VOL. 4 • NO. 1 • JANUARY 2009

CHEST Physician

THE NEWSPAPER OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS

JOHN MCCAULLEY/UNIVERSITY OF PITTSBURGH MEDICAL CENTER

Hospital blood management programs are a growing phenomenon, said Dr. Jonathan Waters of the University of Pittsburgh.

Blood Costs, Benefits Are a Delicate Balance

BY MICHELE G. SULLIVAN
Elsevier Global Medical News

Faced with skyrocketing costs, a dwindling supply, and ever-increasing demand, hospitals are finding ways to optimally manage one of their most precious resources—blood.

"The supply of blood in this country is decreasing as the need continues to rise," said Dr. Ajay Kumar, medical director of blood management at the Cleveland Clinic. It's a perfect storm of sorts, he said in an interview. "We're operating more, doing more complex surgery, and our patients consist of a larger pool of the aging population. There is a projected deficit of blood by 2030—and it looks like it will be quite an imbalance, with a shortage of up to 4 million units per year."

But the looming shortfall is just one prod for hospitals to reexamine their blood use policies.

Although most blood comes from free donation, it's not cheap to store it, keep track of it, or use it. And there's no denying that blood transfusion exposes patients to a unique set of health risks, said Deborah Tolich, R.N., regional director for blood management at the Cleveland Clinic.

Immunomodulation is probably the most significant of

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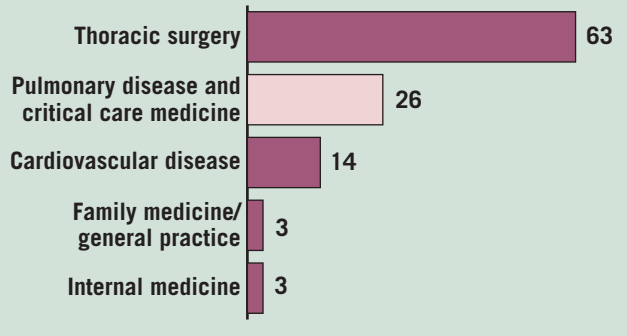
VITAL SIGNS

Number of People per Active Physician By Specialty, 2007

(In thousands)



Source: 2008 Physician Specialty Data, Association of American Medical Colleges

ELSEVIER GLOBAL MEDICAL NEWS

FDA Panels: 'No' to LABA Monotherapy, 'Yes' to Combo Tx

Use of LABAs for asthma debated.

BY ELIZABETH MECHCATIE
Elsevier Global Medical News

ROCKVILLE, MD. — The benefits of the single-ingredient, long-acting β-agonist products salmeterol (Serevent) and formoterol (Foradil) do not outweigh their risks when used for treating asthma in adults, adolescents, and children, according to a majority of the three Food and Drug Administration advisory panels who reviewed the safety of the drugs.

However, most of the panelists at the joint meeting Dec. 10-11 of the FDA's Pulmonary-Allergy Drugs Advisory Committee, Drug Safety and Risk Management Advisory Committee, and Pediatric Advisory Committee agreed that the benefits of Advair, which combines salmeterol with the inhaled corticosteroid (ICS) fluticasone, and Symbicort, which combines formoterol with the ICS budesonide, outweighed the risks when used to treat asthma in adults and adolescents.

The panel members recommended that safety be further studied in randomized, controlled trials; that health care practitioners and patients be educated about the importance of an ICS as a first-line treatment for asthma; and that a long-acting β-agonist (LABA) always be combined with an ICS. The FDA usually follows the recommendations of its advisory panels, which are not binding.

The three committees met to review the risks and benefits of the four inhaled LABAs marketed in the United States for adults and children with asthma. The committees also discussed whether the drugs

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Sleep Institute® American College of Chest Physicians

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OSA Is Common in Post-MI Patients

BY BRUCE JANCIN
Elsevier Global Medical News

NEW ORLEANS — Obstructive sleep apnea is common in patients who have recently had a myocardial infarction and is closely linked to the presence of complex ventricular arrhythmias.

These findings from an Italian observational study have two important implications worthy of further investigation, Dr. Stefano Fumagalli said at the annual scientific sessions of the American Heart Association.

One possibility raised by the study is that continuous positive airway pressure for the treatment of obstructive sleep apnea (OSA) in affected patients post MI might improve cardiovascular outcomes. The other potential implication is that an evaluation for OSA might prove useful in deciding whether to place an implantable cardioverter-defibrillator in a patient with a reduced left ventricular ejection fraction post MI, according to Dr. Fumagalli of the University of Florence (Italy).

He reported on 107 consecutive patients who underwent sleep studies 1 month following acute MIs. Seventy-six percent of patients had primary percutaneous coronary intervention for their MI, which was an ST-elevation MI in more than two-thirds of study participants. Men composed 83% of the consecutive patient series. Participants' mean body weight was 78 kg.

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CHEST Physician Adds to Its Editorial Team

It is with pleasure that we welcome the following ACCP members filling CHEST PHYSICIAN positions:

New Editor in Chief

► **Dr. Paul A. Selecky, FCCP,** has assumed the position of editor in chief. Dr. Selecky served as deputy editor and is a 2-year veteran of the newspaper's editorial advisory board. He is clinical professor of medicine at UCLA; and medical director of the Pulmonary Department, Sleep Disorders Center, and Palliative Medicine Service, Hoag Hospital, Newport Beach, Calif. Dr. Selecky is a past chair of the ACCP Continuing Education Committee and a past president of NAMDRC. He has participated in ACCP committees, including Ethics, Government Relations, and Health and Science Policy. He is a past chair of the Respiratory Care NetWork.

DR. SELECKY

New Section Editors

► **Dr. Neil Halpern, FCCP,** has assumed the position of section editor for Critical Care Commentary. Dr. Halpern is currently chief of critical care medicine and medical director of respiratory therapy at the Memorial Sloan-Kettering Cancer Center, New York, and is professor of medicine and anesthesiology at the Weill Medical College of Cornell University, New York. He is a Fellow of the ACCP. Dr. Halpern is a prolific author and noted speaker, specializing in cost and use of critical care in America, technology introduction in critical care, and innovations in ICU design.

DR. HALPERN

► **Dr. James Parish, FCCP,** has assumed the position of section editor for Sleep Strategies. Dr. Parish is currently chair of the Division of Pulmonary Medicine and associate professor of medicine at Mayo Clinic College of Medicine in Scottsdale, Ariz. He is board-certified in internal medicine, pulmonary medicine, and sleep medicine through the American Board of Internal Medicine. He is a Fellow of the ACCP, a member of the ACCP Sleep Institute, and on the steering committee of the ACCP Sleep Medicine NetWork. Dr. Parish has served as chair of the ACCP Government Relations Committee and ACCP Governor for Arizona.

DR. PARISH

New Editorial Advisory Board Members

► **Dr. Richard Fischel, FCCP,** is currently the director of thoracic oncology at Hoag Hospital in Newport Beach, Calif. He is chief of surgery and director of the Lung Center at Chapman Medical Center, a Medicare-approved lung volume reduction surgery site. He is a board-certified general thoracic surgeon specializing in minimally invasive thoracic surgery. Dr. Fischel also serves as the president of the Orange County Board of the American Lung Association. He received a PhD in surgery and immunology at the University of Minnesota for his work in the field of xenotransplantation.

► **Dr. Burt Lesnick, FCCP,** is a practicing pediatric pulmonologist in Atlanta, where he is managing partner of Georgia Pediatric Pulmonology Associates, a group of 11 pediatric pulmonologists. He also serves as chief of the Department of Medicine for Children's Healthcare of Atlanta. Dr. Lesnick is a Fellow of the ACCP and serves the ACCP as vice-chair of the Pediatric Chest Medicine NetWork, steering committee member of the Private Practice NetWork, and member of the Practice Management Committee. He is the alternate ACCP representative to the AMA RUC (RBRVS Update Committee).

