Disease Management and the Pulmonary Patient

The twin issues of escalating health-care costs and concerns about quality of health outcomes have resulted in a growing industry, centered on developing methods and programs that improve health-care delivery. Managed care was an early approach to cost containment, but, more recently, population-based programs, termed *disease management*, that shift the focus more toward improving outcomes in addition to controlling cost, are becoming popular.

Disease management is not a new concept, but its widespread implementation in large populations has been made possible by sophisticated computer platforms, software, and call centers that allow efficient communication with large numbers of patients from a central location. A number of models are used in disease management programs. I will discuss programs that include components for both providers and patients, although some programs are oriented just toward patients or work just through providers.

In 1999, the Disease Management Association of America (DMAA) was formed. The DMAA Web site (www.dmaa.org/definition.html) offers a generally accepted definition of disease management programs. It states that full-service programs must include six elements: (1) population identification processes; (2) evidence-based practice guidelines; (3) collaborative practice models, including physician and support-service providers; (4) patient self-management education; (5) process and outcomes measurement, evaluation, and management; and (6) a routine reporting and feedback loop. The National Committee for Quality Assurance provides accreditation programs for organizations that take responsibility for content and systems development and the operation of disease management and certification programs for organizations that provide some, but not all, of these services (www.ncqa.org/Programs/Accreditation/Certification/DMAA/DM%20Brochure.pdf).

In larger programs, patient call centers are typically staffed with experienced medical professionals that can include nurses, dietitians, social workers, respiratory therapists, pharmacists, and other health-care providers.

Less often, programs have a "live" component, with medical professionals who visit more complex patients. In addition to the patient-facing component, programs typically have provider (physician) components that include informational and patient report mailings, and, in some cases, on-the-ground provider representatives to interface directly with providers.

Large-scale disease management programs are usually provided by third-party payers, either by engaging disease management vendors or by using internally developed programs. A growing number of government payers, including the Centers for Medicare and Medicaid Services, has initiated disease management strategies. Other programs, addressing smaller population bases or specific diseases, have been developed by employers (usually through disease management vendors), pharmaceutical companies, pharmacy benefit managers, providers, and other groups. Many of these are smaller programs and may have less sophisticated structures than those described above and less emphasis on outcomes reporting. They also often address different geographic and demographic populations.

Generally, disease management programs address those chronic diseases that are common, that represent large chunks of health-care spending, and for which there is a body of evidence to support standard treatment practices. These diseases are also those that have wide variation in management practices around the country, despite the existence of published, evidence-based guidelines. The five diseases—two of them pulmonary—that are usually considered to fit these criteria are asthma, COPD, coronary artery disease, congestive heart failure, and diabetes. Comorbidities, like anxiety, depression, hypertension, and obesity, are increasingly included, either as integral or add-on elements in management programs. In addition, some conditions, like back pain, that represent a major component of disability costs and lost productivity for employers, are sometimes targeted.

The Asthma Model: How might an asthma disease management program work? An employer would purchase an asthma disease management program, most likely through an insurer. The first step would be to identify appropriate employees for the program by applying a selection algorithm, based on claims history (usually at least a year), including office visits, hospitalizations, emergency department use, and pharmacy use. The selection algorithm may be more or less selective depending on the part of the asthma population the employer wishes to target. Stratification is usually based on the number and costs of claims. Predictive modeling may also be used to further characterize the population and predict future care utilization.

Typically, patients in the highest risk group are selected for periodic telephone contact. Other patients may receive minimal telephone contact, only mailings, or no intervention. During telephone contact, disease managers assess the patients' level of knowledge and understanding of their disease, their medications, and preventive measures, as well as less tangible issues, like attitudes toward caregivers and their ability to function in the health-care system. Disease managers then use information from evidence-based guidelines to educate patients on gaps in their knowledge and adherence to their physician's treatment plans. The conversations can be quite focused. If, for example, a patient has had two recent emergency department visits for asthma and no filled prescriptions for inhaled corticosteroids, the disease manager may explore reasons for that gap (*eg*, too expensive, afraid of steroids, did not get a prescription) and help the patient understand the consequences of the gap. The resolution might be a specific plan to address unresolved issues that the patient can discuss with the physician or to get a prescription filled. Alternatively, the disease manager might detect that job stress or family issues have resulted in the patient resuming smoking and other behaviors that are affecting his/her ability to adequately manage his/her disease. Such discoveries present an opportunity to assist the patient with stress management techniques and smoking cessation. The frequency of contact is variable, determined, in part, by the disease management resources, the patient's needs, and the perceived ability to make an impact.

Provider components of disease management programs are generally not patient-specific but, rather, include distribution of evidence-based management guidelines and programs supporting specific initiatives, such as improved appropriate use of inhaled corticosteroids.

Outcomes Measurement: A primary feature of disease management programs is outcomes measurement. The outcomes measured vary according to the disease and are generally expressed across the population (not on an individual basis) in a specific disease management program. Measures may include not only reduced acute care utilization, but also clinical indicators, that are believed or proven to result in improved disease management and decreased morbidity.

In asthma programs, typical outcome measures are reduction of hospitalizations and emergency department visits and sustained use of inhaled corticosteroids in the high-risk asthma population. These measures, while felt to reflect better management, are somewhat restricted in breadth and are chosen primarily because they can be measured through claims. Other clinical components that might improve the scope of outcomes measured (*eg*, smoking cessation or stress management counseling) are not usually measured because of the lack of hard endpoints for assessment.

Even when using hard indicators, like claims, accurate measurement of the impact can be difficult. A frequently cited confounder, for example, is the statistical phenomenon of *regression to the mean* (Tinkelman and Wilson. *Am J Manag Care* 2004; 10:948). This term describes the tendency of a series of tracked events to return to a predictable mean without any intervention. Thus, it is possible that, when comparing acute care utilization in a population before and after disease management intervention, any observed reduction in utilization might have occurred without interventions. One of the best ways to deal with regression to the mean is to use a matched control group that does not receive the interventions, but this approach is not usually feasible in disease management programs.

