The use of chlorhexidine-impregnated dressings over insertion sites reduced major catheter-related infections by 60%.

**Dressings Cut Catheter-Related ICU Infections**

**By Mary Ann Moon**

Elsevier Global Medical News

The rate of major catheter-related infections among ICU patients decreased by 60% when dressings impregnated with chlorhexidine gluconate were secured over insertion sites for arterial or central venous catheters, investigators reported.

That decrease was achieved among ICU patients participating in a multicenter study in France, even though the background rate of catheter-related infections already was extremely low, said Dr. Jean-Francois Timsit of University Joseph Fourier, Grenoble, France, and his associates.

They conducted a randomized, controlled trial to assess chlorhexidine-impregnated sponges, because small, unpublished studies of the dressings had yielded promising results. The trial involved 1,636 medical and surgical patients treated in seven ICUs at three university hospitals and two general hospitals. The patients were randomly assigned to receive either chlorhexidine dressings or standard dressings over catheter insertion sites.

Use of the chlorhexidine dressings cut the rate of major catheter-related infections from 1.4/1,000 catheter-days to 0.6/1,000 catheter-days. That protective effect was consistent both for gram-negative and gram-positive organisms, as well as for arterial and central venous catheters, the investigators said (JAMA 2009;301:1231-41).

Skin and catheter cultures showed a significant decrease in bacterial colonization with the chlorhexidine dressings.

The researchers estimated that the number needed to treat to prevent one major infection was 117 catheters.

Eight patients developed contact dermatitis with the chlorhexidine dressings, which resolved when the dressings were removed. All eight patients had multiple organ failures, subcutaneous edema, and fragile skin.

Dr. Timsit and his colleagues also studied whether decreasing skin and catheter cultures cut the rate of major catheter-related infections. They found that the number needed to treat was 117.

**Study: PPI Was No Help for Poorly Controlled Asthma**

**Results cast doubt on impact of reflux.**

**By Robert Finn**

Elsevier Global Medical News

Aggressive control of gastroesophageal reflux does not appear to improve asthma symptoms, a study has shown.

The findings challenge the theory that people with poorly controlled asthma frequently have reflux, and that treatment would lead to better asthma control.

The multicenter, double-blind, randomized controlled trial involved 412 adults whose symptoms of asthma were inadequately controlled despite the use of moderate to high doses of inhaled corticosteroids. Participants were assigned to receive either a placebo or 40 mg of esomeprazole, a proton pump inhibitor, twice daily for 24 weeks. This dose was higher than that typically used to treat symptomatic gastroesophageal reflux (N. Engl. J. Med. 2009;360:1487-99).

The study was conducted by the research group of the American Lung Association Asthma Clinical Research Centers, and the article was prepared by a writing committee led by Dr. John G. Mastronarde of Ohio State University Medical College, Columbus.

Although only 15% of the participants reported a history of gastroesophageal reflux, ambulatory pH monitoring revealed that 41% of patients in the placebo group and 40% in the esomeprazole group had evidence of reflux. This is a common finding among patients with asthma—for many, their reflux is asymptomatic.

Patients kept daily diaries of their asthma symptoms, and they were assessed by Skin and catheter cultures.

See PPI • page 3

**NCCN Updates Lung Cancer Guidelines**

**By Damian McNamara**

Elsevier Global Medical News

Hollywood, Fla. — Updates to the National Comprehensive Cancer Network’s clinical guidelines add regimens containing cetuximab or pemetrexed to first-line treatment options for recurrent or metastatic non-small cell lung cancer.

A cetuximab (Erbitux), vinorelbine (Navelbine), and cisplatin regimen is now an option for patients who have a performance status of 0-1 and meet criteria for use of cetuximab. Another choice combines cisplatin and pemetrexed (Alimta) for this same group of patients.

For patients with a performance status of 2, the NCCN also added the option of cetuximab, vinorelbine, and cisplatin, again with the proviso that the patient meet cetuximab criteria, including EGFR (epidermal growth factor receptor) expression by immunohistochemistry.

“Best supportive care or palliative care is still recommended...”

See Lung Cancer • page 2

**Sleep Institute**

American College of Chest Physicians

**Sleep Strategies**

OSA in pregnancy can have significant consequences.

See page 11.
Panel Revises Cancer Guidelines

Lung Cancer • from page 1

for performance status 1-4 patients,” Dr. David S. Ettinger, FCCP, said in a presentation of the updated guidelines at the annual conference of the NCCN.

Pemetrexed maintenance therapy also was added as an option until progression for patients with nonsquamous histology who experience tumor response or stable disease after two cycles of first-line chemotherapy.

This was a category 2B recommendation, however, indicating that the 30 physicians on the guidelines panel were not in complete agreement.

Pemetrexed won Food and Drug Administration approval in September 2008 for use in combination with cisplatin as a first-line therapy for locally advanced or metastatic nonsquamous non-small cell lung cancer. It is not indicated in squamous cell lung cancer.

Cetuximab is not FDA approved in NSCLC. When defining criteria for cetuximab use, the NCCN cited the abstract for the phase III PLEX (Cisplatin/Vinorelbine +/- Cetuximab as First-Line Treatment of Advanced Non-Small Cell Lung Cancer) study, which showed a small survival benefit in combination with cisplatin and vinorelbine; it was presented during the 2008 annual meeting of the American Society of Clinical Oncology.

“What takes precedence over any of these guidelines is participation in a clinical trial,” said Dr. Ettinger, professor of oncology at Johns Hopkins University in Baltimore. The panel removed three adjuvant chemotherapy regimens that were previously recommended for patients who had comorbidities or were unable to tolerate cisplatin. The drugs of gemcitabine (Gemzar) plus carboplatin; docetaxel (Taxotere) plus carboplatin; and gemcitabine plus docetaxel are no longer recommended.

The guideline panel also added information to systemic therapy recommendations for advanced or metastatic disease, including first-, second-, and third-line strategies. This “clarifies some of the recommendations we would use,” Dr. Ettinger said.

One new clarification states that a third cytotoxic drug in first-line therapy for advanced or metastatic disease does not increase survival, with the exception of bevacizumab (Avastin) and cetuximab in treatment-naive patients who have a performance status of 0.

Erlotinib (Tarceva) is also a first-line option +/- chemotherapy for patients who have an EGFR mutation or gene amplification, or who have never smoked. This is a category B recommendation, however, and the update now states that therapy other than erlotinib should be considered for any patient with a KRAS gene mutation.

Docetaxel, pemetrexed, and erlotinib are second-line therapy recommendations. “If you are using pemetrexed, your only choices would be docetaxel and erlotinib,” Dr. Ettinger said.