► **Dr. Nirupam Singh** is practicing full-time critical care at Hoag Hospital in Newport Beach, Calif. After finishing medical school with the University of Delhi in India, Dr. Singh did his residency at Upstate Medical Center in Syracuse, N.Y. He subsequently finished fellowship training in pulmonary and critical care at Tufts/New England Medical Center in Boston. Dr. Singh's areas of interest include hypothermia after cardiac arrest and patient ventilator synchrony. ■

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Practice Management

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CHEST PHYSICIAN Is Online

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

Sleep Apnea

Post-MI • *from page 1*

The mean apnea-hypopnea index (AHI) was 14.3 events/hr. A normal AHI—that is, a value less than 5—was present in only 26% of patients. Some 40% percent of participants had an AHI greater than 15, indicative of OSA of at least moderate severity.

Fifty-two patients had complex ventricular arrhythmias on 24-hour Holter monitoring. Their mean AHI was 16.8, significantly greater than the AHI of 12.2 in patients without complex ventricular arrhythmias.

In a multivariate regression analysis, the strongest predictor of OSA was the presence of complex ventricular arrhythmias, which conferred a 5.8-fold increased risk. Other independent predictors of OSA were an increased serum creatinine, the presence of aortic insufficiency, and greater body weight.

Dr. Fumagalli noted that, although OSA previously has been linked to hypertension, atrial fibrillation, and heart failure, there have been few prior studies investigating a possible association with ischemic heart disease. ■

Dr. Stephen A. Geraci, FCCP, comments: *Scientifically, I would bet that many—if not most—patients had OSA before their MI, and that many had heart failure before and/or after. Some percentage of sudden death is likely from infarction, though a concept exceedingly difficult to prove. In a perfect world, we would pick up the OSA before their MI, as it is no great stretch to see a relationship between the sympathetic activation causing plaque destabilization and MI. It is likely that nobody's algorithm has "sleep study" on the post-MI order set. This doesn't say that we should, but it alerts people to the possibility.*

CHEST PHYSICIAN

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

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Address Changes: Fax changes of address (with old mailing label) to 973-290-8245.

POSTMASTER: Send change of address (with old mailing label) to CHEST PHYSICIAN, 60 B Columbia Rd., 2nd flr., Morristown, NJ 07960.

CHEST PHYSICIAN (ISSN 1558-6200) is published monthly for the American College of Chest Physicians by Elsevier Inc., 60 B Columbia Rd., 2nd flr., Morristown, NJ 07960, 973-290-8200, fax 973-290-8250.

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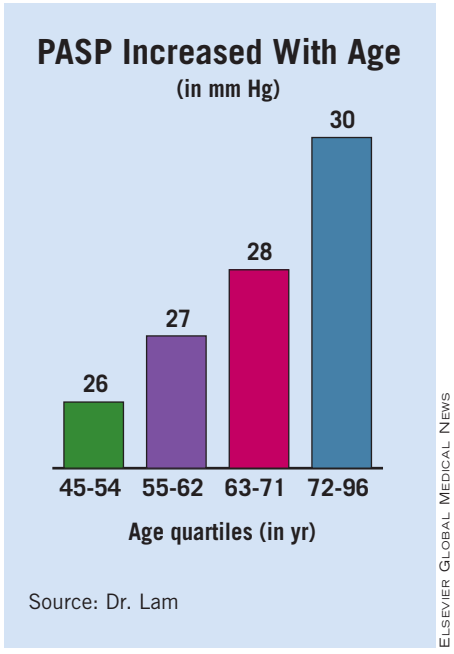
Pulmonary Artery Pressure Rise Linked to Mortality

BY MITCHEL L. ZOLER
Elsevier Global Medical News

NEW ORLEANS — Pulmonary artery systolic pressure may increase with age among unselected, otherwise healthy people in the general population, based on a cross-sectional study of more than 1,400 people.

In addition, the age-associated rise in pulmonary artery systolic pressure (PASP), which was strikingly parallel with the age-related rise in systolic blood pressure, was also independently associated with an increased risk for death.



ELSEVIER GLOBAL MEDICAL NEWS

For every 10–mm Hg rise in PASP among unselected, otherwise healthy people in the general population, the risk of death rose 2.7-fold in an analysis that adjusted for age, Dr. Carolyn S. Lam reported at the annual Scientific Sessions of the American Heart Association.

"This is the first population-based evidence for an age-related rise in PASP," said Dr. Lam, a cardiologist at the Mayo Clinic in Rochester, Minn.

Results from prior studies had found a similar age-related rise in PASP, but it was in patients who had been sick enough to be referred for assessment by right heart catheterization or by echocardiography.

"What was interesting was it was so analogous to the rise in systolic blood pressure," she noted. Dr. Lam and her associates speculated that the age-related rise in PASP may be related to increased arterial stiffness with age, the process that is believed to also underlie increased systolic blood pressure with age.

The study included 1,413 residents of Olmsted County, Minn., age 45 years or older, who were seen at the Mayo Clinic for routine physical examinations. None of those people was initially diagnosed with cardiovascular disease. As part of their examination, however, they underwent an echocardiography study that measured their tricuspid regurgitation velocity. That value was used to calculate their PASP. Their average age was 63 years, 57% were men, and their average body mass index was about 28 kg/m^2.

'This is the first population-based evidence for an age-related rise' in pulmonary artery systolic pressure.

DR. LAM

The median PASP in the group was 26 mm Hg, with an intraquartile range of 24-30 mm Hg. Dr. Lam divided the subjects into quartiles by age, and found that their PASP steadily rose with age, from an average of 26 mm Hg among those aged 45-54 years to an average of 30 mm Hg among those aged 72 years or older (see graphic). Those age quartiles also showed the expected, age-related rise in systolic blood pressure.

Although the increments in systolic pressure with age were greater than the rise in PASP, that was because systolic blood pressures generally are higher. When the age-related rise in PASP was adjusted by the baseline level in the youngest quartile, the age-related rise was "strikingly similar" to the age-related rise for systolic blood pressure, Dr. Lam said.

In addition, the age-related rise in PASP was independent of the age-related rise in pulse pressure and in diastolic dysfunction.

To assess the impact of a rise in PASP on survival, Dr. Lam limited her analysis to the 778 people from the study group who were completely free of any cardiopulmonary disease based on their physical examination. Some of those "healthy" people had PASP levels that were as high as 66 mm Hg.

Analysis showed that the risk of death increased with increased PASP regardless of age, suggesting that PASP may be a "lifelong risk factor," Dr. Lam said.

The findings suggest that drug interventions aimed at reducing PASP, with agents such as calcium-channel blockers or phosphodiesterase-5 inhibitors such as sildenafil, may help reduce PASP-related deaths.

Before a study is done to test the efficacy of treatments aimed at lowering PASP, however, the prognostic role of elevated PASP must be explored in additional studies in different populations, Dr. Lam cautioned. ■

Respiratory Illnesses Tied to Later Asthma

BY SUSAN LONDON
Elsevier Global Medical News

SEATTLE — Children prone to atopy are more likely to develop asthma if they frequently have moderate to severe respiratory illnesses in the first years of life, according to results of a prospective cohort study. Moreover, these illnesses do not protect against other atopic conditions.

Childhood respiratory illnesses cause considerable morbidity, contribute to parental absence from work, and are one of the most common causes of health care visits among the pediatric population, lead author Dr. Christine Virnig noted at the annual meeting of the American College of Allergy, Asthma, and Immunology.

"We sought to further understand the risk factors for and atopic consequences of having frequent respiratory illnesses during the first 3 years of life," she said.

The investigators analyzed data from 277 children in the Childhood Origins of Asthma (COAST) study, which enrolled a birth cohort of infants who were at high risk for atopic conditions because at least one parent had allergies, asthma, or both.

During the children's first 3 years of life, parents completed a scorecard whenever their child had a respiratory illness to document the frequency and severity of these illnesses, said Dr. Virnig, an allergy and immunology fellow at the University of Wisconsin, Madison.

The children's personal, family, and environmental characteristics were assessed between birth and 6 years. Total IgE levels, eosinophil counts, levels of antigen-specific IgE to food and airborne allergens, and presence of atopic dermatitis were assessed at 1, 3, and 6 years, and the presence of asthma was assessed at 6 years.

Scorecard results indicated that 8% of the children did not have any moderate to severe respiratory illnesses (MSIs) during the first 3 years of life, whereas 9% had frequent MSIs (12 or more), Dr. Virnig reported.

Not unexpectedly, she said, children who had frequent MSIs were significantly more likely to have attended day care in their first 6 months of life, compared with their counterparts who did not have any MSIs during those years (64% vs. 27%).

