Lung Reduction in Emphysema Aids Select Patients
‘The survival after LVRS is excellent.’

BY SUSAN LONDON
Elsevier Global Medical News

VANCOUVER, B.C. — Lung volume reduction surgery is safe and effective for the treatment of advanced emphysema in appropriately selected patients, according to the experience at Columbia University Medical Center, New York. Among 49 patients who underwent LVRS at the center during a period of roughly 5 years, all of whom fell into group 1 or 2 as previously established by the National Emphysema Treatment Trial (NETT), none died within 90 days. Some 43% experienced air leaks, but the leaks were manageable.

The patients had a 3-year actuarial survival rate of 95%, and their BODE (body mass index, airflow obstruction, dyspnea, and exercise capacity) index, used to estimate prognosis in this population, fell from 4.9 preoperatively to 2.6 at 1 year on a scale ranging from 0 to 10.

“Surgical LVRS should be considered the treatment of choice for patients with upper lobe–predominant emphysema meeting selection criteria established by NETT,” Dr. Mark Ellis Ginsburg said in a presentation of study results at CHEST 2010, the annual meeting of the American College of Chest Physicians. “I think it is the gold standard against which new technologies should be judged.”

However, just 119 LVRS procedures were performed in the United States in 2008, despite the favorable NETT findings for certain patients and coverage of the procedure by the Centers for Medicare and Medicaid Services for qualifying patients and centers.

He speculated that pulmonologists’ poor view of LVRS against influenza is called for this year. • 9

Healthy People 2020: Sleep Health New Goal

BY SHARON WORCESTER
Elsevier Global Medical News

The Department of Health and Human Services has launched its Healthy People 2020 goals, and among the objectives set forth in its “ambitious, yet achievable” 10-year agenda for improving the nation’s health are substantial improvements in sleep health, respiratory disease outcomes, and levels of tobacco use.

Sleep Health
Sleep health is a new topic in the Healthy People initiative. The main focus is on increasing public knowledge of how adequate sleep and treatment of sleep disorders improves health, productivity, wellness, quality of life, and safety on the roads and in the workplace.

“Poor sleep health is a common problem, with 25% of U.S. adults reporting insufficient sleep or rest at least 5 out of every 10 days,” the report states.

The public health burden is substantial, and awareness of the problem is lacking; thus, Healthy People 2020 seeks to provide a “well-coordinated strategy to improve sleep-related health.”

Objectives are to:

► Increase the proportion of persons with symptoms of obstructive sleep apnea who seek medical care (from 25.5% to 28%).

► Reduce the rate of vehicular crashes per 100 million miles traveled that are due to drowsy driving (from 2.7 to 2.1).

► Increase the proportion of students in grades 9-12 who get sufficient sleep, defined as 8 hours or more on an average school night (from 30.9% to 33.2%).

► Increase the proportion of adults who get sufficient sleep, defined as 8 or more hours for adults age or older. If at

H1N1 Influenza Still a Threat to Kids

BY LAIRD HARRISON
Elsevier Global Medical News

LAS VEGAS – It’s not over yet. Though the H1N1 2009 pandemic influenza strain did not wreak the havoc that was feared, it killed more children than its seasonal flu cousins last season and may well repeat that performance if not enough people get vaccinated, according to Dr. Christopher J. Harrison of Children’s Mercy Hospital in Kansas City.

“Maybe it didn’t kill as many adults, but children were disproportionately affected,” said Dr. Harrison, who is also director of the Infectious Disease Research Laboratory and professor of pediatrics at the University of Missouri–Kansas City School of Medicine, in a presentation at a pediatric update sponsored by the American Academy of Pediatrics California District 9. “Pregnant women were disproportionately hit as well.”

This season, public health authorities are recommending vaccination for everyone who is 6 months of age or older. If at
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Don’t wait, refer early

- Early referrals to a PH Specialist help provide comprehensive care

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November was Pulmonary Hypertension Awareness Month. Here’s how you can help.