It is important to distinguish disease management from case management, a traditional service offered through managed care plans.

Case management is specific-patient-focused. A care plan is usually developed for a patient's particular needs, and the case manager acts to ensure that the necessary services are accessed, so the patient is less likely to utilize emergency and inpatient services. Some of the activities supported by case management are ensuring that home care services are appropriately engaged, coordinating discharge plans, and helping to arrange transportation for medical services when necessary. In case management, cost savings are estimated based on the specific interventions made for that specific patient. Disease management, on the other hand, is population-based and preventive-focused, and cost savings and outcomes are reported across the population under management.

Questions remain about how to best identify high-risk populations, determine the highest impact interventions, and identify the best ways to capture and measure outcomes. Nevertheless, disease management is a promising first approach to deal with some of the failings of our ailing health-care system. ■

Janet R. Maurer, MD, FCCP
Anthem, AZ

Deborah Shure, MD, Master FCCP
Editor, *Pulmonary Perspectives*

Aymarah Robles, MD, FCCP
Deputy Editor, *Pulmonary Perspectives*

Editor's Insight

Disease management will likely become an important term in pulmonary practice. It is clear that a variety of interventions are necessary at many levels to try to ensure quality health-care delivery. Many questions remain unanswered at the moment, with respect to disease management, as it applies to pulmonary disease. Early studies have not always shown efficacy in asthma endpoints. Available and measurable endpoints will be key in assessing programs. It is not a simple matter, and the choices are important, because they will affect program designs and their ultimate applicability. The design of programs may also have to be tapered to specific populations, based on socioeconomic and cultural factors.

—Editor

NEWS FROM THE COLLEGE

AMERICAN COLLEGE OF CHEST PHYSICIANS

PRESIDENT'S REPORT

Cooperation Across Continents

BY DR. W. MICHAEL ALBERTS, FCCP

I am composing this month's President's Report while awaiting my return flight from Buenos Aires, Argentina, having just attended a 2-day meeting of the Forum of International Respiratory Societies (FIRS). This organization was formed several years ago with two objectives: united advocacy in matters of global respiratory health and the identification of new areas for global initiatives.

Membership of the Forum is composed of international professional societies that have respiratory disease as a primary interest. Founding members are the American College of Chest Physicians (ACCP), the American Thoracic Society (ATS), the Asociacion Latinoamericana del Torax (ALAT), the Asia Pacific Society of Respirology (APSR), the European Respiratory Society (ERS), and the International Union Against Tuberculosis and Lung Disease (IUATLD). Efforts are underway to include areas of the world not well represented by the founding members (*eg*, Africa, India, the Middle East, etc). Although traveling so far for a 2-day meeting was taxing, it was well worth the effort.

As respiratory disease plays a significant role in the health of the global population, FIRS is positioned to make a difference. As examples, the group received the final report of the Task Force on Biomass Effect on Lung Health (a major health issue in some areas of the world). An interim report was presented by the Task Force on PFTs in Limited Health Care Resources Countries (an effort to define the lowest level of PFT compatible with good medical practice at the level of primary care in difficult environments). Discussions were held on the FIRS-supported World Health Organization (WHO) program on the "Practical Approach to Lung Health" (the so-called PAL program is an approach to the management of patients with respiratory symptoms who seek care at public health facilities in low and middle income countries). Among several other topics, discussions were held on the activities of the Working Group on Tobacco and on the status of the Framework Convention for Tobacco Control.

I presented a proposal for a new Task Force on the Response to Disasters (both natural and manmade). Starting with the ACCP and The CHEST Foundation experience with responding to 9/11, Hurricanes Katrina and Rita, and the tsunami, among others, the group discussed the various individual society programs for disaster preparedness and disaster response. It was decided that a first step would be to catalog the currently available resources and expertise and then share "best practices."

From this brief report, I hope that ACCP members can appreciate the potential of FIRS and similar efforts. The world is getting smaller every day, and we are all global citizens. By sharing good ideas and cooperating across continents, the medical community may be able to lead the way to better and healthier lives for the world's people. ■

Editor's Picks: This Month in *CHEST*

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

▶ **Bronchoscopic Lung Volume Reduction for End-Stage Emphysema: Report on the First 98 Patients**
Dr. Innes Y. P Wan, et al.

▶ **Effects of Tiotropium With and Without Formoterol on Airflow Obstruction and Resting Hyperinflation in Patients With COPD**
Dr. Jan A. van Noord, FCCP, et al.

▶ **Low Sputum Eosinophils Predict the Lack of Response to Beclomethasone in Symptomatic Asthmatic Patients**
Dr. Elena Bacci, et al.

▶ **Applied Medical Informatics for the Chest Physician: Information you can USE! Part 2**
Dr. William F. Bria II

www.chestjournal.com

ACCP Cough Guidelines Garner Front-Page Spots

BY JENNIFER STAWARZ
Public Relations Manager

The ACCP started 2006 with a bang by releasing its new Diagnosis and Management of Cough: ACCP Evidence-Based Clinical Practice Guidelines, which include more than 200 recommendations for diagnosing and managing acute, subacute, and chronic cough in adults and children.

To spread the word about the new guidelines, press materials were sent to nearly 500 media professionals in the United States and Canada.

Press materials emphasized the ACCP recommendation against over-the-counter cough medications due to their ineffectiveness in managing cough.

Within 2 weeks of the release of the guidelines, news about the guidelines saturated the media and led to an unprecedented amount of domestic and international coverage for the ACCP.

