

CHEST *Physician*

THE OFFICIAL NEWS PUBLICATION OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS



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The new CPR guidelines emphasize continuous chest compression with minimal interruptions for ventilation and rhythm checks.

Chest Compressions Are Central in CPR Update

BY KATE JOHNSON
Elsevier Global Medical News

Improving the quality of cardiopulmonary resuscitation skills among both the lay public and health care professionals is the central theme of the American Heart Association's new guidelines—and optimizing chest compression is the means to that end.

"Push hard, push fast, allow full chest recoil after each compression, and minimize interruptions to chest compressions," said the authors of the 2005 AHA Guidelines for CPR and ECC (emergency cardiovascular care) published in a supplement to the journal *Circulation* (www.circulationaha.org).

The revised guidelines are

aimed at improving the survival rate for out-of-hospital cardiac arrest, which "remains low worldwide, averaging 6% or less," Mary Fran Hazinski, R.N., of Vanderbilt Children's Hospital, Nashville, Tenn., and her colleagues noted in an accompanying summary of the key changes from the previous guidelines, issued in 2000 (*Circulation* 2005;112:IV206-IV211).

While the research behind the new guidelines included debate about all aspects of detection and treatment of cardiac arrest, "the last summation returned to the beginning question: How do we get more bystanders and health care providers to perform CPR and to perform it well?" they said.

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Move Over, MRSA: Tough *Acinetobacter* Threatens Hospitals

Nosocomial superbug infections climb.

BY KERRI WACHTER
Elsevier Global Medical News

WASHINGTON — The United States may be poised on the brink of the next drug-resistant infection epidemic, with outbreaks of *Acinetobacter baumannii* already appearing in hospitals here, according to experts speaking at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

The spread of the bacteria has already reached epidemic proportions in Israeli and Latin American hospitals, and is a serious problem in Europe as well. In fact, "*Acinetobacter* has been designated as the gram-negative MRSA [methicillin-resistant *Staphylococcus aureus*]," said Dr. Harald Seifert, a professor at the University of Cologne's Institute of Medical Microbiology and Hygiene.

"We're not only dealing with an increasing incidence of multiresistant *Acinetobacter*, but we seem to be dealing with an increasing absolute incidence of

Acinetobacter," said Dr. Anthony D. Harris, an epidemiologist for the University of Maryland Medical System, Baltimore.

Acinetobacter baumannii is a nonmotile, gram-negative bacterium that affects mainly immunocompromised patients, particularly patients in the ICU setting or those who have been hospitalized for long periods, Dr. Seifert said at the meeting sponsored by the American Society for Microbiology. Though the organism can cause a wide range of infections, the most common are respiratory tract, bloodstream, urinary tract, skin and soft tissue, and wound infections.

In particular, it is the most important pathogen causing pneumonia in patients who are on a ventilator, Dr. Harris said.

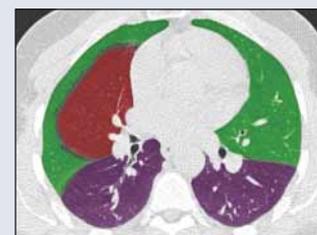
About half of *Acinetobacter* infections are sepsis- or ventilator-associated pneumonias, based on data from several series, said Dr. Yehuda Carmeli, head of the division of epidemiology at

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CMS to Cut Medicare Fees 4.4%

BY JENNIFER LUBELL
Elsevier Global Medical News

Physicians face at least a month's worth of Medicare payment reductions if Congress doesn't reconcile on the provisions of a spending bill by the end of January.

"Physicians once again have been penalized by a Medicare reimbursement formula that might negatively impact our ability to care for our patients," said Dr. W. Michael Alberts, FCCP, President of the American College of Chest Physicians. "The time has come for Congress to seriously consider replacing this formula with one that accurately reflects the costs of medical care."

The 2006 Medicare physician payment cut of 4.4%, which began Jan. 1, is the first of 6 years

of planned cuts totaling 26%. During this same time, practice costs will increase at least 15%, according to statistics from the American Medical Association.

A measure to stop the 4.4% cut went unaddressed when procedural issues in the Senate and House prevented final action on the 2005 budget reconciliation package.

The Senate's version of the bill originally contained a 1%

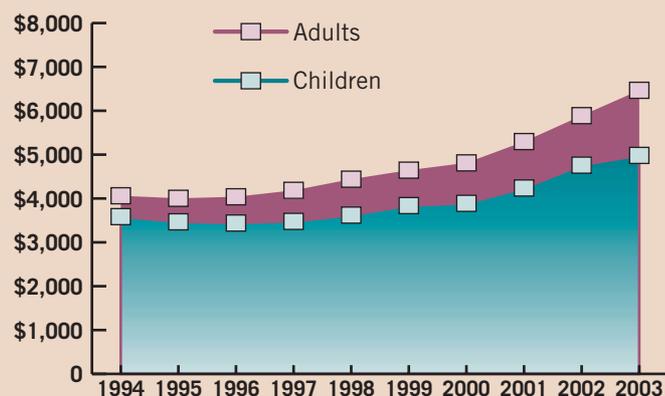
increase, tied to certain pay-for-performance measures opposed by some medical groups. In the end, however, the Senate opted to eliminate the 1% update and institute a freeze measure instead.

Although both houses approved the pay freeze, the Senate accepted a number of procedural moves that altered the

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VITAL SIGNS

Median Hospital Charges for Bronchitis, Asthma



Note: Based on weighted national estimates from the Healthcare Cost and Utilization Project's Nationwide Inpatient Sample.

Source: U.S. Agency for Healthcare Research and Quality

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Resuscitation Guide Revamped

CPR • from page 1

"Our greatest challenge and highest priority is the training of lay rescuers and health care providers in simple, high-quality CPR skills that can be easily taught, remembered, and implemented to save lives," according to Ms. Hazinski and her associates.

Evidence shows that "few victims of cardiac arrest receive CPR, and even fewer receive high-quality CPR," they said.

To address this issue, the authors recommend a simplification of previous instructions on CPR, with a stronger emphasis on continuous chest compression with minimal interruptions for ventilation and rhythm checks.

"The combination of inadequate and interrupted chest compressions and excessive ventilation rates reduces cardiac output and coronary and cerebral blood flow and diminishes the likelihood of a successful resuscitation attempt," the authors said.

Thus, a universal compression-ventilation ratio of 30:2 for all lone rescuers (lay or trained) of victims of any age (excluding newborns) is recommended.

Children can be treated using a 15:2 ratio if there are two rescuers present, since asphyxial arrest is more likely in this population. And a priority for ventilation was reaffirmed in the case of newborn resuscitation.

From an emergency medicine perspective, "this will hopefully mean we get a lot more people with pulses from the pre-hospital setting," Dr. Robert O'Connor, one of the authors of the guidelines, said in an interview.

The revised compression ventilation ratio is not so much a de-emphasis of ventilation, but rather a refinement, Dr. O'Connor explained.

"Over the past 5 years, we have learned that with a 15:2 ratio, patients were being inadvertently hyperventilated, which is harmful. If you give 30:2, it gives the adequate number of ventilations per

minute while maintaining a good consistent period of chest compressions," explained Dr. O'Connor, who is the director of the emergency medicine program at Christiana Care Health System in Newark, Del., and professor of emergency medicine at Jefferson Medical College in Philadelphia.

The main change in the guidelines concerning defibrillation is the recommendation for only one shock rather than three, and the emphasis on immediate postshock chest compressions and CPR, rather than rhythm checks.

"This change is based on the high first-shock success rate of new defibrillators and the knowledge that if the first shock fails, intervening chest compressions may improve oxygen and substrate delivery to the myocardium, making the subsequent shock more likely to result in defibrillation," explained Ms. Hazinski and her associates.

Although lay rescuers are encouraged to use automated external defibrillators as soon as possible, emergency medical service providers "may consider about five cycles (or 2 minutes) of CPR before defibrillation for unwitnessed arrest," they suggested.

The first rhythm check should be done about 2 minutes after defibrillation and every subsequent 2 minutes.

Vasopressors and antiarrhythmics should be administered as soon as possible after a rhythm check.

For acute ischemic stroke, there was reaffirmation of the previous recommendation to using tissue plasminogen activator (TPA) therapy "when administered by physicians in hospitals with stroke protocols that rigorously adhere to the eligibility criteria and therapeutic regimen of the National Institute of Neurological Disorders and Stroke (NINDS) protocol," Ms. Hazinski and her associates said.

Reaction to the guidelines from various medical specialties appears positive—par-

ticularly the stronger emphasis on chest compression.

"We brain specialists like anything that keeps the blood flowing and keeps people pumping on the chest," neurologist William M. Coplin said in an interview. "Once you start the heart, you can keep the brain perfused—and that's what's important," said Dr. Coplin of the department of neurology and neurologic surgery at Wayne State University, Detroit.

"We used to worry so much more about getting the lungs working; but we've certainly known for long enough that you can have lower oxygen in your system and as long as the blood is flowing, the brain will survive," he said.

Cardiologist James J. Ferguson III also agrees with the focus on chest compressions as the cornerstone of effective CPR.

"One can infer that too many interruptions, ineffective circulation, and a lack of prioritization may have contributed to less than optimal outcomes in the past," said Dr. Ferguson of Baylor College of Medicine, Houston, and the Texas Heart Institute of St. Luke's Episcopal Hospital there.

Both Dr. Ferguson and Dr. Coplin agreed that the new guidelines may also be useful in overcoming hesitance from bystanders who are worried about disease-exposure with mouth-to-mouth resuscitation.

"By stressing the importance of chest compressions, this may sidestep some of those issues; but it raises the concern that later on in the resuscitation efforts, when ventilation becomes more important, that it may be ignored to some extent," Dr. Ferguson said in an interview.

However, he said that "the working philosophy of 'keep it simple and maximize your early benefit' would seem to provide the most benefit to the most people. Many more people who are saved are saved early, rather than late."

Dr. Coplin also agreed with the effort to simplify procedures. "This isn't supposed to be rocket science," he said. "The idea is to keep things under control until the rocket scientist is available." ■

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FROM THE EDITOR IN CHIEF

Welcome to CHEST PHYSICIAN

Medical news publications face the complex task of getting important information to readers while, at the same time, being useful and interesting. CHEST PHYSICIAN takes a giant leap to help fulfill that mandate.

Starting with this inaugural issue, the American College of Chest Physicians and the Elsevier Society News Group are joining forces to provide the latest clinical and practice management information available to the chest medicine community.

The new CHEST PHYSICIAN delivers timely news articles in pulmonology, critical care, sleep medicine, cardiology, thoracic surgery, and other chest medi-



DR. SUSAN M. HARDING, FCCP

cine-related specialties, covering areas such as new clinical procedures, the newest drug treatment advances, information to help you in your medical practice, and articles dealing with the critical issues facing the health care system.

Each monthly issue features a special "News From the College" section, which includes Educational Insights, The CHEST Foundation, Inside NetWorks, ACCP Institutes, Member Matters, ACCP Worldwide, This Month in CHEST—Editor's Picks, and much more.

Additionally, Pulmonary Perspectives, under the excellent, ongoing editorship of Deborah Shure, M.D., Master FCCP, is now

incorporated into CHEST PHYSICIAN. Each month brings you an article relating important contemporary issues in pulmonary medicine you have come to expect in that publication. The ACCP Critical Care Institute and Sleep Institute will also present regular articles that focus on timely topics in those areas of chest medicine. Each issue of CHEST PHYSICIAN is also available at www.chestnet.org/about/publications.

CHEST PHYSICIAN will strive to be the one source chest physicians and their teams can rely on to find the information they need. In the process, we hope to better prepare you for the challenges you encounter in your practice every day and assist you in providing the highest quality patient-focused care.

Send us your feedback, your thoughts,

and your opinions. If you like an article, or if you disagree with an opinion voiced by a colleague, send an e-mail to chestphysiciannews@chestnet.org. This is your publication, and for us to be successful, we need your input.

As Editor in Chief, I look forward to hearing from you. I also look forward to being part of the dynamic team producing this publication. Together, we hope to bring you the latest news and most relevant clinical information available today. ■

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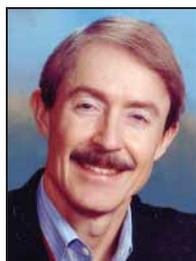
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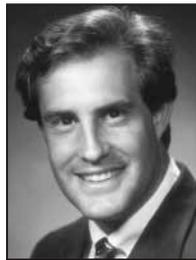
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(not pictured)
Gerard A. Silvestri, M.D., FCCP, is associate professor of medicine at the Medical University of South Carolina in Charleston. Dr. Silvestri is a trustee of The CHEST Foundation and serves on The Foundation Development Committee. He has participated in the ACCP Thoracic Oncology and Interventional Chest/Diagnostic Procedures NetWorks and the Health and Science Policy Committee.

Bacteria Resist Containment

Acinetobacter • from page 1

the Tel Aviv Sourasky Medical Center. Central nervous system infections following neurosurgery are also common.

Acinetobacter outbreaks also have occurred after manmade and natural disasters, including the 1999 earthquake in Turkey, the 2002 terrorist bombing in Bali, and the 2004 tsunami in the Pacific.

The U.S. military has also reported an increasing number of *Acinetobacter* bloodstream infections in soldiers injured in Iraq, Kuwait, and Afghanistan.

Rates Nearly Double

Between 1986 and 2002, the rate of nosocomial pneumonia infections caused by *Acinetobacter* almost doubled in the United States, from 4% to 7%, Dr. Seifert said.

In an analysis of data from the Surveillance and Control of Pathogens of Epidemiologic Importance (SCOPE) program, *Acinetobacter* ranked 10th among causes of 24,179 nosocomial bloodstream infections in U.S. hospitals from 1995 to 2002.

In non-ICU wards, the pathogen accounted for up to 1% of these infections; in ICU wards, *Acinetobacter* accounts for 0.6% of these infections.

"We've had more than 15 hospitals in Maryland in the last 1½-2 years that have reported multiresistant *Acinetobacter*," Dr. Harris said. Outbreaks have also been reported in New York and among soldiers returning from Iraq and Afghanistan.

In Europe, *Acinetobacter* accounts for 2.5% of all bloodstream infections, earning a number 10 ranking there as well, according to the SENTRY Antimicrobial Surveillance Program, which monitors

the predominant pathogens and antimicrobial resistance for both nosocomial and community-acquired infections.

Acinetobacter accounts for an even greater number of respiratory tract infections among hospitalized patients—more than 4% in Europe and 10% in Latin America. In the United States, *Acinetobacter* accounts for 7% of respiratory tract infections in ICUs alone, Dr. Seifert said.

In Israeli hospitals, *Acinetobacter* ranks first or second among causes of bacteremia, Dr. Carmeli said.