For systemic therapy for advanced or metastatic disease, the guidelines recommend only erlotinib as third-line therapy because it has proven survival that is superior to best supportive care. Investigational agents are not recommended as third-line therapies, Dr. Ettinger said.

Principles of radiation therapy for patients with NSCLC also were revised and updated.

The NCCN still does not recommend routine screening with CT. "Available data are conflicting; thus, conclusive data from ongoing national trials are necessary to define the benefits and risks associated with screening for lung cancer with low-dose CT," a new entry in the guidelines explains.

Recommendations for a PET scan were changed to recommend a PET/CT scan. "Addition of CT adds about 10%-15% specificity. You really get better resolution and correlation with PET/CT," said Dr. Ettinger.

Some specific pretreatment recommendations by cancer stage are new since the guidelines were last updated in February 2008. For example, mediastinal lymph node and CT-guided fine-needle aspiration are new options to evaluate the pathologic mediastinal lymph nodes with stage IIIA disease. In addition, endobronchial ultrasound and biopsy is a new option for pretreatment evaluation of stage IIIIB disease (T1-T4 N2 N3).

Also, the guidelines now differentiate adjuvant therapy for patients with T1-T2 N2 mediastinal lymph node–positive findings according to whether disease is local or systemic.

Dr. Ettinger is a consultant for AstraZeneca Pharmaceuticals LP, BioNumerik Pharmaceuticals Inc., Bristol-Myers Squibb Co., Eli Lilly & Co., Genentech Inc., GlaxoSmithKline Inc., Merck & Co., Novartis, Pfizer Inc., Sanofi-Aventis, and Travanti Pharma Inc. He receives grant support from Genentech, Pharmacorp, and Novartis. He is a scientific advisor for AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Genentech, GlaxoSmithKline, ImClone, Merck, Novartis, and Pfizer.
Moxifloxacin Improved TB Triple-Drug Therapy

BY MIRIAM E. TUCKER
Elsevier Global Medical News

Moxifloxacin increased the proportion of tuberculosis cultures converted to negative at 8 weeks by nearly 20% when added to the usual first-line triple-drug treatment regimen in a single-center, phase II trial in Brazil. Compared with control patients who received ethambutol, more patients who received moxifloxacin were culture negative after just 1 week of treatment. While the findings don’t prove that moxifloxacin can shorten overall TB treatment times, “our data add to a growing body of evidence that suggests that moxifloxacin could shorten tuberculosis treatment by initially eradicating a greater number of organisms and improving the sterilizing activity of combination drug regimens,” Dr. Marcus B. Conde and his associates wrote in the Lancet (2009;373:1183-9).

At baseline, the study’s 146 patients were all sputum smear-positive for Mycobacterium tuberculosis that was not resistant to isoniazid, rifampicin, or ethambutol. They received recommended doses of isoniazid, rifampicin, and pyrazinamide by directly observed treatment and were randomized to receive either 400 mg moxifloxacin with an ethambutol placebo or 15-20 mg/kg ethambutol plus moxifloxacin placebo.

Negative sputum cultures were achieved at week 8 by 59 of the 74 patients in the moxifloxacin group (79.7%), compared with 45 of 72 with ethambutol (62.5%), a difference of 17.2%.

Among only the subjects who had sputum culture data at 8 weeks, those proportions were 59 of 64 with moxifloxacin (92.1%), versus 45 of 61 controls (73.7%), for a difference of 18.4%. (All missing data were deemed as treatment failures in the intent-to-treat analysis.)

After 1 week, 9 of 69 in the moxifloxacin group (13%) had negative sputum cultures, compared with 2 of the 68 ethambutol subjects (3%), said Dr. Conde of Federal University of Rio de Janeiro and his associates, who included researchers from his own institution and from the Johns Hopkins University, Baltimore. At every week after enrollment, patients assigned to moxifloxacin had a higher rate of culture conversion than did those assigned to ethambutol, and the differences were significant at every time point except for weeks 6 and 7. The median time to consistently negative cultures was 35.0 days in the treatment group, compared with 48.5 days for the control group.

Adverse events did not differ by treatment. There were eight serious events in each group, in a total of 12 patients. Only one event, a grade 3 cutaneous reaction, was deemed to be related to the study drug—and that was to ethambutol, not moxifloxacin. Only five patients discontinued treatment because of toxic effects, and no clinically or statistically significant changes in the QTc interval were recorded in patients in either group.

Seven patients had recurrence of TB—three in the moxifloxacin group at 11, 16, and 27 months after completing treatment, and four in the ethambutol group at 6, 7, 22, and 32 months. Six of the seven isolates were tested for drug resistance, and all remained susceptible to isoniazid and rifampicin, Dr. Conde and his associates wrote.

No drug previously has been shown to substantially enhance the activity of the isoniazid/rifampicin/pyrazinamide combination, noted Dr. Hans L. Rieder in an accompanying editorial.

“The trial’s finding that culture conversion to negative occurred in 80% of patients in the moxifloxacin group, compared with 63% in the control group is, therefore, surprisingly large,” said Dr. Rieder of the tuberculosis department, International Union Against Tuberculosis and Lung Disease, Kirchlinnach, Switzerland.

Fourth-generation fluoroquinolones appear to have similar bactericidal activity to isoniazid—and possibly better sterilizing capability. Thus, moxifloxacin might even improve the efficacy of triple therapy for TB that is multidrug resistant (resistant to isoniazid plus rifampicin), Dr. Rieder added, as long as it isn’t extensively drug resistant.

The study was funded by the U.S. Food and Drug Administration Office of Orphan Product Development, with additional support from the U.S. National Institutes of Health. All of the authors declared that they have no conflicts of interest.

Mannitol Challenge Tested Asthma Quickly

BY HEIDI SPLETE
Elsevier Global Medical News

WASHINGTON — A mannitol challenge test was safe, easy to perform, and took significantly less time than a methacholine test did when used to evaluate adult asthma patients, based on data from a study of 49 participants. These tests are time consuming and patients, based on data from a study of 49 participants, took significantly less time than a methacholine test did when used to evaluate adult asthma patients, based on data from a study of 49 participants.

The findings were presented at the annual meeting of the American Academy of Allergy, Asthma, and Immunology. Overall, the mannitol challenge test took an average of 27 minutes, versus 56 minutes for a methacholine test, a significant time savings. Two patients were excluded because of a ratio of forced expiratory volume in 1 second (FEV1) to forced vital capacity (FVC) of less than 70%.

Each participant underwent a mannitol challenge 1 week after undergoing a methacholine challenge. The mannitol was loaded into an inhaler, and no special equipment was required.

