FDA Approves First Pandemic Avian Flu Vaccine

Several million doses to be stockpiled.

By Elizabeth Mechcatie
Elsevier Global Medical News

The Food and Drug Administration’s approval of the first vaccine in the United States for use in an avian influenza virus pandemic is an important—and urgently needed—step toward protecting the nation against the H5N1 virus, federal officials said.

Last month’s approval is for active immunization against influenza disease caused by the H5N1 A/Vietnam/1203/2004 influenza virus in adults aged 18-64 who may be at an increased risk of exposure to the H5N1 influenza virus. If needed, the inactivated avian influenza vaccine would be administered intramuscularly as two 90-mcg doses, 28 days apart.

The vaccine, based on the A/Vietnam strain of the H5N1 avian influenza virus and manufactured by Sanofi Pasteur under contract with the U.S. government, will not be available commercially. The vaccine has been purchased by the federal government to be part of the U.S. Strategic National Stockpile, maintained by the Centers for Disease Control and Prevention, and will be distributed if needed. Several million doses of the vaccine will be stockpiled, according to Norman Baylor, Ph.D., director of the Office of Vaccines Research and Review in the FDA’s Center for Biologics Evaluation and Research.

The approval of the vaccine “is an important step in enhancing our nation’s readiness against a possible pandemic and enhances our ability to protect those who could be at increased risk of exposure to the H5N1 virus at some point,” Dr. Baylor said during a press briefing held to announce the approval. Those at increased risk would be determined by federal officials, he said.

The dosage was determined in a prospective, multicenter, clinical trial. The vaccine has been incorporated into an intramuscular formulation to be administered intramuscularly as two 90-mcg doses, 28 days apart.

The vaccine would be administered to those identified by federal officials to be at increased risk of exposure to the H5N1 virus, including but not limited to healthcare workers, military service members, veterinarians, poultry workers, and people who have had close contact with MRSA-infected individuals, the CDC said (MMWR 2007;56:325-9). During December 2006 to January 2007, 10 cases of severe MRSA CAP were reported to the CDC from Louisiana and Georgia. Patient ages ranged from 4 months to 48 years; eight were younger than 30 years. Five were female and five male. Six of the 10 patients died, including 4 children aged 8-14 years.

Chester Bloom

Pulmonary Perspectives
Is Timing Everything?
Evaluating timeliness of care in lung cancer raises questions.

Critical Care Medicine
Dental Deterrent
How an oral care regimen reduced ventilator-associated pneumonia.

Practice Trends
DME Bidding
CMS wants competition for CPAP, respiratory assist devices, wheelchairs.

MRSA CAP Presents a Serious Threat

By Miriam E. Tucker
Elsevier Global Medical News

Be alert for severe cases of community-acquired pneumonia that might be caused by methicillin-resistant Staphylococcus aureus, the Centers for Disease Control and Prevention advised. Although uncommon, community-acquired pneumonia (CAP) can be caused by methicillin-resistant S. aureus (MRSA). Such cases often affect young, otherwise healthy individuals and can be rapidly fatal. MRSA should be suspected in patients with severe pneumonia, especially during the influenza season, and in those with cavitary infiltrates. The index of suspicion for MRSA CAP should be particularly increased in those who have a history of MRSA skin infection or who have had close contact with MRSA-infected individuals.

Four patients had documentation of recent MRSA skin and soft-tissue infection or were living with someone who did. In all 10 cases, influenza-like illness had been diagnosed either prior to or concurrent with CAP. Six patients had laboratory-confirmed influenza. Of six for whom vaccination status was available, none had received influenza vaccine.

VITAL SIGNS
Prevalence of Cigarette Smoking

- 11.5%-20.0%
- 20.1%-22.0%
- 22.1%-28.7%

Note: Based on 2005 data for adults 18 and older who have smoked 100 cigarettes and are current smokers. Source: American Cancer Society

Chester Bloom
Biomarkers Show Promise

Flu Vaccine Called a ‘Stopgap’

Nitric Oxide

Dr. Debley said, “It is easier and more fun to perform than spirometry, and the kids don’t seem to mind it.”

Another promising future tool is the measurement of biomarkers in exhaled breath condensate (EBC), which is achieved by cooling or freezing exhaled breath. It is then analyzed for the presence of inflammatory mediators, cytokines, and other proteins that have been detected in EBC.

EBC is another area of interest, although the field is still in its infancy, compared with eNO. Dr. Debley said. In patients with asthma, leukotrienes and interleukin-4 levels in EBC are reported to be higher, compared with those in healthy individuals. However, published literature has been inconsistent with regard to levels of leukotrienes and other mediators in EBC between asthma and healthy patients, and in some cases, attempts to detect leukotrienes in EBC using commercially available assays have been unsuccessful.

Dr. Debley is currently conducting a longitudinal National Institutes of Health-funded study at Seattle Children’s Hospital that is evaluating the use of EBC in wheezy toddlers and infants to identify which children with recurrent wheezing will respond to asthma medications and go on to develop persistent asthma.

RNFroy Graham, FCCP comments:

Exhaled nitric oxide increasingly appears to be a valuable measure of airway inflammation. Clear links in the reliability of symptom reports and technical limitations in both the performance and interpretation of spirometry, particularly in young children, suggest it is indeed a time for the reliable measurement of airway inflammation. Such measurement may well prove invaluable in assessing both disease severity and the response to anti-inflammatory therapy. The heterogeneity of the inflammatory response among individuals and the clinical evidence of varied response to various anti-inflammatory agents support the measurement of exhaled nitric oxide as a superbly discriminative tool in clinical management.

Dr. Doreen Addriozzo-Harris, FCCP comments:

These short durations suggest that the influenza virus and the MRSA infections probably occur independently, rather than the more classically described biphasic clinical course of CAP symptoms following flu illness, the CDC noted.

Infections Likely Concomitant

MRSA

and limited data, if the pandemic is an influenza pandemic or in situations of potential high-risk exposure. Studies of the vaccine in pediatric and geriatric populations are ongoing.

At the panel meeting, panelists and FDA officials referred to the vaccine as an “interim” or “stopgap” vaccine. Whereas the dose of the vaccine is relatively high, compared with seasonal influenza vaccines, research is being done to develop a better vaccine, Dr. Baylor said during the press briefing. No one can predict what strains will be the cause of a pandemic if one occurs, but “we also know that from very preliminary and limited data, if the pandemic is an H5N1-like virus, this vaccine might provide some cross-protection,” he said.

Information on U.S. pandemic flu preparedness is at www.pandemicflu.gov.
NPI Web Site Has Problems

Unfortunately, the article on the National Provider Identifier sounds more like a sales pitch for the Centers for Medicare and Medicaid Services than a balanced report (“National Provider Identifier Sign-Up Deadline Is May 23,” March 2007, p. 2). The NPI Web site, application process, and customer support are mediocre at best. Among the Web site’s many problems are the following:

► There is a lack of clarity regarding which fields are optional and which are required.
► There is a lack of a Social Security number, yet there is no statement as to the security of the online process.
► It is unclear how many medical licenses need to be registered. There is no place for additional state licenses.
► You need to print every individual page for a hard copy. The CMS does not provide a PDF format option for download, printing, and submission.

The last statement, “I agree to keep the NPPES (National Plan and Provider Enumeration System) updated with any changes to data listed on this application form within 30 days of the effective date of the change.” This places the submitting physician in an awkward position, because it is unrealistic to expect future updates of every piece of information with 30 days.

The CMS does not state how the information will be shared and de-identified. For all of the hype and importance of this major national initiative, you would think the online submission process would be a seamless, elegant system. Quite the contrary.

Dr. Chris Patricelli
Anchorage, Alaska

U.S. Tuberculosis Rates Declining in the Young

(per 100,000 population)

Data Watch

Source: Centers for Disease Control and Prevention

Dr. Jackson is chief of pediatric infectious diseases at Children’s Mercy Hospital, Kansas City, and professor of pediatrics at the University of Missouri-Kansas City.
TB Rates at All-Time Low, but Decline Has Slowed

**Foreign-born individuals and racial/ethnic minority populations continue to be disproportionately affected.**

**BY MIRIAM E. TUCKER**

Elsevier Global Medical News

The U.S. tuberculosis rate hit an all-time low in 2006, but the rate of decline has slowed recently. The average annual percentage decline in the TB incidence rate was 7.3% per year during 1993-2000, but the rate of decline dropped to just 1.8% per year during 2006, the CDC said (MMWR 2007;56:245-50).

Foreign-born individuals and racial/ethnic minority populations continue to be disproportionately affected by TB in the United States. In 2006, the TB rate among individuals born outside the United States was 9.5 times that of those born in the country, while the rates among blacks, Asians, and Hispanics was 8.4, 2.2, and 2.6 times higher than among whites, respectively.

The proportion of TB cases among foreign-born individuals has increased each year since 1993. In 2006, 56% of those cases were from just five countries: Mexico, the Philippines, Vietnam, India, and China. Most of the foreign-born individuals in the United States who progress from latent TB infection to TB disease initially became infected while abroad. Thus, “if the global TB pandemic remains unmitigated, eliminating TB in the United States will be extremely difficult,” the CDC said.

A total of 124 cases of multidrug-resistant TB (MBR TB) were reported in 2005, the most recent year for which complete drug susceptibility data are available. The proportion of MDR TB cases—defined as resistance to at least two first-line therapies, isoniazid and rifampin—remained constant at 1.2% from 2004 to 2005. In 2005, foreign-born individuals accounted for all the 124 MDR TB cases, the CDC said.

The number of extensively drug-resistant TB (XDR TB) cases didn’t change substantially from 1993-1999 to 2000-2006, but the characteristics of cases shifted in parallel with the changing epidemiology of TB in general and of MDR TB in particular. During 1993-1999, 32 reported cases met the criteria for XDR TB (resistance to isoniazid and rifampin, and to any second-line fluoroquinolone and at least one injectable drug), compared with 17 during 2005-2006 (MMWR 2007;56:250-3).

As with the overall TB rates, the overall numbers declined while the proportion among foreign-born individuals rose, from 79% in 1999-2000 to 80% in 2005. Other changes in XDR TB epidemiology included a decrease in the proportion of cases among HIV-infected individuals and an increase in the proportion of patients who are Asian, they said.

Effective treatment of MDR TB requires administration for 18-24 months of 4-6 drugs to which the infecting organism is susceptible, including multiple second-line drugs. Beginning in the 1980s, the use of second-line drugs increased substantially as physicians and TB control programs treated growing numbers of MDR TB cases. Increased use of these drugs resulted in MDR TB strains with extensive resistance to both first- and second-line drugs, the CDC said.

Progress has been made on several new drugs in the past year, with health professionals currently being conducted with six agents in five different drug classes. The CDC’s TB Trials Consortium, in collaboration with the Global Alliance for TB Drug Development, has completed two preliminary trials with moxifloxacin. Those studies are expected to lay the groundwork for a trial of a third treatment of MDR TB. The consortium is also nearing completion of a trial of a 3-month rifapentine-based treatment for latent TB infection.

**Use Caution in Diagnosing Asthma in Black Women**

**BY DOUG BRUNK**

Elsevier Global Medical News

San Diego — Asthma may be overdiagnosed in many obese African American women who present with dyspnea, results from a small pilot study suggest.

The finding is important because the incidence rates of asthma and obesity have increased over the last 20 years, especially among African American women, Dr. Daniel Waggoner reported during his poster session at the annual meeting of the American Academy of Allergy, Asthma, and Immunology.