Resistance Is Rising

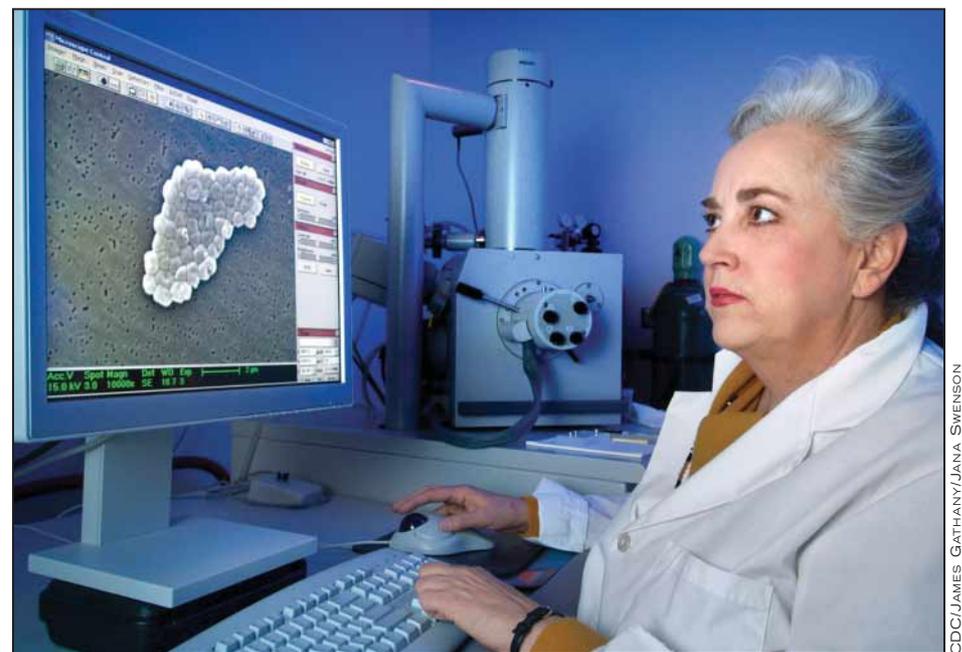
Of particular concern is *Acinetobacter* resistance to an increasing number of antimicrobial agents and developing pan-resistant strains, Dr. Seifert said. Strains that are resistant to every antimicrobial class on the market are now common in some parts of the world.

"Antibiotic-resistant *Acinetobacter* has had a sharp increase in the last decade basically worldwide," Dr. Harris said. Resistance has been reported for aminopenicillins, first- and second-generation cephalosporins, cephamycins, most aminoglycosides, and tetracyclines, among others. Unique clones have been reported that are resistant to several drugs.

The likelihood of mismatch between chosen therapy and drug susceptibility is very high—almost 100%—because many *Acinetobacter* strains are multidrug resistant.

"In many cases, we don't have any effective treatment," Dr. Carmeli said. He related trying as many as five antibiotics at the same time to treat patients.

"We desperately need new antibiotics



CDC microbiologist Janice Carr scans a specimen of *Acinetobacter baumannii*, whose spread has reached epidemic proportions in Latin American and Israeli hospitals.

for gram-negative bacteria. Few are in the pipeline," Dr. Harris said. Those that are under investigation are related to currently approved drugs for gram-negative organisms and "are unlikely to solve some of our major, resistant, gram-negative bacterial problems, including *Acinetobacter*."

Mortality can be high for patients with *Acinetobacter* infections. According to one study of three Israeli hospitals, fatality rates for bloodstream infections caused by multidrug-resistant *Acinetobacter* averaged about 50% (J. Hosp. Infect. 2005;60:256-60).

Dr. Carmeli and his colleagues performed a matched case-control study of 118 patients with a positive culture for multidrug-resistant *Acinetobacter* (susceptibility to carbapenems, colistin, and ampicillin-sulbactam) during a 6-month period. Mortality in patients was 36%, compared with

21% in controls, for an adjusted odds ratio of 6.23. Average length of stay for patients with *Acinetobacter* was 28 days, compared with 17 days for controls, but the difference was not statistically significant.

"Most of the mortality, in my experience, is concentrated in patients who have either sepsis or pneumonia," Dr. Carmeli said.

Eradication Efforts Stymied

"Another characteristic feature of *Acinetobacter baumannii* is the propensity for epidemic spread," Dr. Seifert said. The organism is easily transmitted by person-to-person contact.

"Once it's established in your hospital, it's very difficult to get rid of it," said Dr. Carmeli, who is also a research staff member at Beth Israel Deaconess Medical Center and Harvard Medical School in Boston. He noted that in one ICU ward in Israel, the staff was able to eliminate *Clostridium difficile* and MRSA through strict infection control measures, "but did not make any change in *Acinetobacter* at all."

More worrying, environmental contamination may play a role in the spread of the bacterium. *Acinetobacter* can live on a dry surface for a month or longer. Contamination times of 3 months have even been reported.

In Israel, not only is *Acinetobacter* spreading beyond ICUs as patients are moved to other wards, but the outbreaks are also polyclonal. Hospital staff must contend with more than one clone in more than one ward, making eradication virtually impossible.

Based on the current epidemiology of *Acinetobacter* in Israeli hospitals, Dr. Carmeli estimates that at the peak of a U.S. epidemic, physicians here could expect to see 280,000 cases each year, including 120,000 cases of pneumonia or sepsis and 30,000 cases of attributable mortality.

Also worrying is the fact that no one is clear on what interventions work to prevent the spread. A number of interventions have been attempted, but "at this point, to be rather frank, none have proved rather successful in light of the rapid spread," Dr. Harris said.

"The same measures that worked to control things in our medical ICU did not work at all in controlling our outbreaks in shock/trauma," he noted.

Multidrug-Resistant *Acinetobacter* Poses Challenge

WASHINGTON — Multidrug resistance poses a serious problem for treating *Acinetobacter baumannii* infections, and one expert offered his thoughts on the choice of therapy at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

"Most of the problems around the world are [*Acinetobacter* strains] that have become resistant to everything," said Dr. James J. Rahal, the director of the infectious disease section at New York Hospital Queens and a professor of medicine at Weill Medical College of Cornell University, New York.

The carbapenems and ampicillin-sulbactam have retained in vitro and clinical activities against *Acinetobacter*, but a growing number of reports have documented resistance to these drugs. Physicians have turned to nontraditional agents, such as colistin and polymyxin B, which had lost favor in the antibiotic arsenal because of concerns about nephrotoxicity.

Dr. Rahal offered this advice:

► Cephalosporins should probably be avoided for the treatment of *Acinetobacter*, with the possible exception of using them in combination with an aminoglycoside.

► For susceptible *Acinetobacter* strains, trimethoprim-sulfamethoxazole, quinolones, and ampicillin-sulbactam may be effective as single therapies.

► Carbapenems remain the drugs of choice. It's unclear whether combination therapy with another drug might prevent the development of resistance to the carbapenems.

► Colistin and polymyxin B have been shown to be effective clinically. "From my review, I have concluded that the efficacy is clearly less in serious pulmonary infection ... so higher-than-usual doses should be considered," Dr. Rahal said.

► The addition of rifampin to single-drug therapy should be considered. "The contribution of rifampin to anti-gram-negative therapy has been demonstrated both clinically and in vitro for many years," he said.

Research based on other organisms shows promise that combination therapy using two or more different classes of antibiotics results in a synergistic effect that is efficacious and may stave off bacterial resistance to single therapies.

"My inclination is that double therapy in fact might prevent the evolution

of resistance, but that is a question that has been in the literature for a long time and never proven," Dr. Rahal said at the meeting sponsored by the American Society for Microbiology.

Researchers and physicians alike have been focusing on the use of combinations of colistin, polymyxin B, rifampin, and imipenem, although other drug combinations have been considered as well.

"It seems that the most active combinations are those that add either imipenem or rifampin or both to polymyxin B," said Dr. Rahal, based on his own research.

Another interesting aspect that has emerged is dosage, he said. The usual dosage of colistin is 5 mg/kg per day, but researchers have experimented with dosages as high as 15 mg/kg per day.

In 2005, the Food and Drug Administration approved Tygacil (tigecycline), a novel broad-spectrum antibiotic active against methicillin-resistant *Staphylococcus aureus*. The drug shows activity in vitro against multidrug-resistant *Acinetobacter*, but what effect the drug will have clinically is unknown, Dr. Rahal said.

—Kerri Wachter

GUEST EDITORIAL

Inhaled Corticosteroids and Fetal Growth

The widespread prescribing of corticosteroids in medicine includes many clinical situations during pregnancy, which naturally raises concerns about the safety of these drugs in pregnant women. Over the past several years, information has begun to accumulate on the safety of inhaled corticosteroids in this population.

In October, the largest study to date, conducted by the Organization of Teratology Information Services (OTIS), on the use of asthma medications—corticosteroids and β_2 -agonists—during pregnancy and their effects on fetal growth was published. The main finding was that treatment of pregnant women with β_2 -agonists and inhaled steroids did not have adverse effects on fetal growth and that systemic corticosteroids had a minimal effect on birth weight and length.

The prospective study compared birth size and the incidence of babies born small for gestational age (SGA) in 654 infants whose mothers had taken inhaled or

systemic corticosteroids and β_2 -agonists for asthma during pregnancy with birth size and incidence of SGA in 303 infants whose mothers did not have asthma. Women from North America were enrolled between 1998 and 2003. There were



BY DR. GIDEON KOREN

no significant differences in the incidence of SGA for weight between the groups. Birth weight was slightly reduced among those exposed to systemic steroids: the mean birth weight, adjusted for other risk factors, was 3,373 g, compared with a mean of 3,540 g among controls, 3,552 g among those exposed to β_2 -agonists only, and 3,524 g among those exposed to inhaled steroids.

Mean birth weight and mean birth length, adjusted for risk factors, among infants whose mothers had been treated with inhaled steroids were not significantly different from those of controls or of infants whose mothers had used β_2 -agonists only. The adjusted mean birth lengths were 51.3 cm in the inhaled steroid group and 51.5 cm in the β_2 -agonist group.

The authors, from the University of California, San Diego and the OTIS Research Group, concluded that these results were “reassuring and support the recommendations of adequate control of severe asthma during pregnancy,” and that “the modest effect of systemic steroids on fetal growth should be weighed against the necessity to achieve adequate control of severe persistent asthma and to prevent hypoxia during pregnancy” (J. Allergy Clin. Immunol. 2005;116:503-9).

While these conclusions are not novel, this study is a major breakthrough because it combines information from teratology information centers to provide much larger numbers than were available previously.

Women and physicians should be informed there are some risks: In 2000, my colleagues and I published a metaanalysis of all available studies of women given high-dose steroids during pregnancy. The results clearly indicated that the use of systemic steroids in the first trimester was associated with a two- to threefold higher risk of oral clefts (Teratology 2000;62:385-92).

However, inhaled corticosteroids, commonly used as first-line therapy for asth-

ma, result in an extremely low systemic dose, and none of the available reviews on the use of inhaled steroids during pregnancy have found any association with a greater risk of oral clefts. The β_2 -agonist albuterol is not teratogenic.

There is emerging evidence that repeated weekly corticosteroid injections for fetal lung maturation in cases of premature rupture of the membranes may result in brain damage in some babies. But this is not relevant to the use of inhaled corticosteroids in pregnant women with asthma.

Therefore, based on this recent study and previous data, pregnant women should be encouraged not to neglect their asthma therapy because of concerns about potential effects on the fetus. ■

DR. KOREN is professor of pediatrics, pharmacology, pharmacy, medicine, and medical genetics at the University of Toronto. He heads the Research Leadership in Better Pharmacotherapy During Pregnancy and Lactation at the Hospital for Sick Children, Toronto, where he is director of the Motherisk Program, a teratogen information service (www.motherisk.org).

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Early Echocardiogram May Alter Shock Tx

BY BOB BABINSKI
Elsevier Global Medical News

MONTREAL — Dr. Anthony Manasia of New York's Mt. Sinai School of Medicine is making the case for early goal-directed echocardiography for patients admitted in shock to the ICU.

In a small, ongoing study, Dr. Manasia has found that early echos have had an impact on treatment in more than half of the 24 patients he has evaluated.

For his study, shock is defined as hypotension (mean arterial pressure less than 65 mm Hg or systolic blood pressure less than 90 mm Hg, or a 40% decrease in systolic blood pressure, compared with baseline) or need of vasopressor therapy following an adequate fluid challenge, associated with either hyperlactatemia, oliguria/anuria or an increase in serum creatinine."

The patients' first echo was performed upon entry into the ICU—average time to echo from onset of shock was 5.4 hours—with a second echo taking place within the next 24 hours. All procedures were performed by an echo-trained intensivist not involved in the patient's care.

Based on echo information (left ventricular preload and global contractility), the primary ICU team revised each patient's medical treatment plan regarding

intravenous fluid management and vasopressor therapy, Dr. Manasia said at the annual meeting of the American College of Chest Physicians. Changes in medical management were recorded following each echo and compared with decisions made prior to the echo.

Dr. Manasia found that nearly 40% of patients had their initial treatment plan changed after their first echo. Another 17% had changes made after their second echo.

"Although the numbers that I presented are small, I feel that changing the therapeutic intervention in 37.5% of patients in shock is important. Also, the use of echocardiography by intensivists will have a major impact on how they treat patients in the early phases of shock. This is when we can make the most difference," he said.

With these early results suggesting that serial echos in shock patients may be used to tailor therapy in the early resuscitation phase, Dr. Manasia wants to find out more.

"What needs to be studied is whether or not there is a change in outcome," he said. "This may be difficult to prove, since a very large number of patients would have to be studied. Also, echocardiography is a diagnostic tool and not a therapy." ■

Higher Rate of Dysrhythmias Found in Dopamine Patients

Norepinephrine might be best for septic shock.

BY BOB BABINSKI
Elsevier Global Medical News

MONTREAL — A large increase in cardiac dysrhythmias was associated with dopamine, compared with norepinephrine, as a vasopressor therapy in septic shock, but there was no difference in mortality, Dr. Jaime J. Simon Grahe said at the annual meeting of the American College of Chest Physicians.

Dr. Simon Grahe and her colleagues conducted a treatment study of 66 septic shock patients in the medical ICU at Rush University, Chicago. Thirty-five patients were prospectively randomized to receive dopamine as a first-line vasopressor, and 31 were randomized to norepinephrine. Acute Physiology and Chronic Health Evaluation (APACHE II) scores, gender, and age were all similar at baseline between the two groups. All patients were treated with early goal-directed medical therapy, including fluid resuscitation, antibiotics, tight glycemic control, and management of adrenal insufficiency, according to Dr. Simon Grahe of Rush University.

When the maximum dose of either drug was reached, "patients received vasopressin at a fixed rate of 0.04 units per minute, followed by titration of phenyle-

phrine to maintain the blood pressure goal" (mean arterial pressure greater than 60 mm Hg, or systolic blood pressure greater than 90 mm Hg), she said.

"To the best of my knowledge, [this is] the first clinical study to look at dopamine versus norepinephrine in a randomized, controlled fashion," she said in an interview.

"Our study was designed to look at mortality as a primary end point. During an interim safety analysis, we found a difference in arrhythmogenicity," she said.

In all, 31% of the dopamine group experienced dysrhythmias, compared with 3% of the norepinephrine group, a statistically significant difference. There was no significant difference in mortality (dopamine 40%, norepinephrine 41.8%).

"Given the significant difference in the incidence of cardiac dysrhythmias associated with dopamine administration in septic shock patients, consideration should be given to using norepinephrine over dopamine as a first-line vasopressor agent in septic shock, especially in patients with a history of arrhythmia or cardiac [problems]," Dr. Simon Grahe said. "Patients with a history of prior arrhythmias had a statistically significant greater likelihood of developing cardiac dysrhythmias when on vasopressors," she said. ■

Postop Infection Rate Dropped With Early Enteral Feeding

Don't delay feeding even in critically ill patients.

BY BOB BABINSKI
Elsevier Global Medical News

MONTREAL — Proper nutrition for critically ill patients significantly reduces infection rates and hospital length of stay, Dr. Paul E. Marik, FCCP, said at the annual meeting of the American College of Chest Physicians.

"If there is a bowel, use it," a smiling Dr. Marik told the attendees, advocating the value of enteral feeding. "There is no disease process that benefits from starvation," said Dr. Marik, director of pulmonary and critical medicine at Jefferson Medical College, Philadelphia.

In a systematic review of 15 studies of 753 hospitalized patients who were either critically ill or injured, he found a significant benefit to early versus delayed feeding (Crit. Care Med. 2001;29:2264-70).