There was a variance in procedure time for both tests among different centers participating in the study, which suggests a learning curve, Dr. DeMore noted. But the mannitol test is safe and well tolerated as part of a larger asthma trial, and the results suggest that it may be a useful option for clinicians once they learn the technique. As part of a larger study, “we hope to contrast mannitol vs. methacholine to characterize asthma phenotypes and predict responses to corticosteroids,” Dr. DeMore said.

Dr. DeMore had no financial conflicts to disclose.
**Adult Asthma Patients Lack Treatment Knowledge**

**BY DENISE NAPOLI**
Elsevier Global Medical News

WASHINGTON — Nearly half (42%) of adult asthma patients incorrectly believed they could stop taking their controller medications when their symptoms subsided, according to a recent survey.

Furthermore, only 94% of patients indicated that they understood the difference between controller medications and quick-relief medications. 69% also believed that quick-relief medications could be taken on a daily basis.

The findings, from the General Awareness and Perceptions II (GAP II) survey, were presented in a poster at the annual meeting of the American Academy of Allergy, Asthma, and Immunology.

According to the authors, led by Dr. Reynold A. Panettieri of the University of Pennsylvania, Philadelphia, the survey results underscore a need for more asthma education among physicians and patients.

“It is never appropriate to stop or taper controlled asthma medication,” he said in an interview. “Asthma is a chronic disease that requires long-term control even when symptoms are not present.”

A total of 1,001 adult patients and 100 primary care physicians completed the survey between June 27 and August 18, 2008. Among the physicians, 41% indicated that they treated 15 or more asthma patients per week, and 26% indicated that they had been in practice for more than 20 years. Among patients, the mean age was 47 years, slightly more than one-third had completed college or graduate study, and 62% used controller medications. A total of 59% used rescue medications.

The survey also revealed that 55% of patients believed their asthma was well controlled if they logged just one emergency department visit per year, and 56% believed that their asthma could qualify as well controlled even with two urgent doctor visits per year.

“If patients have a positive experience at their doctor appointments, they want to ask questions and are well informed, they’re more likely to remain compliant with their medication,” Dr. Panettieri said.

The study was a follow-up to GAP I, conducted in 2007, whose results are available at www.asthmagap.com. The current study was conducted under the auspices of the Asthma and Allergy Foundation of America with support from AstraZeneca.

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**Medicaid Status Linked To Uncontrolled Asthma**

**BY KERRI WAchter**
Elsevier Global Medical News

WASHINGTON — Medicaid insurance, low levels of education, and recent cold/flu or sinus infection were linked to an increased risk of uncontrolled asthma in a study of almost 2,000 adult primary care patients.

Patients with less than a high school education were four times as likely to have uncontrolled asthma (adjusted odds ratio 4.09) as those with more education. Richard H. Stanford, Pharm.D., reported at the annual meeting of the American Academy of Allergy, Asthma and Immunology.

Likewise, those patients with Medicaid insurance and recent respiratory-related medical visits were more than twice as likely to have uncontrolled asthma, with adjusted odds ratios (OR) of 2.44 and 2.37, respectively. Dr. Stanford is the director of U.S. Health Outcomes at GlaxoSmithKline.

The study included 1,902 adult patients from primary care practices around the country. Before seeing their physicians, participants completed a brief, self-administered questionnaire that included questions about asthma control, patient demographics, individual health behaviors, patient medical history, asthma exacerbation history for the last year, and reason for seeing their primary care physician.

A total of 30% of participants had mild asthma, 44% had moderate asthma, and 6% had severe asthma.

In all, more than half of the patients (57%) had uncontrolled asthma. Overall, 40% of patients were seeing their primary care physicians for respiratory-related visits.

Asthma exacerbation in the last year, use of medications for nasal allergies, and exposure to secondhand smoke were dropped from the final model, while sex, age, and race were added to the model.

Other factors associated with increased likelihood of having poorly controlled asthma included the presence of gastroesophageal reflux disease/acid reflux/chronic heartburn (OR 1.44), current smoker status (OR 1.83), and body mass index greater than 30 kg/m² (OR 1.54).
ICU Patients in Danger of Injected Drug Errors

BY MICHELE G. SULLIVAN
Elsevier Global Medical News

One-third of patients hospitalized in intensive care units experienced at least one parenteral medication error during their period, with some suffering permanent injury and even death as a result of the mistakes, a prospective study has shown.

The medication errors were associated with increasing complexity of illness, demands on nursing care, and increasing numbers of injected drugs, Dr. Andreas Valentin and his colleagues reported in BMJ (2009; doi:10.1136/bmj.b814).

The data, based on a self-report questionnaire, give only a glimpse into what might be an even greater problem, wrote Dr. Valentin, director of the intensive care unit at the Medical University of Vienna. “Considering that this number might underestimate the frequency and consequences of errors, these results might be of even greater clinical significance,” Dr. Valentin wrote. “Our study shows that the administration of parenteral medication is a weak point in patient safety in intensive care.”

The study included 1,328 patients in 13 intensive care units in 27 countries, including 2 in the United States. During the 24-hour study period, staffs were asked to fill out a single questionnaire at the bedside of each patient. The survey asked if, and at what time, any parenteral medication error had occurred.

The patients’ median age was 62 years. The median Sepsis-Related Organ Failure Assessment (SOFAS) score was 5, indicating dysfunction in one organ system. Nursing manpower was estimated as well. The median score was 27, indicating that a given patient would consume 59% of the workload that one unit nurse could perform in 24 hours.

Among the 1,328 patients, 861 medication errors affecting 441 patients were reported; 250 patients experienced one error and 191 experienced more than one. That translated to a rate of 74.5 errors per 100 patient-days. Of the 113 units in the study, only 21 (19%) reported medication errors.

The most frequent errors were medication given at the wrong time (386), followed by missed medications (259), wrong dose (118), wrong drug (61), or wrong route of administration (37). Most of the mistakes occurred during routine care (69%); only 4% occurred during emergencies and 3% during an urgent crisis with another patient in the unit. Staffs reported that workload and stress contributed to 32% of errors.

The errors resulted in no change in status for 71% of the patients involved. However, seven patients were permanently harmed, and five patients died as a result of mistakes. A multivariate analysis showed that every instance of organ failure increased the risk of medication error by 19%, for each additional patient on a nurse’s roster, the risk increased by 30%.

One of the most significant factors was administering a medication that had been prepared by a pharmacist, which nearly tripled the risk of a medication error (odds ratio 2.6). In contrast, the authors wrote, “the risks for such an event were lower when nurses labeled syringes that they themselves had prepared. This can be seen as an example of reducing complexity and avoiding gaps in information and communication in the process of care by preparing medication at the place where it is needed.” Factors that significantly decreased the risk of errors were the presence of an existing critical incident reporting system (31% decrease), and routine medication checks at shift change (32% decrease).