“If somebody gives you a very good history of asthma symptoms, sometimes it’s a little bit easier to make the diagnosis,” Dr. Waggoner, of the division of allergy and immunology at Creighton University School of Medicine, said at an interview. “But if somebody comes in with rather nebulous symptoms, it’s very important to get some objective testing to make a diagnosis [of asthma], because many medications [for it] have side effects, and they’re expensive.”

He and his associates evaluated 18 African American women aged 19-90 years who live in or near Omaha and who had a physician diagnosis of asthma for at least 3 months. All had a body mass index (kg/m²) of 30 or greater, an FEV₁ (forced expiratory volume in 1 second) value of 65% or greater, and symptoms of dyspnea.

Over the course of three office visits, the researchers performed the following measurements in each patient to verify the asthma diagnosis: spirometry with postbronchodilator values, exhaled nitric oxide (eNO), methacholine challenges, and full-body plethysmography. Each of the four tests was considered a positive criterion for the diagnosis of asthma.

Dr. Waggoner said that of the 18 patients, 8 (44%) had a positive metha-choline challenge, 1 (6%) had demonstrated airway reversibility on spirometry, 10 (56%) had elevated eNO, and 6 (33%) had airflow obstruction as measured by plethysmography.

No patient met all four criteria for the diagnosis of asthma, and only 9% met two or more of the criteria.

“Only one patient did not have an albuterol prescription,” Dr. Waggoner added. “I was really surprised that we didn’t have at least a handful more [who] demonstrated reversibility with albuterol or a bronchodilator.”

In their poster, the researchers concluded that in African American women who present with dyspnea, “an eNO and methacholine challenge should be considered to confirm or refute the diagnosis of asthma. Full-body plethysmography may provide clues to etiologies of dyspnea other than asthma (e.g., obesity, physiologic trapping) associated with obesity.”

The study was funded by the State of Nebraska Tobacco Settlement.
Resistant Influenza B Virus
As Virulent As Wild Type

A Japanese study shows a ‘low but appreciable’ rate of emergence of mutant influenza B strains.

BY MARY ANN MOON
Elsevier Global Medical News

Influenza B viruses with partial resistance to neuraminidase inhibitors have emerged during routine antiviral therapy and appear to be transmitted from person to person within communities as well as within families.

That finding emerged from a Japanese study.

So far, the rate of emergence of resistant influenza B viruses appears to be “low but appreciable” at 1.4%, and the mutant viruses appear to be as virulent as wild-type viruses, Dr. Shuji Hatakeyama and associates wrote.

In an editorial comment accompanying this report, Dr. Anne Moscona and Dr. Jennifer McKimm-Breschkin said that until now, the medical community has been somewhat complacent about resistant influenza B because little resistance of these viruses has been documented. Moreover, the few resistant strains that have emerged in animal and in vitro studies appeared to have compromised infectivity and transmissibility.

“This has led to the belief that significant transmission is unlikely to occur among humans,” they wrote.

Now the findings of Dr. Hatakeyama and associates make it “strikingly clear” that resistant strains are already circulating among humans and that they induce infection with the same duration of symptoms, level of viral shedding, and clinical outcome as nonresistant strains.

These findings mean that “it is no longer possible to be confident that resistant strains will have little effect on epidemic or pandemic influenza.” wrote the editorialists.

Dr. Hatakeyama of the University of Tokyo and associates tracked patterns of resistance and transmission during an influenza B outbreak in the winter of 2004-2005 that caused a widespread epidemic in Japan, the country with the highest use family members and among members of the same community (JAMA 2007;297:1435-42).

There were no differences in symptoms, clinical course, or viral shedding between subjects infected with resistant strains of the virus and those who had wild-type viruses. This result indicated that these mutant viruses “do not lose virulence even though they have evolved to a status that is less sensitive to the drug,” they noted.

In their editorial comment, Dr. Moscona of Weill Medical College of Cornell University, New York, and Dr. McKimm-Breschkin of Molecular and Health Technologies, Parkville, Australia, said, “Contrary to what had been hoped until now, some resistant variants are virulent pathogens.”

“The presence of low-level resistance sets the stage for selective pressure for development of high-level resistance,” they noted (JAMA 2007;297:1492-3).

IT IS NO LONGER POSSIBLE TO BE CONFIDENT THAT RESISTANT STRAINS WILL HAVE LITTLE EFFECT ON EPIDEMIC OR PANDEMIC INFLUENZA.”

Flu Pandemic Fears Spur New Antiviral, Diagnostic Tests

BY BRUCE K. DIXON
Elsevier Global Medical News

KEYSTONE, COLO. — Health care professionals should prepare for a worldwide influenza outbreak that could be more deadly than the Spanish flu pandemic of 1918, which infected one-third of the world’s population and killed half a million Americans, Dr. Gwen Huiit noted at a meeting on allergy/clinical immunology, asthma, and pulmonary medicine.

At the locus of concern is H5N1, or avian influenza A, a strain against which the world population has no immunity, and which is resistant to established antivirals, said Dr. Huiit, director of infection control at the National Jewish Medical and Research Center, Denver.

“This new strain is highly pathogenic for humans, and although it remains largely confined to bird populations and has not been found to be highly transmissible in its current form, many experts believe H5N1 is only one small mutation away from being easily transmissible from person to person,” she said at the meeting, sponsored by the National Jewish Medical and Research Center.

Dr. Huiit presented a depressing worst case scenario for the United States: An estimated 10 million hospitalizations, 2 million deaths, overwhelmed hospitals and public health services, the closing of schools for 3 months, workers unable to leave home, assigned grocery shopping days, and a devastated economy that could take years to recover.

And symptoms may be more severe than they were in the Spanish flu pandemic. “With H5N1, you start out with fever, cough, and myalgias, and ophthalmitis is commonly associated with this virus. Then we see rapid progression to pneumonia within 3-4 days, and the patient goes directly into adult respiratory distress syndrome, similar to [severe acute respiratory syndrome],” Dr. Huiit explained, adding that encephalitis may be an additional sequela.

At the end of 2006, the World Health Organization reported a total of 261 cases of H5N1 influenza with 157 deaths, which places the death rate from Avian flu at 60%. The death rate from ordinary flu is 0.1%.

Adding to the woes of a pandemic is the threat of methicillin-resistant Staphylococcus aureus (MRSA), Dr. Huitt said. “You survive the pandemic and then you get a severe MRSA pneumonia, which is known to come in and set up shop after our normal season. What happens then?”

The federal Department of Health and Human Services would activate the National Response Plan used for terrorism, major disasters, and other emergencies so that transportation, communications, emergency management, mass care, housing, and human services are put to their best use.

Unfortunately, during a national quarantine and the distribution of surgical masks to prevent droplet inoculation, Dr. Huitt remarked, the horse already will be out of the barn.

“All this would happen after the fact; we will already be behind the eight ball, because those early stages of infection are asymptomatic yet are shedding huge amounts of the virus,” Dr. Huitt said, noting that H5N1 has an incubation period of up to 5 days.

A happier, less likely scenario has the coming pandemic resembling the 1958 Hong Kong flu, which killed about 34,000 Americans. However, experience with H5N1 suggests that we should be ready for the worst, Dr. Huitt warned. She urged all health care professionals to remain alert and follow strict infection control procedures, especially frequent hand washing.

“H5N1 can live on hard surfaces for up to 2 days,” she said. “Transfer of the virus has been documented after it’s been on a person’s hands for 24 hours after that person touched a contaminated surface.”

Not all the news is bleak. In partnership with the Centers for Disease Control and Prevention, the University of Colorado at Boulder is developing a diagnostic test called the Flu Chip, which can determine the genetic signatures of specific influenza isolates from patient samples within hours.

“The Flu Chip has been almost 100% accurate in identifying the different types of influenza A, and that would be a huge advantage in a pandemic,” Dr. Huitt said.

A promising DNA vaccine has profited about 80% immunogenicity in monkeys. The first trial in humans was launched in December. And because DNA vaccine manufacturing does not rely on the use of chicken eggs, it can be produced much more quickly.

H5N1 is resistant to the antivirals amantadine and rimantadine, but Dr. Huiit discussed a new drug on the horizon called peramivir, a neuraminidase inhibitor that may have utility against H5N1.

In preclinical studies, avian influenza has been shown to be sensitive to peramivir, leading researchers to believe that in the proper formulation, the drug may be effective against the virus in humans. Dr. Huitt said the drug currently is available only in intramuscular and intravenous preparations, which would make large-scale administration impractical. “But critically ill people could be given this drug very quickly.”

Dr. Huitt urged all health care practitioners to make frequent visits to WHO and U.S. government Web sites, including www.pandemicflu.gov and www.cdc.gov/flu. Once in the CDC site, click on “information for specific groups,” then “health professionals.”

Dr. Huitt is on the speakers’ bureau and has consulted for Pfizer, maker of a pandemic influenza vaccine, and is on the speakers’ bureau for Hill-Rom Inc.
Vaccine Cut Pneumonia Admissions by 39% in Children

By Mary Ann Moon
Elsevier Global Medical News

SAN DIEGO — Inner-city obese children with moderate to severe asthma require significantly more hospitalizations, more visits to the emergency department, and more steroid bursts than do their nonobese counterparts, Dr. Fatima Hassan reported during a poster session at the annual meeting of the American Academy of Allergy, Asthma, and Immunology.

The findings add to mounting evidence that suggests an association between obesity and the severity and frequency of asthma symptoms in children.

“It’s not only the asthma symptoms that are affected by obesity,” Dr. Fatima Hassan, a third-year pediatric resident at Woodhull Medical and Mental Health Center, New York, said in an interview. “There are also effects on the general health profile, such as children who become depressed by their asthma symptoms and severity, and by the number of days they have to stay in the hospital.”

She and her associates at Children’s Hospital of Michigan in Detroit reviewed the medical charts of 109 inner-city children aged 6-18 years who were being followed in a high-risk clinic for people with moderate to severe asthma. They divided the children into obese and nonobese groups and compared their outcomes over a 2-year period.

Obesity was defined as having a body mass index greater than or equal to the 95th percentile as determined by National Health and Nutrition Examination Survey (NHANES I) age- and gender-specific data.

Of the 109 children, 43 were obese and 66 were not. Children in the obese group required significantly more hospitalizations than did children in the nonobese group (71 vs. 30, respectively), as well as more visits to the emergency department (194 vs. 30, respectively), and more steroid bursts (168 vs. 30, respectively).

Obese children had a significantly lower average spirometric ratio of forced expiratory volume in 1 second (FEV1) to forced vital capacity (FVC), compared with their nonobese counterparts (76% vs. 83%, respectively), but their average FEV1 values were not statistically different from that of the nonobese children (83% vs. 87%, respectively).

That discrepancy may have to do with other confounding factors such as obstructive sleep apnea and gastroesophageal reflux disease, they wrote.

Dr. Hassan noted that the prevalence of obesity among this study population was 39%, which is about twice as high as the prevalence in the general pediatric population, which ranges from 16% to 20%.

She acknowledged that advising obese children with asthma to lose weight can be tricky. “Some parents don’t believe that the children are obese and don’t see it as a problem,” Dr. Hassan said.

Obese children have lower average spirometric ratio.

One limitation of the study was that it did not include children with the mild persistent form of asthma. The study was funded by the Michigan Department of Community Health.

Dr. LeRoy Graham, FCCP, comments: Obesity is now well recognized as an important comorbid condition in childhood asthma. The current study suggests obesity is also related to physiologic severity in inner-city children with asthma. This is an important finding in a population characterized by disparate morbidity and mortality attributable to asthma. Clearly, additional study and the development of multidisciplinary disease management paradigms are sorely needed in this population.