The review included hospitalized adults in one of the following categories: postoperative, traumas, head injuries, burns, or medical intensive care unit.

Those who received enteral feeding within 36 hours after surgery were less likely to develop infections than those whose feeding was delayed (relative risk of 0.45). That same group also saw a significant mean reduction in hospital stay of 2.2 days. There were no significant differences in mortality or noninfectious complications between the two groups.

"Feeding should be started as soon as possi-

ble," Dr. Marik said. "There's no clinical condition that necessitates delay of feeding."

In a separate metaanalysis of parenteral versus early enteral nutrition in acute pancreatitis, Dr. Marik found that early enteral nutrition was associated with significantly lower rates of mortality, infection, surgical intervention, and complications other than infection (BMJ 2004;328:1407).

"Nutrient augmentation of blood flow aids oxygen delivery to the gut and absorption of nutrients following a meal," he said. "Flow is increased in all layers of the gut—the mucosa, submucosa, and muscularis. In contrast, gut blood flow is diminished during fasting. This effect of nutrients on blood flow is known as the postprandial hyperemic response."

Dr. Marik recommended placement of a nasogastric or oral gastric tube on admission to the intensive care unit. If the patient is intolerant, feeding should be done with a small bowel tube, he said.

As for the quantity of nutrient intake, his evidence-based recommendations suggest that feeding begin at 33%-66% of the calculated intake. That level is determined using the following formula: 15-20 kcal/kg per day and 40-60 cc/hour. This level should be maintained for 3-5 days. As the patient improves, the level can be increased to full intake over another 3-5 days. Full intake is determined by this formula: 20-25 kcal/kg per day, and 60-75 cc/hour. ■

Glutamine Given After Surgery Cut Hospital Stays by 1 Day

BY BETSY BATES
Elsevier Global Medical News

SAN FRANCISCO — Enteral administration of the nutrient glutamine within 8 hours of major surgery boosted antioxidant production and reduced patients' length of stay by a day, according to a Canadian study reported by Dr. Adebola O.E. Obayan at the annual clinical congress of the American College of Surgeons.

"Surgery is a controlled form of trauma, the commonest cause of oxidative stress," explained Dr. Obayan, a surgeon at the University of Saskatchewan in Saskatoon. Knowing that the loss of up to

40% of natural glutamine levels after surgery places the body in a state of oxidative stress, Dr. Obayan and associates hypothesized that providing supplemental glutamine would foster healing while preventing oxidative stress. They enrolled 69 patients undergoing elective surgery in a prospective, randomized, double-blind trial at the Royal University Hospital in Saskatoon, Sask. The

surgical procedures included hepatobiliary, pancreatic, cardiorespiratory, thoracic, plastic, and oncologic surgeries, as well as neurosurgery.

Half of the patients received alanyl-glutamine supplementation (0.3 g/kg) through feeding tubes, while the others received a placebo.

Results showed that the supplemental glutamine significantly increased plasma glutamine and antioxidant levels at 24

hours; it also significantly reduced strong oxidant production.

The average length of stay was reduced by 1 day among patients receiving glutamine when the investigators accounted for the severity of patients' illnesses and

the complexity of their procedures. Resource intensity weighting analysis, a measure of cost adjusted by case complexity, found a profoundly significant cost savings in patients undergoing more complex procedures.

University of Saskatchewan surgeons now give oral glutamine preoperatively to patients having general or orthopedic surgery, he said. ■

PLASMA GLUTAMINE AND ANTIOXIDANT LEVELS INCREASED SIGNIFICANTLY AT 24 HOURS, AND STRONG OXIDANT PRODUCTION WAS REDUCED.

Atrial Pacing Didn't Dent Sleep Apnea, Hypopnea

BY MARTHA KERR
Elsevier Global Medical News

Atrial overdrive pacing proved ineffective in most cases of obstructive sleep apnea-hypopnea syndrome, while nasal continuous positive airway pressure showed strong efficacy, according to a comparison study by Greek researchers.

Dr. Emmanuel N. Simantirakis and colleagues at Heraklion (Crete) University Hospital, Greece, implanted dual-chamber pacemakers in 16 patients with moderate or severe sleep apnea, documented sleep-related bradycardias, and normal ventricular function (N. Engl. J. Med. 2005;353:2568-77).

Patients had a mean baseline apnea-hypopnea index of 49 and had

at least two self-reported syncopal episodes in the preceding year. Diagnosis of sleep apnea-hypopnea was confirmed on polysomnography.

All pacemakers were initially programmed to initiate atrial pacing when the heart rate fell below 40 beats per minute.

After 48 hours, half of the patients had their pacemakers programmed for atrial overdrive pacing, with pacing at a rate of greater than 15 beats per minute or greater than their normal nocturnal heart rate. The rest of the patients remained on backup atrial pacing plus nasal continuous positive airway pressure (n-CPAP).

One month later, the two groups

switched therapies. The researchers followed the patients for another month.

Atrial overdrive pacing had virtually no effect on the average apnea-hypopnea index at 1 month, which rose from 49 at baseline to 49.2. The increase was not statistically significant. In contrast, n-CPAP significantly improved the average apnea-hypopnea index after 1 month of therapy, which fell from 49 at baseline to 2.7. Arousal index, desaturation index, and all other variables measured except total sleep time showed improvements with n-CPAP, while atrial overdrive pacing had no measurable effect on the variables, the researchers said.

"We were unable to show any beneficial effect of pacing in reducing the number of episodes of apnea or hypopnea per hour," the investigators wrote.

The findings of the study, however, may not apply in general to all patients who are suffering from obstructive sleep apnea-hypopnea syndrome, they cautioned.

The failure of atrial overdrive pacing to improve symptoms "suggests that overdrive pacing is likely to have a very limited role in this setting," Dr. Daniel J. Gottlieb of Boston University said in an accompanying editorial (N. Engl. J. Med. 2005;353:2604-6).

"Phenotypes will be identified in which modification of neuromuscular factors will play a useful therapeutic role," he added. ■

ATRIAL OVERDRIVE PACING HAD VIRTUALLY NO EFFECT ON THE AVERAGE APNEA-HYPOPNEA INDEX AT 1 MONTH, WHEREAS n-CPAP IMPROVED THE INDEX SIGNIFICANTLY.

Adjustable Oral Appliance Cut Snoring Rate and Loudness

Surprisingly, the device reduced palatal flutter snoring.

BY ELAINE ZABLOCKI
Elsevier Global Medical News

LOS ANGELES — A custom-made oral appliance can significantly decrease snoring rates, Dr. Eric A. Mair said at the annual meeting of the American Academy of Otolaryngology-Head and Neck Surgery Foundation.

Using the Thornton Adjustable Positioner II (TAP II), researchers found that the device reduced lingual snoring, and, unexpectedly, reduced palatal snoring even more.

The TAP II device was created by a prosthodontist, with separate maxillary and mandibular components. It is gradually adjusted to move the lower jaw forward by up to a maximum of 6 mm of protrusion.

"This is a very nice oral appliance," said Dr. Mair, director of pediatric otolaryngology at Wilford Hall Medical Center, Lackland Air Force, San Antonio. "It is different from the devices you may see at the local drugstore for \$29.95. Those 'boil and bite' appliances can lead to problems with dental malocclusion."

In this prospective, observational clinical trial, patients wore the device for 3 weeks. During that period, the device was gradually adjusted by 0.25 mm at a time. At the end of 3 weeks, changes in sleep and snoring patterns were observed.

Of the initially recruited 57 patients, 17 did not complete the study because of military transfers or deployments, dental problems, temporomandibular joint pain, or other reasons. On average, the study participants were 44.8 years old, weighed 187 pounds, and had a respiratory disturbance index of 14.4, with 364 snoring events/hour.

Researchers used the SNAP device, developed by Snap Labs, Glenview, Ill., to

measure overnight snoring. This device records continuous pulse-oximetry data and makes an acoustical recording from a microphone positioned near the patient's upper lip. Proprietary software analyzes the recorded sounds to determine the amount and anatomic site of snoring.

After using the TAP II for 3 weeks, snoring decreased from 364 to 216 events per hour. Average and maximal snoring loudness decreased about 5 dB each, which was statistically significant.

The percentage of all snoring sounds originating from the palate decreased from 66% to 47%. The percentage of snoring originating from the tongue base increased from 11% to 16.6% (not statistically significant), while the number of tongue-based events decreased.

"TAP II is effective in reducing palatal flutter snoring as measured by an objective test, and this demonstrates that oral appliances can have dynamic physiologic effects at airway levels other than the tongue base," Dr. Mair said.

The study enrolled only 10 patients with significant obstructive sleep apnea, thus decreasing its power to detect changes in sleep apnea with oral appliance use.

After the study period, the respiratory disturbance index declined from 14.4 to 10.4, not quite reaching statistical significance. The apnea index declined from 5.1 to 3.2; the hypopnea index declined from 10.2 to 7.6.

Patients reported a low amount of jaw and tooth pain associated with TAP II and had good compliance during the study period. However, after completion of the 3-week study, patients were followed for 6 months, during which time compliance declined, with about 50% of patients reporting use of the TAP II on at least 50% of nights. ■

African Americans Need Education on Sleep Apnea Risks

BY ELAINE ZABLOCKI
Elsevier Global Medical News

LOS ANGELES — African Americans are at increased risk for obstructive sleep apnea, compared with whites, but their bed partners are less likely to encourage them to seek treatment, Dr. Michael Friedman reported at the annual meeting of the American Academy of Otolaryngology-Head and Neck Surgery Foundation.

Studies on the incidence of sleep apnea have focused primarily on whites, leaving the incidence among African Americans unknown, Dr. Friedman said. However, hypertension rates are twice as high among African Americans. Obesity, a strong risk factor for obstructive sleep apnea, is also more prevalent in this population.

"The comorbid conditions—hypertension, obesity, and cardiovascular disease—create the need to identify and treat sleep apnea in African Americans," said Dr. Friedman, chairman of the section of head and neck surgery at Rush University Medical Center, Chicago.

Most people don't seek treatment for sleep apnea on their own.

Instead, they tend to come in at the urging of their bed partner. Dr. Friedman and his colleagues hypothesized that differences in social attitudes might affect the likelihood of people seeking treatment.

The investigators interviewed 523 people, most of them aged 25-55 years.

Investigators offered a free ear, nose, and throat screening plus a gift to couples at the Chicago Health Fair, attended by 80,000 people.

Participants received a simple physical exam and answered questions on the frequency and intensity of snoring, daytime sleepiness, observed apnea, and morning headaches.

Participants were asked questions to evaluate their attitudes about snoring.

One partner was identified as the actual study participant; the other partner agreed with the first partner's answers to the screening questions.

The study group included 287 people of African American descent and 236 of white

descent. There were no differences between the two groups in terms of age or sex distribution, but the mean body mass index in African Americans was significantly higher, compared with whites.

Neck size tended to be larger among African Americans. Snoring severity, measured on a subjective 10-point scale, was found to be about 1 point more severe in African Americans.

Oropharyngeal examinations demonstrated that African Americans tended toward larger tonsils and higher Friedman tongue positions (FTP), both increasing

the likelihood of obstructive sleep apnea. Friedman tongue positions III and IV indicate hypopharyngeal obstruction and 79% of African Americans had either FTP III or FTP IV, while only 55% of whites had FTP III or IV.

When the researchers asked questions about attitudes towards snoring, they found significant differences.

More than 30% of African Americans considered snoring to be normal, compared with 18% of whites. African Americans were less likely to leave the room, or to be asked to leave the room, due to snoring.

"African Americans have more severe symptoms. They are more likely to consider snoring to be normal and less likely to be asked to leave the room due to snoring," Dr. Friedman said.

"The question is, are they therefore less likely to seek treatment? One conclusion is clear: African Americans need more education about obstructive sleep apnea and encouragement to seek diagnosis and treatment," he said. ■

AFRICAN AMERICANS ARE MORE LIKELY TO CONSIDER SNORING TO BE NORMAL AND LESS LIKELY TO BE ASKED TO LEAVE THE ROOM DUE TO SNORING.

FDA Advisory Targets Long-Acting Bronchodilator Safety

Products 'may increase the chance of severe asthma episodes and death when those episodes occur.'

BY ELIZABETH MEHCATIE
Elsevier Global Medical News

Long-acting β_2 -adrenergic agonists should not be the first medicine physicians prescribe for asthma and should be added to treatment only when patients do not adequately respond to other asthma medications, according to a public health advisory issued by the Food and Drug Administration in November.

Although these bronchodilators reduce the frequency of asthma episodes, they "may increase the chance of severe asthma episodes and death when those episodes occur," the advisory said.

The FDA has asked that the manufacturers of the long-acting β_2 -adrenergic agonist (LABA) products update their product labels with these warnings and provide a medication guide explaining these risks to patients when they fill or refill prescriptions.

The three products available in the United States are formoterol fumarate inhalation powder (Foradil) and salmeterol xinafoate inhalation powder (Serevent), which contain the LABA alone, and Advair

Diskus, which contains both salmeterol and the inhaled corticosteroid (ICS) fluticasone. All three products are approved for maintenance therapy and prevention of bronchospasm in adults, adolescents, and children, but not for acute relief of bronchospasm.

GlaxoSmithKline, the manufacturer of Advair and Serevent, disagrees with the proposed labeling changes, it said in a statement. The changes are "inconsistent" with the National Heart, Lung, and Blood Institute (NHLBI) asthma treatment guidelines and with the standard of care for asthma therapy, "which could put many patients at risk of uncontrolled asthma," the statement said. Further, the company is working with the FDA to "address the differences of opinion about how best to communicate the benefit risk profile of these medicines for optimal patient care."

A spokesperson for Novartis, the manufacturer (with Schering-Plough) of Foradil, said the company was working with the FDA on the most appropriate language for the package label and medication guide.

(The LABAs are also approved for chronic obstructive pulmonary disease, but the advisory says that information is not available to determine whether similar concerns exist when LABAs are used to treat COPD or exercise-induced wheezing.)

The latest NHLBI asthma guidelines, published in 2002, recommend an LABA and ICS as the treatment of choice for patients with moderate or severe persistent asthma. The guidelines do not suggest that such patients have to fail treatment with an ICS first, said Dr. Harold S. Nelson, a member of the expert panel and senior staff physician at the National Jewish Medical and Research Center in Denver.

Treatment with an ICS alone is recommended for mild persistent asthma, Dr. Nelson said in an interview. The NHLBI panel recommendations were based on a large number of studies that directly compared medication regimens that added an LABA to low-dose ICS with those that doubled or more than doubled ICS dose, and for every outcome, the LABA plus low-dose ICS was superior, he added.

Dr. Nelson said he was concerned that the advisory could result in inferior treatment, with some patients with moderate to severe persistent asthma being taken off an LABA, and that the patient medication

guide will be unnecessarily alarming and could result in some patients stopping the drug without consulting their physician.

Dr. Nelson also said he was concerned that the advisory implies a causality that has not been established.

The advisory refers to the Salmeterol Multicenter Asthma Research Trial (SMART)—a large, randomized, double-blind trial of asthma patients begun in 1996 by GlaxoSmithKline—which compared the safety of salmeterol with that of placebo when added to the usual asthma treatment.

The trial was stopped early in January 2003, after 30,000 patients had been enrolled, when an interim analysis found 13 asthma-related deaths over 28 weeks of treatment among those on salmeterol (0.10%) vs. 3 in those on placebo (0.02%). The increase in risk resulted in the addition of a black box warning to the label of salmeterol products in August 2003. ■

The FDA advisory is available on the FDA Web site at www.fda.gov/cder/drug/infopage/LABA/default.htm. The 2002 NHLBI asthma guidelines are available at www.nhlbi.nih.gov/guidelines/asthma/index.htm. Updated guidelines are expected to be released in the summer of 2006.