A few easily implemented changes could help reduce the number of errors, the authors suggested. ICUs should have a critical incident reporting system and routine checks of perfusers and infusion pumps at every shift change. In addition, “Unit administrators should be aware that an increasing number of beds and an increasing ratio of patients to nurses are risk factors for occurrence,” the researchers noted.

Central Line–Associated MRSA Decreasing in ICUs

BY MARY ANN MOON
Elsevier Global Medical News

The incidence of methicillin-resistant Staphylococcus aureus bloodstream infections related to the placement of central lines has declined in recent years in all major types of adult ICUs and has remained stable in non–neonatal pediatric ICUs, according to a recent report.

These findings suggest that prevention efforts are succeeding for this subgroup of MRSA patients, said Dr. Deron C. Burton and associates at the Centers for Disease Control and Prevention.

To characterize trends in MRSA incidence, the researchers assessed surveillance data reported to the CDC by 1,684 ICUs in 43 states during 1997-2007. In all, 33,587 central line–associated bloodstream infections were reported, of which 2,498 (7%) were MRSA.

In all, 33,587 central line–associated bloodstream infections occurred against the backdrop of an increase in overall MRSA infections. It is likely that this reduction was related to a range of interventions that have been implemented during the last decade, including better hand hygiene practices, adoption of standardized line insertion and care practices, proper barrier precautions, improved catheter technology, and shorter periods of indwelling catheter use in patients, Dr. Climo said (JAMA 2009;301:772-3).

The report offers “encouraging news,” commented Kathy Warye, CIO of the Association for Professionals in Infection Control and Epidemiology.

The findings show that health care–associated infections “can be prevented in a very vulnerable group of patients when institutions consistently implement evidence-based prevention strategies,” Ms. Warye said in a statement. Noting that 67% of MRSA cases occur outside the ICU, she urged health care leaders to “turn their attention to the ... floors where people are being treated for general medical conditions like diabetes, pulmonary and cardiac problems.”
CHEST, the official peer-reviewed publication of the American College of Chest Physicians (ACCP), has recently been selected as one of the “100 most influential journals in the world in medicine and biology” by the Special Libraries Association (SLA), an international organization with more than 11,000 members.

Being selected as one of the 100 most influential journals is a great honor. It’s a celebration and a validation of the past 75 years of trying to publish the best and most relevant topics in clinical chest medicine,” said CHEST Editor in Chief Dr. Richard S. Irwin, FCCP. “Because CHEST was selected by individuals familiar with medical journals and their usefulness to readers in libraries and institutions, we can surmise that CHEST is deserving of this honor because it is relevant, respected, and useful to its audience.”

In celebration of its centennial, the SLA had 666 members of its Biomedical and Life Sciences Division (DBIO) identify the 100 most influential journals in medicine and biology over the last 100 years, an exclusive list known as the DBIO 100. The SLA evaluated up to 34 journals in each of three categories: clinical medicine and allied health sciences; molecular and cellular biology; and natural history. CHEST was not only considered to be among the DBIO 100 but also among the 33–34 most influential journals in clinical medicine and allied health sciences.

CHEST was also the only respiratory or respiratory-related journal chosen in this elite group, beating the second-place respiratory journal by three times the number of votes, and stands among other revered journals, such as Cell, Circulation, JAMA, Nature, New England Journal of Medicine, Science, and The Lancet.

“Sharing this honor with some of the world’s top medical journals is very humbling and energizing at the same time and provides us with a great sense of pride,” said Dr. Irwin. “It is also a validation of our strategy to provide our readers what they need. We hope this is a harbinger of even greater things to come.”

Published since 1935, CHEST is known for providing cutting-edge, and often provocative, clinical research in the areas of pulmonary, critical care, thoracic surgery, cardiopulmonary interactions and, more recently, sleep medicine. This dedication to providing readers with the most current knowledge in chest medicine has kept journal content fresh and exciting and leaves readers anticipating their next issues.

“The DBIO Top 100 designation reinforces our commitment to publishing a highly respected and relevant peer-reviewed medical journal that gets to the heart—and lungs—of CHEST’s vision of being the leading resource for the improvement of cardiopulmonary health and critical care worldwide,” said CHEST Executive Editor Stephen J. Welch. “Because the journal is arguably the most visible and tangible product of the ACCP, this award enhances the reputation of the ACCP and should be a great source of pride for ACCP members.”

In the last decade alone, CHEST has added several new features to keep up with reader demand and to adapt to changing technology. In 2007, CHEST launched its extensive archiving system, where subscribers can research journal articles as far back as 1935 free.

And, just this year, CHEST launched its Interactive Physiology Grand Rounds, enabling readers to manipulate specialized medical procedures animated on screen through the online version of the journal.

“As we know from ACCP’s March 2009 Continuing Medical Education initiative to commemorate 75 years of exceptional medical research published in the journal, Guest editors Dr. Loren J. Harris, FCCP and Dr. Glenn Tillotson, FCCP, will identify the top 75 articles from the past 75 years of CHEST. These landmark articles—in the areas of tuberculosis, lung cancer, sepsis, thoracic and cardiac surgery, critical care, sleep apnea, and more—will be featured in a special 75th anniversary monograph to be released at CHEST 2009.”

For 75 years, CHEST has embodied the unique quality of combining a focused clinical orientation with a multidisciplinary coverage of topics. It truly reflects the ACCP’s mission of improving patient care through education,” said CHEST Publisher Alvin Lopez, MA, FCCP(Hon). “The combination of expert commentaries, high-quality clinical research, reviews of current topics, and case-based educational sections has developed over the years and been tweaked by each editor. And we’re not done yet.”

The SLA is a nonprofit global organization for innovative information professionals and their strategic partners. SLA serves more than 11,000 corporate, academic, government, and other information specialists in 75 countries.

To learn more about the SLA or the award, please visit http://units.sla.org/division/dbio/publications/resources/dbio100.html.
ProAir® HFA is indicated in patients 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.

Important Safety Information

- Inhaled albuterol sulfate can produce paradoxical bronchospasm that may be life-threatening. It should be recognized that paradoxical bronchospasm, when associated with inhaled formulations, frequently occurs with the first use of a new canister.
- Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs in patients with asthma.
- ProAir® HFA, as with all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders (especially coronary insufficiency, cardiac arrhythmias, and hypertension), convulsive disorders, hyperthyroidism, and diabetes.
- Potential drug interactions can occur with beta-blockers, diuretics, digoxin, or monoamine oxidase inhibitors, and tricyclic antidepressants.
- Do not exceed the recommended dose.
- Adverse events, which occurred at an incidence rate of at least 3% with ProAir® HFA, include headache, tachycardia, pain, dizziness, pharyngitis, and rhinitis.