Newspaper Coverage

Front Page
- *USA Today*
- *Chicago Tribune*
- *Chicago Sun-Times*

Other Coverage
- *Wall Street Journal*
- *Los Angeles Times*
- *Washington Post*

Television Coverage
- ABC Good Morning America
- NBC Today Show
- CBS The Early Show
- ABC World News Tonight
- CNN Headline News

More than **750** television broadcast segments across the United States and Canada

More than 50 interviews were arranged in 1 week for Dr. Richard S. Irwin, FCCP, Chair of the guidelines; guidelines authors, Dr. Peter Dicpinigaitis, FCCP, Dr. Louis Boulet, FCCP, Dr. Anne Chang, FCCP, Dr. Mark Rosen, FCCP; and ACCP President Dr. W. Michael Alberts, FCCP.

National and local print and television coverage reached the top 50 US markets.

International coverage was also impressive, with numerous print and broadcast stories in Canada and additional media coverage reaching as far as Great Britain, Australia, and Japan.

A special thank you to Drs. Richard Irwin and Peter Dicpinigaitis, for the countless interviews they provided for media, and to the members of the guidelines committee for their dedication to the committee and their commitment to improving the lives of patients with cough and other respiratory illnesses. ■

AMERICAN COLLEGE OF CHEST PHYSICIANS

NEWS FROM THE COLLEGE

EDUCATION INSIGHTS

What Should Quality Improvement Mean to the ACCP Member?

BY SANDRA ZELMAN LEWIS, PHD
ACCP Research Specialist
AND
ED DELLERT, RN, MBA
ACCP Vice President, Educational Resources

Most individuals are continually engaged in the practice of improving performance and processes in an effort to continually improve patient care. Health-care systems have experienced this for a number of years with similar goals in mind.

However, third-party payors and purchasers challenge the medical community to increasingly conform to required standards of quality or performance measures, in an attempt to reduce errors but, primarily, to control escalating health-care costs (Baumann and Dellert. *Chest* 2006; 129:188-191).

It is not unusual with this increased scrutiny to find hesitation among practicing physicians. In fact, such hesitation might not be the most successful strategy. Physicians could find that it is better to be involved in the process (as opposed to being outside of the process) of developing these performance measures and continually monitoring both the measures and their use, as the medical environment changes. Medical professional societies should and are working to represent the interest of their members in the development and implementation of these measures and the resultant reporting of the aggregated data.

It is with this concept in mind that the American College of Chest Physicians (ACCP) has developed multiple approaches to participating in the development and administration of national quality improvement efforts to assist its members. As a first step, the ACCP Quality Improvement Committee (QIC) has been formed. This committee is charged with initiating an assessment of performance measures developed by other organizations and determining the appropriateness of the measures for ACCP members. One of the first goals of this newborn committee is to develop criteria for such approval.

Most of the current performance measures are being developed, endorsed, and implemented by strategic partners of the ACCP. In addition to continuing participation in the AMA Physicians' Consortium for Performance Improvement, the ACCP has recently joined as a voting member of both the Ambulatory Care Quality Alliance and the National Quality Forum, where ACCP members have been appointed to working groups on National Consensus Standards for Prevention and Care of Venous Thromboembolism and the Pulmonary Consensus Standards Maintenance Committee. To facilitate and influence the principles upon which performance measures should be based, the new QIC will develop criteria to determine which evidence-based guideline recommendations are appropriate or not appropriate for the development of performance measures.

Eventually, the committee will be charged with the development of tools, based on endorsed performance measures, that can by used by ACCP members for the purpose of clinical quality improvement and toward individual maintenance of certification. This would complete the cycle and serve the ACCP membership as the escalating movement for standards-based quality improvement reaches the individual physician's office. Watch the ACCP Web site, www.chestnet.org and future issues of *CHEST Physician* for updates on quality improvement efforts. ■

The CHEST Foundation's 2006 Award Opportunities

THE CHEST FOUNDATION
Helping You Help Your Patients
Live and Breathe Easier

Leadership

▶ **Roger C. Bone Advances in End-of-Life Care Award for Leadership in End-of-Life Care**
DEADLINE: April 15, 2006

Clinical Research

▶ **The Association of Specialty Professors (ASP)/CHEST Foundation Geriatric Development Research Award**
DEADLINE: March 31, 2006

▶ **The CHEST Foundation Clinical Research Award in Women's Health**
DEADLINE: May 15, 2006

▶ **The CHEST Foundation and the LUNGevity Foundation Clinical Research Award in Lung Cancer**
DEADLINE: April 28, 2006

▶ **Alpha-1 Foundation/CHEST Foundation Clinical Research Award in Alpha-1 Antitrypsin (AAT) Deficiency**
DEADLINE: April 28, 2006

▶ **The American Society of Transplantation (AST)/CHEST Foundation Clinical Research Award in Lung Transplantation**
DEADLINE: April 28, 2006

▶ **Clinical Research Trainee Awards**
DEADLINE: May 1, 2006

Humanitarian Awards

▶ **Humanitarian Recognition Awards**
DEADLINE: May 15, 2006

▶ **Humanitarian Project Development Grants**
In 2006, special Humanitarian Project Development Grants will be given to projects focused on recovery from Hurricanes Katrina, Wilma, and Rita in the United States Gulf Coast area. Please see the application form for more information.
DEADLINE: June 15, 2006

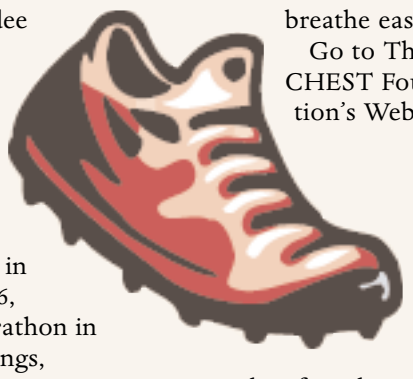
www.chestfoundation.org

Donate to The CHEST Foundation and Support A Marathon Team!

New for 2006 and a unique way to raise funds for The CHEST Foundation, a marathon team under the leadership of Shandee Chernow, is seeking donations to The CHEST Foundation.