Previous assumptions that suggest that most of the disparity relates merely to nonadherence and lower socioeconomic status are no longer acceptable.

Program’s Savings Pay For CF Screening

By Jonathan Gardner
Elsevier Global Medical News

The United Kingdom’s new cystic fibrin screening program for newborns can avert enough treatment costs to pay for itself, according to the analysis of treatment costs.

With CF patients diagnosed clinically, newborns diagnosed through a measurement of immunoreactive trypsin on a dried blood spot were significantly less expensive to treat. Based on the analysis, the researchers estimate that a screening program would have cost slightly less than $3 million in 2002 if it had been in place across the entire United Kingdom. The researchers estimate a mean drug-cost savings of $1.4 million and a median of $947,032 (Lancet 2007;369:1187-95).

“The argument that to wait until patients present with symptoms is potentially more cost-effective than to diagnose early and prophylactically, thereby saving the money that would otherwise have been spent on prophylactic and preventative treatment, does not hold true,” wrote Erika J. Sims, Ph.D., of the health economics group at the University of East Anglia, Norwich, England, and her colleagues.

In an accompanying editorial, Dr. Bridge Walker and Dr. Kevin Gaskin, of the University of Sydney, wrote that the analysis should buttress earlier findings that screening for cystic fibrosis is cost effective.

The researchers analyzed treatment and cost data from 53 specialized centers and clinics contained in the U.K. Cystic Fibrin Database. Patients were divided into groups based on whether they were identified by screening within 2 months of birth or by clinical indications, with those presenting based on meconium ileus or family history excluded.

The researchers calculated the costs of long-term therapies and intravenous antibiotics, and extrapolated the costs of a Scottish screening program in place since 2002 across the entire United Kingd, recalculating to U.S. dollars. They identified 184 patients diagnosed through screening (53% homozygous for delta F508) and 951 clinically diagnosed (56% homozygous). From ages 1 to 9 years, median treatment costs for those mixed pheno- types identified by screening were $352 (mean $7,228) a year, compared with median treatment costs for those clinically diagnosed of $2,442 (mean $12,908) a year.

For those homozygous patients, treatment costs at age 1-9 years for those identified through screening were $2,090 (mean $6,302), a year, compared with $2,516 (mean $12,981) a year for those diag- nosed clinically.

Study Finds Link Between Obesity And Asthma Severity in Children

By Doug Brunk
Elsevier Global Medical News

Obese Children Have Lower Average Spirometric Ratio

<table>
<thead>
<tr>
<th>Ratio of FEV1/FVC</th>
<th>Nonobese (n = 66)</th>
<th>Obese (n = 43)</th>
</tr>
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<tbody>
<tr>
<td>85%</td>
<td>76%</td>
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Source: Dr. Hassan

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Timeliness of Care in Lung Cancer

Only a few studies have examined the relationship between timeliness of care and survival, and the results of these studies have been mixed. Others have examined the time interval, median tumor cross-sectional diameter increased by 19% (range 0 to 373%)..


In the only non-European study, Quartermann et al. Thorax Cardiovasc Surg 2003; 51:445. Median time between hospitalization and treatment ranged from 3 weeks to 3 months.

Few published studies have attempted to identify predictors of more timely care. While several reported that age was not associated with delays in diagnosis or treatment, one small study (n=83) found that patients younger than age 45 were less likely to seek evaluation within 3 months of the onset of symptoms (Bourke et al. Chest 1992; 102:1723).

No study, to my knowledge, has examined the relationship between the timeliness of care and other patient factors (eg, race/ethnicity, comorbidities, etc) or institutional characteristics. Only a few studies have examined the relationship between timeliness of care and survival, and the results of these studies have been mixed.

Two studies from Japan reported worse survival in patients who experienced longer delays after suspicious nodules were detected by lung cancer screening. In one study, median survival was approximately 35 months for patients with diagnostic delays less than 4 months, compared with 20 months for patients with longer delays (p<0.05) (Kanashiki et al. Oncol Rep 2003; 10:649).

Likewise, another study found that, after adjusting for age, gender, histology, stage, and treatment, the hazard of death was twice as high in patients who had a 1-year delay in diagnosis because the radiographic abnormality was seen only in retrospect (hazard ratio [HR] 2.2, 95% CI 1.4 to 2.8) (Kashibawara et al. Lung Cancer 2003; 40:67).

These studies are limited by the presence of symptoms at the time of presentation. One study from Sweden examined timeliness of care and survival in a relatively large sample (n=466) and heterogeneous sample of patients with NSCLC (Myrdal et al. Thorax 2004; 59:45). Median time from symptom onset to treatment was 4.0 months (interquartile range [IQR] 3.0 to 7.1 months), and median time from hospitalization to treatment was 1.6 months (IQR 0.9 to 2.4 months). This is a confounding of selection by treatment because patients who had more severe disease were more likely to be referred for surgical intervention.

At the debate about screening for lung cancer in asymptomatic patients continues, often ignored are issues relevant to the care of patients who do have lung cancer. Dr. Gould raises many important questions about the timeliness of care in these patients: What symptoms, especially in patients with underlying lung disease, should prompt general practitioners to consider the diagnosis of lung cancer? How quickly should general practitioners and their pulmonary consultants move in establishing the diagnosis of lung cancer? Once the diagnosis of lung cancer is confirmed, will expedited staging and treatment improve outcomes?

There is an obvious lack of recent information addressing these questions. Further research on ways to improve the timely identification and treatment of lung cancer patients, as Dr. Gould correctly points out, should be a priority. —Editor
President’s Report

Capitol Hill Caucus: Part II—ACCP Goes to Washington

Last month, I discussed the attitudes of Americans regarding health care. Polls from both political parties agree that most Americans identify rising health-care costs, declining access to care, and the 46 million Americans with no health insurance as the most important domestic issues today.

At the 14th Annual ACCP Capitol Hill Caucus in March, 81 ACCP members and staff met with members of Congress and their staffs to discuss issues that are important to our patients and our profession. Not one of us don’t get courses in lobbying during medical school or residency, so on Monday afternoon, we learned some of the basics. Knowing that you have about 15 minutes to make your points before being ushered out and another group comes in to express their concerns, you have to be organized and stay rigorously on message.

We were prepared with our talking points and noted to keep three things in mind: (1) Be brief. (2) Be accurate. (3) Say something new.

A personal story about a specific patient was recommended as a particularly effective tactic to get the Legislative Aids (LA) interested. And, the LAs do run the agenda.

Finally, we were instructed to be sure to make the “ask,” and we had two high-priority “asks.”

The first was to fix the “sustainable growth rate” (SGR) formula for Medicare physician reimbursement. We followed the same script as last year but had to come back because this problem seems too sticky to get fixed in the current political climate.

Briefly, the SGR is intended to link Medicare payments to the gross domestic product (GDP). However, when growth in medical care expenditures per beneficiary exceeds the growth rate of the GDP, then physician payments get reduced.

Practice costs have risen at rates higher than the GDP and inflation for several years, and the SGR formula called for cuts in reimbursement every year. Congress allowed a 5% cut in 2002 but froze the cut every year since and added small positive updates in 2003 to 2005 (but not matching inflation).

At the end of 2006, Congress froze Medicare payments, postponing the 5% cut until the end of 2007, when physicians are facing a 10% payment cut if no action is taken. With the costs of practice rising out of physicians’ control, a 10% reduction in payment will force many to stop seeing Medicare patients. And worse, since Medicare payments are tied to the entire health-care sector, these effects will be amplified through private, Medicaid, and military reimbursement formulas. So, there is nothing “sustainable” or “growing” about the SGR, except for, maybe, the hardship it causes practicing physicians.

Our proposal (along with most of our colleagues) is to scrap the SGR formula and replace it with payments linked to the Medicare Economic Index (MEI), which tracks increases in practice costs over time. We believe this is reasonable, and also fair, as physicians are the only providers subject to the impossible SGR formula.

The problem is that implementing another system will cost billions of dollars, and as we all know, that is a tough “ask” in the current climate. And whoever said life is fair?

Our other major issue relates to the current and worsening shortage in the critical care workforce. Briefly, there are already too few critical care clinicians of all disciplines (nurses, respiratory therapists, pharmacists) to provide proper care for patients already in our ICUs, and the numbers of providers are not projected to increase fast enough to keep pace with the aging of the population who will require intensive care.

Largely through efforts of the ACCP, in close collaboration with the American Association of Critical-Care Nurses, American Thoracic Society, and Society of Critical Care Medicine, we worked with Senator Richard Durbin (D-IL) and Senator Mike Crapo (R-ID) to draft the Patient-Focused Critical Care Enhancement Act (S.718), introduced in the Senate on February 28, 2007.

This proposed legislation represents a first step to address this workforce shortage by funding $5 million for research and $4 million for demonstration projects on ICU practice and organization, coordinated community and regional approaches, family assistance programs, and the use of telemedicine technology, especially in rural areas underserved by the critical care workforce.

In addition, it calls for the recruitment of at least 50 intensivists yearly into the National Health Service Corps Loan Repayment Program. (The bill and other materials related to the critical care workforce shortage can be found at www.chestnet.org/practice/get/DOQITWorkforce.php.)

On Tuesday morning, we heard from one Senator and four Representatives, two of whom were physicians. They all agreed that the problems of the uninsured and rising health-care costs were dire, and that the SGR sorely needs fixing.

To me, the most thoughtfully and compelling of the group was Representative Tom Allen of Maine. Full disclosure: yes, I am a registered Democrat, and no, I do not live in Maine and have not, nor will I conceivably ever, vote for him. Living in Maine is not my destiny. I identified the central issue: What is the role of government in health care? Is it to improve the lives and health of our citizens, or is it to stay out of the way and let the market take care of it? He pointed out correctly that somehow other free and affluent societies like ours cover everyone at two-thirds the cost of the United States, with the same outcomes.

Medicare and Medicaid will not survive if the SGR is not changed and providers stop participating.

He even offered some constructive and feasible solutions, including subsidizing small business to provide health insurance for employees, covering all children, and allowing everyone to buy into Medicare, with a subsidy if they need one. He also was a sponsor of the Pulmonary and Cardiac Rehabilitation Act (S.329/H.R.552) that provides a $5 million rehabilitation benefit for all Medicare recipients. This is obviously important to our patients and to ACCP members and worthy of serious support by all of us.

In the afternoon, we all were scheduled to meet in the offices of our respective members of Congress. A few met with the Senators and Representatives personally but most with the health-care LAs. Speaking for myself, the LAs of my Representatives and Senators knew all about the SGR problem and would love to fix it. After all, I’m from New York, the blues of blue states, where we think spending money on health care is OK, even if taxes go up some. But nobody quite knows how to fix SGR, especially in the current political and economic environment.

We suggested linking it to the Medicare Economic Index, but they replied that it would cost billions, and we countered that it was necessary. They agreed a fix was needed, and they would transmit our message to their boss. They didn’t know about the workforce legislation, but we provided the verbal and written support, and they promised to look at it and bring it to their boss. I was impressed by their grasp of health-care issues, and sorry for them because there was a line of people with other passionate concerns behind us, and they would have to be as polite and attentive as they were to us.

But, I also believe that all of the members of Congress would get all of our messages, and, maybe, the messages will have a positive impact. Besides, the ATS has a caucus too, and the ACCP will be back next year to Congress to remind them about these issues, along with some new ones.

Photos from the 2007 ACCP Capitol Hill Caucus can be found at www.chestnet.org/practice/er/index.php.

Practice Management

CMS Opens the Online Doors to Its New DOQ-IT University

The Centers for Medicare and Medicaid Services (CMS) has announced the national launch of DOQ-IT (Doctor’s Office Quality Information Technology) University, or DOQ-IT U, to support health information technology in physician offices.