In 2008, there were over 14 million prescriptions for ProAir HFA, more than all other albuterol HFA inhalers combined.

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Please see brief summary of Full Prescribing Information on adjacent pages.
PROAIR HFA Inhalation Aerosol is indicated for the prevention of exercise-induced bronchospasm in patients 12 years of age and older.

Use of PROAIR HFA Inhalation Aerosol may be associated with the following:

<table>
<thead>
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<th>Common</th>
<th>Rare</th>
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1. Exercise-Induced Bronchospasm

PROAIR HFA Inhalation Aerosol is indicated for the prevention of exercise-induced bronchospasm in patients 12 years of age and older.

2. Deterioration of Asthma

Patients with asthma. The exact cause of death is unknown, but cardiac arrest following an unexpected development of a severe acute asthmatic crisis and subsequent hypoxia is suspected.

3. Cardiac Effects

Like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

4. Hypokalemia

 Immediately hypersensitivity reactions may occur after administration of albuterol sulfate, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, anaphylaxis, and/or oropharyngeal edema. The potential for hypersensitivity reactions in the clinical evaluation of patients who experience immediate hypersensitivity reactions while receiving PROAIR HFA Inhalation Aerosol.

5. Do Not Exceed Recommended Dose

Females have been reported in association with excessive use of inhaled sympathomimetic drugs in patients 12 years of age and older. Serious, although rare cases of sympathomimetic amines, should produce clinically significant cardiovascular effects in some patients as measured by pulse rate, blood pressure, and/or symptoms. Although such effects are uncommon after administration of PROAIR HFA Inhalation Aerosol at recommended doses, if they occur, they may need to be discontinued. In addition, beta-agonists have been reported to produce ECG changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression. Therefore, PROAIR HFA Inhalation Aerosol, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

6. ADVERSE REACTIONS

Use of PROAIR HFA may be associated with the following:

- Immediate hypersensitivity reactions
- Hypokalemia

A total of 1090 subjects were treated with PROAIR HFA Inhalation Aerosol, or with the same formulation of albuterol as in PROAIR HFA Inhalation Aerosol. In clinical studies, the incidence of adverse events was determined in blinded, placebo-controlled, randomized clinical trials comparing PROAIR HFA Inhalation Aerosol to placebo in patients 12 to 76 years of age with asthma. The table lists the incidence of adverse events (whether considered related or unrelated to drug) which occurred at an incidence rate of at least 3% in the PROAIR HFA Inhalation Aerosol group compared to the placebo group.

Adverse Experience Incidences (% of Patients) in a Six-Week Clinical Trial*

<table>
<thead>
<tr>
<th>Body System/Adverse Event (any severity term)</th>
<th>PROAIR HFA Inhalation Aerosol (N = 58)</th>
<th>Placebo Matched HFA-134a Active Comparator (N = 56)</th>
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<tbody>
<tr>
<td>Respiratory Tract</td>
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<tr>
<td>- Body as a Whole</td>
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</tbody>
</table>

* This table includes all adverse events (whether considered related or related to drug) which occurred at an incidence rate of at least 3% in the PROAIR HFA Inhalation Aerosol group compared to the placebo group in a six-week clinical trial.

7. DRUG INTERACTIONS

Because of the potential for beta-agonist interference with uterine contractility, use of PROAIR HFA Inhalation Aerosol for treatment of bronchospasm in children 12 years of age and older with reversible obstructive airway disease is based on one 6-week, double-blind, active-comparator study in 116 patients 12 to 76 years of age. Patients in this study received PROAIR HFA Inhalation Aerosol four times daily with placebo, and single-dose crossover study comparing doses of 90, 180, and 270 mcg with placebo. The safety and effectiveness of PROAIR HFA Inhalation Aerosol for treatment of exercise-induced bronchospasm in children 12 years of age and older is based on one single-dose crossover study in 24 adult patients and one exercise-induced bronchospasm doses of 180 mcg with placebo [see Clinical Studies (14.2)].

The safety of PROAIR HFA Inhalation Aerosol in children 4 to 11 years of age is based on one 3-week clinical study in 59 patients 4 to 11 years of age with asthma and 3-week study with 5 patients 12 years of age and older. The safety and effectiveness of PROAIR HFA Inhalation Aerosol in children 4 to 11 years of age is based on one single-dose crossover study in 95 asthmatic children 4 to 11 years of age comparing a dose of 180 mcg four times daily with placebo [see Clinical Studies (14.2)].

The safety and effectiveness of PROAIR HFA Inhalation Aerosol in pediatric patients below the age of 4 years has not been established.

8. GERIATRIC USE

Clinical studies of PROAIR HFA Inhalation Aerosol did not include sufficient numbers of patients aged 65 years and older to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection in elderly patients should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy [see Warnings and Precautions (5.4, 5.17)].
Dr. Bird Receives the Presidential Citizens Medal

D r. Forrest Bird, the inventor of the first modern respirator, can now add the honor of receiving the Presidential Citizens Medal to his many accomplishments. In December 2008, President George W. Bush awarded Dr. Bird with the Presidential Citizens Medal—one of the highest honors the President can confer upon a civilian, second only to the Presidential Medal of Freedom. This honor was established in 1969 to recognize US citizens who have performed exemplary deeds of service.

The ACCP and CHEST Foundation congratulate Dr. Bird on receiving this high honor and are grateful to Dr. Bird for allowing The Foundation to be included among those that have recognized him for his exceptional career in the field of respiratory medicine. At CHEST 2008 in Philadelphia, Pennsylvania, The CHEST Foundation recognized Dr. Bird, who is a physician, pilot, and inventor of the Bird Mark 7, one of the first modern respirators. The Foundation also established the Forrest M. Bird, MD, PhD, ScD Endowment in Mechanical Ventilation to honor him and his life-saving contributions to advance mechanical ventilation. At the Making a Difference Awards Dinner, Dr. Bird’s family, friends, and colleagues paid tribute to him for his outstanding career as an inventor and his numerous achievements in the area of respiratory medicine.

If you wish to donate to the Forrest M. Bird, MD, PhD, ScD Endowment in Mechanical Ventilation, please contact Teri Ruiz at truiz@chestnet.org, or visit www.chestfoundation.org, select the Make A Donation icon, and click the Donations link under Forrest M. Bird MD, PhD, ScD Endowment in Mechanical Ventilation.

Making a Difference Awards Dinner

Save the Date—The CHEST Foundation’s 11th Annual Making a Difference Awards Dinner will take place on Saturday, October 31, 2009, 7:00 PM – 10:30 PM, at the Manchester Grand Hyatt, San Diego, California.