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ABSTRACT SUBMISSION DEADLINE: APRIL 21, 2006

Adding Acetylcysteine May Slow IPF Progression

BY SHARON WORCESTER
Elsevier Global Medical News

The addition of the antioxidant acetylcysteine to the standard treatment for idiopathic pulmonary fibrosis showed potential promise in slowing the disease progression in patients in a randomized, controlled study.

A total of 182 patients with usual interstitial pneumonia were randomized to receive standard treatment with prednisone and azathioprine plus placebo or the standard treatment plus 600 mg acetylcysteine given three times daily. The absolute difference in the change from baseline among the 71 patients in the acetylcysteine group and the 68 in the placebo group for whom data were analyzed was 0.18 liters (relative difference of 9%) for vital capacity, and 0.75 mmol/min per kilopascal (relative difference of 24%) for single-breath carbon monoxide diffusing capacity (N. Engl. J. Med. 2005;353:2229-41).

The number and type of adverse events were similar in the two groups, except those in the acetylcysteine group had a significantly lower rate of bone marrow toxicity. Mortality at up to 1 month after treatment completion was also similar at 9% for the acetylcysteine group and 11% for the placebo group, Dr. Maurits Demedts of Katholieke Universiteit Leuven (Belgium) and colleagues reported.

Although the beneficial effects of acetylcysteine did not translate into a significant survival benefit, the results of this multinational, double-blind study have clinical relevance, according to the investigators.

Adding acetylcysteine was previously shown to restore depleted pulmonary glutathione levels and improve lung function in patients with fibrosing alveoli when given at the same high dose used in the present study. Its addition is rational in those with idiopathic pulmonary fibrosis (IPF). Larger studies are needed to determine the effects of acetylcysteine on survival, they said.

The researchers also noted that the present study "does not permit firm conclusions regarding the effects and side effects of treatment with prednisone plus azathioprine given that there was no placebo group for these drugs."

In an accompanying editorial, Dr. Gary W. Hunninghake, FCCP, director of the pulmonary, critical care, and occupational medicine division at the University of Iowa, Iowa City, said that it is plausible that acetylcysteine is directly beneficial as a therapy for IPF, but that it is also possible that the prednisone and azathioprine combination is toxic to IPF patients, and that acetylcysteine prevents the toxicity (N. Engl. J. Med. 2005;353:2285-7). "A prospective study comparing prednisone and azathioprine with placebo is needed to address this issue," he wrote. ■

High-Res CT Shows Effects of Allergen Long After Exposure

BY PATRICE WENDLING
Elsevier Global Medical News

CHICAGO — For the first time, researchers have shown that lung function remains impaired in people with asthma for up to 22 hours after exposure to cat allergens, even after outward symptoms have abated.

High-resolution CT showed significant air trapping, suggesting that constriction and inflammation of the small airways remain long after initial exposure, Jared W. Allen, Ph.D., reported at the annual meeting of the Radiological Society of North America.

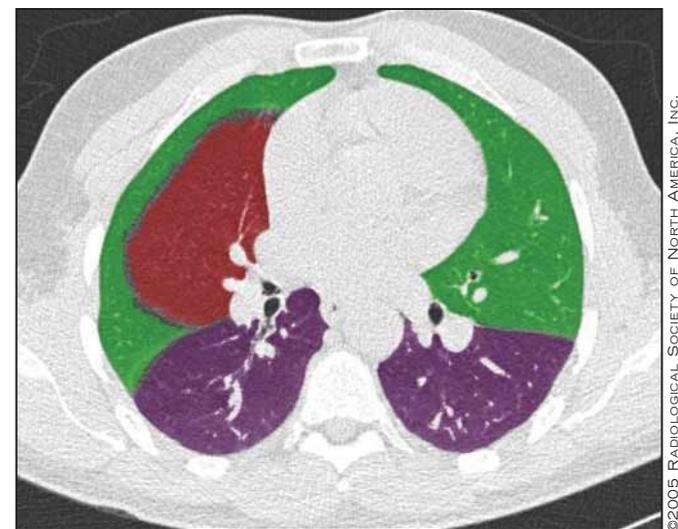
High-resolution CT analysis is a safe, noninvasive means of evaluating these airways that is not possible with conventional pulmonary tests, said Dr. Allen, a researcher at the University of California, Los Angeles.

He presented data from a pilot study in which 10 patients with known allergy to cats were evaluated with pulmonary function tests and high-resolution CT scans before and 6 and 22 hours after allergen exposure. The baseline and 22-hr CT studies were performed before and after methacholine challenge testing. Patients were hooked up to a spirometer when they entered the CT scanner.

All scans were acquired on the same scanner. The lungs were segmented into 12 regions of interest from which lung attenuation curves were derived.

All patients exhibited an immediate decline (mean decrease 30%) in forced expiratory volume in 1 second (FEV₁). At 22 hours after exposure, the decline in FEV₁ was no longer significant (5%).

Median and 10th percentile lung attenuation curves, however, remained significantly left-shifted at 22 hours, indicating increased air trapping (mean change -15.88 HU and -10.42 HU, respectively). Methacholine challenge testing caused a further shift of the median (-16.85 HU) and 10th percentile (-12.81 HU) compared with baseline. ■



High-resolution CT can quantify the impact of allergens on specific lung lobe areas.

New Drug Topped Bupropion for Smoking Cessation

BY MITCHEL L. ZOLER
Elsevier Global Medical News

DALLAS — The first agent from a new drug class was safe and effective in helping patients stop smoking in three phase III studies that involved more than 3,000 patients.

Treatment with varenicline, a selective nicotinic acetylcholine receptor partial agonist, led to smoking quit rates that doubled what was achieved with bupropion (Zyban, GlaxoSmithKline) and quadrupled the rate with placebo in a pair of acute therapy studies, Serena Tonstad, M.D., reported at the annual scientific sessions of the American Heart Association.

The third study showed that 24 weeks of treatment with varenicline was safe and better maintained abstinence from smoking than a 12-week course of the drug.

All of the studies were sponsored by Pfizer Inc., which is developing the drug and plans to market it as Champix. The phase III data presented at the meeting was part of a new drug application submitted to the Food and Drug Administration in November, according to a statement released by Pfizer. Dr. Tonstad has received honoraria from Pfizer as a speaker and a consultant.

Varenicline was designed by researchers as a nonnicotine agent that is both an an-

tagonist and partial agonist for the nicotine receptor. As an antagonist, the drug prevents nicotine from binding to its receptor, thus reducing the positive reinforcement that usually accompanies smoking and "breaking the cycle of addiction," said Dr. Tonstad, department of preventive cardiology, Ullevål University Hospital, Oslo.

The drug's agonist side means that it also partially activates the nicotine receptor, which blunts withdrawal symptoms and curbs craving after patients stop smoking.

The two acute treatment studies had an identical design and were done at centers in the United States. Each study included slightly more than 1,000 people who smoked about a pack of cigarettes daily and had smoked for about 25 years. All the participants were motivated to quit.

They were randomized to treatment with 1-mg varenicline b.i.d., 150-mg bupropion b.i.d., or placebo. After receiving their assigned agents for 7 days while continuing to smoke, the participants were told to stop smoking on day 8. Treatment continued for another 11 weeks, during which they had weekly examinations and attended brief weekly motivational support sessions that focused on the behavioral aspects of smoking cessation.

Successful cessation, the primary end point of both studies, was defined as not inhaling even a single puff of cigarette

smoke during the last 4 weeks of treatment. Abstinence was monitored during weekly clinic visits by expired carbon monoxide levels.

In both studies, during weeks 9-12 of treatment, 44% of those in the varenicline group abstained from smoking, as did 30% of those in the bupropion group and 18% of those in the placebo group.

Statistical analysis calculated that the odds ratio of smoking cessation was nearly fourfold higher in the varenicline group than in placebo patients, and nearly twice as high in the varenicline group than in those receiving bupropion—the only drug approved in the United States for smoking cessation. All of the rate differences between the varenicline and comparator groups were statistically significant.

A secondary end point for both studies was the rate of confirmed, continuous abstinence during the 44-week period starting with the ninth week of treatment and continuing to 1 year after the start of the study. (Participants were treated for the first 4 weeks and during weeks 9-12, and then were off treatment for the next 40 weeks.)

Abstinence rates during this period were about 22% for the varenicline-treated people in both studies, compared with a 16% rate in those treated with bupropion and about 9% in those who got placebo.

The third study, done in the United

States and at sites in other countries, began with 1,927 people who received 1-mg varenicline b.i.d. on an open-label basis for 12 weeks. At the end of this period, 1,236 (64%) patients remained abstinent from smoking and were eligible for the maintenance phase. The second half of the study randomized 602 people to continue to receive varenicline for a second 12-week period, and 604 were randomized to placebo.

During weeks 13-24, continuous abstinence from smoking was achieved at a rate of 71% in the varenicline group and a rate of 50% in the placebo group, a statistically significant difference. From week 13 to 52, the abstinence rates were 44% in the group treated for 24 weeks, compared with a 37% rate in those treated for 12 weeks, said Dr. Tonstad, who is also a professor of nutrition at the University of Oslo.

In all patients, the most common adverse effect from varenicline was nausea, which overall affected about 30% of those taking the drug. In about two-thirds of people who had nausea, the effect was mild. Other reported adverse effects were headache and vivid dreams. In general, varenicline appeared safe and was well tolerated, said Dr. Tonstad, but she did not report any data on hepatic and renal function in patients taking the drug. Weight gain was similar in the varenicline and placebo groups. ■

Tool Flags Uncontrolled Asthma

BY BETSY BATES
Elsevier Global Medical News

ANAHEIM, CALIF. — A simple, seven-question pictorial tool can give a pediatrician an instant snapshot of whether a patient's asthma is well controlled at the time of an office visit.

Children aged 4-11 years and their caregivers can complete the Childhood Asthma Control Test in 1-2 minutes.

The answers reliably predict which asthma patients are doing well and which require focused attention, reported Dr. Andrew H. Liu, a pediatric allergist and immunologist at the National Jewish Medical and Research Center in Denver.

The questionnaire was developed by Dr. Liu and 11 other pediatric allergy and pulmonology specialists whose working group initially tested 21 questions on 344 pediatric asthma patients and their caregivers to see which correlated best with asthma control, as defined by lung function and clinical assessments by specialists.

The cohort included children with moderate to severe asthma (38%), as well as many with mild to moderate asthma. Almost a third of the patients were considered by specialists to have asthma that was controlled poorly or not at all.

Results of a validation study were present-

ed at the annual meeting of the American College of Allergy, Asthma, and Immunology.

Four questions answered by children (with pictures to assist them) and three questions answered by caregivers were most predictive of asthma control in a subset of 257 children randomly chosen from the sample. (See box.)

Sometimes, the topics overlapped. For example, both children and caregivers are asked about asthma-driven nighttime awakenings. This reflects the fact, as studies have shown, that caregivers and children do not always share common perceptions, Dr. Liu said.

The scores discriminated well between children who were not controlled versus controlled, based on specialists' ratings of control, the need for a change in the patient's therapy, and the percentage of predicted forced expiratory volume in 1 second (FEV₁).

The highest possible score is 27. A score of 19 served as a reliable cutoff in the cohort, said Dr. Todd A. Mahr, director of pediatric allergy and clinical immunology at Gunderson Lutheran Medical Center in La Crosse, Wisc., and a member of the working group. A score of 19 or less had a sensitivity of 68% and specificity of 74% in predicting whether asthma was under control. At that threshold, 72% of children were correctly classified, he said.

A grant from GlaxoSmithKline provided funding for the study. ■

Asthma Control Questionnaire

For Children Aged 4-11

• How is your asthma today?

Very bad (0).

Bad (1).

Good (2).

Very good (3).

• How much of a problem is your asthma when you run, exercise, or play sports?

It's a big problem. I can't do what I want to do (0).

It's a problem and I don't like it (1).

It's a little problem but it's OK (2).

It's not a problem (3).

• Do you cough because of your asthma?

Yes, all of the time (0).

Yes, most of the time (1).

Yes, some of the time (2).

No, none of the time (3).

• Do you wake up during the night because of your asthma?

Yes, all of the time (0).

Yes, most of the time (1).

Yes, some of the time (2).

No, none of the time (3).

For the Caregiver

• During the past 4 weeks, on average, how many days did your child have any daytime asthma symptoms?

Every day (0).

19-24 days per month (1).

11-18 days per month (2).

4-10 days per month (3).

1-3 days per month (4).

Not at all (5).

• During the past 4 weeks, on average, how many days did your child wheeze during the day because of asthma?

Every day (0).

19-24 days per month (1).

11-18 days per month (2).

4-10 days per month (3).

1-3 days per month (4).

Not at all (5).

• During the past 4 weeks, on average, how many days did your child wake up during the night because of asthma?

Every day (0).

19-24 days per month (1).

11-18 days per month (2).

4-10 days per month (3).

1-3 days per month (4).

Not at all (5).

Source: Dr. Liu

AMERICAN COLLEGE OF CHEST PHYSICIANS

2006

January 19-22

Sleep Medicine 2006
Scottsdale, Arizona

March 31-April 2

Celebration of Pediatric
Pulmonology 2006
San Juan, Puerto Rico

April 6-9

2006 Multidisciplinary
Update in Pulmonary and
Critical Care Medicine
Scottsdale, Arizona

May 26-28

ACCP Clinical Grand Rounds
on Cardiothoracic Surgery
and Critical Care
Chicago, Illinois

August 25-28

ACCP Sleep Board
Review Course 2006
Orlando, Florida

August 25-29

ACCP Critical Care Board
Review Course 2006
Orlando, Florida

August 29-September 3

ACCP Pulmonary Board
Review Course 2006
Orlando, Florida

October 21-26

CHEST 2006
Salt Lake City, Utah

Future CHEST Meeting

October 20-25

CHEST 2007
Chicago, Illinois

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■ ACCP-Endorsed Courses

EducationCalendar

Learn more about ACCP-sponsored and ACCP-endorsed educational courses.

www.chestnet.org/education/calendar.php

(800) 343-2227 or (847) 498-1400

NEWS FROM THE COLLEGE



PRESIDENT'S REPORT

CHEST Physician: New Directions, Enduring Values

Let me be among the first to welcome you to the inaugural issue of CHEST PHYSICIAN, a new publication of the American College of Chest Physicians.

CHEST PHYSICIAN was created to meet the informational needs of our membership and takes the place of the venerable

ChestSoundings. Many will miss the folksy character of the quarterly *ChestSoundings*, but this new monthly publication will quickly prove to be a worthy (and valuable) replacement.

Up front, I wish to thank its editor-in-chief, Dr. Sue Harding, and her editorial advisory board for assuming the responsibility of producing a periodical of this nature. Having reviewed the



BY W. MICHAEL ALBERTS, MD, FCCP

prepublication issue, I am impressed with the effort and pleased that the ACCP has taken this step.

As President of the College, I have been asked to write a column for each issue. I am honored to do so and pleased with the opportunity to communicate through this publication.

Over the course of the year, I will plan to discuss issues of importance to the membership, highlighting areas addressed by the Executive Committee and the Board of Regents.

By way of background, the Board of Regents meets three times during the year (at the annual CHEST meeting, a spring meeting, and a summer meeting). The Executive Committee (consisting of the President, President-

Elect, Immediate Past President, Treasurer, Chair of the Council of Networks, Chair of the Council of Governors, and a representative Regent-at-Large) "meets" every other week during a regularly scheduled conference call. The Executive Committee also convenes on an urgent basis when an issue must be addressed between scheduled meetings. This seems to be occurring more and more often, as the pace of change in our profession quickens.

The theme for my year as President is "enhancing the value of ACCP membership." It is important to remember that the ACCP exists solely to benefit its members, but in a very special way. The College exists to support and assist the membership in delivering patient-focused care.