But in a surprising finding, children with frequent MSIs also were significantly more likely to have been exclusively breastfed for the first 6 months of life (52% vs. 18%).

This association remained significant when the number of MSIs was analyzed as a continuous variable, but the ranges of values overlapped considerably. "Therefore, the clinical significance of this finding is very uncertain," Dr. Virnig commented, adding that it would not justify altering recommendations to breastfeed.

Children with frequent MSIs also were marginally more likely to have a mother who had asthma. A variety of other factors—sex, birth weight, presence of an older sibling, smoke exposure, a cat or dog in the home at birth, and paternal asthma—did not differ between groups.

The prevalence of asthma at age 6 was significantly higher among children having frequent MSIs than in children having none of them (59% vs. 9%). This association also remained significant when the number of illnesses was analyzed as a continuous variable, although the ranges of values again overlapped.

There was no significant difference between the two groups in terms of atopic dermatitis, the presence of food-specific IgE, or the presence of aeroallergen-specific IgE—or eosinophil counts at any of the ages studied.

Dr. Virnig acknowledged that the findings appear to be at odds with the hygiene hypothesis, which proposes that early infectious illnesses protect against subsequent allergies.

However, she noted, evidence supporting this hypothesis has generally been strongest for gastrointestinal illnesses, while several studies have in fact found an opposite pattern for respiratory illnesses, particularly those of the lower respiratory tract.

Dr. Virnig reported that she had no conflicts of interest in association with the study. ■

First Editor in Chief Ends Her Term

ACCP

The ACCP gratefully recognizes Dr. Susan M. Harding, FCCP, (right) and Arren Graf (left).

In January 2006, the first edition of CHEST PHYSICIAN was ushered in by its first editor in chief, Dr. Susan M. Harding, FCCP, and so began the road to success of the new ACCP newspaper aimed at providing relevant clinical information and the latest news in chest medicine, plus ACCP updates, to members and others.

During the past 3 years, Dr. Harding has built a publication that offers timely, relevant updates for ACCP members and others. Her excellent editorial skills, attention to detail, and broad chest medicine knowledge have been evident in every issue, and the popularity and value of CHEST PHYSICIAN to our members are much to her credit. The ACCP gratefully recognizes Dr. Harding and her indispensable editorial assistant, Arren Graf, for their selfless provision of time and effort in making CHEST PHYSICIAN the upstanding, professional chest medicine news vehicle it is today.

Thank you, Dr. Harding and Arren! ■

Hospitals Test Blood Programs

Blood Costs • *from page 1*

these, she said in an interview. "Even though patients don't have a major reaction to a transfusion, it does depress the immune system. And when you are dealing with people who are already sick enough to need a transfusion, this puts them at an even higher risk of infection, longer length of stay, and a host of other complications."

The risk of blood-borne infections, while minimized with donor screening methods, can never be completely eliminated, she added. "We have the safest blood supply in the world, but we can never make it 100% safe."

And the very storage techniques that extend blood's shelf life also contribute to its demise, she added. "We keep blood for up to 42 days, but even after 14 days in storage, you can see changes," Ms. Tolich said, including lesions on the red cells that can cause capillary occlusion.

A Cleveland Clinic study pointed out the risks of using stored blood in a group of cardiac patients.

Compared with those who received blood stored a median of 11 days, patients who received blood stored a median of 20 days were more likely to die in the hospital, and have longer periods of intubation, more renal failure, and more sepsis. Even at 1 year, patients who got the older blood were more likely to have died (N. Engl. J. Med. 2008;358:1229-39).

Economics cap off the clinical issues. According to the National Blood Data Resource Center, the 15 million or so annual allogeneic blood transfusions in the United States cost more than $2 billion—not including the costs of any transfusion-related complications.

A 2007 report by the American Association of Blood Banks concluded costs to use blood rose by more than 6% per unit from 2005 to 2006.

Using Blood Better

The Cleveland Clinic program is one of the country's most mature. It was the first to gain accreditation by the only group that offers such an endorsement, the American Association of Blood Banks.

Because there are no national requirements, hospitals are developing their own programs individually and at their own pace, Dr. Kumar said. "Everyone is in a different stage of development, and no one has the perfect system."

At his facility, however, physician accountability is the primary focus. Scorecards detailing transfusion practices are becoming part of every physician's annual review.

"Every blood order has to indicate the reason. We expect physicians to examine patients at the bedside before ordering blood, and document the reason for the decision," Dr. Kumar said. "We're also making staff physicians responsible for what their residents are doing—it's been a really radical change."

There's no one-size-fits-all algorithm deciding who gets blood and who doesn't, Dr. Kumar said. "We judge each patient on their clinical characteristics before giving blood.

"If an 82-year-old lady with hemoglobin of 9 g/dL after surgery feels terrible and gets out of breath, a transfusion is probably a good idea," he explained. "But a healthy 32-year-old man with the same hemoglobin after surgery might feel fine, because his body is able to compensate. The trigger changes with the patient."

Preoperative conditioning is an important part of the program, Ms. Tolich said. In the weeks before a scheduled surgery, patients with low hemoglobin visit outpatient anemia clinics. Red cell growth factor and intravenous iron are good options for building up hemoglobin.

Normovolemic hemodilution can be employed shortly before surgery. "In the holding area, we withdraw blood and replace it with an equal part of intravenous solution," Ms. Tolich explained. "When they lose blood during surgery, they're losing fewer red blood cells. Then the stored blood can be re-administered."

Self-banking isn't really a good option, Ms. Tolich added. "This is not supported by the medical evidence. It makes patients anemic going into surgery, so they're not only more likely to need that blood, but additional donor blood," she said. "And if all of the predonated blood isn't used, it has to be disposed of as medical waste. Predonation is also actually more expensive than using donor blood."

It's no surprise that the Cleveland Clinic program resembles that of the University of Pittsburgh Medical Center—Dr. Jonathan Waters, medical director of the University of Pittsburgh Health System's perioperative blood management program founded the Ohio program.

In addition to preoperative conditioning, the Pittsburgh program employs intraoperative blood cell salvage. Shed blood is collected, filtered, washed, and re-administered during surgery. The hospitals in Dr. Waters' institution perform about 8,000 salvage procedures yearly.

The Pittsburgh program also relies heavily on point-of-care testing.

"These devices measure blood parameters with a very small volume of blood, and the turnaround is 30 seconds. This allows you to strategize how to transfuse the patient," Dr. Waters said.

With the old 1-hour turnaround time for these tests, "if someone was bleeding, you just gave them everything you had," he said. "Since we've turned to point-of-care testing, we've had a 70% decrease in blood use."

That kind of reduction soon pays for any investment in transfusion-minimizing equipment, Dr. Waters pointed out.

A 2007 study concluded that the intraoperative blood cell salvage service at the Cleveland Clinic, which initially cost $103,500, paid for itself with 2 months' worth of reduced blood costs (Anesth. Analg. 2007;104:869-75).

Voluntary—for Now

Hospital blood management programs are a growing phenomenon, but by no means a universal one. Accreditation is based on voluntary compliance with standards set forth by the American Association of Blood Banks, but that may change in the future, Dr. Waters said.

"Two years ago, the Joint Commission formed a committee with representatives from interested parties on the provider side to determine if the commission should develop evidence-based blood management performance measures, which everyone thought was a good idea," Dr. Waters noted.

The committee came up with 19 possible measures, ranging from administrative to clinical, and posted them on the Internet for public comment. That comment period is over now, and the committee is about to winnow the measures down to a more practical number.

Funding could throw a wrench in the process, though, said Linda Hanold, the Joint Commission's director of quality measurement. Bayer Healthcare Pharmaceuticals funded the initial phase of the project with an unrestricted educational grant. But the money has run out, and Ms. Hanold isn't sure where the next grant might come from.

"Developing these measures usually takes about 27 months and costs around $600,000," she said.

If funding is secured, the measures will go through a testing process before publication in 2010. If not, the Joint Commission will publish the prospective performance measures and supporting evidence as a monograph, probably sometime in 2009. Either way, the measures will reside in the Joint Commission's Measure Reserve Library, ready for implementation if a national mandate is handed down.