This year’s event will feature a celebration of the 75th anniversary of the ACCP—75 years of inspiration for its members and their patients. In addition, the Alvin Lever, MA, FCCP(Fon), and Norine Lever, PhD Honorary Endowment will be announced, and The Foundation will also recognize ACCP members’ pro bono service by conferring the D. Robert McCaffree, MD, Master FCCP Humanitarian Awards to those members with winning humanitarian service projects from around the world.

Registration will begin July 1, 2009, at www.chestfoundation.org. Price per ticket is $150. Please contact Teri Ruiz at truiz@chestnet.org.

ACCP Leaders Take the Challenge

The CHEST Foundation is working to increase participation from leadership by engaging them with fundraising on The Foundation’s behalf. This year, The CHEST Foundation’s Development Committee has established two separate challenges—the ACCP Governors’ Challenge and the ACCP NetWorks’ Steering Committee Challenge. The ultimate goal of these two challenges is to increase awareness of The Foundation’s four areas of focus: tobacco prevention, humanitarian service, clinical research, and critical care/end-of-life care.

Although these challenges were announced this spring, the donor gift tracking for both challenges will be retroactive to July 1, 2008, and will run through September 30, 2009. These challenges will work in the following way:

Governors in the United States and Canada who accept the challenge will help fund raise by contacting members from their states and provinces who have not yet donated in the current fiscal year.

NetWork Chairs who accept the challenge will help fund raise by contacting their NetWork’s Steering Committee members who have not yet donated in the current fiscal year.

Participating Governors and NetWork Chairs will be asked to fund raise by letter, e-mail, and phone. The minimum request will be for a $100 annual gift. Contact information, solicitor scripts, and fact sheets about The CHEST Foundation will be provided. All Governors and NetWork Chairs are encouraged to seek out other members to help them in this effort.

Donor recognition will be immediate, with Governors and NetWork Chairs sending either personalized notes to their contacts who have donated, or they can choose to be a cosigner of The Foundation’s tax-deduction thank you letter.

Monthly summary data will be provided by The CHEST Foundation for the Council of Governors and Council of NetWorks to review. In addition, each participating Governor and NetWork Chair will be provided with month-end status reports.

Winners of both challenges will be determined based upon a ratio of the number of possible donors vs actual number donating.

The winning fund raisers for the Governors’ Challenge and the NetWorks’ Steering Committee Challenge will each be provided with four free tickets to the 11th Annual Making a Difference Awards Dinner and will be featured in articles in The CHEST Foundation’s newsletter, Extraordinair, and in the ACCP’s CHEST Physician.

CHEST 2009 in San Diego: Nice Weather We’re Having

The US Weather Bureau describes San Diego’s climate as the most nearly perfect in America. It can be characterized as Mediterranean-like, with warm winters and cool summers. The typical San Diego weather forecast of “sunny and mild” is one reason why so many people love to visit and another why you’ll want to attend CHEST 2009.

What makes the San Diego climate so perfect? The prevailing breezes from the Pacific Ocean temper the weather in San Diego and protect it from extreme weather conditions. It is uniquely located to avoid the summer monsoons that blow south across Mexico and Arizona. Since the jet stream usually tracks north of San Diego, it rarely experiences heavy rainfall or violent winter storms.

The potential for a favorable forecast is a plus when deciding “weather” to attend CHEST 2009. If you’re coming from an area with less favorable weather conditions, you can expect milder, more pleasant conditions as you take advantage of the year’s best learning opportunity in clinical chest medicine.

CHEST 2009 takes place in San Diego, California, October 31 through November 5. Recognized around the world as the authority in clinical chest medicine, CHEST 2009 will offer unique opportunities for clinical education and professional growth. CHEST 2009 also marks the start of a year-long celebration of the ACCP’s 75th anniversary—75 years of inspiring leadership, education, clinical practice, and communication. Watch for special celebrations and events. Early registration fees for CHEST 2009 are in effect now, and ACCP members can save up to $155. Register at www.chestnet.org.
Alpha₁-antitrypsin deficiency (AATD) is the most well-characterized genetic risk factor for COPD. However, this is a rare disease with the frequency of the PiZZ or PiSZ severe AATD genotypes being less than 1% in the general population. Since AATD is a genetic disease and genes don’t change, if testing is performed only once in a lifetime, those who have previously tested positive for AATD should not require repeated testing. Some COPD clinics use chart markers or other strategies to determine which patients with COPD have been previously tested for AATD.

It is my opinion that comprehensive targeted testing for AATD should be performed in the United States. The benefits of testing include more than a discussion of the utility of IV augmentation therapy. Those of us with an active AATD clinic population recognize this community as an empowered group of individuals. Current data suggest that this genetic diagnosis enhances smoking cessation. Individuals with AATD may choose to join disease management groups that have been shown to improve COPD outcomes, reduce ED visits, and improve SF-36 quality of life scores. Importantly, these benefits come, in part, from the community of patients with AATD. This requires that your institution provides resources available to them to improve their COPD management.

References

Dr. Charlie Strange, FCCP, Professor of Pulmonary and Critical Care Medicine
Medical University of South Carolina
Charleston, SC

Editor’s Insight
I have a confession to make. I have never identified a patient with alpha₁-antitrypsin deficiency. The cynic would respond by saying that is because the disease is so unusual. It is an unusual disease, possibly occurring in 1 of every 100 to 200 patients with COPD.

However, I know that the real answer is that I have not screened patients as often as I should. Professor Strange makes a very important point when he emphasizes that we cannot identify these patients by a certain clinical phenotype. He also refers to the recent article by Campos and colleagues who reviewed clinical characteristics of 922 patients receiving augmentation therapy.

The average age at diagnosis of these 922 patients was 43.5 years, and many older patients had markedly prolonged delays (years and decades) before the diagnosis was established.

For any practicing pulmonologist, Professor Strange’s recommendation to screen often should be heeded. The screening approach is well standardized, simple, relatively inexpensive, and accurate. The implications for the patient and family members of establishing this diagnosis are important.