The new interactive learning tool educates physicians in the adoption and implementation of electronic health records and care management practices.

DOQ-IT U is an interactive, Web-based tool designed to provide solo and small-to-medium-sized physician practices with the education for successful health information technology adoption, including lessons on culture change, vendor selection, and operational redesign, along with clinical processes. The nationally available e-learning system is available at no charge.

To view the entire press release, please go to: www.cms.hhs.gov/apps/media/press_releases.asp.
Healthy Work Environments: True Collaboration

BY DEBRA GERARDI, RN, MPH, JD

The AACN Standards for Establishing and Sustaining Healthy Work Environments require that ‘every team member embrace true collaboration as an ongoing process and invest in its development to ensure a sustained culture of collaboration.’

The creation of cultures in which everyone is accountable for achieving common goals, respectful professional conduct, integration of diverse viewpoints, and engagement in difficult conversations requires us to focus on skills and processes currently underrepresented in our clinical work environments. Expanding our capacity to collaborate with colleagues at each of these levels enhances our ability to partner with patients and families in meaningful ways. Collaborating across professions is challenging. Recent studies reveal that physicians and nurses have different perceptions regarding levels of collaboration, cooperation, and conflict.

In a survey of intensive care nurses and physicians, 73% of physicians believed that collaboration with nurses was high or very high, while only 33% of nurses in the same units believed that to be true. A 2001 study looked at how hospital professionals handle interprofessional conflicts. The researchers found that, before recognizing conflict, physicians tolerate more stress and disagreement than members of other professional groups. Improving interprofessional collaboration requires that we develop shared meaning around these concepts before developing skills to improve how we engage with each other. To collaborate effectively and navigate the space where trust, respect, reputation, and integrity lie, we must master four basic skills: to be present in the moment, listen openly, problem-solve together, and make the other person look good. Expanding our capacity to focus and be present when communicating with colleagues is an essential first skill. Listening openly requires that we approach interactions with curiosity rather than certainty. Being open and listening below the surface to what is really being said saves time and builds trust.

Professional training often reinforces the myth that we are solely responsible for patient care. Interdependencies are integral to complex environments, and developing the ability to problem-solve together expands our capacity for developing more effective and accurate solutions.

To do no harm, we must work together. Complexity dictates that no one has enough information to care individually for the patient. Coming together is the only way to consistently prevent harm to patients. Strategies for fostering collaborative work environments include:

- Creation, use, and evaluation of processes that define accountability for collaboration
- Skills training in communication, teamwork, negotiation, and conflict resolution
- Expanded opportunity for interprofessional partnerships and joint decision making
- Organizational commitment to provide time needed to address and resolve disputes
- Creation of codes of conduct and universal agreements to behave professionally and respectfully
- Creation of processes that support conflict resolution at all levels of the organization and that make use of trained facilitators or mediators within or external to the organization when appropriate

Consistently address behaviors that disrupt the work environment or lead to unsafe care. Collaboration occurs at the intersection between self-reflection and active engagement; it is simultaneously a conscious act by individuals and the product of group wisdom. Collaboration requires time and commitment; in return, we gain understanding, build trust, discover common purpose, and expand possibility. Collaboration is our means for working better together and not just working side-by-side.

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

References:

Ms. Gerardi is Chair, Program on Health Care Collaboration and Conflict Resolution, Werner Institute for Negotiation and Dispute Resolution, Creighton University School of Law. She can be reached at debragerardi@creighton.edu.

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ACCP PRODUCT OF THE MONTH
COPD: Emerging Trends in Treatment Options—Podcast

As chronic obstructive pulmonary disease (COPD) becomes more prevalent and associated mortality rates continue to rise, the need for better treatment options and different delivery systems is high. This virtual symposium podcast from the CHEST 2006 satellite will provide the most current information regarding diagnostic tools and treatment opportunities. Drs. Neil R. MacIntyre, FCCP, Stephen C. Lazarus, FCCP and Fernando J. Martinez, FCCP, will review advanced studies and ideas for future treatments and other pharmacologic options in their presentations. To view the virtual satellite symposium podcast, please visit the ACCP online education site at www.chestnet.org/education online/index.php and click on the podcast link.

NOW SHOWING ON CHESTNET.ORG
What do patients want and need from physicians, and where do the problems and pitfalls lie?

In September 2006, the ACCP Sleep Institute sponsored a 1.5-day conference with the aim of developing a continuity of care model for long-term management of obstructive sleep apnea (OSA). We invited pulmonary/sleep medicine specialists, primary care physicians, home-care company representatives, continuous positive airway pressure (CPAP) and other sleeprelated equipment manufacturers, insurance company representatives, and, perhaps, most importantly, four patients with OSA.

The patient spokesperson was Dave Hargett, a retired Sears manager who lives in the Chicago suburbs, about 40 miles from the ACCP headquarters in Northbrook, IL. He was such an exceptionally articulate and passionate spokesperson for the patient perspective, I wanted to give him another venue to share his message about OSA.

I interviewed Dave recently about his experience with OSA, what patients want and need from their physicians, and where the problems and pitfalls lie in developing a strong and successful partnership between patient and physician. We also talked about what possible solutions might exist to improve patient-physician partnering and patient outcomes.

Charles Atwood: Dave, thanks for agreeing to be interviewed for Sleep Strategies.

Dave Hargett: You’re welcome.

Atwood: If you are willing to talk about your experience with sleep apnea, I think it would be a good place to start.

Hargett: I was diagnosed with OSA in 1994. I read a newspaper story about sleep apnea and thought I had all the symptoms mentioned in the article and should get checked out. Six months later, I talked to my primary physician about it. Admitting he knew nothing about sleep, he referred me to a sleep specialist. After a few insurance hassles, I had a diagnostic sleep study. The study showed severe OSA. My apnea-hypopnea index was 82, with desaturations as low as 52%. The night my sleep physician received the results, I started receiving CPAP at a temporary setting of 8 cm. Ultimately, pressure went to 13 cm, but, even at the initial setting of 8 cm, I felt tremendously better after a week of use. I was able to cut out my 2-hour Saturday and Sunday naps after only 4 days! I still use CPAP today at a pressure of 12 cm.

While I’ve had cardiac bypass surgery, an open cholecystectomy, and other health issues, I still feel better today at age 58 than I did with untreated apnea at age 45. To paraphrase a country song, “I was much too young to feel that damn old.”

Atwood: What is your connection now to the sleep field?

Hargett: I am an apnea patient turned sleep activist and advocate. I’m serving my 4th year as Chairman of the American Sleep Apnea Association (ASAA). I also volunteer in the Chicago area as an A.W.A.K.E. group leader, where I run two separate A.W.A.K.E. groups.

Atwood: A.W.A.K.E. (Alert, Well, And Keeping Energetic) groups are sleep apnea patient support groups fostered by the ASAA. Hargett: That’s right. A.W.A.K.E. groups provide a way to offer patient education and compliance tips. We’re always looking for more sleep centers to start up and to sponsor groups. I also respond to e-mail questions that come through the ASAA Web site. I answer 250 to 300 e-mails per month from patients who have questions about diagnosis and therapy. I spend hours each month talking to patients on the phone. I also do public speaking on sleep apnea.

Atwood: From your viewpoint as a very knowledgeable patient and patient advocate for sleep medicine, what do you see as some of the problems that patients face in getting help for OSA?

Hargett: The first and most serious problem is that many physicians just do not know very much about sleep disorders or they don’t take them seriously.

My own family physician is a very good doctor, but he does not have a single question about sleep on his office health questionnaires. He knows that I have sleep apnea and asks me about it regularly now, but I have no idea how often he recognizes it in other patients—probably not enough.

Atwood: What do your friends in A.W.A.K.E. meetings tell you about their experiences?

Hargett: They are confused. Their primary care physician may have referred them to a sleep laboratory for testing, but the sleep laboratory staff has no long-term connection with the patient because they are mainly there to do sleep studies. Patients may work with a home-care company who provides their CPAP machine, but the home-care company is paid for equipment, not follow-up care. Many companies do the best they can to provide support, but there is a limit.

Some patients I know have never seen a physician knowledgeable about sleep medicine. They have been diagnosed with a serious disorder, one associated with serious consequences to quality of life, heart disease, risk of car crashes, etc. They have a therapy prescribed and then are left without anyone really to help them.

I often tell people that for patients with sleep disorders, managed health care means “manage your own health care.” Ask questions. Learn. Find help. Manage your own care.

Atwood: What are physicians weakest at in the OSA diagnosis and treatment process?

Hargett: At the primary level, recognition of sleep disorders is improving, but it is still the weakest point. Patients are frequently in denial about sleep problems. They don’t mention all their symptoms, and physicians don’t put together all the clues.

Primary physicians also need to do a better job following up with their patients with sleep apnea. I realize a primary care physician may not know very much about sleep apnea or treatment options, but at least they could encourage their patients to follow up with knowledgeable specialists or even home-care companies if they have problems with therapy.

This is not happening. Primary care physicians are not asking how CPAP therapy is going or if patients are even using it regularly. On the other hand, patients should be more proactive in discussing their apnea with their primary physicians.

Most sleep specialists are great at diagnosis, but I see major weakness still in educating patients about their disorder and therapy options.

Once the prescription is written for CPAP or the patient is passed on to an apnea dentist or a surgeon, many of the specialists lose track of their patients. No one is following up to ensure compliance with therapy.

Personally, I believe that patients who have severe sleep apnea, as I do, need a competent specialist to help manage this problem. Because sleep apnea touches on so many other aspects of health, severe disease can really be distressing. Having a good sleep specialist on your medical team is important.

My sleep specialist is a pulmonary physician who is board-certified in sleep medicine. He has been very helpful, and I see him once a year.

Atwood: The ACCP is currently implementing a primary care education program directed at “front-line” physicians—family physicians, general internists, and others who work in primary care. What can we do to better educate patients about sleep apnea? What do patients want to know about this condition?

Hargett: Patients ask me all the time: “What is sleep apnea?” These questions come from people diagnosed with apnea and already receiving therapy. Patients are hungry for information about their diagnosis and what therapy is best. Physicians should take the time to explain things up front so that the patients can understand the issues and be more comfortable with the chosen therapy.

Patients receiving CPAP also need to be reassured that CPAP therapy is very manageable. Too often, I hear people say “I can’t wear a mask” or “I can’t use that machine the rest of my life.” I tell patients it’s like wearing glasses. You need glasses to see and you need the CPAP to breathe when you sleep. Glasses have to be adjusted; they slip on your nose slightly, just like a CPAP mask at night. They have to be cleaned regularly, just like your mask and headgear. Occasionally, you need to see your eye doctor to get your prescription checked, just as you may need a follow-up titration study.

Compared with the benefits gained, the hassle of therapy is not that much.

Atwood: Thanks, Dave, for your time and insights into how patients deal with and feel about sleep apnea.

Dr. Charles W. Atwood, Jr., FCCP
Section Editor, Sleep Strategies
Help us explore the way we look at idiopathic pulmonary fibrosis (IPF)

IPF has been associated with increased levels of endothelin (ET), a 21–amino acid peptide with diverse biological functions and pathological effects. Patients with IPF demonstrate elevated ET plasma concentrations and ET expression in the lung tissue. Among the resources provided is a regularly updated curriculum of current articles and published papers on pulmonary vascular disease. The NetWork is also compiling a list of physicians treating pulmonary hypertension to serve as a resource for members. An online questionnaire will be posted on the Web page. The NetWork recently conducted a survey on the...
A landmark IPF morbidity and mortality trial is under way

Patients are now enrolling in a new IPF trial called BUILD-3. Inclusion criteria include age over 18 years, biopsy-proven IPF diagnosis, and disease duration less than 3 years. Exclusion criteria include interstitial lung disease due to conditions other than IPF, and severe restrictive lung disease.