Until then, organizations can still make free use of the performance measures, Ms. Hanold said. "They can be used at the organizational level, adapted by individual organizations, or promoted for use by professional societies."

But implementation of any performance measures will remain primarily local until and unless legislative action makes measurement of blood management a nationally supported priority.

"These measures won't be used for accreditation until they are endorsed at the national level," Ms. Hanold said. "I can't predict when that will be, but it is an issue receiving growing attention." ■

Dr. Philip Marcus, MPH, comments:
Things we have taken for granted now deserve a second look. We previously used transfusions without thinking twice: A low hematocrit meant a transfusion was going to be ordered. We have learned a lot since those days, and now—with a looming blood shortage and the economics of blood donation, storage, and transfusion—we have re-evaluated how we use this precious commodity. Old blood has already been shown to result in poorer outcomes for those receiving it.

Panels Debate LABAs for Asthma

Monotherapy • *from page 1*

should remain on the market and, if so, how their risks should be managed.

GlaxoSmithKline markets Serevent and Advair, Novartis markets Foradil, and AstraZeneca Pharmaceuticals markets Symbicort. The companies presented their own data analyses at the meeting.

Support for the use of Advair in children aged 4-11 years was mixed: The panels voted 13-11, with 3 abstentions, that Advair's benefits outweighed its risks for the maintenance treatment of asthma. Advair, marketed by GlaxoSmithKline, is approved for children ages 4 years and older. Symbicort is approved for children as young as age 12 years, so the panels did not vote on the younger age group for that product.

The panelists' primary concern was that a LABA not be used as monotherapy for maintenance treatment in patients with asthma. They also recommended that when a LABA is used, it always be combined with an ICS, reflecting current asthma treatment guidelines.

Some panelists noted that the labeling for the single-ingredient products was not strong enough regarding the importance of combining them with an ICS for asthma. The panelists also agreed that more safety data were needed for children using Advair and Symbicort.

LABAs "are too dangerous to use without an ICS for asthma in any age group," said Sean Hennessy, Pharm.D., of the University of Pennsylvania, Philadelphia, and a member of the drug safety committee.

The FDA and the manufacturers agreed that a LABA should never be used without an ICS for treating asthma, although evidence that ICS use with a LABA "nullifies LABA-related risks is lacking," Dr. Andrew Mosholder, a medical officer in the FDA's Office of Surveillance and Epidemiology (OSE), said at the meeting. There was no disagreement that the risk associated with LABAs is real. However, ICS use in studies was usually only documented at baseline, not throughout the studies, Dr. Mosholder noted.

Within the FDA, however, there were mixed opinions about how to deal with the risk. The OSE recommended that the asthma indication for all LABAs be withdrawn for people younger than 18 years, and that the asthma indication for single-ingredient LABAs be removed for all age groups. The Division of Pulmonary and Allergy Drug Products, however, recommended that the LABAs remain on the market for asthma, with stronger labeling that addressed their safety risks.

"There's no doubt" that LABAs have improved the lives of children with asthma, and it would be "irresponsible" to withdraw them from the market, said panelist Dr. Fernando Martinez, director of the Arizona Respiratory Center at the University of Arizona, Tucson. He said he has not prescribed monotherapy with a LABA alone for at least 5 years.

"I don't consider the benefits trivial at all," said Dr. Jesse Joad, another pediatric pulmonologist on the panel, who described the advent of the drugs as a "revolution" in treating pediatric asthma. However, the single-ingredient products should not be used for asthma, said Dr. Joad, professor and vice chair of pediatrics at the University of California, Davis. The availability of Advair in three ICS strengths provides dosing flexibility, she noted.

The meeting was held nearly 6 years after the Salmeterol Multicenter Asthma Research Trial (SMART), a large, randomized, double-blind study comparing salmeterol inhalation aerosol with placebo in about 26,000 people with asthma who were at least age 12 years (about 12% were 12-18 years old). SMART stopped early, in January 2003, because of recruitment problems.

The study results showed a small but significant increase in asthma-related deaths after 28 weeks among patients using salmeterol, compared with patients on placebo (13 deaths vs. 3 deaths, a relative risk of 4.4); the risk appeared to be higher among black patients. A paradoxical finding was that although some severe events increased with treatment, immediate symptoms improved with treatment.

At the December meeting, the FDA presented a new meta-analysis of previously available data obtained from the manufacturers. The data were drawn from 110 trials of Advair, Serevent, Foradil, and Symbicort in about 61,000 people aged 4-100 years (median age 37 years). The median treatment time was about 6 months. About half of patients reported using an ICS at baseline.

LABA treatment was associated with an increased risk of asthma-related events, compared with treatment that did not include a LABA (such as an ICS, short-acting β-agonist, or other non-LABA treatment), as measured by a composite end point of asthma-related deaths, asthma-related intubations, and asthma-related hospitalizations. There were 20 asthma-related deaths: 16 in the LABA group (all in Serevent-treated patients) and 4 in the non-LABA group.

The increased risk associated with LABAs, as measured by the composite end point, was not seen with Advair, according to the FDA. Children ages 4-11 years appeared to be at the greatest risk, compared with other age groups. In addition, black patients were at a greater risk than other races, and women were at a greater risk than men.

The three FDA advisory committees' exact vote tallies were as follows: For Advair, the panels voted 27-0 in favor of the benefit-risk profile for adults 18 years and older, and 23-3 with 1 abstention for adolescents 12-17 years. For Symbicort, for which there are far fewer data than for Advair, the panel voted 26-0 with 1 abstention in favor of the benefit-risk profile in adults 18 years and older, and 20-5 with 2 abstentions for adolescents 12-17 years.

By a vote of 17-10, the panelists agreed that the benefits of Serevent did not outweigh its risks for maintenance treatment of asthma in adults. They reached the same conclusion regarding its use in adolescents (21-6 vote) and in children ages 4-11 years (unanimous vote).

For Foradil, the panels agreed that the benefits did not outweigh its risks in adults by a vote of 18-9, and in adolescents by a vote of 21-6. The panels also unanimously agreed that the benefits of Foradil did not outweigh its risks in younger children. ■

FDA Committees' Ruling on Safety of LABAs: What It Means for Clinicians

BY DR. JAY PETERS, FCCP

Chair, ACCP Airways Disorders NetWork

The Dec. 11, 2008, joint ruling by three of the U.S. Food and Drug Administration's advisory committees should make clinicians stop and consider the risks and benefits of long-acting β-agonist use in patients with asthma.

Fortunately, the joint panel voted unanimously that both salmeterol and formoterol (which are approved for maintenance therapy and prevention of bronchospasms in adults, adolescents, and children) should not be taken off the market. Combined with inhaled corticosteroids (ICS), they have dramatically improved the quality of life for our patients, compared with the era in which theophylline was second-line therapy for moderately severe asthma.

The concern stems from the fact that these agents (LABAs) have clearly been shown to increase the risk of severe asthma exacerbations when taken as monotherapy.[1] The FDA's Office of Surveillance and Epidemiology recommended that the indication for LABAs be withdrawn for asthmatics younger than 18 years of age, based on the potential risks and the limited comparative data in children and young adults.

Answers to the questions related to the comparative effect of increasing ICS to medium dose or adding a LABA or leukotriene blocker to low dose ICS await the completion of the National Institutes of Health's Childhood Asthma Research and Education (CARE) Network study that should be presented in early 2010.

In adult patients, there is little doubt that the combined use of ICS and LABAs has resulted in significant improvement in the quality of life and an overall reduction in asthma exacerbations. The question remains as to what the risks of LABAs are, and whether they are completely ameliorated by the combined use of ICS.

The main concern regarding the risk of LABAs comes from the 2006 SMART study, in which there were 3 deaths out of 13,000 patients in the placebo group and 13 deaths out of 13,000 patients in the active treatment arm.[2] This study also raised concerns that the increased risk of mortality was higher in African Americans. However, only half of patients in the SMART study were using ICS, and documentation of ICS use was not obtained throughout the trial.

The recent FDA analysis of 110 trials of Advair, Serevent, Foradil, and Symbicort should be both a comfort and a warning to physicians. It supports the concept that the combination of ICS/LABA has a very favorable benefit/risk ratio. In this analysis, ICS/LABA (Advair) demonstrated no increased risk of the combined end points (asthma-related deaths, intubations, or hospitalizations), and, importantly, all the LABA deaths were in patients treated with LABA alone.