Also to be emphasized is Dr. Strange’s reference to the Alpha-1 Foundation Research Registry. Encouraging patient participation in this registry may be an important way forward in designing future research projects for this disease.
Snoring and sleep apnea are relatively uncommon in premenopausal women. However, the incidence of sleep apnea and other disturbances markedly increases during pregnancy. We think of pregnancy as a normal physiologic, low risk time. However, preeclampsia (PIH) occurs in 6% or more primipara women. There is mounting evidence that obstructive sleep apnea (OSA) may play a very important role in the pathogenesis of PIH. Since continuous positive airway pressure (CPAP) is a highly effective therapy for OSA, a real opportunity to improve the dire consequences of PIH exists. Estrogen increases rapid eye movement (REM) sleep, decreases sleep latency, and decreases wakefulness after sleep onset. It also increases total sleep time. Progesterone has its effects primarily on non-REM sleep. A sedating effect, similar to that experienced with benzodiazepines, is attributed to progesterone. Sleep latency and wakefulness after sleep onset are decreased by the progesterone effect. Changes in sleep cycle (eg, worse sleep, lower efficiency as a response to the hormonal changes) are worsened in 10% of women in relation to the menstrual cycle. A menstrual period hypopomnina has been described, as well. It begins soon after menarche and then recurs in 6- to 10-day episodes. Poor sleep becomes the rule rather than the exception for many pregnant women. In one study, 68% of women reported a change in sleep patterns—especially in the third trimester (Schweiger. Am J Obstet Gynecol 1972; 114:879). Etiologic factors include a rise in progesterone and consequent fatigue, body temperature rise, respiratory rate rise, and frequent need to urinate. There are important physiologic changes due to elevation of the diaphragm from abdominal mass effect and due to the increased vascular load from a one-third increase in blood volume. Sleep architecture worsens during pregnancy, with effects beginning at 12 weeks and extending into early postpartum. REM decreases, increased awakenings occur, and sleep efficiency drops. Mindell and Jacobson (J Obstet Gynecol Neonatal Nurs 2000; 29:590) surveyed 127 consecutive pregnant patients and found a large percentage experienced sleep disturbance. Onset of snoring was up to 31% by the third trimester. Restless sleep and awakenings were very common. In addition, symptoms of periodic limb movement disorder were reported in 26.5%. This is likely due to pregnancy-related iron deficiency. There is a possible association of sleep deprivation and premature labor. In addition, new-onset snoring is associated with fetal growth retardation, decreased APGAR scores, and increased fetal complications. Snoring is more common in men than in women. Even among habitually snoring women, apnea-hypopnea index (AHI) values are much lower than in men. OSA is present in 2 to 8% of all women and slightly lower values are found in women of childbearing age. Snoring occurs in 4% of women prior to pregnancy, but its incidence increases to 25% in pregnant women. Changes in pregnancy that influence the development of OSA include gestational weight gain, nasopharyngeal and upper airway edema, and drop in functional residual capacity due to diaphragm compromise and mass effect and increased arousals. There are mitigating pregnancy changes that decrease OSA risk. However, the balance of these factors is uncertain. Continued on following page.
What value do physicians currently place on continuing medical education once they have advanced into their career path? Is CME effective today and does physician lifelong learning really affect patient care by improving clinical knowledge, performance, and patient outcomes? Is CME simply a system to help physicians fulfill a requirement, or does it effectively improve physician practice leading to better health care? These are not new questions, but, over the years, there have been some interesting developments.

This has led to a March 2009 ACCP publication of an evidence-based guideline (Chest 2009; 135:1S-7S) that makes recommendations on the effectiveness of CME. This initiative began in 2005, when the ACCP proposed and obtained acceptance from the Agency for Healthcare Research and Quality to acceptance from the Agency for Healthcare Research and Quality to help physicians fulfill a system to help physicians fulfill a requirement, or does it effectively improve physician practice leading to better health care? These are not new questions, but, over the years, there have been some interesting developments.

The ACCPs guideline also focused upon formative assessment, as opposed to summative education and evaluation. Summative assessments review performance at some point in time but are not designed to help the physician learner during the educational process. Formative assessment, however, occurs when the physician learner is given feedback in a way that enables improved learning or performance. Formative assessment can significantly affect physician learning by affording the opportunity to evaluate and self-assess knowledge, skills, judgment, and professional values, helping to identify gaps in knowledge or skills and to encourage lifelong learning. This process allows feedback to physician learners that they are providing standards of care for their patients and advances positive changes in standards of care.

By contrast, the use of traditional lecture-based education as the only means of instruction does not provide a formative process to bring change to physician knowledge, behavior, or clinical care. Lecture-based instruction alone has proved the least effective way to learn. Evidence review has shown that incorporating formative assessment into CME activities, using diversified teaching modalities, is the most effective method. Which teaching combination and how much intensity are yet to be determined.

The field of CME is changing rapidly, for both the physician educator and learner. The ACCP evidence-based guideline on effectiveness of CME provides an extensive review, recommendations, and a foundation for what the immediate future will look like. For more information on this guideline, go to www.chestjournal.org.

Continued from previous page is definitely tilted to an increase in snoring and OSA in pregnant women. Franklin et al. (Chest 2000; 117:137) found that prior habitual snorers had an increased incidence of hypertension and/or PIH during pregnancy than did case-matched nonsnoring control subjects. Gestational age and APCR scores were less than those for control subjects. PIH occurs in 6 to 8% of all pregnancies. Perinatal mortality increases fivefold in patients with PIH (Dekker. Clin Obstet Gynecol 2000; 117:137). OSA in pregnancy is thought to be important in the pathogenesis of PIH. It is hypothesized that placental development (and perhaps underperfusion) is a critical factor in the pathogenesis of PIH. Oxidative stress may lead to release of various factors that may then lead to endothelial dysfunction. The coagulation system is activated; microvascular angiopathy develops, as well as vasoconstriction, resulting in onset of edema, hypertension, or worse.

So a putative mechanism could be viewed as outlined in the figure below. Yinon and colleagues (Eur Respir J 2006; 27:328) demonstrated that the AHI is abnormal in patients with PIH as compared with matched control subjects. There are early reports of the efficacy of CPAP therapy in pregnant patients with OSA and, perhaps, in modulating PIH (Edwards et al. Am J Respir Crit Care Med 2000; 162:242). A small study by Guillemainault and colleagues (Sleep Med 2007; 9:9), in which early CPAP was used in first trimester women with PIH risk factors, showed a reduction in maternal AHI but no change in maternal fetal outcomes. A second study by the same group (Poyares et al. Sleep Med 2007; 9:13) did show improved blood pressure control, as well as improved fetal outcomes in a group of high risk patients treated with nasal CPAP.

Women have a higher incidence of sleep disorders than is currently recognized in clinical practice. There are many reasons for worsened sleep during pregnancy. Awakenings are common, as is the occurrence of periodic limb movement disorder. The incidence of snoring and obstructive sleep apnea increases significantly in pregnancy. OSA in pregnancy has significant consequences and may be an important component of the pathogenesis of PIH. This is a fertile area for future research.

Dr. Antonette Williams, Assistant Professor, and Dr. James A Barker, FCCP, Professor and Chief Division of Pulmonary/Critical Care/Sleep Disorders University of South Carolina School of Medicine at Palmetto Richland Hospital Columbia, SC
ACCP Members Visit Capitol Hill for Annual Caucus

On March 9-10, 2009, more than 60 ACCP members descended on Washington, DC, for the 16th Annual ACCP Capitol Hill Caucus. Attendees met with 185 Senate and Representative offices to urge legislators to address the critical care workforce shortage and highlight the importance of the US Food and Drug Administration (FDA) having meaningful authority to regulate tobacco products.