The five-member team will participate in the June 4, 2006, Steamboat Marathon in Steamboat Springs, Colorado.

Your donation will help The CHEST Foundation in its four key areas of Humanitarian Service, Clinical Research, Critical Care, and Tobacco Prevention to help patients and their families live and breathe easier.



Go to The CHEST Foundation's Web site, www.chestfoundation.org, and click on the line that includes the words "Support a Marathon Team." ■

Ambassadors Group Announces New Initiative, Poster Contest

New Initiative for Ambassadors Group

Starting at CHEST 2006 in Salt Lake City, the Ambassadors Group will support one Humanitarian Award winner whose project focuses on lung health and/or children's health. Members plan to raise funds for the $5,000 award by securing direct donations to The CHEST Foundation or encouraging members to purchase the "Love Your Lungs" wristbands, sell them, and return their proceeds to The CHEST Foundation, or donate them to those who present the very successful Lung Lessons™ program to elementary school children. If you need more information, please contact the Ambassadors staff liaisons, Sue Ciezadlo (sciezadlo@chestnet.org) or Sandy Lewis (slewis@chestnet.org).

THE CHEST FOUNDATION
AMBASSADORS GROUP

CHEST 2006 Poster Contest Underway

If you have a creative child, grandchild, niece, or nephew who loves to draw and is 8 to 14 years old, the Ambassadors Group asks that you encourage them to enter the CHEST 2006 Poster Contest now.

Entries should focus on the theme of "Love Your Lungs," be on 8 ½" x 11" paper, and not include any photographs or computer drawings.

All entries must be received at The CHEST Foundation before May 1, 2006.

For more information and a submission form, please go to The CHEST Foundation's Ambassadors Web page, which can be found at www.chestfoundation.org/specialInitiatives/ambassadorsGroup.php. ■

NEWS FROM THE COLLEGE

AMERICAN COLLEGE OF CHEST PHYSICIANS

Inside NetWorks: Increasing Membership Value in Many Ways

Pediatric Chest Medicine

The Pediatric Chest Medicine NetWork is excited to be involved with two important ACCP activities, the Celebration of Pediatric Pulmonology 2006 course and the development of a new consensus statement about muscular dystrophy. Celebration of Pediatric Pulmonology is a course sponsored by the ACCP and the American Academy of Pediatrics. Drs. LeRoy M. Graham, FCCP, Dennis Gurwitz, FAAP, and Pedro M. Mayol, FCCP, are the co-directors. The course is held this year in San Juan, Puerto Rico, from March 31 through April 2. Leading pediatric pulmonologists from North America and Central America will be lecturing on a wide variety of topics. There will also be workshops on sleep medicine, bronchoscopy, pediatric radiology, and asthma. Dr. Lynn Taussig, CEO of National Jewish Hospital and a leader in cystic fibrosis and asthma epidemiology, will receive the Kendig Award. This award is bestowed on a physician who has had life-long contributions and achievements in the field of pediatric pulmonology. Registrations are currently being accepted at www.chestnet.org.

Dr. David J. Birnkrant, FCCP, is chairing the working group to develop the consensus statement, entitled Respiratory Support of Patients With Duchenne Muscular Dystrophy During Sedation and Anesthesia. "All professionals involved in the care of children and young adults with neuromuscular disease must face the problem of the risks of sedation and anesthesia," states Dr. Birnkrant. "The consensus statement will benefit pulmonologists, respiratory therapists, neurologists, anesthesiologists, intensivists, surgeons, and all others involved in the care of people with neuromuscular disease who need sedation or anesthesia." Dr. Howard B. Panitch, FCCP, is the co-chair for this project.

Practice Administration

Calling all practice administrators! Did you know the Practice Administration NetWork includes physicians and practice administrators from all across the nation? It has become common knowledge that many of the best-managed practices are led by knowledgeable physician-administrator teams. NetWork members share common practice problems and their resolutions via conference calls, e-mails, and sessions held during the annual CHEST meeting. Areas of expertise within the NetWork are electronic medical records, proper coding, and revenue cycle management.

Your practice can realize the many benefits of your administrator becoming an ACCP member by visiting www.chestnet.org/membership/join/allied.php and reviewing the requirements for Allied Health Membership. If you have questions regarding membership, contact member@chestnet.org or call Cristina Vock in the Membership Department, at (847) 498-8359.

For more information about the Practice Administration NetWork, one of the many benefits of ACCP membership, visit the NetWork's Web page, at www.chestnet.org/networks/practice_admin.

Private Practice

The Private Practice NetWork successfully planned and held the 5th Annual Leadership Development Program for Private Practice Physicians at CHEST 2005 in Montréal, Canada. Planning for the 2006 program is now underway. The goal of this program is to increase the participation of private practice physicians in the leadership ranks of the ACCP.

Many alumni of the previous programs have now become more active members in the ACCP and serve in key leadership roles. The conference offers an excellent opportunity to learn how each and every member of the organization can participate. The program is open to any private practice physician who has been in practice for at least 3 years. All are encouraged to apply to this year's program. It is recommended that application be made as soon as possible. For more information on this program, e-mail Marla Brichta, Private Practice NetWork staff liaison, at mbrichta@chestnet.org.

The NetWork continues to grow, and all ACCP members are invited to become active members of the NetWork. The members of the NetWork Steering Committee are open to suggestions as to how the Private Practice NetWork may serve its members. For more information, please visit the NetWork Web page, at www.chestnet.org/networks/private_practice.

Pulmonary Physiology, Function, and Rehabilitation

The Pulmonary Physiology, Function, and Rehabilitation NetWork focuses on increasing the understanding of pulmonary physiology and function and incorporating that knowledge into clinical practice, including pulmonary rehabilitation. Our goal is to provide leadership, education, effective communication, and advocacy in these important areas of physiology.