It should also serve as a warning that when LABAs and ICS are written as separate prescriptions (which often occurs for reasons of cost/insurance plans), poorly compliant patients who fill only one medication and rely on their long-acting bronchodilator place themselves at increased risk for severe exacerbation or death.

Overall, I think clinicians should rely on the National Asthma Education and Prevention Program's Expert Panel guidelines that considered these issues in depth when they wrote the 2007 EPR-3: Guidelines for the Diagnosis and Management of Asthma.[3] The combination of ICS/LABA should not be used in patients with mild asthma, and step-down therapy should be considered in every asthmatic patient who has been stable for 3-6 months. Physicians should reserve the use of ICS/LABA as preferred therapy for persistent asthma only when indicated (step 3 therapy in children 5-11 years of age, and in children 12 years of age or older/adults; step 4 therapy in children 0-4 years of age).

There is no doubt that LABAs should not be used as monotherapy for asthma management in either children or adults and that physicians should assess the benefits and risks in patients at high risk for severe exacerbation and in poorly compliant patients.

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PRACTICE MANAGEMENT

New Medicare Fee Schedule Payments Compared With 2008

The Centers for Medicare & Medicaid Services (CMS) reported the 2009 Medicare conversion factor of $36.0666 as a 1.1% increase over 2008. This conversion factor is actually $2.02 lower than the 2008 Medicare conversion factor of $38.09.

However, Dr. Scott Manaker, FCCP, the ACCP advisor to the AMA Relative Value Scale (RVS) Update Committee (RUC) says, "While the conversion factor is lower, there is actually an increase in overall payment for physician services."

The overall impact for this year for pulmonary medicine is reported by CMS as a positive 3%. Last year, there was a reduction in physician work relative values as a result of budget neutrality, which was meant to offset increases to the evaluation and management codes, including critical care services, determined through the RUC's third Five-Year Review.

Organized medicine questioned CMS about this and, in 2009, it has been corrected. "This results in a lowering of the conversion factor but an increase in value for most of the work we do, resulting in higher payments for evaluation and management services; however, there is a lower value for technical and procedural services," said Dr. Michael Nelson, FCCP, Chair, ACCP's Practice Management Committee.

The accompanying table of selective pulmonary services and procedures provides some examples of the changes and represents nationalized payment rates. A physician's individual rate is affected by a geographic practice cost index factor based on where your practice is located.

The final rule can be reviewed at www.access.gpo.gov/su_docs/fedreg/a081119c.html. Visit the expanded and continually updated ACCP Practice Management Web page at www.chestnet.org/practice/pm/index.php. ■

Medicare Physician Fee Schedule Nationalized Payments

(Subject to Geographic Adjustments)

CPT	Descriptor	2009 Nonfacility (office)	2008 Nonfacility (office)	Percent change	2009 Facility (hospital, OPD)	2008 Facility (hospital, OPD)	Percent change
31620	EBUS	$263.29	$273.08	–3.7%	$68.89	$67.79	+1.6%
31622	Dx bronch/wash	296.11	307.74	–3.9%	141.38	137.49	+2.8%
31623	Dx bronch/brush	323.52	337.83	–4.4%	142.46	138.64	+2.7%
31624	Dx bronch/lavage	300.80	313.46	–4.2%	142.82	138.64	+3.0%
31625	Bronch w/biopsies	324.60	334.78	–3.1%	166.63	161.87	+3.0%
94010	Breathing capacity test	32.82	33.90	–3.3%	NA	NA	
-26	Professional component	8.30	8.00	+3.7%	8.30	8.00	+3.7%
-TC	Technical component	24.53	25.90	–5.6%	NA	NA	
94060	Evaluation of wheezing	57.71	58.27	–1.0%	NA	NA	
-26	Professional component	14.43	13.71	+5.0%	14.43	13.71	+5.0%
-TC	Technical component	43.28	44.56	–2.9%	NA	NA	
95012	Exhaled NO	19.48	19.04	+2.3%	NA	NA	
95811	Polysomnography/CPAP	845.40	891.24	–5.4%	NA	NA	
-26	Professional component	181.78	176.34	+3.0%	181.78	176.34	+3.0%
-TC	Technical component	663.63	714.89	–7.7%	NA	NA	
99213	Office/outpatient established	61.31	59.80	+2.5%	44.72	41.90	+6.4%
99214	Office/outpatient established	92.33	89.89	+2.7%	69.25	65.51	+5.5%
99215	Office/outpatient established	124.79	121.50	+2.7%	98.46	94.07	+4.5%
99233	Subsequent hospital care	NA	NA		95.58	90.65	+5.2%
99244	Office consultation	184.30	179.01	+2.9%	154.00	145.49	+5.5%
99254	Inpatient consultation	NA	NA		165.55	156.54	+5.5%
99291	Critical care, 1st hour	253.91	250.99	+1.2%	212.07	204.15	+3.8%
99292	Critical care, additional 30 min	114.69	111.98	+2.4%	106.04	102.45	+3.4%

Meet New Ambassadors Group Chair

Born and raised in Richmond, Virginia, Susan Mathers is delighted to serve as the Ambassadors Group Chair for 2008-2009. Susan is the wife of Dr. James A. L. Mathers, Jr., FCCP, the ACCP President for 2008-2009.

She has two older brothers, a younger sister, and a father who is doing great at 85. She quit work to help her dad take care of her mother who had Alzheimer disease for 14 years and says it taught her a lot about life and what is really important. Susan has one son, Matthew, 28, who recently got engaged.

MS. MATHERS

Susan went to Stratford College in Danville, VA, and majored in art history (and having fun!). She loves to walk outside 4 miles a day (weather permitting) and, in addition, enjoys decorating, hunting for unusual bargains, and kayaking. Her greatest joy is doing things for and with her husband, Jim, their families, and friends.

As Ambassadors Group Chair, she would like to continue the presentations at the CHEST meetings from international members of the Ambassadors Group. The presentations on India at CHEST 2008 by Anita and Pratima Mathur and Sabiha Raoof were excellent and enjoyed by all. She noted that being an Ambassadors Group member has afforded her the opportunity to make many new friends from all over the United States and the world. She would like to present the Lung Lessons[SM] program, developed by The CHEST Foundation, in schools, similar to what Susan Kvale does when accompanying her husband on ACCP trips. She invites other members to help present these lessons, as well.

As Chair, she welcomes new ideas or worthwhile projects that will help further the work of The CHEST Foundation. One area she would like to focus on is the damage secondhand smoke causes to children and, in particular, those with asthma. "We need to educate parents and other family members who smoke that secondhand smoke affects the lungs of their children and exacerbates asthma," she said. "The result is not only frequent physician and emergency room visits but possible long-term lung damage." ■

SLEEP STRATEGIES

Home Sleep Apnea Testing Final Regulations Debut

The Grateful Dead once sang the song "Truckin" with the famous lyrics, "what a long, strange trip it's been." Physicians who practice sleep medicine have certainly observed a long, strange trip over recent years. Indeed, few would disagree that it has been a long, strange road to the present state of affairs, whereby the Centers for Medicare and Medicaid Services (CMS) approved reimbursement for home sleep apnea testing (HSAT), also referred to as portable monitoring (PM), for the diagnosis of obstructive sleep apnea (OSA) and continuous positive airway pressure (CPAP) treatment.

In the early 1990s, there was limited scientific information that existed regarding efficacy, accuracy, validity, utility, cost effectiveness, and limitations of portable equipment, but there was enough information to warrant a practice parameter paper to review the current knowledge base, at the time, regarding PM in the assessment of OSA (Standards of Practice Committee. *Chest* 1994; 17:372). The use of PM was not supported in that document.

In the subsequent decade, many additional studies emerged on the utility of HSAT in diagnosing OSA. By the early 2000s, this topic had become very controversial, with strongly held opinions by the proponents of HSAT and its opponents. In 2003, a systematic review sponsored by the ACCP, the American Academy of Sleep Medicine, and the American Thoracic Society, found that the evidence in the literature at that time did not support the use of PM in the unattended setting for the diagnosis of OSA (Flemons et al. *Chest* 2003; 124:1543; Chesson et al. *Chest* 2003; 26:907). Also raised were several secondary questions regarding PM, including the reproducibility of PM, the failure rate and need for retesting, the cost-benefit analysis, and the appropriate type of patient best suited for PM.