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(Identifier # NCT00391443)
ACCP To Attend Guidelines International Network Conference

BY CARLA T. HERRERIAS, MPH; SANDRA ZELMAN-LEWIS, PHD; AND JULIA HEITZER, MS

This summer, a member of the Health and Science Policy (HSP) Committee and HSP staff will be attending the 4th Guidelines International Network (G-I-N) conference in Toronto, being held in North America for the first time.

The themes of this conference are as follows: setting standards in guideline development; translating knowledge and implementation of guidelines; and evaluating the impact of guidelines. This conference will bring together both members and nonmembers of the G-I-N, guideline developers and adapters, clinicians, policy makers, and many others.

The G-I-N is an international not-for-profit association of organizations and individuals involved in the development and use of clinical practice guidelines. G-I-N seeks to improve the quality of health care by promoting systematic practice guidelines and their application into practice.1

The ACCP, through the HSP Committee, has submitted two abstracts for the conference. The first focuses on the ACCP guideline methodology, including an overall summary of our grading system and how it was developed. It also addresses resource allocation and patient preferences. The second abstract describes a project at Nemours Clinical Management Program, Orlando, FL, to measure standards of care in pediatrics through the development of critical data elements, identified by linking content experts to experts in evidence-based medicine. Critical data elements can be valuable tools for measuring standards of care. The Nemours project utilizes the ACCP grading system.

Furthermore, the HSP Committee has made a decision to address the implementation of ACCP clinical practice guidelines. Through its continuing association with the Agency for Healthcare Research and Quality, specifically Translating Research Into Practice, the ACCP has learned about implementation techniques that are in use at various institutions here and abroad. The Guidelines Implementation Subcommittee was formed in late 2006, with the initial goal of assessing which formats ACCP members would find useful for implementation tools that could be incorporated into practice in their local settings. This subcommittee is developing a session on implementation of guidelines for CHEST 2007. Watch for more information on upcoming guidelines and implementation tools on the HSP Web site, at www.chestnet.org.

Attendance at this conference and membership in the G-I-N provides the ACCP a valuable opportunity to network and develop relationships both nationally and internationally, with other guideline developers and those who focus on dissemination and implementation of clinical practice guidelines.

ACCP WORLDWIDE

The 7th ACCP Central America Pro Bono CME Course

BY DR. UDAYA B. S. PRAKASH, FCCP

The 7th Annual ACCP Central America pro bono CME course on March 27-28, 2007, was successfully concluded as part of the XXI Congreso de la Federación Centroamericana y del Caribe de Neumología y Cirugía del Tórax, March 27-30, 2007, San Pedro de Macoris, República Dominicana. The 5-day congress was attended by more than 420 physicians from 20 countries. The 1.5-day ACCP course was attended by approximately 145 physicians.

The ACCP pro bono faculty included: Dr. Carlos M. Alvarado-Galvez, FCCP (Tegucigalpa, Honduras); Dr. V. Theodore Barnett, FCCP (Milwaukee, WI); Dr. Naresh A. Dewan, FCCP (Omaha, NE); Dr. Rodolfo C. Morice, FCCP (Houston, TX); Dr. Udaya B. S. Prakash, FCCP (Rochester, MN); and Dr. Sandra K. Willsie, FCCP (Kansas City, MO). The ACCP scientific program director was Dr. Udaya B. S. Prakash, FCCP. The co-director and president of the Federation congress was Dr. Eduardo Gastreute de Windt.

The scientific program included formal lectures and a workshop on bronchoscopy. The topics were selected by the organizers and included asthma, pleural effusions, sleep-disordered breathing, ACCP lung cancer guidelines, pulmonary complications of AIDS, and more.

The 8th ACCP Central America pro bono CME course is scheduled (pending approval from ACCP leadership) for March 4-5, 2008, at the Intercontinental Hotel, Managua, Nicaragua.

CHEST 2007 and Chicago:
A Tourist’s To-Do List

BY DR. UDAYA B. S. PRAKASH, FCCP

As “The City That Works,” Chicago certainly provides all of the amenities necessary for a top-notch meeting, such as CHEST 2007. But, the city has so much more to offer! Whether by foot, bus, or boat—on land, lake, river, or in the sky, here are just a few of the must-see and do’s while visiting Chicago.

Perhaps one of the best ways to see the city is from 1,000 feet straight up, made possible by visiting the Sears Tower Sky Deck or the John Hancock Observatory. From your perch, you’ll be able to see many of Chicago’s famous attractions, like Navy Pier, Buckingham Fountain, the Millennium Park Bean, and the Lincoln Park Zoo, to name a few.

But, if you prefer being a little closer to the ground, many year-round tours are available by bus and boat. Your hotel’s concierge is the perfect place to make arrangements.

Some of the city’s finest hidden gems include local art galleries and small performing arts studios, but Chicago also offers some of the world’s finest and largest museums. A quick trip over to Museum Campus offers the opportunity to choose from three of Chicago’s best—the Field Museum, Shedd Aquarium, or Adler Planetarium. And, just down the road in either direction, you’ll find the Museum of Science and Industry or the Art Institute of Chicago. If you plan on visiting more than one, consider purchasing the CityPass, which includes admission to a number of museums for a flat fee.

With all there is to see and do, it’ll be a wonder if you can fit it all in—but that doesn’t mean you shouldn’t try. Everything this city has to offer, from its famous landmarks to world-renowned attractions, are just a few of the reasons why Chicago is our kind of a town and the perfect place for CHEST 2007!

For more information about Chicago, go to www.choosechicago.com/default.html.

Stay tuned for more details about CHEST 2007, October 20-25, coming soon!
The Right Tools.

Making a Difference Society: New Category Introduced

The Making a Difference Society debuted at CHEST 2006 and 50 ACCP members committed to being Difference Makers by becoming Charter Members of the Society at the $1,000+ level. Making a Difference Society donors are annual contributors giving in the $1,000 to $25,000 range.

The debut of this Society created an interest among new fellows (up to 5-years out of training), as well as among affiliate and allied members. The second phase of the Making a Difference Society—New ACCP Members has been launched. The giving levels for New ACCP Members have been reduced to allow for participation that may be more attainable. This new program’s tax-deductible contributions will range from $100 to $1,000 annually.

Benefits shared by both types of Making a Difference Society donors will be a listing in The CHEST Foundation’s Annual Report and complimentary Making a Difference Award Dinner tickets for annual giving of $500 (one ticket) and $1,000 (two tickets). In addition, donors will receive special recognition as Medallion Difference Makers for those contributing at the highest level within their respective giving level.

These annual gifts allow The Foundation’s work to continue in the four focus areas that ACCP members are already familiar with: tobacco prevention, critical care and family assistance, clinical research, and humanitarian awards. Our goal has been consistent: helping you help your patients live and breathe easier. You may make your Making a Difference Society donations by credit card online at www.chestfoundation.org. If you prefer, mail a check to the attention of Marilyn Lederer at The CHEST Foundation, 3300 Dundee Road, Northbrook, IL 60062. If you would like to have more information about the Making a a Difference Society, please contact Teri Ruiz at truz@chestnet.org.

Don’t Miss the Making a Difference Awards Dinner

This year’s Making a Difference Awards Dinner will be held during CHEST 2007 on Saturday, October 20, 2007, 7:00 PM to 10:30 PM, at the architecturally significant Chicago Cultural Center.

Join your ACCP colleagues and friends in honoring the distinguished career of ACCP Past President, Dr. Thomas L. Petty, Master FCCP. The CHEST Foundation, along with lead sponsor, Boehringer Ingelheim Pharmaceuticals, Inc., has established an endowment in his honor. The Thomas L. Petty, MD, FCCP, Endowment in COPD Research will fund COPD research and other activities to improve care for patients with COPD. This is the ninth consecutive year that The CHEST Foundation will recognize ACCP members’ important pro bono service around the world. Grant and award monies total $150,000 and will support 14 outstanding sustainable community projects. There will be four winning Humanitarian Project Development Grants, nine winners of the Humanitarian Recognition Award, and one Ambassadors Group Humanitarian Recognition Award winner.

Registration will be available online starting July 2, 2007, at www.chestfoundation.org. Price per ticket is $150. Making a Difference Society Members at the $500 and $1,000+ levels will be provided with one or two tickets, respectively. Contact Teri Ruiz at truz@chestnet.org.

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San Diego — An oral care regimen administered every 4 hours significantly decreased the rate of ventilator-associated pneumonia in a population of pediatric burn patients, Debbie Chapyak, R.N., said at the annual meeting of the American Burn Association. Although oral hygiene is considered standard nursing care, “it is often neglected,” said Ms. Chapyak of the Shriners Hospitals for Children–Northern California. “Due to the presence of the endotracheal tube, traditional tooth brushing is difficult.”

She and her associates evaluated the impact of a new oral care protocol on the rate of ventilator-associated pneumonia (VAP) in 70 acute burn patients—all of whom required more than 48 hours of ventilator support—admitted to the hospital over a 2-year period. Before the new protocol was introduced, the researchers used swabs to administer Nystatin solution 5 mL to the oral cavity every 6 hours and Peridex 5 mL every 12 hours.

No tooth brushing or suctioning of subglottic secretions was done.

The new protocol consisted of administering the Q-Care Oral Care Cleansing System by Sage Products. With this product, the teeth and surface of the gum are brushed with a suction swab and antiseptic rinse every 4 hours. Each package contains enough oral care for 24 hours.

Of the 70 patients, 30 underwent oral care before the new protocol was introduced (controls) while 40 underwent oral care with the new protocol. There were no differences in mean age or VAP risk factors between the two groups, but patients in the new protocol group had larger burns and a higher percentage of full-thickness burns than did the controls.

Ms. Chapyak reported that 15 patients in the control group (50%) developed VAP, compared with 11 patients in the new protocol group (28%).

This represented a drop from 28 cases of VAP per 1,000 ventilator days in control group to 14 cases of VAP per 1,000 ventilator days in the new protocol group, a difference that was statistically significant.

The small sample size and the use of historical controls were the limitations of the study included. “We were unable to account for possible protocol lapses, and we were unable to assess the frequency of actual oral care before the protocol,” she said.

The investigators reported no financial ties to Sage Products.

The researchers collected plasma on days 1 and 5 of the study to test for biomarkers indicating systemic inflammation and dysregulated coagulation.

In addition, all patients were prospectively evaluated daily regarding their Agitation-Sedation Scale and for the presence of delirium with the Confusion Assessment Method for the ICU (CAM-ICU). The research was supported by the National Institutes of Health and the Saint Thomas Foundation.

The 139 patients involved in the biomarker study were predominantly older, with a mean age of 63 years. About half of the patients were women, and the population was critically ill with a median APACHE II score of 27. Among about half of the patients in the cohort there were no differences in mean age and sex distribution. The population was critically ill with a median APACHE II score of 27. Among the 96 survivors, however, soluble tumor necrosis factor receptor 1 (sTNFR1), neutrophil gelatinase-associated lipocandin (NGAL), dimer, and protein C were each independently and significantly associated with the total duration of delirium.

As concentrations of the markers increased, indicating increased inflammation—sTNFR1 and NGAL—increased, patients were more likely to have prolonged delirium. The same was true of rising dimer concentrations, which indicate abnormally increased coagulation. As protein C concentration increased, however, indicating normal coagulation, the duration of delirium decreased.