On day 1, participants gathered at the FairFax at Embassy Row to receive background information regarding the priority legislative issues for chest medicine and organized medicine generalists. Attendees included Meg Richardon, Campaign for Tobacco-Free Kids; Todd Askew, American Medical Association; Phil Porte, NAMS-DC, and ACCP’s legislative counsel, Michael Caba, Esq, Holland & Knight. Attendees also received insider tips and techniques to help influence elected officials from “Advocacy Guru,” Stephanie Vance. The dinner speaker featured Michael Gaba, Esq, Holland & Knight.

The following morning participants reconvened on Capitol Hill to gain insights into the inner workings of congressional offices from Erika Orloff, Senior Legislative Affairs Officer for Health Care for Repressive Bart Stupak (D-MI-1), and Cheryl Jaeger, Senior Policy Advisor to House Republican Whip Eric Cantor (R-VA-7).

Jeffrey Teitz, Chief Counsel for Policy to Senator Edward Kennedy (D-MA), also spoke to attendees regarding the Family Smoking Prevention and Tobacco Control Act, which, if enacted, would, for the first time, grant authority to the FDA to regulate tobacco.

Dr. Maria Jason, FCCP, Mid-Atlantic Pulmonary Clinic, Kensington, Maryland, commented that “the Caucus continues to be a great experience. Each year I go, I learn more and want to be even more involved. This year, the third for me, I learned even more about the importance and effectiveness of having an ongoing relationship with the legislative office.”

Dr. Dennis Moritz, FCCP, ACCP Governor for West Virginia, described the Caucus as “one of the best learning experiences that I ever had - I cannot wait to get home to share all my new knowledge of these topics with my colleagues - to not just ACCP members, but all folks involved in medicine.”

Coinciding with the Caucus was a new ACCP Advocacy campaign, in which ACCP members who were not able to attend the Caucus were asked to amplify our message on the Hill by e-mailing messages to their own Representatives and Senators regarding the legislative priorities discussed at the Caucus. We had an enthusiastic response from members to support our message. Also, this new year was the development of three advocacy podcasts that discuss the critical care workforce shortage, FDA regulation of tobacco, and the Obama health-care plan. The podcasts are available on the ACCP Grassroots Advocacy Web site at www.chestnet.org/advocacy. Also, visit this site soon for information on the 17th Annual ACCP Capitol Hill Caucus in spring 2010.
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The Berkshires-Western Massachusetts

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SERIOUS INFECTION

ZYVOX—proven efficacy in nosocomial pneumonia, including those due to MRSA**

ZYVOX is indicated in the treatment of nosocomial pneumonia caused by Staphylococcus aureus (methicillin-susceptible and -resistant strains) or Streptococcus pneumoniae (including multidrug-resistant strains [MDRSP]). MDRSP refers to isolates resistant to 2 or more of the following antibiotics: penicillin, second-generation cephalosporins, macrolides, tetracycline, and trimethoprim/sulfamethoxazole.

ZYVOX should not be used in patients taking any medicinal product which inhibits monoamine oxidases A or B (e.g. phenelzine, isocarboxazid) or within 2 weeks of taking any such medicinal product.

Unless patients are monitored for potential increases in blood pressure, ZYVOX should not be administered to patients with uncontrolled hypertension, pheochromocytoma, thyrotoxicosis and/or patients taking any of the following types of medications: directly and indirectly acting sympathomimetic agents (e.g. pseudoephedrine), vasopressive agents (e.g. ephedrine, epinephrine), and dopaminergic agents (e.g. dopamine, dobutamine).

Unless patients are carefully observed for signs and/or symptoms of serotonin syndrome, ZYVOX should not be administered to patients with carcinoid syndrome and/or patients taking any of the following medications: serotonin reuptake inhibitors, tricyclic antidepressants, serotonin 5-HT1 receptor agonists (triptans), meperidine, or buspirone.

Myelosuppression (including anemia, leukopenia, pancytopenia, and thrombocytopenia) has been reported in patients receiving ZYVOX. In cases where the outcome is known, when ZYVOX was discontinued, the affected hematologic parameters have risen toward pretreatment levels. Complete blood counts should be monitored weekly in patients who receive ZYVOX, particularly in those who receive ZYVOX for longer than 2 weeks, those with preexisting myelosuppression, those receiving concomitant drugs that produce bone marrow suppression, or those with a chronic infection who have received previous or concomitant antibiotic therapy. Discontinuation of therapy with ZYVOX should be considered in patients who develop or have worsening myelosuppression.

ZYVOX is not approved and should not be used for the treatment of patients with catheter-related bloodstream infections or catheter-site infections.

ZYVOX has no clinical activity against Gram-negative pathogens and is not indicated for the treatment of Gram-negative infections. It is critical that specific Gram-negative therapy be initiated immediately if a concomitant Gram-negative pathogen is documented or suspected.

Lactic acidosis has been reported with the use of ZYVOX. In reported cases, patients experienced repeated episodes of nausea and vomiting. Patients who develop recurrent nausea or vomiting, unexplained acidosis, or a low bicarbonate level while receiving ZYVOX should receive immediate medical evaluation.

Spontaneous reports of serotonin syndrome associated with the coadministration of ZYVOX and serotonergic agents, including antidepressants such as selective serotonin reuptake inhibitors (SSRIs), have been reported. Where administration of ZYVOX and concomitant serotonergic agents is clinically appropriate, patients should be closely observed for signs and symptoms of serotonin syndrome such as cognitive dysfunction, hyperreflexia, and incoordination. If signs or symptoms occur, physicians should consider discontinuation of either one or both agents.

Peripheral and optic neuropathy have been reported in patients treated with ZYVOX, primarily those patients treated for longer than the maximum recommended duration of 28 days. If patients experience symptoms of visual impairment, such as changes in visual acuity, changes in color vision, blurred vision, or visual field defect, prompt ophthalmic evaluation is recommended. Visual function should be monitored in all patients taking ZYVOX for extended periods (≥3 months) and in all patients reporting new visual symptoms regardless of length of therapy with ZYVOX. If peripheral or optic neuropathy occurs, the continued use of ZYVOX in these patients should be weighed against the potential risks.

Convulsions have been reported in patients when treated with ZYVOX. In some of these cases, a history of seizures or risk factors for seizures was reported.

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

The most commonly reported adverse events in adults across clinical trials were nausea, headache, and diarrhea.

**Metabolic acidosis has been reported with the use of ZYVOX.**