Sleep Institute®
American College of Chest Physicians

In 2004, as a result of that review, CMS determined that only polysomnography done in a facility-based sleep laboratory be used to identify patients with OSA. CMS then received a request to modify this decision to include the use of portable multichannel HSAT devices as an alternative to facility-based polysomnography in the evaluation of OSA. Despite this, CMS reported their final decision in April 2005. CMS found that the evidence at that time was not adequate to support and, hence, reimburse for, the use of unattended portable multichannel sleep testing adequate for the diagnosis of OSA and the prescription of CPAP.

Just a few years later, in March 2007, at the request of the American Academy of Otolaryngology-Head and Neck Surgery, CMS agreed to open up the issue and review it again. Some observers noted that the rapid rise in Medicare reimbursements for sleep studies—$62 million in 2001 to $215 million in 2005—was a concern. It also was recognized that several large organizations, such as Kaiser Permanente and some Veterans Administration hospitals, reported using PM successfully in the diagnosis of OSA and treatment with CPAP. A long review process followed, involving expert review of the medical literature and written public opinion. The ACCP provided written comments based on feedback from members of the ACCP Sleep Institute and Sleep Medicine NetWork. Additionally, an open public hearing was held by an expert panel at CMS headquarters in Baltimore, MD, on September 12, 2007.

On March 13, 2008, a decision memo was issued by CMS (CAG-00093R2) that, for the first time, allowed CPAP coverage based on the results of an HSAT. After receiving commentary from the ACCP and many other national organizations, the final national coverage determination (NCD) memo was posted in October and contained several specific provisions for reimbursement that will change the practice of sleep medicine (www.cms.hhs.gov/transmittals/downloads/R96NCD.pdf).

The NCD placed an emphasis on providing quality service to the patient before and after the sleep study in the treatment of OSA and not just on interpretation of the sleep study. This NCD dictated several new stipulations that determined the rules for CPAP reimbursement from the four durable medical equipment Medicare administrative carriers (DME MACs). The good news is that the regulations from all four are exactly the same.

There are some key features of which physicians who care for patients with

Continued on following page

Continued from previous page

OSA should be aware. Initially, the patient must have a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for OSA. This evaluation needs to include the following elements:

History

- Signs and symptoms of sleep-disordered breathing, including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, and morning headaches
- Duration of symptoms
- Validated sleep hygiene inventory, such as the Epworth sleepiness scale

Physical Exam

- Focused cardiopulmonary and upper airway system evaluation
- Neck circumference
- Body mass index (BMI)

The initial CPAP coverage for adults could occur if OSA was diagnosed using a clinical evaluation and a positive polysomnogram was performed either in a sleep laboratory or by unattended home sleep monitoring using a type 2, 3, or 4 device (measuring at least three channels that must include respiratory effort and nasal pressure or airflow). The threshold apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) must be ≥15 events per hour of sleep (AHI) or continuous monitoring (RDI) or ≥5 events, with documented symptoms of excessive daytime sleepiness; impaired cognition, mood disorders or insomnia; or documented hypertension, ischemic heart disease, or history of stroke. This initial coverage for CPAP is initially limited to a 12-week period.

Extending the CPAP prescription beyond 12 weeks is now dependent on a mandatory face-to-face reevaluation of the patient that must occur between 31 and 90 days. CPAP will be subsequently covered only for those beneficiaries who fulfill the following two requirements: (1) the OSA must have improved as a result of CPAP treatment, which can be documented simply by a physician interview, and (2) objective evidence of adherence to use of the CPAP device must be reviewed by the treating physician and available upon request. Adherence to therapy is defined as use of CPAP 4 h per night or more on 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial usage. The responsibility for the objective compliance data is placed upon the DME vendor filing the claim with the regional DME MAC. This has already resulted in DME vendors making arrangements for the download of the data with the patient directly or working out an arrangement with nearby prescribing physicians.

This becomes complicated for patients who have not adhered to treatment. Beneficiaries who fail the initial 12-week trial are eligible to requalify for CPAP devices. However, they must undergo both a new face-to-face clinical reevaluation by the treating physician, to determine the etiology of the failure to respond to CPAP therapy, and a repeat sleep test in a facility-based setting (type 1 study). If the physician decides to switch to a bilevel device, only a new prescription is needed. The prescription can be mailed to the patient; however, the patient will have to demonstrate the treatment adherence behavior necessary to complete the compliance statement for a respiratory assist device.

This, however, is only half of the story. There is another aspect necessary for understanding reimbursement when an HSAT device is involved in diagnosing OSA. So far, the discussion has concerned what is required for a patient to receive reimbursement for a CPAP prescription. The DME MACs control reimbursement for CPAP but have nothing to do with payment for the HSAT. Payment to the physician and facility for performing and interpreting an HSAT is governed by a different set of rules. Payment for the HSAT is governed by whichever regional carrier is responsible for the patient being treated, and the rules are covered by 1 of 14 local coverage determinations (LCDs). These rules vary significantly among the various local carriers and are not tied to all the specifics of the NCD. For example, CIGNA is one carrier that has decided some issues on its own (www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0158_coveragepositioncriteria_obstructive_sleep_apnea_diag_trtment_svc.pdf).

CIGNA refused to cover type 4 devices, including WatchPAT (Itamar Medical; Framingham, MA), which was allowed by the NCD for CPAP coverage. This carrier also determined that split-night studies will be covered only if the AHI is >20 during the diagnostic portion of the test. This can be determined in as little as 2 h of recording time; recall that the old "2-h rule" (2 h of actual sleep required to determine an AHI) is now dismissed by virtually all carriers. Some clinicians initiate CPAP at an AHI as low as 5 because some carriers will not cover a second sleep study for titration.

The bottom line is that the DME MAC NCD can be fulfilled with one set of rules to provide coverage for the CPAP prescription, but there may be a different set of rules governing reimbursement for the actual sleep studies performed. Each physician should consult the Web site of the Medicare carrier for their region to be aware of specific rules.

Some final interesting issues are apparent that the ACCP and other societies may need to address. These rulings may not lead to fewer facility-based studies. The standard of care still dictates the performance of some type of titration study, which, if conducted in the sleep lab, is actually more costly after a home sleep test (HST) than a split-night study alone. Note that comments about auto-PAP titration are conspicuously absent from the NCD and DME LCD. It would be difficult to cover, given that there is no unique auto-PAP code.

Even though the burden of documentation will be on the DME vendor, it will inevitably fall back to the physicians who interpret and order the studies. One also wonders if there might be a minimum quota for HST, but the pressure to perform more HSTs may actually come from private payers. This may result in many labs being forced to offer HST at a loss, as CMS proposes reimbursement to be near $200.

There is no national standardization for the LCDs, and this will result in a complex playing field and possible frequent denials of coverage. Lastly, the Office of Inspector General at the US Department of Health and Human Services has announced that it will launch a campaign to audit sleep centers throughout the country to confirm that charges are legitimate. It is certain that some ACCP members will have their billing/medical records reviewed by the Office of Inspector General investigators.

For ACCP members, the good news is that the ACCP, through the ACCP Sleep Institute, the Sleep Medicine NetWork, the Practice Management Committee, the Government Relations Committee, and the ACCP staff supporting each of these committees, is actively involved in monitoring all these developments on behalf of its members. The ACCP has the ability to respond rapidly to any changes affecting the quality of care we provide our patients. ■

Dr. Peter C. Gay, FCCP
Mayo Clinic
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Career Initiative Unveiled at CHEST 2008

In a new education initiative aimed at promoting careers in pulmonary, critical care, and/or sleep medicine, the American College of Chest Physicians invited medical students and residents in the northeast region of the county to attend CHEST 2008 in Philadelphia.

The ACCP's primary goal was to provide students and residents an opportunity to attend the ACCP annual meeting and hear from leading experts in these fields. Students and residents enjoyed complimentary registration and were able to participate in a rich educational day of programming, consisting of an overview and orientation to pulmonary, critical care, and sleep medicine career opportunities; scientific abstract presentation sessions; complimentary lunch in the exhibit hall; poster grand rounds; and hands-on clinical education in the Simulation Center. Students were also invited to attend the CHEST Challenge Championship and Awards Reception as an educational and networking opportunity.