The results indicate that inflammation and coagulopathy are important contributors to the development of brain dysfunction in ICU patients. “These markers are not specific to brain dysfunction, however, and our next step will be to identify novel markers of critical illness-associated brain dysfunction,” Dr. Girard said.

Minocycline-Rifampin–Coated Catheters Beneficial in Burn Unit

San Diego — The introduction of minocycline-rifampin–impregnated catheters was associated with a significant reduction of catheter-related bloodstream infections in burn intensive care unit patients and a significant drop in health care costs, Dr. Nichole S. Meissner reported during the annual meeting of the American Burn Association.

According to the National Healthcare Safety Network, an average of seven catheter-related bloodstream infections per 1,000 line-days occur in the burn intensive care unit, compared with four infections per 1,000 line-days in the medical-surgical ICU. “Many burn centers have adopted a policy of routine changes to keep these rates at acceptable low levels,” said Dr. Meissner, a resident in the department of surgery at the University of California, Irvine Medical Center.

“This consumes time and resources, and places the patient at increased risk with each procedure,” she said. She added that the minocycline-rifampin–impregnated catheters have lower rates of infection, compared with chlorhexidine silver sulfadiazine–impregnated catheters, and lower rates of colonization compared with silver-platinum–carbon–impregnated catheters. “An optimal catheter policy will reduce the risk of catheter-related bloodstream infection and at the same time reduce the patient exposure to risk associated with catheter insertion,” she said.

During the study’s preintervention period (May 2000 through June 2001), she and her associates changed the indwelling catheters in burn ICU patients every 3-4 days via new puncture. During the intervention period (July 2003 through June 2006), the researchers used minocycline-rifampin–impregnated catheters on all patients in the burn ICU who required catheterization. They allowed the catheters to remain in place for 7 days during the first 6 months, and for up to 14 days during the rest of the study period. The lines could be removed at any time based on the attending’s discretion.

The researchers used multivariate analysis to determine the association between biomarker concentrations and the duration of delirium after adjusting for age, severity of illness, sepsis, baseline cognitive impairment, and total dose of sedative and analgesic drugs given in the ICU.

Among all 139 patients, multiple biomarkers were associated with duration of acute brain dysfunction, but that analysis can be complicated by the early death of some patients, Dr. Girard said.

Among the 96 survivors, however, soluble tumor necrosis factor receptor 1 (sTNFR1), neutrophil gelatinase-associated lipocandin (NGAL), dimer, and protein C were each independently and significantly associated with the total duration of delirium.

The results indicate that inflammation and coagulopathy are important contributors to the development of brain dysfunction in ICU patients. “These markers are not specific to brain dysfunction, however, and our next step will be to identify novel markers of critical illness-associated brain dysfunction,” Dr. Girard said.

Biomarkers Shed Light on Acute Brain Dysfunction in Critically Ill Patients

Orlando — Certain biomarkers of inflammation and coagulopathy are altered in critically ill patients with acute brain dysfunction, according to preliminary research presented by Dr. Timothy D. Girard of Vanderbilt University, Nashville, Tenn.

Markers indicating inflammation and abnormally increased coagulation were associated with an increased number of days of delirium or coma in critically ill patients, Dr. Girard said at the annual congress of the Society of Critical Care Medicine.

Dr. Girard and his colleagues evaluated 139 mechanically ventilated patients in the ICU, all of whom were enrolled in a clinical trial studying daily spontaneous breathing with or without spontaneous awakening. The researchers collected plasma on days 1 and 5 of the study to test for biomarkers indicative of systemic inflammation and dysregulated coagulation.

In addition, all patients were prospectively evaluated daily regarding their Agitation-Sedation Scale and for the presence of delirium with the Confusion Assessment Method for the ICU.

The research was supported by the National Institutes of Health and the Saint Thomas Foundation.

The 139 patients involved in the biomarker study were predominantly older, with a mean age of 63 years. About half of the patients were women, and the population was critically ill with a median APACHE II score of 27. About half of the patients in the cohort had sepsis or acute respiratory distress syndrome.

The researchers used multivariate analysis to determine the association between biomarker concentrations and the duration of delirium after adjusting for age, severity of illness, sepsis, baseline cognitive impairment, and total dose of sedative and analgesic drugs given in the ICU.

Among all 139 patients, multiple biomarkers were associated with duration of acute brain dysfunction, but that analysis can be complicated by the early death of some patients, Dr. Girard said.

Among the 96 survivors, however, soluble tumor necrosis factor receptor 1 (sTNFR1), neutrophil gelatinase-associated lipocandin (NGAL), dimer, and protein C were each independently and significantly associated with the total duration of delirium.

As concentrations of the markers increased, indicating increased inflammation—sTNFR1 and NGAL—an increased number of days of delirium was associated. However, this consumed time and resources, and places the patient at increased risk with each procedure. An optimal catheter policy will reduce the risk of catheter-related bloodstream infection and at the same time reduce the patient exposure to risk associated with catheter insertion.
SALT LAKE CITY — Recombinant human hyaluronidase makes it possible to safely hydrate patients subcutaneously with a gravity line feed at flow rates approaching 500 cc/hour, according to a preliminary study presented at the annual meeting of the American Academy of Hospice and Palliative Medicine and the Hospice and Palliative Nurses Association.

Administering parenteral fluid subcutaneously has obvious advantages over using the intravenous route, but clinical use has been limited by concerns about flow rate and discomfort. Recombinant human hyaluronidase (Hylenex) addresses those concerns. Dr. Jay Thomas said. “We were able to deliver Ringer’s solution in a clinically relevant time frame without a pump and in a way that was very well tolerated, and we can start thinking about replacing some of our [intravenous] hydration,” said Dr. Thomas, clinical medical director of the Center for Palliative Studies at San Diego Hospice, which is affiliated with the University of California, San Diego.

Hylenex recombinant injection was approved by the Food and Drug Administration in 2005 as an adjuvant agent to increase the absorption and dispersion of other injected drugs and remains the only FDA-approved hyaluronidase from a recombinant human source. This prospective, double-blind, randomized, placebo-controlled trial, known as INFUSE-LR (Increased Flow Utilizing Subcutaneously Enabled Lactated Ringer’s), recruited 54 volunteers. Each volunteer received subcutaneous injections simultaneously in both upper arms through 24-gauge catheters connected to 500-cc bags of Ringer’s lactate solution hung from scales so that their weight could be monitored.

A pharmacist prepared injections of either 1 cc of Hylenex of varying doses or saline, after which the intravenous bags were opened to gravity, Dr. Thomas said. “In the arms that received hyaluronidase, flow rates were increased fourfold, compared to placebo arms,” he said, adding that the overall mean flow rate for subcutaneous infusion with Hylenex was 464 mL/hr vs. 118 mL/hr with placebo. The subcutaneous infusion rate, when preceded by Hylenex, was closer in flow to a standardized intravenous infusion rate than to the subcutaneous infusion rate with placebo, based on flow rates in five participants in the pilot phase of the study, according to data furnished by Halozyme Therapeutics Inc. and Baxter Healthcare Corp., makers of Hylenex.

In addition, there was visible distortion of the arms that did not receive Hylenex. Edema was quantified as mild, moderate, or severe. Gross edema was dramatically decreased by the enzyme, and severe edema occurred only in placebo arms, he said.

There were no major adverse systemic events, and based on the adverse event profile, Hylenex was at least as well tolerated as placebo, he added.

Dr. Thomas disclosed no relevant financial relationships.

Enzyme Speeds Subcutaneous Fluid Infusion Rate

Increased edema is evident in the subject’s right arm, which received an infusion without Hylenex, compared with the left arm, which received the enzyme.

Photos courtesy Dr. Jay Thomas

Enzyme Speeds Subcutaneous Fluid Infusion Rate

BY BRUCE K. DIXON
Elsevier Global Medical News

AMERICAN COLLEGE OF CHEST PHYSICIANS

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<td>Noninvasive Mechanical</td>
<td>June 22-24</td>
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(800) 343-2227 or (847) 498-1400
Opioid Medication Errors Common in Hospitals

Salt Lake City — Opioid administration and prescribing errors are common in hospitals, and frequently result in uncontrolled pain as well as overdoses, according to a retrospective study presented at the annual meeting of the American Academy of Hospice and Palliative Medicine and the Hospice and Palliative Nurses Association.

“Most of the issues were due to administration by nurses, and underdoses were frequently reported as medical errors in these hospitals,” Dr. Sydney Morris Dy said.

The investigators mined 6 years of data from MEDMARX, an anonymous national medication error reporting database used by about 850 hospitals, and quantitatively described all harmful opioid errors that occurred on regular patient care units that did not involve death, the researchers reported.

Free text error descriptions also were analyzed, added Dr. Dy, of the department of health services research division, Johns Hopkins University, Baltimore.

Of 644 harmful error reports from 222 facilities, 60% were route of administration errors, and 20% were prescribing errors. “Most of the errors were related to faulty communication, lack of knowledge, performance deficits, or not following protocol,” Dr. Dy said.

One-fourth of the errors caused underdosing, and half caused overdosing, she added. Improper dose and prescribing errors were significantly more common with morphine (47%) or hydromorphone (42%) than with the other opioids included in the study: meperidine, oxycodone, and fentanyl.

“Some of these errors were due to the physician writing the prescription in milligrams and the nurse giving an intravenous dose in milliliters,” said Dr. Dy.

Omission errors were most common with oxycodone (23%) and fentanyl patches (35%), and wrong route of administration was most common with meperidine (34% vs. 3% for morphine), the investigators reported.

In the quantitative analysis, the researchers found that common problems included:

- Starting intravenous morphine at a dose that was too high, or starting hydro- morphone at a dose that would have been appropriate for morphine.
- Confusing immediate-release oxycodone with sustained-release oxycodone.
- Neglecting to change or remove fentanyl patches.
- Administering meperidine intravenously instead of intramuscularly.

These study findings already have prompted discussion of improvements at Johns Hopkins Hospital, where plans are underway to change educational procedures to include starting doses and to change practice guidelines to, among other things, recommend that prescriptions be written in units of both milligrams and milliliters.

“These patterns of errors should be considered when prescribing, administering, and dispensing opioids, and should be incorporated into pain guidelines, education, and quality improvement programs,” Dr. Dy said.

The study was limited by the absence of data on the relative frequency of opioid use in the hospitals, so there could be no determination about which of the five opioids caused the most harm. Also, there was no ability to check on the validity of the error reports, and all findings pertained only to the hospital setting, she said.

Hospice Patients Not Getting Full Benefit of Inhalers

Salt Lake City — Hospice practitioners are not adequately trained in the use of inhaled medications, according to a study presented at the annual meeting of the American Academy of Hospice and Palliative Medicine and the Hospice and Palliative Nurses Association.

The study, presented at a poster session, revealed knowledge gaps in patient assessment, pharmacology, and pharmacokinetics of inhaled medications and inhalation-delivery technique among a study group of 50 hospice nurses, according to Laura T. Scarpaci, Pharm.D.

It’s evident that formal education of hospice practitioners regarding the delivery of inhaled bronchodilator and anti-inflammatory medications is needed, said Dr. Scarpaci, manager of clinical education at ExcelRX Inc. in Philadelphia.

The nurses completed a written questionnaire that gathered demographic data, as well as information about previous training with an inhaler device, administration, pharmacokinetics, mechanism of action, patient assessment, and nursing technique. Additionally, each nurse demonstrated the use of a metered-dose inhaler, a spacer (a supplementary device that eliminates the need to inhale simultaneously with device actuation), a dry powder inhaler, and a nebulizer, while being observed by a pharmacist trained in the use of inhalers.