This can be defined broadly, but the

bottom line is that the College is here to help its members help their patients. We should be and will be asking the membership, "How can the College help you help your patients?" and then deliver. Our agenda for the year will be guided by what our members value.

One of the keys to enhancing value is to improve communication both to the members and from the members. CHEST PHYSICIAN will assist in providing information to the members. Conversely, I would like to solicit your input and counsel on items of importance to you and your patients. If you have a good idea, a question, a comment, or even a complaint, please contact me through the ACCP headquarters in Northbrook, or by e-mail at malberts@chestnet.org.

Once again, welcome to CHEST PHYSICIAN.

CHEST 2005: The Meeting That Took Us 'Over the Top'

BY PAM GOORSKY

ACCP Assistant Vice President,
Editorial Services

As ACCP staff members gathered on stage after the Jeopardy-style CHEST Challenge, Al Lever, ACCP Executive Vice President and CEO, held up a sign to them with the answer written on it: "5,000."

"So, what is the question?" he asked. Most of us knew we were very close to breaking an attendance record, and Al confirmed our suspicions. CHEST 2005 registration had gone over the top and surpassed the magic number of 5,000 professional registrants. And when the final figures came in, the total, all-inclusive attendance topped 7,500!

CHEST 2005 broke the attendance

record and provided an unmatched venue of education, innovation, conversation, and celebration.

Education? ACCP sets the standard for clinical chest medicine education. CHEST 2005 even raised that standard and offered attendees an unmatched, comprehensive menu of learning opportunities: postgraduate courses; satellite symposia; more than 170 general sessions; literature reviews; curriculum-based learning sessions; ABIM SEP study sessions; cram courses for board review; keynote, honor, and memorial lectures presented by notable experts in their respective fields; and evidence-based guideline sessions and updates.

Innovation raised its intriguing head throughout CHEST 2005. Attendees watched demonstrations of simulation

education in the exhibit hall, where patient models were used that simulated clinical experiences in chest medicine. Elementary school children participated in hands-on lung-learning experiences during the annual ACCP Industry Advisory Council and CHEST Foundation Community Outreach Event. Hundreds of posters and case reports presented new procedures, new results, and new ideas.

Conversation is never lacking at a CHEST meeting. The 2005 Convocation dais was the largest ever, comprising more than 170 participants, where friends, old and new, welcomed the

new FCCPs and conversed among themselves about their professions, their families, and their futures. Panel discussions spurred sessions full of enthusiasm, and meet-the-professor opportunities offered discourse with the experts. The President's Reception and Reunions and the NetWork open meetings allowed time for groups sharing

Continued on following page

CHEST 2005
October 29 ~ November 3, 2005
Montréal, Québec, Canada



CHEST 2005 tops the magic number of 5,000 professional registrants.



Patient models simulate clinical experiences in chest medicine.

Editor's Picks: This Month in CHEST

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

► **The Salmeterol Multicenter Asthma Research Trial: A Comparison of Usual Pharmacotherapy for Asthma or Usual Pharmacotherapy Plus Salmeterol.** Harold S. Nelson, M.D., Scott T. Weiss, M.D., M.S., Eugene R. Bleecker, M.D., FCCP, Steven W. Yancey, M.S., Paul M. Dorinsky, M.D., FCCP, and the SMART study group.

► **Formoterol 24 mcg bid and Serious Asthma Exacerbations: Similar Rates Compared With Formoterol 12 mcg bid, With and Without Extra Doses Taken On-Demand, and Placebo.** James D. Wolfe, M.D., FCCP, Craig LaForce, M.D., Bruce Friedman, M.D., William Sokol, M.D., Denise Till, M.Sc.,

Giovanni Della Cioppa, M.D., Andre van As, M.D., Ph.D., FCCP.

► **A CPAP Trial as a Novel Approach to the Diagnosis of the Obstructive Sleep Apnea Syndrome.** Oliver Senn, M.D., Thomas Brack, M.D., FCCP, Erich W. Russi, M.D., FCCP, and Konrad E. Bloch, M.D., FCCP.

► **Grading Strength of Recommendations and Quality of Evidence in Clinical Guidelines: Report from an American College of Chest Physicians Task Force.** Gordon H. Guyatt, M.D., M.Sc., FCCP, David D. Gutterman, M.D., FCCP, Michael H. Baumann, M.D., M.Sc., FCCP, Doreen J. Addrizzo-Harris, M.D., FCCP, Elaine M. Hylek, M.D., M.P.H., Barbara A. Phillips, M.D., FCCP, Gary E. Raskob, Ph.D., Sandra Zelman Lewis, Ph.D., Holger J. Schünemann, M.D., Ph.D., FCCP.

► **Addressing Resource Allocation Issues in Recommendations from Clinical Practice Guideline Panels: Suggestions from an American College of Chest**

Physicians Task Force. Gordon H. Guyatt, M.D., M.Sc., FCCP, Michael H. Baumann, M.D., M.Sc., FCCP, Stephen G. Pauker, M.D., Jonathan Halperin, M.D., Janet R. Maurer, M.D., M.B.A., FCCP, Douglas K. Owens, M.D., Anna N. A. Tosteson, Sc.D., Brian W. Carlin, M.D., FCCP, David D. Gutterman, M.D., FCCP, Martin Prins, M.D., Sandra Zelman Lewis, Ph.D., Holger J. Schünemann, M.D., Ph.D., FCCP.

► **Colonization of SARS-Associated Coronavirus Among Health-Care Workers Screened by Nasopharyngeal Swab.** Hsin-Tsung Ho, M.D., Ph.D., Mau-Sun Chang, Ph.D., Tsai-Yin Wei, M.S., Wen-Shyang Hsieh, M.S., Chia-Chien Hung, M.S., Hwei-Mei Yang, B.S., Yen-Ta Lu, M.D., Ph.D.

► **Cilomilast for COPD: Results of a 6-Month, Placebo-Controlled Study of a Potent, Selective Inhibitor of Phosphodiesterase 4.** Stephen I. Rennard, M.D., FCCP, Neil Schachter, M.D., Mary Elizabeth Streck, M.D., Kathleen Ann Rickard, M.D., Ohad Amit, Ph.D.

Continued from previous page

similar interests to convene, converse, and collaborate.

Our CHEST 2005 partner societies, the Canadian Thoracic Society and the American Association for Bronchology, met for their annual assemblies, and ACCP leaders met with many other partnering societies, including the European Respiratory Society, the American Thoracic Society, and the American Association of Critical-Care Nurses, to discuss mutual goals.

And finally, the celebrations—and there were many.

We celebrated A. Jay Block, M.D., Master FCCP, and his accomplishments, as he retired as editor-in-chief of CHEST. We

praised and acknowledged renowned leaders in science and medicine through honor and memorial lectures and awards. We welcomed 137 new FCCPs into the College and a new President, W. Michael Alberts, M.D., FCCP.

And we celebrated winners—lots of them. Awards for humanitarian service, clinical research, young investigators, best posters, best case reports, CHEST Challenge, lung health walk/run winners, exhibit hall bingo winners.

Visit our Web site (www.chestnet.org, www.chestfoundation.org) to see all of these winners!

Stay tuned for CHEST 2006, Oct. 21-26, in Salt Lake City, Utah, which will take us to even greater heights.



School children take part in hands-on lung-learning experiences.



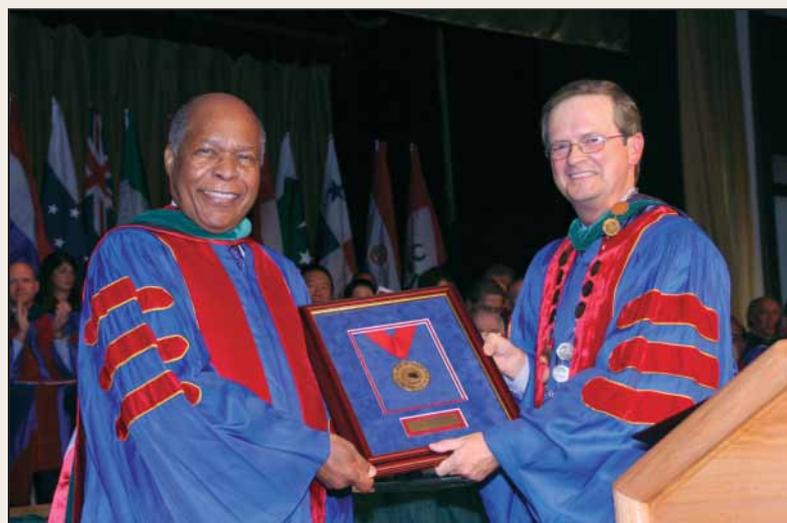
Poster and case report researchers present new results and new ideas.



Mayo Clinic President and CEO Denis A. Cortese, MD, FCCP, gives keynote.



A. Jay Block, MD, Master FCCP, accepts Soffer Award for Editorial Excellence.



Louis W. Sullivan, MD, receives an Honorary Fellow Award from Dr. Alberts.

NEWS FROM THE COLLEGE



EDUCATION INSIGHTS

The Evolution of Continuing Medical Education

BY ED DELLERT, R.N., M.B.A.
ACCP Vice President, Educational Resources

Most physicians in the United States think of continuing medical education as those activities they attend weekly in their local medical community and, occasionally, at some national meetings.

Often, these educational activities center around lecture-based teaching, as most physicians are accustomed to this teaching methodology.

Today, however, we are in an environment of increasing amounts of information, and it comes to us in many forms. Technology is one of the key drivers behind this increase, yet most knowledge-transfer in medicine still relies upon lectures and medical journals. Although these two learning methodologies do provide learning opportunities, they do

not necessarily address physicians' need to manage information and determine different methodologies' impact on physician behavior change.

A study by Geoff Norman, Ph.D., of the McMaster University psychology department, indicated that physician learning strategies must include a structured practice audit, the use of simulation exercises with standardized patients, and patient and colleague feedback. Moving physicians toward these types of learning strategies is challenging, as evidenced by Dr. Jeremy Grimshaw and colleagues of the Ottawa Health Research Institute, who noted that most physicians currently spend less than 1 hour per week updating their knowledge base.

The overwhelming denominator is time. Continuing medical education, however, must evolve as physicians'

needs are changing. An increased emphasis upon outcomes, certification and recertification requirements, accreditation and licensure scrutiny, and validation of educational learning experiences are driving the change in physician needs.

Professional societies will be instrumental in helping their physician members better understand and prioritize this learning evolution in continuing medical education. Specifically, physicians will want to know how best to meet the increasing demands being placed upon them in the most efficient way possible.

As a result, physicians will need to be provided useful tools that will enable them to be more comfortable with different learning methodologies that are more focused upon self-assessment, personal techniques of reflective learning, outcomes analysis,

root-cause analysis, and other areas.

Reform for continuing medical education is inevitable. This evolution stems from multiple sources, with a focus upon patient safety, competency, lifelong learning needs, and physician behavior change.

I would encourage that this evolution be seen not as a complexity in one's career, but as one that takes the desire to obtain the latest information and knowledge to increase the quality of health care for patients, who are looking to the medical community to serve their needs.

References

- Norman GR, Shannon SI, Marrin LM. *BMJ* 2004; 328:999-1001
- Grimshaw JM, Eccles MP, Walker AE, et al. *J Contin Educ Health Prof* 2002; 22:237-243

The ACCP Institutes

The ACCP Institutes are centers of excellence created to provide an opportunity for the ACCP to focus the combined resources of current ACCP professional resources, The CHEST Foundation, other societies, patient advocacy groups, and industry representatives. The Institutes will develop new educational and research activities for our members and all health care professionals who are committed to excellence in critical care and sleep medicine.

As a valued member of the ACCP, you benefit from all the Institutes' newly developed professional resources. Visit the Institutes' Web site at www.chestnet.org/institutes.

At CHEST 2005 in Montreal, the Institutes again proved successful in continuing to communicate their vision, mission, and project goals to ACCP membership.

The Sleep Institute

The Sleep Institute and its industry partners are beginning discussions with the American Academy of Family Practice regarding plans to collaborate on taking sleep education directly into the primary care community.

The Sleep Institute recognizes the challenge presented by providing proper diagnosis and management of patients with sleep disorders. In the 2005 National Sleep Foundation's Sleep in America poll, the percentage of Americans at risk for a sleep disorder was

estimated at 34%. Nearly 70% of respondents also indicated that their physician had never asked them about sleep as a health issue. These results bring to

light both an unmet educational need and a significant risk to patients' health.

The ACCP-SI and its collaborators will participate in an exciting educational opportunity to bridge the knowledge gap and improve diagnosis, treatment, and patient compliance. Programs will be held in regional sleep centers and incorporate content developed by an expert panel of sleep specialists. Content will be developed and focus groups will meet during the first quarter of 2006.

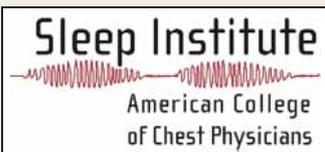
The Critical Care Institute

The Critical Care Institute is proud to announce that Eli Lilly has been named as a founding sponsor, and we look forward to working together on projects that promote excellence in the care of the critically ill. One project in development is an interdisciplinary

pain management workshop with practical tools physicians and nurses can utilize at the ICU bedside. ACCP-CCI's founding partner, the American Association of Critical-Care Nurses, in conjunction with the ACCP-CCI



steering committee, is currently reviewing pain literature and has planned a workshop preparation session during the spring 2006 ACCP Board of Regents meeting. In addition, the ACCP Continuing Education Committee has asked the CCI steering committee to develop main topic areas for its critical care core curriculum. The core curriculum topics will be used as a guide for submission to the *CHEST* journal and *CHEST PHYSICIAN*.



The ACCP Practice Management Department Is Working for You

Take advantage of Practice Management Department (PMD) resources to run a more efficient practice. Purchase the expanded and reorganized 10th edition of *Appropriate Coding for Critical Care Services and Pulmonary Medicine, 2006*.

Recently, several ACCP members contacted the PMD for help with Medicare documentation audits of their evaluation and management services, particularly critical care CPT 99291 and 99292. Despite very long documentation (4-5 pages!), basic information was missed, such as noting total time spent for these time-based codes. In addition, document why and how the patient is critically ill. For example,

document not only what you are doing, but describe all the organ systems failing or at risk, not just respiratory failure. Appropriate ICD-9-CM diagnostic coding with your CPT 99291 supports the medical necessity of the visit.

Coding Changes

Some new ICD-9-CM codes that became effective on October 1, 2005, are: new sleep codes, 327.00-327.8; a new code, V46.13, encounter for weaning from respirator (ventilator); and a new code, 799.02, for hypoxemia.

Relevant CPT changes include the deletion, effective Jan. 1, 2006, of inpatient consultation codes 99261-99263

and confirmatory consultation codes 99271-99275. In addition, Nursing Facility Care codes for new or established patients have been deleted and replaced by CPT 99304-99310.

For the American Medical Association CPT and RVS Specialty Society Update Committee (RUC), ACCP has very active advisors. Steve Peters, MD, FCCP, is the CPT Advisor, and Edward Diamond, MD, FCCP, is the RUC Advisor. Scott Manaker, MD, FCCP, is a RUC member. Diane Krier-Morrow, MBA, MPH, CCS-P, staffs their efforts for CPT in collaboration with the American Thoracic Society Advisors: Stephen Hoffmann, MD, FCCP, for CPT and

Alan Plummer, MD, FCCP, for ATS.

ACCP hosted a meeting of pulmonary, critical care, and sleep Contractor (Carrier) Advisory Committee (CAC) representatives to state Medicare contractors (formerly called carriers) at CHEST 2005. ACCP is still trying to identify all the CAC representatives and is missing several states. We are beginning quarterly conference calls in January and April. If you fulfill this role for your state and have not been contacted by us, please let us know.