Based on the success of this year's program, medical students and residents on the West coast will be invited to attend a similar program at CHEST 2009 in San Diego, CA. ■

Please see Brief Summary of complete Prescribing Information, including Boxed Warning, on following page.

BROVANA is indicated for the long-term, twice-daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. BROVANA is for use by nebulization only.

Important Safety Information

Long-acting beta$_2$-adrenergic agonists may increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta$_2$-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol may apply to arformoterol (a long-acting beta$_2$-adrenergic agonist), the active ingredient in BROVANA.

BROVANA is not indicated for the treatment of acute episodes of bronchospasm, ie, rescue therapy, and does not replace fast-acting rescue inhalers.

BROVANA should not be initiated in patients with acutely deteriorating COPD, which may be a life-threatening condition.

BROVANA should not be used in conjunction with other inhaled, long-acting beta$_2$-agonists. BROVANA should not be used with other medications containing long-acting beta$_2$-agonists. Patients who have been taking inhaled short-acting beta$_2$-agonists on a regular basis should be instructed to discontinue their regular use and to use them only for symptomatic relief for acute respiratory symptoms.

As with other inhaled beta$_2$-agonists, BROVANA can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, BROVANA should be discontinued immediately and alternative therapy instituted.

BROVANA, like other beta$_2$-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, blood pressure, and/or symptoms.

BROVANA, as with other beta$_2$-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval because the action of adrenergic agonists on the cardiovascular system may be potentiated by these agents.

The most common adverse events reported in patients taking BROVANA, and occurring more frequently than in patients taking placebo, were pain (8% vs 5%), chest pain (7% vs 6%), back pain (6% vs 2%), diarrhea (6% vs 4%), and sinusitis (5% vs 4%).

References: 1. BROVANA (prescribing information). Marlborough, MA: Sepracor Inc; August 2008. **2.** Baumgartner RA, Hanania NA, Calhoun WJ, et al. Nebulized arformoterol in patients with COPD: a 12-week, multicenter, randomized, double-blind, double-dummy, placebo- and active-controlled trial. *Clin Ther.* 2007;29(2):261-278. **3.** Data on file, Sepracor Inc. CSR-091-050, Table 14.2.11.2.

11/08 BRO138-08

BROVANA for patients with COPD requiring maintenance therapy

Bob's back…

Breathing

Not an actual patient.

*BROVANA has not been demonstrated to have an impact on progression of disease or survival of patients with COPD.

†Clinical trial A was one of two identical 12-week, double-blind, placebo- and active-controlled, randomized, multicenter, parallel-group studies that included a comparison of BROVANA 15 mcg twice daily with placebo.

The results from clinical trial B were similar to clinical trial A.

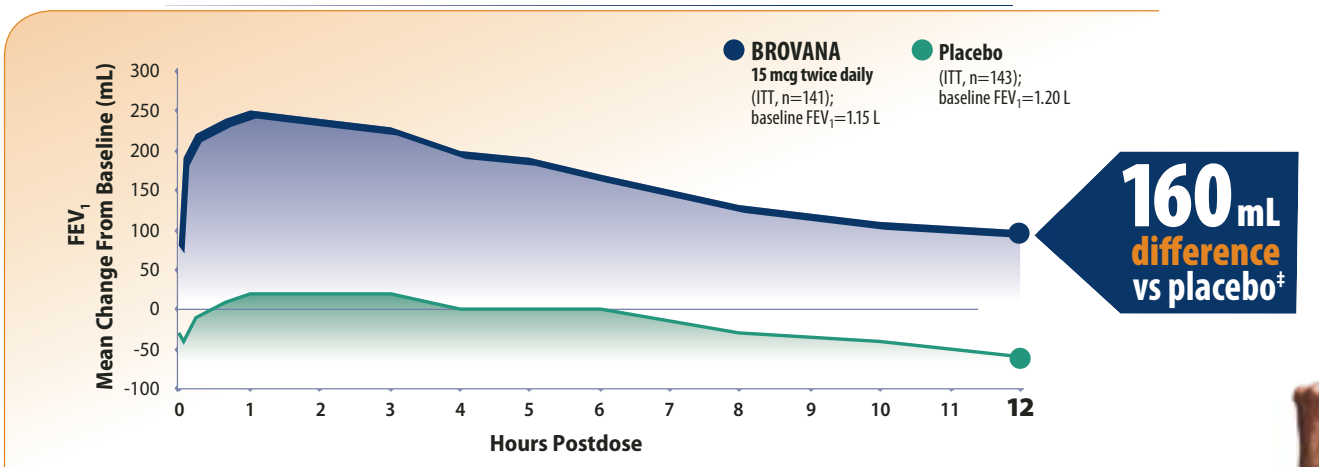
better, living better*

with **BROVANA** just twice a day

Sustained relief and twice-daily dosing help COPD patients get back to daily living

Sustained effective relief for a **full 12 hours**[1]

Mean change in FEV_1 over time at 12 weeks: clinical trial A[†2,3]



‡100-mL increase from study baseline in mean FEV_1 at 12 hours (Week 12), while the placebo group had a 60-mL decrease.[3] Overall efficacy was maintained throughout the 12-week trial. Some tolerance to the bronchodilator effect of BROVANA was observed after 6 weeks of dosing (at the end of the dosing interval), although the FEV_1 improvement remained statistically significant. This was not accompanied by other clinical manifestations of tolerance.[2]

Relief that works within minutes

6.7-minute median time to onset (15% increase in FEV_1)[1]

- BROVANA is not indicated for the treatment of acute episodes of bronchospasm. Patients on BROVANA should always have access to rescue therapy

Well tolerated

- Patients receiving BROVANA 15 mcg twice daily experienced an incidence of adverse events (AEs) comparable with placebo[1]
- Most common AEs were pain, chest pain, back pain, diarrhea, and sinusitis

Nebulized bronchodilator therapy

for patients with COPD

Have your patients experience BROVANA

For samples, ask your Sepracor representative

Brovana® 15 mcg
(arformoterol tartrate) Inhalation Solution

Get them back into daily living

NETWORKS

JUPITER, Allergen Immunotherapy, Critical Care Education

Cardiovascular Medicine and Surgery

The JUPITER trial (Justification for the Use of Statins in Prevention: An Interventional Trial Evaluating Rosuvastatin), a heavily publicized trial, screened 89,890 subjects for cardiovascular risk factors, and enrolled 17,802 subjects with the following entry criteria constellation: men 50 or women 60 years of age or older, without history of CAD, LDL-cholesterol level of < 130 mg/dL, and high-sensitivity C-reactive protein (CRP) level of ≥ 2.0 mg/L or more.

Subjects received either 20 mg of rosuvastatin or placebo. Primary endpoint was the composite of MI, stroke, arterial revascularization, hospitalization for unstable angina, or death from cardiovascular causes. The trial was designed for a follow-up of 4 years but was prematurely stopped after 1.9 years, due to a significant reduction in the primary endpoint in the treatment group (142 vs 251 events in the placebo group). The authors argue rosuvastatin should be considered even in healthy, normolipidemic individuals with elevated high sensitivity CRP.

There may be several concerns to consider: (1) The absolute (not relative) risk reduction was 1.8 to 0.9%, thus 120 participants needed to be treated for 1.9 years to prevent an event. This would amount to roughly $500,000 per life saved. (2) The study was already targeting people with elevated BMI and an increased incidence of metabolic syndrome. Abdominal obesity and insulin resistance were probably prevalent in this study group; they alone could account for the therapy success. The higher levels of glycosylated hemoglobin and incidence of diabetes in the rosuvastatin group are disconcerting; longer follow-up may have been helpful.

JUPITER raises interesting questions about the role of biomarkers in cardiac prevention, and how aggressive we should become in the CV preventive arena. It remains to be seen if we should alter our current practice.