The percentage of steps completed correctly by the nurses ranged from 35% with the dry powder inhaler to 77% with the metered-dose inhaler. (See box.) For a dyspnea patient, 52% of the nurses said they would perform symptom assessment; only 2.5% said they would ask the patient to rate his dyspnea severity.

Dr. Scarpaci and her coinvestigator Mary McPherson, Pharm.D., said that all hospice patients using metered-dose inhalers should be encouraged to use a spacer.

Controlled breathing is difficult for patients with a terminal illness, and a metered-dose inhaler with a spacer, in addition to allowing the patient to breathe more normally, provides the same drug delivery as using the more invasive and expensive nebulizer, “said Dr. McPherson, a professor at the University of Maryland School of Pharmacy, Baltimore.

This study followed a pilot study that suggested that instructing hospice patients in the proper use of inhalers improved dyspnea, Dr. McPherson explained in an interview. “It led us to wonder why patients were doing such a bad job with their inhalers.”

In one hospice studied, of the 1,300 patients admitted over a 1-year period, 20% were using an inhaled medication. “So it’s important that patients know how to use these devices because over 80% of people with terminal illness develop dyspnea,” said Dr. McPherson.

“The physician, the nurse, and the pharmacist may all believe that the other person is instructing patients in the proper use of their inhalers. Instead of making that assumption, all those involved in the care of hospice patients should take the initiative and provide counseling and education,” Dr. Scarpaci said in an interview.

Average Percentage of Steps Completed Correctly By Nurses Demonstrating Delivery Devices

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<thead>
<tr>
<th>Device Type</th>
<th>Percentage of Steps Completed Correctly</th>
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<tr>
<td>MDI, spacer, and mask</td>
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<tr>
<td>Nebulizer</td>
<td>38%</td>
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<tr>
<td>Dry powder inhaler</td>
<td>35%</td>
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Obesity Didn’t Boost Morbidity Risk After Pulmonary Surgery

BY BRUCE JANCIN
Elsevier Global Medical News

SAN DIEGO — Contrary to conventional surgical wisdom, obesity doesn’t increase the perioperative morbidity or mortality associated with major pulmonary surgery, according to two studies presented at the annual meeting of the Society of Thoracic Surgeons.

The studies involved large patient populations: one undergoing anatomic resection for non-small cell lung cancer, the other pulmonary transplantation.

“The results of our study are provocative and challenge the assumptions about outcomes following thoracic surgery in obese patients. Our results suggest that it is unwarranted to avoid surgical intervention in obese patients who are otherwise appropriate candidates for resection of lung cancer,” observed Dr. Philip W. Smith of the University of Virginia, Charlottesville.

Obesity used to be uncommon in lung cancer patients. Not any longer.

“In our recent institutional experience, about two-thirds of lung cancer patients are overweight and one-quarter are obese prior to resection,” explained Dr. Smith, who predicted the trend is likely to accelerate.

“With childhood and teenage obesity on the rise, the epidemic of obesity will continue to expand, and thoracic surgeons will see increasing numbers of obese patients with lung cancer,” he said.

He compared outcomes in 127 obese and 372 overweight or normal-weight patients in a consecutive series undergoing anatomic resection for non-small cell lung cancer.

In contrast to his working hypothesis, obesity wasn’t associated with greater morbidity or mortality.

Indeed, the 30-day overall mortality of 1.4% was similar in both groups. Average hospital length of stay and 30-day readmission rates were also similar.

One or more complications occurred in 33% of nonobese and 31% of obese patients.

Most intriguing, respiratory complications occurred in 22% of nonobese patients but only 14% of obese patients, a difference that barely missed statistical significance.

Dr. Smith didn’t conduct a cost analysis, but he said that even without any increase in complications, these patients require more use of health care resources, including specialized equipment, demands upon staff, longer operating room times, and increased medication requirements.

Dr. Smith’s report met with a degree of skepticism.

“I think we should send all our obese patients to Charlottesville,” quipped session cochair Dr. G. Alexander Patterson, FCCP, the Evaerts A. Graham Professor of Surgery and chief of the division of cardiothoracic surgery and section of general thoracic surgery at Washington University, St. Louis.

“I don’t believe your study. It can’t be true,” the surgeon added with a smile.

But audience member Dr. Carolyn E. Reed, FCCP, hastened to reassure Dr. Smith that she believes it is true.

Dr. Reed and her colleagues at the Medical University of South Carolina, Charleston, recently reviewed their esophagectomy outcomes in obese vs. nonobese patients and were similarly surprised by the results.

“Our findings absolutely mimmicked yours,” said Dr. Reed, professor of surgery and chief of general thoracic surgery at the university.

She added that she suspects but can’t prove the explanation is that obese patients undergoing thoracic surgery are managed more aggressively at the first sign of any problem.

Elsewhere at the meeting, Dr. Ricardo S. Santos of the University of Pittsburgh reported that preoperative weight had no impact upon lung transplantation outcomes in 517 patients who underwent the procedure there. It is the largest series reported to date.

Some of our patients come from other centers where they were declined for lung transplantation because their BMI [body mass index] was 32 or 33 kg/m²,” he explained. “We’ll accept them for evaluation and proceed with lung transplantation if we don’t present any other major comorbidities.”

Using BMI as the sole criterion to preclude transplantation “is not acceptable,” Dr. Santos concluded.

Dr. Robert Cerfolio, FCCP comments:

Smith and colleagues have provided a timely report given the epidemic of obesity not only in the United States but also worldwide.

Increased weight and body mass index, just like advanced age, should not be a reason to deny a patient an operation that has the potential to provide benefit or cure.

Although these patients do require some special postoperative considerations, the vast majority—if motivated—can safely undergo surgical resection of any type.
Size Matters in Talc Poudrage for Pneumothorax

BY BRUCE JANCIN
Elsevier Global Medical News

SAN DIEGO — The key to complica-
tion-free videotoracoscopic talc poudrage for primary spontaneous pneumothorax is to use talc of relatively large particle size, Dr. Giuseppe Cardillo asserted at the annual meeting of the Society of Thoracic Surgeons. This is the treatment of choice for re-
current and complicated primary sponta-
aneous pneumothorax, he said. In his series of 861 patients treated during a 9-year pe-
riod—the largest by far ever reported—the treatment success rate was in excess of 98% with a postoperative morbidity rate of 3.4%.

Talc is inexpensive, readily available, and provides better efficacy and fewer re-
currences than any other agent available for chemical pleurodesis, added Dr. Cardilli-
lo of Carlo Forlanini Hospital, Rome, and the University of Rome La Sapienza.

There are no controlled trials to provide guidance as to optimal dosage. Some sur-
geons administer as much as 10 g. His own practice is to nebulize 2 g of talc into the
pleural cavity.

Primary spontaneous pneumothorax is chieflv a disease of otherwise healthy young men. The incidence has been placed at 18-28 cases per 100,000 popula-
tion per year in men—peaking in their 20s—and at 1.2-6.2 cases per 100,000 per year among women. The diagnosis is read-
ily made by chest x-ray.

Smoking plays an important role in this form of lung disease. The lifetime risk of primary spontaneous pneumothorax in otherwise healthy male smokers has been estimated at up to 12%, that’s more than 100-fold greater than the risk in non-
smoking men.

Smoking also figures prominently in the recurrence risk after talc poudrage. In fact, smoking is the only identifiable risk factor for recurrence. In Dr. Cardillo’s se-
ries, the recurrence rate was 2.5% in smokers, compared with 0.6% in non-
smokers.

Like most experts, he advocates treating a first episode of primary spontaneous pneumothorax by simple intercostal chest drainage. Surgery is appropriate for a re-
current episode or a complicated first episode marked by bilateral involvement or failure of the lung to fully reexpand af-
ter chest drainage.

He and his colleagues perform the video-assisted thoracic surgery under gen-
eral anesthesia, and tailor the procedure to the results of intraoperative staging using Vanderschueren’s classification. Stage I disease, with no endoscopic abnormalities, is treated by talc poudrage only. For stage II, marked by pleuropulmonary adhesions, the surgeons lyse all adhesions and per-
form talc poudrage. For stages III and IV, they staple the blebs and bullide in addition to doing talc poudrage.

In their 861-patient series, the 3.4% com-
pliation rate was manifested mainly by lo-
ternal pleural effusion, prolonged air
leak, and subcutaneous emphysema, all of
which resolved spontaneously.

The mean hospital stay was 5.6 days. Two-thirds of patients returned to work within 21 days, and 91% returned within
30 days. At discharge, 13% of patients re-
ported moderate to severe paresthesia, which resolved spontaneously within 6 months in all cases.

The median particle size of the asbestos-
free talc preparation used by the Italians was 25.6 mcn. Only 11% of the particles are smaller than 5 mcn, compared with 90-80% in samples reported from the United States and South America. Dr. Cardillo is convinced that the large particle size pro-
tects against adult respiratory distress syn-
drome and empyema, neither of which occurred in his series.

Audience members expressed some concern about the unknown long-term ad-
verse effects of talc poudrage in young
patients with many decades of life re-
maining. Dr. Cardillo replied that no prob-
lems have emerged with up to 9 years’ follow-up thus far in his series. The results of repeated pulmonary function tests in a 26-patient subset have been normal. He conceded, however, that reentering the chest in the event of future thoracic surgery ”will be a big problem.”

Dr. Robert Cerfolio, FCCP, comments:
Dr. Cardillo has reported his experience on using talc for benign disease. Although we agree that firm data are lacking to support “problems” with talc in young patients with benign disease, the jury is out and will be for another 50 years in these patients. Because the natural long-term history of talc in these patients is unknown and because so many physicians worry about it causing constriction and maybe even cancer, we still prefer to use mechanical pleurodesis with VATS pleurectomy and intentionally apply a staple line on the apex of the lung and in a few other areas that are buttressed with strips that help create adhesions between the lung and chest wall.

This technique also works in 98%-99% of patients as well, and avoids talc. The article is important, however, and the size and amount of talc is also important. The long-term follow-
up (21-50 years) on these patients will provide important information to all of us.

Medication Error Rates Are Highest in Perioperative Areas

BY ELIZABETH MECHCATIE
Elsevier Global Medical News

ROCKVILLE, MD. — More than 11,000 perioperative medication errors were re-
ported to a national database of hospital medication errors between 1998 and 2005. Of these, 9% resulted in harm, according to a report issued by the US Pharma-
copeia.

The database, known as MEDMARX, is operated by the USP and is the largest na-
tional database of hospital medication er-
erors in the United States, receiving about
15,000 new reports every month.

The 5% rate of harmful errors is about threefold higher than the proportion of medication errors resulting in harm in all other areas of the hospital combined. The proportion of perioperative medication er-
rors that resulted in harm was higher among patients under age 17 than among older patients.

Among medication errors that re-
sulted in harm, there were four deaths, in-
cluding one pediatric patient, according to Diane D. Cousins, a registered pharmacist and vice president of the Center for the Advancement of Patient Safety at the USP.

A total of 739 drug products were in-
volved in errors, the most common of
which were the antibiotics cefazolin and vancomycin; the analgesics morphine, fen-
tanyl, and meperidine; the sedative mida-
zolam; and heparin, Ms. Cousins said.

There were 165 drugs (22%) involved in harmful errors, most commonly mor-
phine, fentanyl, and cefazolin.

Errors included administering the wrong medication or the wrong amount of
medication, administering medication at the wrong time, omitting a medication or a dose, or administering medication in-
correctly.