Some of the important tasks that we have performed in the past year include organizing outstanding physiology-based presentations for the annual CHEST meeting; working with the ACCP Health and Science Policy Committee to update the Pulmonary Rehabilitation Joint ACCP/AACVPR evidence-based guidelines; and completing a survey of ACCP members, with regard to physiologic educational needs in pulmonary function testing, exercise testing, pulmonary procedures, and ventilator management.

This survey will be published soon and made available to ACCP members. In addition, we are working to address the perceived educational needs as part of the curriculum for CHEST 2006.

As with any ACCP NetWork, accomplishments are possible only through the members who take the time to volunteer and provide input.

If your interest lies in pulmonary physiology, and/or in advocacy toward improving clinical practice and rehabilitation through improving our physiologic knowledge, please consider joining the NetWork.

To find out more about the NetWork, visit www.chestnet.org/networks/ppfr/. ■

Deep-Vein Thrombosis: Are You Aware?

March 2006 has again been designated DVT Awareness Month.

The ACCP will be supporting the Coalition to Prevent Deep-Vein Thrombosis (DVT) in raising awareness of this commonly occurring medical condition and its potentially fatal complication, pulmonary embolism (PE). ACCP members and their institutions are encouraged to organize activities at the local level to observe the month locally.

Local events and activities can provide an important opportunity to raise awareness of the 7th ACCP Conference on Antithrombotic and Thrombolytic Therapy: Evidence-Based Guidelines, published in *CHEST* in September 2004 and available at www.chestjournal.org.

DVT Awareness Month was officially recognized by US Senate Resolution 56 in 2005. This year, the Coalition—which comprises more than 35 representatives from nationally known medical societies, patient advocacy groups, and other public health organizations—will focus its multifaceted campaign on raising awareness among consumers, health-care professionals, and policy-makers about DVT and PE on a national and local level.

The spokesperson for the 2006 campaign will again be Melanie Bloom, widow of NBC correspondent David Bloom. Ms. Bloom spoke at CHEST 2005 in Montréal, as the national patient advocate in support of the Coalition's efforts.

Mrs. Bloom's personal commitment to this cause has had a tremendous impact on the awareness of DVT. She is now leading the charge across the country for DVT patients and their families as they share their stories to raise awareness of this condition.

According to the American Heart Association, up to 2 million Americans are affected annually by DVT. In the United States, of those who develop PE, up to 200,000 will die—which is more than from breast cancer and AIDS combined. Yet, a national survey released by the American Public Health Association found that most Americans (74%) have little or no awareness of DVT.

ACCP

Dr. Paul Kvale, FCCP, visits with CHEST 2005 guest speaker, Melanie Bloom.

The Coalition to Prevent DVT has coordinated DVT Awareness Month efforts since its launch in March 2003. Resources that clinicians and health-care organizations may use to help observe DVT Awareness Month can be found at the Coalition's Web site, www.preventdvt.org, and also on the ACCP Web page at www.chestnet.org. ■

AMERICAN COLLEGE OF CHEST PHYSICIANS

NEWS FROM THE COLLEGE

SLEEP STRATEGIES

Time to Treat Obstructive Sleep Apnea Like a Chronic Disease

Obstructive sleep apnea (OSA) is a common disease that is easy to diagnose, has significant associated health risks if left untreated, and is relatively difficult to successfully treat long-term. The prevalence of sleep apnea in North America is estimated to be anywhere from 3 to 28% for an apnea-hypopnea index of 5. This prevalence is similar to chronic diseases, such as diabetes and asthma, yet OSA has no where near the recognition by the public or by many physicians. With an aging population and an obesity epidemic, the prevalence is likely to rise. There is also growing evidence that untreated sleep apnea increases the risk of stroke and cardiac disease, likely through recurrent intermittent hypoxia. There is unequivocal evidence that untreated sleep apnea is associated with an increase in automobile accidents. Serious complications and an increasing prevalence of untreated OSA make effective diagnosis and treatment imperative.

If OSA is treated, the best evidence shows that the risk of automobile accidents and cardiovascular morbidity and mortality risk decreases and that quality of life is improved. There is no doubt that positive airway pressure (PAP) treatment works and greatly benefits patients with OSA. Fortunately, patients usually accept initial treatment, and most patients will accept a trial of PAP therapy at home after a physician prescribes it.

Long-term adherence to PAP, however, is really the goal of therapy, since the deleterious effects of OSA will return if treatment is stopped and no other therapy takes its place. In this sense, PAP is a successful treatment, but not a cure, for OSA.

Long-term Treatment of OSA

In order to ensure long-term success with any therapy, the patient and the caregivers must be committed to long-term care, including periodic reassessments of therapy and being open to new therapies, as they are developed. Unfortunately, long-term care of the patient with OSA has not been a priority for the pulmonary/sleep medicine community. Diagnosing patients with OSA has been the priority for many physicians in this field. There are large economic incentives for this, as sleep laboratories can be lucrative ventures.

Sleep Institute
American College of Chest Physicians

However, if the prevalence of OSA is already high and likely to climb higher, it is reasonable to ask, "Who will be managing these patients over the long-term?"

The answer is "We are not sure." We are afraid that many patients with OSA are not being seen for follow-up after therapy is started. Lack of follow-up results because patients abandon effective therapy when they get little support from the medical community when problems with the therapy arise.

Sleep Apnea: Acute Episode of Care vs Chronic Disease

Some pulmonary/sleep medicine physicians think of sleep apnea as an acute episode of care in which a patient presents with certain symptoms suggesting that a sleep disorder is present; a test is performed (perhaps after the patient waited 2 months for it); sleep apnea is diagnosed; and PAP therapy is prescribed. This prescription is then sent to a home medical equipment supplier. What happens next? The aftercare of the patient with OSA is largely undefined. Some patients adapt to PAP therapy readily and have no problems. Others reject the therapy, almost from the beginning, and put the PAP machine in the closet where it stays unused.