Dr. Thomas Behrenbeck, FCCP
NetWork Chair

Further Reading

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Tracy. *Arterioscler Thromb Vasc Biol* 2001; 21:881-883

Clinical Pulmonary Medicine

Allergen-specific immunotherapy, which involves repeated administration of an allergen to IgE-sensitized allergic individuals to induce clinical and immunologic tolerance (Alvarez-Cuesta, et al. *Allergy* 2006; 61:1) is regarded as controversial due to risk of severe anaphylaxis (Lockey et al. *J Allergy Clin Immunol* 1987; 76:660; Bousquet et al. *J Allergy Clin Immunol* 1989; 83:797).

Although allergen avoidance and pharmacotherapy form the basis of asthma treatment, immunotherapy is effective in reducing symptoms induced by dust mite, animal dander, cockroach, pollen, and mold (Bousquet et al. *Allergy* 1998; 53:1). Recent Cochrane analysis (Abramson et al. The Cochrane Database of Systematic Reviews 2008, Issue 4. Art No. CD001186. DOI: 10.1002/14651858.CD001186) of 3,506 participants (3,188 asthmatics) demonstrated significant reduction in asthma symptoms and medications, and improvement in bronchial hyperreactivity (BHR) following immunotherapy.

NHLBI recommends immunotherapy for patients with allergic asthma who need low to medium dose inhaled corticosteroids (NIH Publication no. 08-4051, available from www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm). Notably, patients with exacerbations requiring hospitalizations or intubations (Amin et al. *J Allergy Clin Immunol* 2006; 117:169), FEV_1 <70% predicted (Rank and Li. *Mayo Clin Proc* 2007; 82:1119), or unstable asthma receiving long-term oral

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glucocorticoids (Reid et al. *J Allergy Clin Immunol* 1993; 92:6) are not suitable for immunotherapy, as they are at risk for severe bronchospasm. Evaluation of sensitization is a prerequisite.

While subcutaneous immunotherapy is the established treatment, sublingual immunotherapy is a viable alternative, since no serious reactions have been reported, and self-administration obviates frequent physician visits for injections (Mungan et al. *Ann Allergy Asthma Immunol* 1999; 82:485).

Bronchial Thermoplasty

Increased airway smooth-muscle mass is observed in patients with severe or fatal asthma (Carroll et al. *Am Rev Respir Dis* 1993; 147:405). Bronchial thermoplasty (BT) delivers radiofrequency energy to the bronchial wall through a catheter with expandable four-arm-basket via bronchoscopy. While airway cells are susceptible to heat injury, complete anatomic reconstitution occurs except for smooth muscle (Cox et al. *Eur Respir J* 2004; 24:659).

In the Asthma the Intervention Trial (Cox et al. *N Engl J Med* 2007; 356:1327), where 110 moderate to severe-persistent asthmatics were randomized to standard medical care with and without BT, those who received BT had fewer exacerbations; improved peak flow rates; more symptom-free-days; and better symptom scores, quality of life, and asthma control questionnaire responses. As the study was not blinded, improved subjective outcomes with BT that did not correspond to objective measurements (FEV_1, BHR) are a concern, and results comparing BT with sham bronchoscopy are eagerly awaited.

Asthma treatment is evolving beyond steroids and bronchodilation and into disease-modifying interventions with immunotherapy and BT.

Dr. Pyng Lee, FCCP
NetWork Steering Committee Member

Critical Care

CHEST 2008 provided an excellent opportunity for the Critical Care NetWork to reflect on a very successful year. The NetWork meeting was highlighted by a presentation by Dr. Kay Guntupalli, FCCP, ACCP President-Elect and recipient of the 2007-2008 Distinguished Scholar Award, for her project, "Development and Validation of the Educational Materials for Use by the Critical Care Health-care Team and Patient/Family for Use in the Critical Care Units."

The NetWork also sponsored a wide variety of outstanding educational offerings.

The ACCP is sponsoring several critical care courses at its Simulation Center for Advanced Clinical Education in Northbrook, IL, in early 2009. For more information or to register, visit www.chestnet.org/simulation/programs.php.

We would like to invite interested members to join one of the six subcommittees that are responsible for the majority of our NetWork activities. Please visit www.chestnet.org/networks/critical_care/index.php for more information.

We are working very hard to increase your resources on the Critical Care NetWork Web page, and we need your help!

We are looking for individuals who are interested in submitting clinical vignettes, images, and tracings for the NetWork Online Puzzler.

Submissions should be under 800 words and include a summary of relevant clinical information and a brief discussion of one to two key points with up to five references. Contact me at alexander.niven@us.army.mil with submissions or questions.

LTC Alexander Niven, MC, USA, FCCP
NetWork Chair

This Month in *CHEST*: Editor's Picks

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

▶ **Survival for Patients With HIV Admitted to the ICU Continues To Improve in the Current Era of Combination Antiretroviral Therapy.** *By Dr. K. Powell, et al.*

▶ **The Effects of Flexible Bronchoscopy on Mechanical Ventilation in a Pediatric Lung Model.** *By Dr. D. Hsia, et al.*

▶ **A Phase 3, Randomized, Double-Blind, Study To Assess the Efficacy and Safety of Fospropofol Disodium Injection for Moderate Sedation in Patients Under-going Flexible Bronchoscopy.** *By Dr. G. A. Silvestri, FCCP, et al.*

▶ INTERACTIVE PHYSIOLOGY GRAND ROUNDS
Assessment of Pleural Pressure in the Evaluation of Pleural Effusions. *By Dr. D. Feller-Kopman, et al (new series including online animation).*

▶ RECENT ADVANCES IN CHEST MEDICINE
Critical-Illness-Related Corticosteroid Insufficiency. *By Dr. P. E. Marik, FCCP.*

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Treating GERD in Asthma Improved Lung Function

BY SUSAN LONDON

Elsevier Global Medical News

SEATTLE — Treating gastroesophageal reflux disease in children with persistent asthma improved lung function in the long term, new data show. Moreover, medical and surgical treatments appeared to work equally well.

Roughly two-thirds of nonatopic children with persistent asthma also have gastroesophageal reflux disease (GERD), and that disease appears to exacerbate the asthma, Dr. Aaron K. Kobernick said at the annual meeting of the American College of Allergy, Asthma, and Immunology. Studies of GERD treatment in this context have focused on asthma medication use and have been relatively short.

Roughly two-thirds of nonatopic children with persistent asthma also have gastroesophageal reflux disease.

DR. KOBERNICK

"We know that with asthma, short-term studies are just not as reliable," Dr. Kobernick said. "Because asthma is a disease of exacerbation and remission, the longer we look at asthma and outcomes in asthma, the better off we are going to be."

In a prospective 2-year study, Dr. Kobernick and his colleagues enrolled 62 children between the ages of 6 and 11 years who had moderate persistent asthma but did not have atopy or risk factors for wheezing. At baseline, all of the children underwent spirometry and extended esophageal pH monitoring. The latter testing revealed that the majority of the children also had GERD.

Of the children with asthma and GERD, 32 were treated with medical therapy for GERD consisting of proton pump inhibitors and prokinetic agents and 12 underwent surgical fundoplication; they also received asthma therapy. The 18 children who did not have comorbid GERD received asthma therapy only.

The three groups were similar with respect to age, sex, socioeconomic status, duration of illness, and initial spirometry findings, according to Dr. Kobernick, a medicine and pediatrics resident at Tulane University in New Orleans.

After 2 years of treatment, the average annual number of asthma exacerbations per child was significantly lower, by about 75%, among both the children with medically treated GERD (0.68) and the children with surgically treated GERD (0.79), compared with their GERD-free counterparts treated for asthma alone (2.9), Dr. Kobernick reported. The difference between the medically and surgically treated GERD groups was not significant.

The percentage of children who had an improvement in forced expiratory volume in 1 second (FEV_1) by more than 20% from baseline was significantly greater in the groups given medical GERD treatment (47%) and surgical GERD treatment (58%), compared with the group given asthma therapy alone (28%).

Similarly, the percentage of children having an improvement in forced expiratory flow in mid-expiration ($FEF_{25\%-75\%}$) by more than 20% from baseline was significantly greater with added medical GERD treatment (22%) and surgical GERD treatment (25%), compared with asthma therapy alone (11%).

Dr. Kobernick concluded that the results may underestimate the benefit of anti-GERD treatment, because many children had been previously treated for asthma.

Dr. Kobernick reported that he had no conflicts of interest in association with the study. ■

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