For any coding and reimbursement or practice management issues, contact Marla Brichta, ACCP, at (847) 498-8364 or mbrichta@chestnet.org.

The ACCP and The CHEST Foundation Respond to Hurricane Disasters

ACCP members have responded generously to The CHEST Foundation's Beyond the First Response Matching Gift Fund.

The proceeds of the fund will be used to create a special 2006 Humanitarian Awards Program to support patient-care projects by members most affected by hurricanes Katrina, Rita, and Wilma.

ACCP Members and Friends Donate More Than \$26,000, to Date

ACCP members have responded generously to The CHEST Foundation's



Beyond the First Response Matching Gift Fund.

The ACCP is providing \$25,000 to seed the fund, and The CHEST Foundation will match all donations, dollar for dollar, up to a total of \$100,000.

ACCP members and friends have donated more than \$26,000, to date.

Linking Physicians and Positions

An important component of the ACCP's Beyond the First Response program is to provide an opportunity for members and other health-care professionals impacted by the hurricanes to find new positions.

Many professionals currently displaced from their homes, practices, and hospitals are looking for positions on an interim or permanent basis.

HEALTHeCAREERS, the ACCP's partner and technology foundation for the ACCP online job board, Career Connection, has developed a Web site to help match physicians with positions.

This site also provides an opportunity for those who have created

temporary positions, specifically for health-care professionals displaced by Hurricane Katrina, to post their positions at no charge.

Volunteer positions may be posted under HEALTHeCAREERS Network's new, permanent, volunteer category.

Employers who have permanent, full-time, paid positions are encouraged to continue to post them to the HEALTHeCAREERS or the ACCP Career Connection site.

This service is available for physicians, nurses, and administration staff positions.

The CHEST journal continues to offer free classified print ads for those seeking positions. For more information, visit the HEALTHeCAREERS Web site at www.healthcareers.com/katrina.

Extending ACCP Membership and CHEST Subscriptions

Many members in the Gulf Coast area have been significantly impacted by the hurricanes.

To help during this difficult time, all ACCP membership renewals and CHEST subscriptions in Louisiana, Mississippi, and Alabama have automatically been extended 12 months.

Helping ACCP Members to Communicate and Connect

An Internet blog has been developed to meet the needs of ACCP members who wish to rapidly and easily communicate thoughts and experiences about Hurricane Katrina, its impact, and the recovery effort.

It serves as an important communication mechanism to either post or read information about events, special announcements, or contacts. It connects those looking for information, people, or assistance with those who may be able to help.

ACCP members are encouraged to participate and alert others to the site, especially those in the affected areas.

The blog can be accessed at www.chestnet.org/patients/katrina/index.php.

Reaching Smoking and Nonsmoking Students in Montréal

The third annual college outreach prompted a lively discussion of smoking's consequences.

BY DIANE E. STOVER, M.D., FCCP
 Chair, The CHEST Foundation

The third annual college outreach of The CHEST Foundation and ACCP took place on Halloween night at Bre-Beuf College in Montréal, Quebec, during CHEST 2005.

In past years, we visited sorority women at Stetson University in Florida and the University of Washington in Seattle.

This year was a bit different, because we had a much smaller group than the 25-30 women usually present, and young men were in attendance as well.

As in the past, the discussions lasted much

longer than anticipated, and, as always, were very lively, resulting in an exchange of information that benefited both the students and those of us who attended.

We started out by discussing the Clean Indoor Air Act that Canada will put into effect this year. Two young men who smoked had very different opinions about this law.

One student felt that it greatly im-

pinged upon his rights as a citizen of Canada and that it would make outcasts of smokers.

The other young gentleman smoker felt that it was a good law, and it may help him and others to cut down on smoking.

Interestingly, one of the major reasons he wanted to cut down was not for health reasons but because of the exorbitant cost of a pack of cigarettes in Canada, which is \$8-\$12 Canadian.

We had a long discussion about social smoking, which they considered safe, since it is felt to be nonaddicting and, after all, "not really smoking."

We asked the students, "If it is not smoking, then what is it?" There were no good answers to this question from any of the students.

As we have witnessed in the past, the medical consequences of smoking are not a reality to most young people. They either think that by the time they develop ill health effects from smoking, there will be a cure, or that it just will not happen to them.

However, one young man stated that his great aunt had laryngeal cancer from smoking, and the tracheostomy

frightened him so much that it played a great role in his not smoking.

Additionally, he was an athlete and thought that smoking would impair his ability to excel in cycling.

One young woman, who only smoked socially and could not be convinced that it actually is harmful, was taken aback when told smoking causes premature wrinkling.

That, she stated, might make her think about smoking cessation, even while in clubs.

Another student was initially concerned about the health effects that smoking might have on his body.

He tried one at the age of 11 and, as he said, "nothing happened." He actually felt better, calmer, and more alert.

Then he smoked another and another, and, still, "nothing happened"; now, it is 8 years later, and he is still alive and well.

When you are 19 years old, the concept of mortality is hard to conceive.

Just as we found in our outreach university visits in the United States, young people in Canada seem to have very little concern for the medical consequences of cigarettes and the great addicting power of nicotine.

They believe strongly that, as adults, they have the right to make the decision to smoke, and nobody should try to tamper with that decision.

At the conclusion of our meeting, we asked the students if there were any last questions.

The very outspoken male smoker asked, "So, after hearing all of this,

what are you going to do about young people smoking?" We replied, "We will be persistent, aggressive, and relentless in helping young adults to make educated and informed decisions not to smoke."

I would like to thank Virginia Reichert, N.P., and Patricia Folan, B.S.N., from Northshore University Hospital; Maritza Groth, from Winthrop Hospital; and Mohit Chawla, Rohit Khirbat, and Lewis Voight, from Memorial Sloan-Kettering Cancer Center, for accompanying me.

Also, special thanks to Dr. Voight for translating during the outreach.

Cough Guidelines Debut in CHEST

"Diagnosis and Management of Cough: Evidence-Based Clinical Practice Guidelines" has been published as a supplement to the January issue of CHEST.

The guidelines include comprehensive recommendations for the diagnosis and management of cough in adults and children, specific recommendations for the prevention of whooping cough in adults, and comprehensive evidence-based recommendations for treating cough in children.

For more information or to view the Executive Summary for the guidelines, go to the ACCP Web site at www.chestnet.org.

Pulmonary Perspectives

Antibiotic Resistance Reduction: Is Prudence the Only Way To Control?

Simply cutting back may not be the right solution to slowing the microbes' adaptation.

BY GLENN S. TILLOTSON, PH.D., FCCP, AND JOY CARROLL, B.S.

It is 60 years since Sir Alexander Fleming said, "It is not difficult to make microbes resistant to penicillin in the laboratory by exposing them to concentrations not sufficient to kill them, and the same thing has occasionally happened in the body. . . . Moral: if you use penicillin, use enough" (Fleming. Nobel Lecture. 1945. <http://nobelprize.org/medicine/laureates/1945/fleming-lecture/html>).

This approach was a reiteration of Dr. Ehrlich's prescient lecture in 1913 (Ehrlich. *Lancet* 1913), and, yet, we still strive to ignore these prophecies.

Even recently, it has been shown that low doses of antibiotics, given often for long

periods, will clearly select for the weakest link in a population and lead to resistance emergence (Guillemot et al. *JAMA* 1998; 279:365).

In human medicine, 80 to 90% of antimicrobials are prescribed in the community setting, and some sources estimate that almost half are dubious in their appropriateness.

Indeed, the World Health Organization estimated that respiratory tract infections, which account for many of these prescriptions, account for over 94 disability-adjusted life years lost globally and are the fourth major cause of mortality.

Thus, many authorities espouse that the best way to stop or slow antimicrobial resistance is by using antibiotics less often.

Most experts agree that it is the widespread, poorly controlled use of these vital agents that has led us to where we are presently in the battle against microbes, a battle that the microbes are, unfortunately, winning.

Several recent publications have reported marked reductions in antibiotic use in various countries, and, yet, we seem rarely to look beyond the crude marker of phenotypic resistance reduction as a sign of a positive result. It is as though all we want to do is make resistant strains less common, without regard for the proven benefits of antimicrobial therapy.

The current fear, with regard to resistance, is that there are few signs of any new replacement antimicrobials in devel-

opment, particularly in the community setting. However, we also hear that "resistance does not lead to poorer outcomes," and several studies have used various measures to support this position.

One of the few studies to compare key, clearly measurable parameters over two time periods was undertaken in the United Kingdom, from 1993 to 1994 and 1999 to 2000—between which times major efforts were undertaken by government and other bodies to reduce the amount of antimicrobials prescribed for respiratory tract infections (Price et al. *Respir Med* 2004; 98:17).

In the United Kingdom, pneumonia is responsible for over 10% of all deaths, most of which occur in the elderly (approximately 66,000 in 1999).

Moreover, there were over 79,000 hospital admissions due to community-acquired pneumonia, leading to almost a million patient-days in the hospital.

In the United States, the case-fatality rate associated with pneumonia is 8.8%. Typically, there is seasonal variability in both the morbidity and mortality associated with pneumonia, with the highest rates occurring in the winter months.

Influenza can add to this health-care burden. Indeed, this viral infection predisposes to bacterial infections, suggesting that excess winter mortality may be susceptible to changes in antibiotic prescribing.

During the mid-1990s, United Kingdom government agencies and medical societies developed campaigns to reduce the use of antibiotics, particularly in respiratory tract infections, in the belief that this would reduce and reverse the emergence of resistance.

For the periods 1993 to 1994 and 1999 to 2000, Price and colleagues examined the winter prescribing of antibiotics for specific respiratory tract codes, according to the IMS Health United Kingdom MediPlus® database (Price et al. *Respir Med* 2004; 98:17).

In parallel, the pneumonia mortality and influenza incidences were also collected for these time spans.

Negative binomial regression analysis was used to examine changes over time for mortality and other trends. A sequential model was also used to determine whether the contribution of influenza or

antibiotic prescribing was associated with changes in pneumonia incidence.

The main observation from this analysis was a significant association between the extent of antibiotic use and winter pneumonia mortality.

Accounting for the incidence of influenza, a clear increase in deaths due to pneumonia occurred, while there was a decrease in antibiotic prescriptions written for respiratory tract infections.

There was a 50.6% increase in mortality between 1993 to 1994 and 1999 to 2000, concomitant with a 30% reduction in antibiotics prescribed over the same period. These findings were robust in the face of different analytic methods and approaches.

The authors do raise the question as to causality, due to the study design, and suggest that further studies are required to establish these findings.

They note, however, that the results have implications beyond the United Kingdom.

The myriad of programs designed to simply use fewer antibiotics need to be better assessed in terms of consequences beyond death alone. This type of analysis should be repeated in other countries where accurate health-care data are available.

Simply cutting back may not be the right solution to slowing the microbes' adaptation.

Ehrlich pointed out in 1913 that the victory against the microbes will require that we "allow therapeutic treatment to come into action as early as possible, as under these circumstances, the full success is most easily and most surely attainable" (Ehrlich. *Lancet* 1913). Ehrlich recognized the need to "frapper fort et frapper vite" (hit hard and hit quickly).

In fact, the World Health Organization recommendations support this approach, suggesting the use of the most pharmacologically potent member of the relevant class of antibiotics for a short period to treat effectively and decrease the chance of developing resistance (World Health Organization. *WHO/CDS* 2000; 2:62).

Antibiotic resistance is unlikely to be overcome by innovative research by the pharmaceutical industry, which has had only two new classes approved by the Food and Drug Administration in the last 20 years.

Moreover, of the more than 550 drugs in current development, only six are novel antibiotics.

Simply reducing the amount of antibiotics prescribed is also not the only answer. There are clearly deleterious consequences beyond excess mortality.

Measurement of death is a blunt parameter, because there are many other, perhaps more relevant and quantifiable, outcomes, but too often they are in someone else's silo of responsibility.

With today's computerized health-care record systems, there must be better ways to assess the implications, positive and negative, of merely decreasing antibiotic use.

Perhaps now is the time to alter how we use these drugs, not just simply use less of them.

The application of Ehrlich's century-old ideas, along with modern pharmacodynamics, may help maintain what we currently have, while we await new antimicrobials from industry and other responsible groups. ■

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Editor's Insight

This thoughtful Perspective by authors with both academic and industry experience presents an important concept for our consideration in the difficult issue of antimicrobial resistance.

The bottom line to consider is that we need to use the most active drug in sufficient dosage as early as possible to both treat effectively and reduce resistance.

This advice may be counter to the common view that it is more cost effective to use less expensive antibiotics first and save the more powerful ones for more serious disease.

The data and ideas presented here give us reason to reconsider.

As the authors point out, more studies to determine the best approach are needed, and such studies need to consider both resistance and effective treatment.

Deborah Shure, MD, Master FCCP

Inside NetWorks: From Pandemic Flu to Simulation Education

Affiliate NetWork

The Affiliate NetWork has just completed another very successful year, providing educational and leadership opportunities for its members.

CHEST 2005 provided a highlight for the year's activities. A record number of 300 case reports were submitted by Affiliate NetWork members. Of these, 144 were selected by the Steering Committee for presentation. We would like to thank every member who presented and congratulate those 24 members selected as finalists.

The finals for CHEST Challenge 2005, the Jeopardy-style competition, were held Wednesday evening, November 2, in conjunction with a special awards reception. Play-off contestants included Affiliate members representing the following locations: Coney Island Hospital, Brooklyn, NY; Georgetown University, Washington, DC; Medical University of Ohio at Toledo; New York University/Bellevue Hospital Center, New York, NY; University of California, Davis, Sacra-

mento; University of Iowa, Iowa City; University of Manitoba, Winnipeg, Canada; University of Missouri-Kansas City; and the University of Texas Health Science Center, San Antonio. This year's finalists (University of California, University of Texas Health Science Center, and Coney Island Hospital) participated in an excellent final round, with the University of California rising to the top of the competition.

Airways Disorders NetWork

The Airways NetWork had a most well-attended and vigorous NetWork meeting at CHEST 2005. Complementing the thought-provoking presentation by Alan Fein, M.D., FCCP, on the diverse causes of COPD were the many ideas for CHEST 2006 topics.

The NetWork redefined its role to one of integrating efforts in asthma, COPD, and bronchiectasis/cystic fibrosis (CF). Each area has a subcommittee. For example, the asthma subcommittee's involvement includes developing CHEST

2006 topics and partnering with other NetWorks. This subcommittee also will focus on asthma research awards, development of an Internet catalog of asthma resources, integration with the National Asthma Education and Prevention Program (sponsored by the National Heart, Lung, and Blood Institute), planning for the triennial World Asthma Meeting (to be held in 2007), and assisting with the ACCP Health and Science Policy Committee's development of the occupational asthma clinical practice guideline.

More enthusiasts in these multidimensional areas are welcome.

Cardiovascular Medicine and Surgery NetWork

The Cardiovascular Medicine and Surgery NetWork, formerly the Cardiovascular Disease and Hypertension NetWork, would like to announce its new name and more-encompassing constituency.

This important name change is meant to increase diversity among our membership and improve the communication between cardiac physicians and cardiovascular surgeons. This change will also facilitate joint programming and more broadly appealing topics at future CHEST meetings.

We have also been working on a consensus statement project, called the Evaluation of Secondary Hypertension, which was recently approved by the Council

of Committees. A small NetWork work group is currently writing this statement.

To learn more about this project, please contact us at networks@chestnet.org or visit our Web site at www.chestnet.org/networks/cdh/index.php.