Most patients are somewhere in the middle—struggling with PAP therapy on some nights, having better success on others. These patients may have some success with PAP therapy but are not likely to experience optimal or even acceptable results. If these patients struggle with PAP therapy too long, they are at risk for losing interest in it and giving it up completely.

We have all seen patients who have experienced this last scenario: they have clinically important OSA; PAP therapy was prescribed; and no follow-up was arranged. Meanwhile, the patient struggles with therapy and, eventually, decides to stop using it. These patients frequently can be rescued by a competent clinician willing to invest a little bit of time to troubleshoot why the patient is struggling with treatment. All too often, this does not happen. The sleep laboratory, where the study was performed, may have no long-term relationship with the patient with OSA; sleep studies are performed but no comprehensive care is offered. The study result and the prescription are sent to the referring physician, who is expected to assume responsibility for therapy.

The problem with this scenario is obvious: it is easy to suspect OSA and order a study, but it is quite a different matter to actually manage the patient appropriately, especially when side effects of therapy begin to intrude on success. Some physicians may rely on the home health industry to provide this crucial management, by falsely believing the durable medical equipment company has the personnel and the experience to manage aftercare service. Unfortunately, home health companies have no incentive to provide clinical management for OSA PAP treatment, since they are paid by insurers to provide equipment, not services. Fortunately, many home medical equipment providers do provide some clinical management, or at least suggestions, although it is far from standardized and not reimbursed.

A Chronic Disease Model for OSA

OSA is a chronic disease, and it is time that it was treated like one. Patients with OSA should have long-term access to competent clinicians who are knowledgeable about OSA. In most communities, this will be a pulmonologist or a sleep medicine specialist. Primary care clinicians have virtually no exposure to sleep medicine and OSA clinical management in their training, and it is unrealistic to expect them to carry this load in their practices when nothing in their experience prepares them for it. Pulmonologists receive training in OSA in their fellowships. Unfortunately, the experience is highly variable across fellowship programs, and the emphasis is more likely to be on making the diagnosis than troubleshooting problems with therapy. We must train

Continued on following page

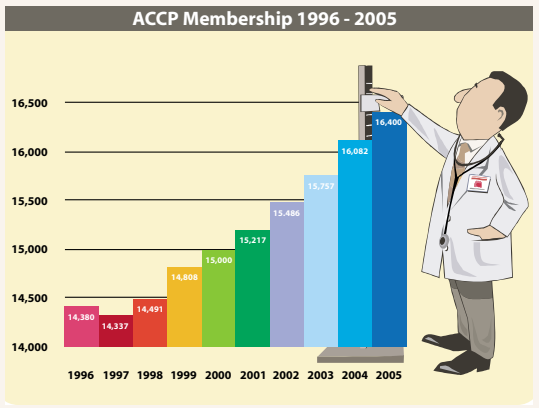
NEWS FROM THE COLLEGE

AMERICAN COLLEGE OF CHEST PHYSICIANS

ACCP Inside View: Membership

BY CHRISTINE DERBES
Manager, ACCP Membership

ACCP membership delivers good value, with great publications like the journal, *CHEST*, a variety of educational opportunities, top-notch representation to government and other groups, and access to a wealth of information on the ACCP Web site. How have these and other member benefits been received by the members? If membership growth is any measure, membership at the ACCP is at an all-time high, maintaining over 16,000 active members for the past 2 years. In 2005, the number of new member applications received reached a 5-year high of over 1,500. This year, new members are able to complete their membership applications online at www.chestnet.org/membership/join/.



Other resources available to the membership on the Web site include the Membership Directory, change of address, dues payment, and Career Connection. The online Membership Directory has been updated and revised. It is now possible to look up an ACCP member not only by last name but also by specialty, country, state, or city. It is also possible to look up ACCP members participating in specific disease registries, including sarcoidosis and idiopathic pulmonary fibrosis. Members can review and refresh their personal information or pay their dues online at www.chestnet.org/membership/. The ACCP Career Connection is the online career service for members to review jobs by specialty and location or to post resumes or CVs for potential employers. Members can also receive e-mailed "job alerts" as new jobs are posted. Employers can post jobs and review candidate responses to their postings.

International members from all over the world contribute to the strength of the ACCP. The international e-membership program launched in early 2005 and offers the option of lower international Member/Fellow dues, based on the World Bank Classification of Gross National Income. Members can continue the "traditional" membership or become e-members. e-Members receive most ACCP communications electronically, including the *CHEST* journal, and an e-newsletter to keep them informed about ACCP educational programs and other offerings, with direct links to the ACCP Web site. Other member benefits remain the same. e-Membership has been rolled out gradually over the past year. As of January 2006, there are over 300 e-members in 35 countries, representing about 13% of the international members and ACCP Fellows. By March 2006, e-membership will be available to all the countries with ACCP members. This category is not available to Allied or Affiliate members.

The ACCP International Regents and Governors are often instrumental in influencing their colleagues to join ACCP. A special thank you and congratulations to Dr. Nan-Shan Zhong, FCCP, the ACCP Regent for the Peoples Republic of China, who recently recruited 50 new Fellows in his country. This year, the International Nominations Subcommittee will meet to select nominees for ACCP International Regent in over 40 countries. All ACCP Fellows in those countries have been invited to submit recommended candidates. New officers begin their terms in October 2006.

ACCP members have access to a diverse array of benefits designed for professional and personal advancement. If you have any questions about membership, please contact the ACCP Membership Department at member@chestnet.org. ■

2006 Industry Advisory Council

The Mission of the ACCP Industry Advisory Council is 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.

Objectives

The ACCP Industry Advisory Council will:

- Serve as a forum for the ACCP, The CHEST Foundation, and the corporate community to discuss key issues and their implications.
- Act as an advisory body to the ACCP for corporate income development and partnering opportunities.
- Advise ACCP on technical and business trends that may influence strategic planning decisions.
- Interact with ACCP by increasing professional development and educational opportunities.
- Advise ACCP on issues that may lead to conflict between the ACCP and industry partners.