In the operating room, omission and wrong drug administration were the most
common mistakes, she said. For example, a surgeon called in an order for a dose of
dexamethasone to be given during surgery that was scheduled a week later, but the order was never recorded. As a result, the patient (a child) never received the drug.

In the postanesthesia care unit setting, the most typical errors involved prescribing and administering incorrect amounts of
drugs, she said. After an elderly patient was
discharged from the postanesthesia care
unit, it was discovered that the patient was receiving an excessive amount of heparin because of a program-
ing error made in the postanesthesia care
unit.

The results were announced during a press briefing sponsored by the USP, which released the report in partnership with the Uniformed Services University of the Health Sciences (USUHS), the Associa-
tion for PeriOperative Registered Nurses (AORN), and the American Society of Per-
ianesthesia Nurses (ASPAN).

Published by the USP Center for the Advancement of Patient Safety, the report is the largest
known national analysis of medication er-
rors related to surgery. Ms. Cousins said during the press conference.

The findings were also provided in a brief ing to 11 national organizations and agencies, with the intention of calling them to action.

The 47 recommendations issued in the report include implementing strategies that improve communication among all perioperative team members, designing a pharmacist to coordinate medication safety, working to ensure that medica-
tions are administered on time, “and call-
ing on manufacturers to provide products in ready-to-use, sterile packaging, espe-
cially for drugs administered to children.”

The report is available (for purchase) at www.usp.org/products/medMarx.

D A T A W A T C H

State Medical Boards’ Serious Disciplinary Actions
(per 1,000 physicians)

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<tr>
<td>WI</td>
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<tr>
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Note: Rate is calculated by averaging the rates from 2003 to 2005. Source: Public Citizen
Competitive Bidding to Debut for Medical Equipment

BY ALICIA AULT
Elevier Global Medical News

Starting in April 2008, retailers and suppliers in 10 metropolitan areas who sell certain durable medical equipment will have to become accredited and enter a competitive bidding process, according to a final rule issued by the Centers for Medicare and Medicaid Services.

Unlike other entities, physicians may opt out of competitive bidding and accreditation, but they will still have to accept a single payment for the durable medical equipment (DME) item instead of a fee schedule-based payment. Acting CMS Administrator Leslie Norwalk said in a briefing with reporters.

The new competitive bidding program was developed to reduce Medicare’s substantial DME expenditures and to decrease the out-of-pocket burden for beneficiaries, who are liable for copayments of 20%.

“The final rule we are announcing today is focused on improving both service delivery and the quality of care, while getting savings for beneficiaries and taxpayers,” Ms. Norwalk said in the briefing.

Beginning in April 2008, Medicare will pay a single amount for each item in those areas instead of basing payments on a fee schedule, as it has in the past.

CMS will expand the program to 70 bidding areas in 2009, and to more CBAs, and to cover more DME items after that, Ms. Norwalk said.

The new process was required by the Medicare Prescription Drug Improvement and Modernization Act of 2003. CMS outlined its intentions in a proposed rule in August 2006. It also gathered data from two pilot studies that ran from 1999 to 2002 in San Antonio and in Polk County, Fla., Ms. Norwalk said. After incorporating public comments and experience from the pilot, CMS published the final rule in the Federal Register.

Suppliers in the following 10 areas will be the first who are subject to the new requirements: Charlotte-Gastonia-Concord, N.C./S.C.; Cincinnati-Middletown, Ohio/Ky./Ind.; Cleveland-Elyria-Mentor, Ohio; Kansas City, Mo./Kans.; Dallas-Fort Worth-Arlington, Tex.; Miami–Fort Lauderdale-Miami Beach, Fla.; Orlando-Kissimmee, Fla.; Pittsburgh; Riverside-San Bernardino-Ontario, Calif.; and San Juan-Caguas-Guaynabo, Puerto Rico.

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Periodic Limb Movements Do Not Equal Restless Legs

BY JANE SALODOF MACNEIL

S COTTSDALE, A RIZ. — Periodic limb movements are common during sleep and should not be confused with restless legs syndrome, Dr. Barbara A. Phillips, FCCP, warned at a meeting on sleep medicine sponsored by the American College of Chest Physicians.

Counting lots of periodic limb movements does not add up to a diagnosis of restless legs syndrome (RLS), according to Dr. Phillips, medical director of the sleep center at Samaritan Hospital in Lexington, Ky. RLS must be diagnosed with a clinical interview.

As many as 85% of RLS patients have periodic limb movement during sleep, but so do many people with other sleep disorders and healthy people with no sleep issues, said Dr. Phillips, a professor of pulmonary and critical care medicine at the University of Kentucky, Lexington. About half the patients tested in a sleep laboratory will have periodic limb movement.

“It doesn’t predict anything. It doesn’t correlate with anything useful. Treating it doesn’t improve patient outcome,” she said, describing the clinical significance of periodic limb movement as controversial. RLS is real, with a prevalence of 3%-13% in the general population, Dr. Phillips reported. Studies have associated it with a poorer quality of life, excessive daytime sleepiness, and depression and anxiety. Current thinking holds that insufficient brain iron causes abnormalities in dopamine function in the brain and spinal cord. These abnormalities, in turn, cause RLS.

Most primary cases of RLS are hereditary, Dr. Phillips said, but iron deficiency anemia, end-stage renal disease, medications (selective serotonin reuptake inhibitors, tetracyclines, dopamine antagonists, and antihistamines), diabetes, rheumatoid arthritis, and peripheral neuropathy can be secondary causes.

About 25% of pregnant women develop RLS, she noted. It has not been shown to cause fetal harm, but approved medications for RLS are contraindicated during pregnancy.

Dr. Phillips emphasized that diagnosis of RLS is based on four core symptoms:

► Patients have an urge to move their limbs. This urge is “usually accompanied or caused by uncomfortable and unpleasant feelings in the limbs.”
► Symptoms start or become worse with rest or inactivity.
► Discomfort is relieved when patients get up or move about.
► Symptoms appear or become worse in the evening or at night.

In addition, Dr. Phillips said family history of RLS, response to dopaminergic therapy, and the presence of periodic limb movements can support a diagnosis but are not diagnostic by themselves.

She suggested the International RLS Rating Scale and Scoring Sheet (www.mdvu.org/library/ratingscales/rls) as a tool for assessing symptom severity. Laboratory testing should include serum ferritin levels and percent of iron saturation.

She also recommended a neurologic assessment, if peripheral neuropathy is suspected, as it can mimic RLS. Likewise, she said children and patients suspected of having coexisting obstructive sleep apnea or narcolepsy should be sent for polysomnography. Differential diagnosis also should include akathisia in patients on a dopamine antagonist and muscle cramps.

Two dopamine agonists are approved for RLS treatment: pramipexole and ropinirole. She recommended that patients with frequent RLS symptoms take one or the other nightly 30-90 minutes before bedtime. Average doses are 0.25 mg/day of pramipexole and 2 mg/day of ropinirole.

Carbidopa and levodopa also are used off label, but Dr. Phillips said neither is likely to be approved for RLS. About 80% of patients develop augmentation in which symptoms become worse with long-term use. Nonetheless, Dr. Phillips said occasional off-label use could help patients who have infrequent symptoms.

Other treatment strategies address factors that aggravate RLS. Dr. Phillips said many patients find that sleep deprivation, alcohol, caffeine, and smoking can make RLS worse, as can too much or too little exercise.

Treating secondary causes such as proven iron deficiency and renal disease also can help. Although Dr. Phillips said to consider discontinuing medications that can worsen RLS, she added that she has never taken a patient off a selective serotonin reuptake inhibitor.
Cancer Facilities Guide Available
The top treatment facilities and specialists for different cancers, plus financial tips, drug information, and success stories, are available in a new guidebook, “Patient Resource: A Cancer Treatment and Facilities Guide for Patients and Their Families.”

Quality Reporting Questions Answered
More than frequently asked questions about the Physician Quality Reporting Initiative are available on the Web site of the Centers for Medicare and Medicaid Services. Visit www.cms.hhs.gov/PQRI, scroll down to “Related Links Inside CMS,” and click on “All PQR FAQs.”

Free Rx Savings Card
The Together Rx Access Card is a free prescription savings card for people who are legal residents of the U.S., are not eligible for Medicare or Medicaid, and cannot afford prescription drug coverage, and meet certain income levels. Most card holders will save 25%-40% on more than 300 brand-name prescription products. Savings also are available for generic products. For more information, visit www.togetherrxaccess.com.

Prescription Assistance Fact Sheet
The National Council on Patient Information and Education is distributing a fact sheet to advise consumers who lack health insurance or prescription drug coverage about prescription assistance programs and prescription savings/discount programs. For more information, read the fact sheet at www.talkaboutrx.org/documents/paps.pdf.

Sleep Apnea Did Not Predict Metabolic Abnormalities
BY SARAH PRESSMAN LOVINGER
Ellever Global Medical News

O bstructive sleep apnea was not associated with an increased risk of metabolic abnormalities in patients with sleep-disordered breathing, according to the results of a new study.

However, obesity was associated with a greater risk of obstructive sleep apnea and metabolic abnormalities.

“We did not find any independent correlation between [apnea-hypopnea index] and metabolic abnormalities,” stated Dr. S.K. Sharma of the division of pulmonary and critical care medicine, All India Institute of Medical Sciences, New Delhi, and colleagues (Sleep Med. 2007:8:12-7).

The researchers evaluated 120 people in a cohort study lasting from April 2003 to March 2005. Using polysomnographic data, they compared lipid parameters in 40 obese apneic participants (apnea-hypopnea index 32.2, range 13-52.8) with 40 obese non-apneic participants (apnea-hypopnea index 2.0, range 0-1) and with 40 normal-weight controls without apnea breathing (AHI 0.7, range 0-1). The parameters included serum lipids, insulin resistance, leptin, and adiponectin levels.

Patients with a body mass index (BMI) of at least 25 kg/m² were considered obese, the definition used by the World Health Organization for South Asia. The ratio of male to female participants was 1:1.1, and the average age was 42.5 years. The researchers excluded subjects determined to have co-morbidities, chronic respiratory failure, and those on chronic steroids or hormone replacement medication.

The results revealed no significant differences in fasting blood sugar, insulin resistance, leptin, and adiponectin levels between the obese group with obstructive sleep apnea (OSA) and the obese control group. The patients in the OSA group had higher lipid levels than did those in the control group, but the difference was not statistically significant.

The investigators did find that obesity as measured by BMI was associated with increased leptin and waist hip ratio was independently associated with OSA. They also found significant differences in serum insulin, fasting blood sugar, leptin, and HDL and LDL cholesterol levels in the non obese group, compared with the normal-weight control group.

Cancer Facilities Guide Available
The top treatment facilities and specialists for different cancers, plus financial tips, drug information, and success stories, are available in a new guidebook, “Patient Resource: A Cancer Treatment and Facilities Guide for Patients and Their Families.” The book is available for free to physicians and costs $6.95 for patients to purchase directly. The guide is available at www.patientresource.net/place-orm.html.

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*For gram-positive infections due to susceptible strains of indicated organisms in treating moderate-to-severe pneumonia or febrile neutropenia.

MAXIPIME is contraindicated in patients who have shown an immediate hypersensitivity reaction to MAXIPIME, cephalosporins, penicillins, or any other β-lactam antibiotics.

In North American clinical trials of MAXIPIME at a dose of 0.5 to 2 g IV q12h, the most common adverse events were local reactions (3%), including phlebitis (1.3%), pain and/or inflammation (0.6%); rash (1.1%). 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 administration of antibacterial agents.

HCA P defined as: healthcare-associated pneumonia.

Please see brief summary of prescribing information on adjacent page.