We discussed several new projects for the upcoming year at our CHEST 2005 business meeting, and we are excited to get started and to share these ideas with you. If you are interested in joining our NetWork, becoming more involved, or simply hearing about what's next, please contact us at networks@chestnet.org.

Chest Infections NetWork

Whether the next pandemic is 2 years or 20 years away, now is a good opportunity to examine the readiness of your health-care organization to deal with the situation. We can expect the following small but eye-opening list of problems:

► **Patient volume.** Where will we care for overflow patients? The po-

tential magnitude of this problem needs further consideration and preparation.

► **Ventilators.** A major pandemic could result in an 8-fold to 10-fold increase in your hospital's incidence of respiratory failure for a sustained period. Rental ventilators will quickly become unavailable.

► **Barrier precautions.** The available supply of masks, gloves, and gowns will likely be consumed early on.

► **Support staff.** A large percentage of your support staff will either be ill themselves or at home caring for sick family members, or will refuse to work out of fear of becoming ill. How will the remaining staff be screened to make sure that those who are contagious do not work?

The Centers for Disease Control and Prevention Web site (www.cdc.gov) features more on the infrastructure and procedural difficulties likely during the next influenza pandemic.

Critical Care NetWork

Your patient develops anaphylactic shock right before your eyes. You struggle to intubate her, but the airway edema is too severe to visualize her vocal cords. She arrests, and you begin CPR.

Critical care is a hands-on specialty.

Gaining practical experience in critical care medicine and maintaining a broad range of skills can be challenging because of the high-risk, high-stakes nature of the specialty and its patient population.

Simulation-based education has been employed in other high-risk professions for decades, and, in recent years, has generated significant interest in the medical community.

The development of high-fidelity patient simulators has provided a new opportunity to provide effective, experience-based medical education and performance improvement without jeopardizing patient safety.

The role of medical simulation in critical care education was a major topic of discussion at the CHEST 2005 Critical Care NetWork meeting.

The complex and procedure-based nature of critical care medicine makes it an ideal area for skills enhancement using simulation scenarios.

The NetWork voted unanimously to form a working group to examine ways to provide ACCP members with more simulation-based, critical care training opportunities.

If you are interested in joining this simulation working group, contact Jennifer Pitts at jpitts@chestnet.org. ■

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SIMULATION SCENARIOS.**

Implanted Device Improved Heart Failure Management

BY MITCHEL L. ZOLER
Elsevier Global Medical News

DALLAS — Management of heart failure patients with data from an implanted device that continuously monitors hemodynamic pressures led to a 25% reduction in total days spent in the hospital among patients with class III heart failure in a controlled study with more than 200 patients.

“The number of days spent in the hospital for decompensated heart failure is the principal driver of cost for heart failure treatment, and this was significantly decreased,” Dr. William T. Abraham said at the annual scientific sessions of the American Heart Association.

Use of the device in both outpatients and in hospitalized patients with heart failure “may make episodes of decompensation less extreme, and may help get patients out of the hospital more quickly,” said Dr. Abraham, professor and director of the division of cardiovascular medicine at Ohio State University in Columbus.

The finding came from new analyses of data collected in the Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure (COMPASS-HF) trial, which tested the clinical impact of managing patients with

intracardiac pressure data collected by the implanted Chronicle device. The device is made by Medtronic, which submitted an application for licensing to the Food and Drug Administration last August that was still pending in January.

The primary end point of the COMPASS-HF was reported last March at the annual meeting of the American College of Cardiology. Although patient management guided by pressure data obtained by the Chronicle device led to a 22% cut in the rate of heart failure-related hospitalizations and emergency department and urgent-care visits, the drop was not statistically significant. However, several secondary analyses also were positive in favor of the device, including a new set of secondary analyses presented by Dr. Abraham, who is a consultant and investigator for Medtronic and has received honoraria from the company for speaking.

He cautioned that the COMPASS-HF study was not designed to provide definitive answers to these secondary analyses, and therefore the findings must be considered exploratory.

In addition, researchers at Medtronic have revised the results presented by Dr. Abraham based on more complete patient follow-up. The revised data showed

that use of data from the Chronicle device cut the number of hospitalized days for heart failure by 20% instead of the 25% difference reported by Dr. Abraham.

In the COMPASS-HF study a total of 274 patients with advanced-stage heart failure underwent surgery to receive the subcutaneously implanted, hemodynamic monitoring device. The intracardiac pressure information collected by the device was used by physicians to guide the management of 134 patients for 6 months. The pressure information was withheld from the treating physicians in the control group of 140 patients. All patients in the study also received optimal medical care based on clinical findings. The benefits of applying information collected by the Chronicle device were greatest in the 85% of patients who entered the study with New York Heart Association class III disease. Those with class IV disease had much less benefit.

The reduction in hospitalized days using data collected by the implanted device was more marked if the analysis excluded outlier patients with hospitalizations that extended beyond 30 days. With this ex-

clusion, use of the Chronicle data cut the total number of hospitalized days by 42% for all patients in the study, and by 38% in the class III-only patients.

Another secondary analysis examined the impact of using data from the Chronicle device on the rate of prolonged or short hospitalizations for heart failure. Among the class III-only patients, use of Chronicle information was associated with an average rate of 0.19 long hospitalizations (more than 5 days) every 6 months, compared with a rate of 0.31 long hospitalizations every 6 months in the control group, a 40% decrease in favor of the device. Use of the device also was associated with a 0.28 rate of short hospitalizations (5 days or less) every 6 months, compared with a rate of 0.42 short hospitalizations every 6 months in the control group.

Some experts expressed concern about paying for this intensive approach to patient management. “How should we decide which patients should get this?” commented Dr. Harlan M. Krumholz, professor of medicine and epidemiology at Yale University, New Haven, Conn. ■

Automated System Monitors Intracardiac Pressures

BY MITCHEL L. ZOLER
Elsevier Global Medical News

DALLAS — An automated system may be able to monitor intracardiac pressures and alert physicians when the pattern suggests impending decompensation, based on a pilot analysis of data collected on 95 acute heart failure events.

The system continuously scans data and notifies the physician when pressures change meaningfully, Dr. Philip B. Adamson said at the annual scientific sessions of the American Heart Association.

The scanning system developed by Dr. Adamson and his associates monitors changes in intracardiac pressures measured by the implanted Chronicle device, which is made by Medtronic Inc. and is under review by the Food and Drug Administration. Dr. Adamson has served as a consultant to Medtronic.

“The key to using this data is to learn the right pressure for each patient,” said Dr. Adamson, director of the Heart Failure Institute at the Oklahoma Heart Hospital, Oklahoma City.

The device was tested on 274 patients with advanced heart failure in the Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure (COMPASS-HF) trial.

Intracardiac pressure data collected by the device were used by physicians to

manage 134 patients. The collected data were not used to manage 140 controls.

Data collected for 56 of the control patients were used in Dr. Adamson’s analysis. These patients had a total of 95 episodes of acute decompensation that resulted in either a hospital admission or treatment in an emergency department or urgent-care clinic.

The automated monitoring focused on estimated pulmonary-artery diastolic pressure. A rule about changes in this pressure

was devised using data gathered before 42 of the 95 events.

The pattern was that events usually occurred about 2 weeks after a significant rise in pulmonary-artery diastolic pressure, said Dr. Adamson. This

criterion identified 35 (83%) of the 42 events.

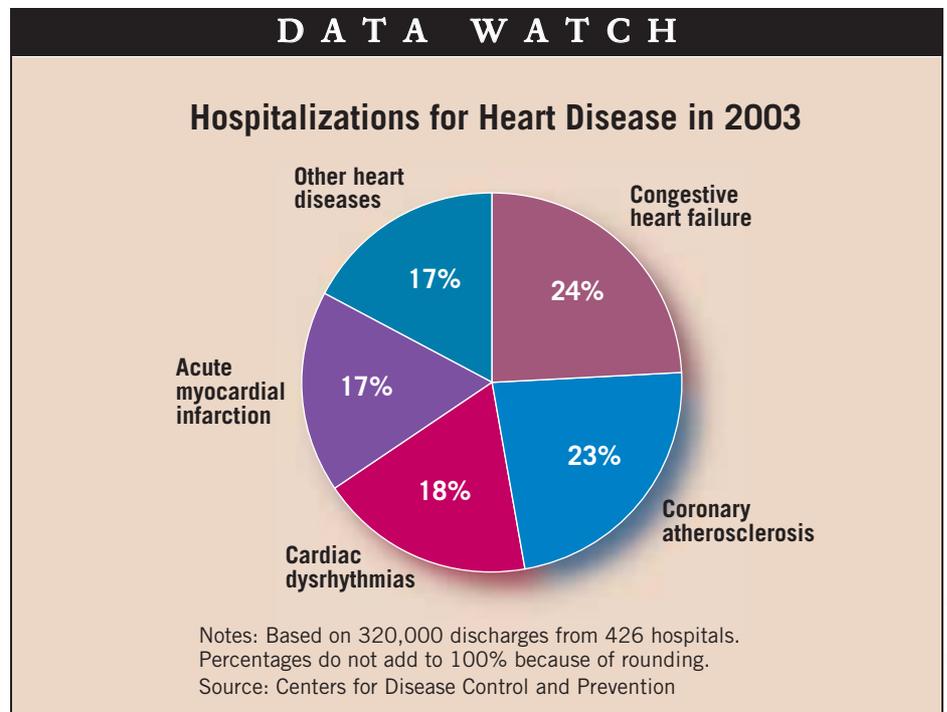
This criterion was then applied on a test basis to the remaining 53 clinical events used in the analysis.

A 7-day average of prior pulmonary-artery diastolic pressures was calculated for each patient every day, and this reference value was applied to each day’s new pressure readings.

Small changes in pulmonary-artery pressure over a long period, or large changes over a short period, were considered flags of an impending event.

Use of this method identified 43 (81%) of the 53 heart failure events included in the test. ■

SMALL CHANGES IN PULMONARY-ARTERY PRESSURE OVER A LONG PERIOD, OR LARGE CHANGES OVER A SHORT PERIOD, WERE FLAGS OF AN IMPENDING EVENT.



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Sleep Center Success Doesn't Happen Overnight

From infrastructure needs to regulatory requirements, a well-run program requires savvy planning.

BY BRUCE K. DIXON
Elsevier Global Medical News

MONTREAL — The field of sleep medicine may be awake with clinical promise, but chest medicine specialists must be alert to the challenging operational demands of running a sleep center, a panel of experts cautioned at the annual meeting of the American College of Chest Physicians.

"The industry revenue forecast is good," said Dr. Richard K. Bogan, FCCP, chairman and chief medical officer of SleepMed Inc. in Columbia, S.C. "The total business—equipment, therapy services, and sleep studies—is a \$1.6 billion industry, and we're seeing tremendous growth in sleep diagnostics."

For hospital sleep labs, the market is only 51% saturated. That leaves plenty of capacity for growth, he said, with referrals coming from pulmonary, family practice, and ear, nose, and throat physicians, as well as from neurologists and cardiologists.

Then there's all that snoring out there.

Depending on age, 20%-40% of adults and 13% of children snore, Dr. Bogan said. Insomnia is a problem with 10% of patients in a primary care practice, and about 3% have restless legs syndrome.

About half of patients present for fatigue, so the primary care physicians try to figure out which ones need to be evaluated. The problem—and opportunity—does not end there, said Dr. Bogan.

More than 90% of patients with mood disorders have some sort of sleep complaint, for example. "If you take patients with refractory depression, 40% may have sleep-disordered breathing," he explained, "and until you correct their sleep abnormality, their mood disorder is not going to significantly improve."

Planning for Success

A successful sleep laboratory starts with a successful business model.

"Develop your business plan, make the process as efficient as you possibly can, look at your market area, and don't hesitate to negotiate reimbursements with third-party payers," Dr. Bogan said.

"Don't just take what they give you, but rather, talk to them and show them the quality of your product, keeping in mind that Medicare reimbursement is more restrictive."

Referrals, added Dr. Bogan, are a major part of the successful business model.

Referrals don't come just because of sleep-disordered breathing—only about 5% of people visit their primary care or other referring physicians to discuss a sleep problem. They come because of fatigue, sleepiness, and mood changes, he explained.

"All these referring physicians have different reasons for sending patients, and you have to be aware of that in terms of your ability to network with those doctors to get these patients in for evaluation," Dr. Bogan said.

The Well-Equipped Center

Adept handling of infrastructure issues will also drive a sleep center's success, said Andrew DesRosiers, director of the sleep disorders center at Caritas Holy Family Hospital and Medical Center in Methuen, Mass.

For example, Mr. DesRosiers said, the American Academy of Sleep Medicine (AASM) gives better scores for accreditation if sleep rooms are greater than 140 square feet and takes away points if they're less than 100 square feet.

"AASM likes them to be dedicated rooms, but they also can be used for office visits, which is desirable with reimbursement rates going down," he said.

His seven-room facility uses Murphy beds. "When a room is vacant, we can fold up the bed and use the space for other services," said Mr. DesRosiers, who is chairman of the American College of Chest Physicians Allied Health Network.

The sleep rooms contain such essentials as a continuous positive airway pressure (CPAP) unit, blood pressure cuff, and ear, nose, and throat exam tools. A pulmonary function test machine, and even an echocardiography machine if you're with a cardiology practice, can be rolled in and out of the sleep rooms.

The rooms have to be sleep friendly, added Mr. DesRosiers. Light fixtures should be on dimmers and located away from beds, and patients are isolated so they can't hear one another snore.

His center moved the beds to insulated outer walls. Air vents were constructed of corrugated HVAC tubing to reduce noise and were moved away from beds. The center used little night lights, available at Home Depot for \$2, said Mr. DesRosiers. The old-style cameras that rotated on noisy mechanisms were replaced with smaller, inconspicuous cameras hidden in a Plexiglass ceiling bubble.

Sleep Medicine's 'Nightmares'

Even those with sound business plans and effective infrastructure will wrestle with what Dr. Steven H. Feinsilver, FCCP, calls "the nightmares" of sleep medicine: malpractice, licensure requirements, and worries about technicians and patients.

Liability does not require direct contact between the patient and the physician. "The four basic elements of malpractice

under tort law are: duty—you have to have some sort of patient-physician relationship, but that doesn't mean you ever met the patient; there has to be something you did wrong; there has to be some causation; and there has to be damage," said Dr. Feinsilver, a pulmonologist at the State University of New York at Stony Brook.

Sleep medicine centers face other legal and regulatory challenges. AASM accreditation, for example, requires that each report include a "treatment requirement," Dr. Feinsilver said.

"I think that's absolutely wrong, and I would like to suggest that you not be in the habit of making treatment recommendations as part of your reports," he cautioned.

Always remember that you as the director are responsible for patients, Dr. Feinsilver said. Know who is coming into your lab, get at least some basic information before the patient arrives, and decide what kind of test you'll need to run, Dr. Feinsilver said. These basic steps are required for accreditation, he added.

Of Licenses and Reporting

Lab directors also have to worry about sleep technologist licensure, Dr. Feinsilver said.

"Some states require that your sleep techs be respiratory therapists, or that you have an RT on staff," he explained. "Also, sleep techs are not considered health care professionals, and they are not required by the AASM to be licensed or certified to accredit your lab."

To complicate matters further, he said, all sleepy drivers and pilots must be reported to the proper licensing bureaus, "which can be a disaster," Dr. Feinsilver said. When there's no obligation to report, do not do so without the patient's permission, he said, adding that a breach of medical confidentiality is allowable if it protects others from harm.

That can mean trouble, Dr. Feinsilver admitted. Fortunately, the American Thoracic Society stated in 1994 that physicians should report sleepy drivers if the patient is sleepy, has sleep apnea, and a history of an accident or an equivalent level of clinical concern, and if the physician can't treat the patient within 2 months, he explained.