ACCP Industry Advisory Council Members

Kathy Lucas, *Interim Chair*

Actelion Pharmaceuticals US, Inc.
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AstraZeneca LP
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CMS Launches Satisfaction Survey

BY DIANE KRIER-MORROW, MBA, MPH, CCS-P

The Centers for Medicare and Medicaid Services (CMS) launched its first ever provider satisfaction survey for Medicare fee-for-service contractors. CMS randomly selected 25,000 providers (physicians, suppliers, health-care practitioners, and institutional providers) of its 1.2 million providers. The 24-page survey is designed so that is can be completed in less than one-half hour. The ACCP hopes you answered the survey if you were selected. The survey focused on seven key areas of provider-contractor interactions: provider communications, provider inquiries, claims processing, appeals, provider enrollment, medical review, and provider audit and reimbursement. We are asking you to inform Marla Brichta at mbrichta@chestnet.org or (847) 498-8364 if you were selected and to provide a brief summary of your comments made on the survey. Your information will help our Practice Management Committee work for you in their monthly conference calls on coding and reimbursement issues. CMS expects to make the survey results available online in early July 2006 and to use the information gathered for contractor oversight and share data with their contractors to improve the services they offer to providers. ■

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pulmonary fellows in comprehensive OSA management.

There are other reasons for long-term care in a chronic disease framework. One is that clinical status changes; OSA, like any other chronic illness, is dynamic. Patients lose and gain weight; they age; and they can develop insomnia or congestive heart failure—all of which affect sleep quality and treatment effectiveness with PAP therapy.

Only periodic reassessment by a competent sleep clinician will help maintain patients receiving PAP therapy and keep their OSA under control.

Making a Chronic Care Model Work

In order to change OSA from an acute episode of care model to a chronic disease model, we have to address practical aspects of clinical practice. In many areas, performing and interpreting tests (such as sleep studies) bring in a higher reimbursement than providing evaluation and management. A realistic, clinically appropriate, and financially viable model for OSA management is needed. Some practices, including our own, have developed such a model using nurse practitioners. Over the past decade, we have employed two nurse practitioners in our sleep medicine center. They see a large majority of our practice's follow-up patients. Our nurse practitioners see all types of sleep disorders, but OSA accounts for the majority of their patients. This approach is financially viable. In addition to understanding and being able to manage the nuances of positive pressure therapy for patients with OSA, they have also become skilled at managing stimulant medications, weight loss therapies, and patients with insomnia.

The field of sleep medicine is growing and maturing. We have the diagnostic tools to readily diagnose OSA. As pulmonologists and sleep medicine practitioners, we need to make sure that our patients with OSA get all the care they need, for as long as they need it. ■

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Section Editor, Sleep Strategies

Treatment Delay, Lung Cancer Outcomes Offer Paradox

BY BRUCE K. DIXON
Elsevier Global Medical News

MONTREAL — Survival times for patients with potentially resectable non–small cell lung cancer could be lengthened by cutting treatment wait time, according to the results of a retrospective study presented by Dr. Michael K. Gould, FCCP, at the CHEST 2005 annual meeting of the American College of Chest Physicians.

However, no such benefit would accrue in patients with more severe disease, Dr. Gould said.

'Patients with shorter treatment delays probably have more severe disease at time of presentation.'
DR. GOULD

To determine the association between treatment wait time and lung cancer outcome, the researchers reviewed the records of 129 consecutive patients diagnosed with non–small cell carcinoma (NSCC) of the lung between Jan. 1, 2002, and Dec. 31, 2003. The cohort was 83% white, the mean age was 67 years, and 98% were men, said Dr. Gould of the Veterans Affairs Palo Alto Health Care System in California.

Half of the 129 veterans had adenocarcinoma, 30% had squamous cell carcinoma, and 18% presented with a solitary pulmonary nodule (SPN). Slightly more than 50% had centrally located tumors, and almost 60% had distant metastases, symptoms related to the primary tumor, or constitutional symptoms.

"One-fourth of the patients had some associated radiographic abnormality, whether it was hilar enlargement, post-destructive pneumonia, or pleural effusion. A sizable minority presented with asymptomatic solitary nodules measuring less than 3 cm in diameter with no associated radiographic finding," Dr. Gould said.

About 25% of the patients were treated with surgery, 35% received radiation therapy, 40% received chemotherapy, and 20% received best supportive care, with some patients receiving some combination of these.

The results of the review showed an association between shorter treatment wait time and more serious disease.

"Patients who had treatment delays of less than 90 days in general had larger tumors and were much more likely to have symptoms and associated radiographic abnormalities," he said. They were less likely to present with a solitary nodule.

This group was much more likely to be admitted to the hospital within 7 days, and to receive only best supportive care rather than surgical treatment.

"About a third of our patients were admitted to our hospital within 7 days of the initial radiographic abnormality. The general sense from our bivariate analyses is that patients with shorter treatment delays probably have more severe disease at time of presentation." Dr. Gould said.

Patients with tumors measuring greater than 3 cm had a fivefold greater likelihood of being treated within 90 days, and those patients with associated radiographic abnormalities or symptoms—adjusting for all other factors—were 2.5 times as likely to receive treatment within 90 days, Dr. Gould reported.

"In this analysis, we treat stage distribution as an outcome, and what we see is that patients treated within 3 months are much more likely to have advanced disease at the time of diagnosis and final staging," Dr. Gould said.

Stage III or IV disease was diagnosed in 80% of patients with shorter treatment delays and 60% of patients with longer delays.

The fact that patients with more serious disease had a shorter wait time confounded the team's ability to calculate an association between wait time and survival.

"We have this interesting yet paradoxical finding that patients treated within 90 days of presentation had a higher risk of death, a difference that was statistically significant both in a categorical analysis and a time-to-event analysis," he said.

The median survival for patients who had longer treatment delays was 535 days, compared with 150 days for those treated within 90 days.

"The only real explanation for this difference is confounding by severity of disease at the time of presentation … we're obviously not randomly assigning patients to either prompt treatment or less prompt treatment. So we hypothesize that patients with more aggressive and advanced disease at time of presentation are promptly diagnosed, promptly treated, and then, despite our best efforts, promptly die, whereas those who have less aggressive or less advanced disease at time of presentation undergo more leisurely work-ups and nevertheless have better survival," Dr. Gould said.

Even after adjusting for tumor characteristics, type of treatment, and patient demographics, shorter treatment delays were still associated with a twofold increase in the risk of death.

Stratification then revealed the flip side of this paradox.

"When we examined the subgroup of 23 patients who presented with asymptomatic solitary nodules, the paradoxical relationship between treatment delay and survival was no longer present. In fact, all five patients with SPNs who were treated within 90 days survived until the end of follow-up, while 3-year survival was under 50% in patients with SPN who had longer treatment delays," he said. The difference was not statistically significant, however, because of the small sample size.

Although the study has weaknesses that limit its statistical power, it also has strengths, Dr. Gould said. "Our sample captured the full spectrum of patients with non–small cell lung cancer, unlike some previous studies that limited enrollment to patients who received surgical treatments and thereby may have systematically excluded patients with the longest delays who may have had the worst outcomes. We used objective measurement time intervals to avoid recall bias, and we measured survival from the time of the first abnormal chest x-ray to minimize lead-time bias," he explained.

"What I suspect …from our initial analyses—and what my clinical intuition tells me—is that patients with the most advanced disease have the least to gain; we're already doing relatively well with them. I think for patients with less aggressive or advanced presentations, that's where we're likely to find our greatest opportunities for improvement," Dr. Gould said.

Citing the biased and confounded nature of previous research, he explained that he and his team conducted their own retrospective study to describe variations in wait times, identify predictors of longer wait times, and examine the effect of wait time on survival.

"Longer wait times contribute to emotional stress in patients and their families, as well as in the physicians caring for those patients. Longer wait times may lead to missed opportunities for cure or palliation. And finally, delays may lead to increased costs," he said.

Dr. Gould is planning a larger study involving 13 Veterans Affairs hospitals.

"The greatest potential impact we can have … is doing things to reduce wait times in people for whom they are long now, that is, people with less aggressive presentations," he said in an interview.

The research was supported by an Advanced Research Career Development Award from the VA Health Services Research and Development Service.

Take Five Steps to Appeal Medicare Part B Denials

BY MARY ELLEN SCHNEIDER
Elsevier Global Medical News

LAS VEGAS — On Jan. 1, Medicare officials implemented a new five-step process for appealing Medicare Part B claims.

The changes apply to Part B initial claim determinations issued and mailed on or after that date, Edward R. Gaines III, senior vice president for compliance and general counsel at Healthcare Business Resources, Inc. of Durham, N.C., said at a meeting on reimbursement sponsored by the American College of Emergency Physicians.

The new process includes some significant procedural differences that could benefit physicians, including an opportunity for an independent review earlier in the process, Mr. Gaines said in an interview. The new process includes these steps:

▶ **Step 1.** The process begins with a "redetermination" of the initial claim decision made by the Part B carrier. The redetermination is also made by the Part B carrier but the appeals decision is made by an employee who was not involved in the initial determination. This is the only step that involves the Part B carrier that made the original decision, Mr. Gaines said.

Physicians have 120 days from the receipt of the notice of initial determination to file an appeal. Mr. Gaines recommended filing all documentation with the letter requesting a redetermination, including case summaries explaining your code selection. Otherwise, the carrier automatically receives up to 14 additional days to its 60-day decision deadline.

▶ **Step 2.** Providers can appeal the redetermination decision in a step called reconsideration. Physicians have 180 days from the date of receipt of the redetermination to file this appeal with the Qualified Independent Contractor (QIC) indicated in the Part B carrier letter.

The redetermination step replaces the old "fair hearing" process. The old process was frequently criticized since the fair hearing officer usually had close ties to the Part B carrier that made the original decision, Mr. Gaines said. He recommended submitting all relevant evidence in support of the claim when the notice of reconsideration is submitted because this is a new review and the QIC will not consider what the carrier ruled previously.

QICs are bound by Medicare national coverage decisions, CMS rulings, laws, and federal regulations. But they are not bound by other documents including local coverage decisions, program guidance, or manual instructions, he said. The reconsideration decision is rendered within 60 days under the appeals process.

▶ **Step 3.** A hearing with an administrative law judge is held in person, by video, or by telephone. Otherwise, the administrative law judge (ALJ) will base his or her decision on the written record. To have an ALJ review the appeal, submit a written request within 60 days of the reconsideration notice. At this level of the appeal, at least $110 must be in dispute. In order to get an in-person hearing, physicians must make that request before the hearing date is set and explain why a telephone or video hearing is not acceptable, Mr. Gaines said. Consider obtaining legal counsel at this point in the process, Mr. Gaines advised.

▶ **Step 4.** If still not satisfied, a provider may appeal to the Medicare Appeals Council. This must be done within 60 days from the receipt of the ALJ decision. The Medicare Appeals Council is another addition to the process. Previously, physicians who wanted to appeal a decision beyond the ALJ would have to go to federal district court, and few physicians took that step, Mr. Gaines said. There is no right to a hearing before the council but physicians can request an oral argument. In addition, parties to the appeal can file briefs.

▶ **Step 5.** The final appeal is to the federal district court. This must be filed within 60 days of the Medicare Appeals Council decision. The case may be filed in the U.S. District Court where the appealing physician resides. At this step in the process, at least $1,090 must still be in dispute.

Since the new process applies only to initial claims determinations issued and mailed on or after Jan. 1, it will take several months to evaluate how the new process works for physicians, Mr. Gaines explained. ■

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