The Shape of Sleep to Come

Legal and reimbursement issues aside, the field of sleep medicine will survive, according to Dr. Charles W. Atwood Jr., FCCP.

The typical sleep lab of the future will be larger, and it will become a volume business, said Dr. Atwood, who is associate director of the University of Pittsburgh Sleep Medicine Center.

"I think, interestingly, that insomnia will replace sleep apnea as the most common disorder sleep doctors deal with, and this will result in new models of care for this disorder," he predicted.

Dr. Atwood also predicted that primary care doctors will play a much larger role in sleep diagnostics—but will refer most cases for management. "We will look back at how we used to be paranoid about primary care 'taking over sleep' and laugh," he concluded. ■

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Congress Delays Solution

Medicare • from page 1

conference report, and the bill had to go back to the House for final approval.

"We got coal in our Christmas stocking," not a positive update or a permanent fix to the formula's sustainable growth rate, Dr. Larry Fields, president of the American Academy of Family Physicians, said in an interview. "Instead of electing to let [House] leaders hash it out and then let the bill go through, Rep. Nancy Pelosi [D-Calif.] demanded a roll call vote—which cannot be taken into consideration until Jan. 31, when Congress returns."

With no legislation passed by both houses and signed by the president, the Centers for Medicare and Medicaid Services is bound by law to put the cuts into place, he added.

The hope is that Congress will wrap up its unfinished work on the omnibus appropriations bill by the end of January. Once the bill is signed, CMS would be required by law not to impose the cut.

"Patients and physicians will not un-

THE HOPE IS THAT CONGRESS WILL WRAP UP ITS UNFINISHED WORK BY THE END OF JANUARY AND REQUIRE CMS BY LAW NOT TO IMPOSE THE CUT.

derstand why technicalities and politics are delaying congressional action to halt devastating Medicare cuts," said Dr. C. Anderson Hedberg, president of the American College of Physicians.

"We call on Congress and CMS to do whatever is necessary to stop the cuts," he added. "Both the House and Senate have agreed the cuts should be halted, and we appreciate their good intentions. Yet we are faced with uncertainty and confusion, instead of the decisive action in Washington that our patients require."

Physicians cannot continue on the current path of being paid less than the cost of providing care without serious consequences for patients, Dr. J. Edward Hill, president of the American Medical Association, said in a statement.

"It is our hope that Congress will immediately take up this issue ... to halt the payment cuts and retroactively adjust payments," he said.

In the meantime, the AMA will continue to advocate for a fair physician payment formula based on practice costs, "as well as continue to advocate for sound quality improvement initiatives."

The sustainable growth rate (SGR) is what's driving the cut in Medicare physician pay. It's a component in the Medicare payment formula that determines the con-

version factor update each year. Errors made to the formula in 1998 and 1999 led to a 5.4% decrease in physician payments in 2002—decreases that will continue unless the payment formula is corrected. Short-term laws enacted by Congress since that time have provided small increases in pay.

The SGR is determined by several factors, including the projected increase in the gross domestic product; in essence, it ties medical spending to the ups and

downs of the national economy.

A national AMA survey found that 38% of physicians would be forced to limit the number of new Medicare patients they accept into their practice when the cut begins. Of those physicians who will continue to treat Medicare patients, 61% told the AMA they planned to defer purchase of new medical equipment, and 54% said they would defer purchase of information technology.

A freeze represents a slight loss to physicians because of inflation, "but certainly, it's better than a 4.4% cut," Dr. Fields said.

Congress should also work to restore money that would be lost by having a

month of reductions, Dr. Fields added.

There's always the slight possibility that they won't act at all, he said. However, he was confident that Congress would solve the SGR problem in the coming year, "so physicians won't have to face future cuts."

Dr. Alberts asked that each member of the American College of Chest Physicians, along with their physician colleagues, e-mail his or her congressional representatives expressing strong opposition to the use of the SGR to establish Medicare reimbursement rates.

Physicians can access the ACCP Web site at www.chestnet.org to contact their representatives. ■



The following is a brief summary. Please consult complete prescribing information.

CONTRAINDICATIONS: MAXIPIME is contraindicated in patients who have shown immediate hypersensitivity reactions to cefepime or the cephalosporin class of antibiotics, penicillins or other beta-lactam antibiotics.
WARNINGS: BEFORE THERAPY WITH MAXIPIME (CEFEPIME HYDROCHLORIDE) FOR INJECTION IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS IMMEDIATE HYPERSENSITIVITY REACTIONS TO CEFEPIME, CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. IF THIS PRODUCT IS TO BE GIVEN TO PENICILLIN-SENSITIVE PATIENTS, CAUTION SHOULD BE EXERCISED BECAUSE CROSS-HYPERSENSITIVITY AMONG BETA-LACTAM ANTIBIOTICS HAS BEEN CLEARLY DOCUMENTED AND MAY OCCUR IN UP TO 10% OF PATIENTS WITH A HISTORY OF PENICILLIN ALLERGY. IF AN ALLERGIC REACTION TO MAXIPIME OCCURS, DISCONTINUE THE DRUG. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE AND OTHER EMERGENCY MEASURES INCLUDING OXYGEN, CORTICOSTEROIDS, INTRAVENOUS FLUIDS, INTRAVENOUS ANTIHISTAMINES, PRESSOR AMINES, AND AIRWAY MANAGEMENT, AS CLINICALLY INDICATED.

In patients with impaired renal function (creatinine clearance ≤ 60 mL/min), the dose of MAXIPIME should be adjusted to compensate for the slower rate of renal elimination. Because high and prolonged serum antibiotic concentrations can occur from usual dosages in patients with renal insufficiency or other conditions that may compromise renal function, the maintenance dosage should be reduced when cefepime is administered to such patients. Continued dosage should be determined by degree of renal impairment, severity of infection, and susceptibility of the causative organisms. (See specific recommendations for dosing adjustment in **DOSAGE AND ADMINISTRATION** section of the complete prescribing information.) During postmarketing surveillance, encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor, and coma), myoclonus, and seizures (see **ADVERSE REACTIONS: Postmarketing Experience**). Most cases occurred in patients with renal impairment who received doses of cefepime that exceeded the recommended dosage schedules. However, some cases of encephalopathy occurred in patients receiving a dosage adjustment for their renal function. In general, symptoms of neurotoxicity resolved after discontinuation of cefepime and/or after hemodialysis.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including MAXIPIME, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents. Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is a primary cause of "antibiotic-associated colitis". After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate-to-severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium difficile* colitis.

PRECAUTIONS: General: Prescribing MAXIPIME in the absence of proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. As with other antimicrobials, prolonged use of MAXIPIME may result in overgrowth of nonsusceptible microorganisms. Repeated evaluation of the patient's condition is essential. Should superinfection occur during therapy, appropriate measures should be taken. Many cephalosporins, including cefepime, have been associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy. Prothrombin time should be monitored in patients at risk, and exogenous vitamin K administered as indicated. Positive direct Coombs' tests have been reported during treatment with MAXIPIME. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug. MAXIPIME should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis. Arginine has been shown to alter glucose metabolism and elevate serum potassium transiently when administered at 33 times the amount provided by the maximum recommended human dose of MAXIPIME. The effect of lower doses is not presently known.

Information for Patients: Patients should be counseled that antibacterial drugs including MAXIPIME should only be used to treat bacterial infections. They do not treat viral infections (eg, the common cold). When MAXIPIME is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by MAXIPIME or other antibacterial drugs in the future.

Drug Interactions: Renal function should be monitored carefully if high doses of aminoglycosides are to be administered with MAXIPIME because of the increased potential of nephrotoxicity and ototoxicity of aminoglycoside antibiotics. Nephrotoxicity has been reported following concomitant administration of other cephalosporins with potent diuretics such as furosemide. **Drug/Laboratory Test Interactions:** The administration of cefepime may result in a false-positive reaction for glucose in the urine when using Clinistix® tablets. It is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix®) be used.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: No long-term animal carcinogenicity studies have been conducted with cefepime. A battery of *in vivo* and *in vitro* genetic toxicity tests, including the Ames Salmonella reverse mutation assay, CHO/HGPRT mammalian cell forward gene mutation assay, chromosomal aberration and sister chromatid exchange assays in human lymphocytes, CHO fibroblast clastogenesis assay, and cytogenetic and micronucleus assays in mice were conducted. The overall conclusion of these tests indicated no definitive evidence of genotoxic potential. No untoward effects on fertility or reproduction have been observed in rats, mice, and rabbits when cefepime is administered subcutaneously at 1 to 4 times the recommended maximum human dose calculated on a mg/m² basis. **Use in Pregnancy—Teratogenic effects—Pregnancy Category B:** Cefepime was not teratogenic or embryocidal when administered during the period of organogenesis to rats at doses up to 1000 mg/kg/day (4 times the recommended maximum human dose calculated on a mg/m² basis) or to mice at doses up to 1200 mg/kg (2 times the recommended maximum human dose calculated on a mg/m² basis) or to rabbits at a dose level of 100 mg/kg (approximately equal to the recommended maximum human dose calculated on a mg/m² basis). There are, however, no adequate and well-controlled studies of cefepime use in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. **Nursing Mothers:** Cefepime is excreted in human breast milk in very low concentrations (0.5 µg/mL). Caution should be exercised when cefepime is administered to a nursing woman. **Labor and Delivery:** Cefepime has not been studied for use during labor and delivery. Treatment should only be given if clearly indicated. **Pediatric Use:** The safety and effectiveness of cefepime in the treatment of uncomplicated and complicated urinary tract infections (including pyelonephritis), uncomplicated skin and skin structure infections, pneumonia, and as empiric therapy for febrile neutropenic patients have been established in the age groups 2 months up to 16 years. Use of

MAXIPIME (cefepime hydrochloride) in these age groups is supported by evidence from adequate and well-controlled studies of cefepime in adults with additional pharmacokinetic and safety data from pediatric trials (see **CLINICAL PHARMACOLOGY** section of the complete prescribing information). Safety and effectiveness in pediatric patients below the age of 2 months have not been established. There are insufficient clinical data to support the use of MAXIPIME in pediatric patients under 2 months of age or for the treatment of serious infections in the pediatric population where the suspected or proven pathogen is *Haemophilus influenzae* type b. IN THOSE PATIENTS IN WHOM MENINGEAL SEEDING FROM A DISTANT INFECTION SITE OR IN WHOM MENINGITIS IS SUSPECTED OR DOCUMENTED, AN ALTERNATE AGENT WITH DEMONSTRATED CLINICAL EFFICACY IN THIS SETTING SHOULD BE USED. **Geriatric Use:** Of the more than 6400 adults treated with MAXIPIME in clinical studies, 35% were 65 years or older while 16% were 75 years or older. When geriatric patients received the usual recommended adult dose, clinical efficacy and safety were comparable to clinical efficacy and safety in nongeriatric adult patients. Serious adverse events have occurred in geriatric patients with renal insufficiency given unadjusted doses of cefepime, including life-threatening or fatal occurrences of the following: encephalopathy, myoclonus, and seizures. (See **WARNINGS AND ADVERSE REACTIONS** sections of the complete prescribing information.) This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and renal function should be monitored. (See **CLINICAL PHARMACOLOGY: Special Populations, WARNINGS, and DOSAGE AND ADMINISTRATION** sections of the complete prescribing information.)

ADVERSE REACTIONS: Clinical Trials: In clinical trials using multiple doses of cefepime, 4137 patients were treated with the recommended dosages of cefepime (500 mg to 2 g IV q12h). There were no deaths or permanent disabilities thought related to drug toxicity. Sixty-four (1.5%) patients discontinued medication due to adverse events thought by the investigators to be possibly, probably, or almost certainly related to drug toxicity. Thirty-three (51%) of these 64 patients who discontinued therapy did so because of rash. The percentage of cefepime-treated patients who discontinued study drug because of drug-related adverse events was very similar at daily doses of 500 mg, 1 g, and 2 g q12h (0.8%, 1.1%, and 2.0%, respectively). However, the incidence of discontinuation due to rash increased with the higher recommend-

INCIDENCE EQUAL TO OR GREATER THAN 1%	Local reactions (3.0%), including phlebitis (1.3%), pain and/or inflammation (0.6%)*; rash (1.1%)
INCIDENCE LESS THAN 1% BUT GREATER THAN 0.1%	Colitis (including pseudomembranous colitis), diarrhea, fever, headache, nausea, oral moniliasis, pruritus, urticaria, vaginitis, vomiting

ed doses. The following adverse events were thought to be probably related to cefepime during evaluation of the drug in clinical trials conducted in North America (n=3125 cefepime-treated patients).

TABLE 1
Adverse Clinical Reactions Cefepime Multiple-Dose Dosing Regimens Clinical Trials—North America

*local reactions, irrespective of relationship to cefepime in those patients who received intravenous infusion (n = 3048).

INCIDENCE EQUAL TO OR GREATER THAN 1%	Positive Coombs' test (without hemolysis) (16.2%); decreased phosphorous (2.8%); increased ALT/SGPT (2.8%), AST/SGOT (2.4%), eosinophils (1.7%); abnormal PTT (1.6%), PT (1.4%)
INCIDENCE LESS THAN 1% BUT GREATER THAN 0.1%	Increased alkaline phosphatase, BUN, calcium, creatinine, phosphorous, potassium, total bilirubin; decreased calcium*, hematocrit, neutrophils, platelets, WBC

At the higher dose of 2 g q8h, the incidence of probably-related adverse events was higher among the 795 patients who received this dose of cefepime. They consisted of rash (4%), diarrhea (3%), nausea (2%), vomiting (1%), pruritus (1%), fever (1%), and headache (1%). The following adverse laboratory changes, irrespective of relationship to therapy with cefepime, were seen during clinical trials conducted in North America.

TABLE 2
Adverse Laboratory Changes Cefepime Multiple-Dose Dosing Regimens Clinical Trials—North America

*Hypocalcemia was more common among elderly patients. Clinical consequences from changes in either calcium or phosphorus were not reported.

A similar safety profile was seen in clinical trials of pediatric patients (See **PRECAUTIONS: Pediatric Use**).

Postmarketing Experience: In addition to the events reported during North American clinical trials with cefepime, the following adverse experiences have been reported during worldwide postmarketing experience. Because of the uncontrolled nature of spontaneous reports, a causal relationship to MAXIPIME treatment has not been determined.

As with some other drugs in this class, encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor, and coma), myoclonus, and seizures have been reported. Although most cases occurred in patients with renal impairment who received doses of cefepime that exceeded the recommended dosage schedules, some cases of encephalopathy occurred in patients receiving a dosage adjustment for their renal function. (See also **WARNINGS**) If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated. Precautions should be taken to adjust daily dosage in patients with renal insufficiency or other conditions that may compromise renal function to reduce antibiotic concentrations that can lead or contribute to these and other serious adverse events, including renal failure.

As with other cephalosporins, anaphylaxis including anaphylactic shock, transient leukopenia, neutropenia, agranulocytosis and thrombocytopenia have been reported. **Cephalosporin-class adverse reactions:** In addition to the adverse reactions listed above that have been observed in patients treated with cefepime the following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibiotics: Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, renal dysfunction, toxic nephropathy, aplastic anemia, hemolytic anemia, hemorrhage, hepatic dysfunction including cholestasis, and pancytopenia.

OVERDOSAGE: Patients who receive an overdose should be carefully observed and given supportive treatment. In the presence of renal insufficiency, hemodialysis, not peritoneal dialysis, is recommended to aid in the removal of cefepime from the body. Accidental overdosing has occurred when large doses were given to patients with impaired renal function. Symptoms of overdose include encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor, and coma), myoclonus, seizures, and neuromuscular excitability. (See **PRECAUTIONS, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION** sections of the complete prescribing information.)

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