Don’t wait, refer early

PH Specialists encourage early referrals of PAH patients regardless of WHO Functional Class (I, II, III, IV)*1-4

Patients receive comprehensive care
- A full support system for PAH patients, including comprehensive medical care, reimbursement opportunities, education, and counseling5-7

Patients gain access to information on the latest clinical trials1,3,5-7
- Patients’ participation helps build clinical trials that provide reliable data relevant to the PAH population1,3,8,9

Help optimize care for your PAH patients with early referrals. Please visit www.PHAssociation.org for more information.

*Adapted from the New York Heart Association (NYHA).

Respiratory Disease
The respiratory disease category focuses on asthma and chronic obstructive pulmonary disease, and the main goal is to “promote respiratory health through better prevention, detection, treatment, and education efforts,” according to the report, which states that asthma affects 23 million people in the United States and COPD affects 13.6 million U.S. adults.

The cost to the health care system is high, and society pays through higher health insurance rates and lost productivity and tax dollars. Annual expenditures for asthma alone are estimated at nearly $21 billion.

Healthy People 2020 seeks to reduce asthma-related deaths, hospitalizations, emergency department visits, activity restrictions, and missed school or work days, and to increase the proportion of asthma sufferers who receive appropriate care. Improved surveillance at the state level is another goal.

For example, goals for 2020 in regard to asthma-related deaths include reductions from 11.0 to 6.0 deaths per 1 million population aged 15-64 years, and from 43.3 to 22.9 per 1 million population aged 65 and older. Goals regarding annual asthma-related hospitalization visits include a reduction from 41.4 to 18.1 per 10,000 children under age 5, from 11.1 to 8.6 per 10,000 people aged 5-64 years, and from 25.3 to 20.3 per 10,000 adults aged 65 years and older.

Goals regarding appropriate asthma care include improvements in the number of patients who receive written asthma management plans, instructions for inhaled use, education about appropriate response to an asthma episode, and follow-up visits each year. COPD-related objectives include reducing activity limitations, death, hospitalizations, and emergency department visits, and improving diagnosis among adults with abnormal lung function.

Specific goals include a reduction from 23.2 to 18.7 in the percentage of adults with COPD aged 45 years and older with activity limitations from COPD, and a reduction from 112.4 to 98.5 in the number of COPD-related deaths per 10,000 people aged 45 years and older.

Tobacco Use
Tobacco use is not a new topic in the Healthy People initiative, but ongoing efforts to reduce use are needed, according to the report, because tobacco use remains the single most preventable cause of death and disease in the United States.

About 443,000 Americans die from tobacco-related illnesses each year, and for every 1 who dies, 20 more suffer with least one serious tobacco-related illness. Healthy People 2020 seeks to “provide a framework for action to reduce tobacco use to the point that it is no longer a public health problem for the nation.”

More than 4 decades of evidence has shown that the toll tobacco use takes on families and communities can be significantly reduced by fully funding tobacco control programs, increasing the prices of tobacco products, enacting smoke-free policies, controlling access to products, reducing tobacco advertising and promotion, implementing anti-tobacco media campaigns, and encouraging and assisting users to quit.

Healthy People 2020 addresses tobacco use prevalence, health system changes, and social and environmental changes. Among the key goals for adults are:

- Reducing the percentage of adult cigarette smokers (from 20.6% to 12.0%).
- Reducing the percentage of adult users of smokeless tobacco (from 2.3% to 0.3%).
- Reducing the percentage of adult cigar smokers (from 2.2% to 0.2%).

In adolescents, goals include reducing the percentage of those who used tobacco in the past month from 26% to 21%, and reducing the percentages who said they used cigarettes, smokeless tobacco, and cigars in the past month from 18.9% to 14%, from 8.9% to 6.9%, and from 14% to 8%, respectively.

Initiation of tobacco use among children, adolescents, and young adults is also addressed, with a goal of reducing it among those aged 12-17 years from 7.7% to 5.7%, and among those aged 18-25 years from 10.8% to 8.8%.

Numerous goals are also set in regard to health system changes, and social and environmental changes.

For example, the report calls for increases in comprehensive Medicaid coverage for nicotine dependency treatment, increased tobacco screening and counseling in health care settings, reductions in the proportion of nonsmokers exposed to secondhand smoke, increases in the proportion of persons covered by worksite policies that prohibit smoking, and increases in tobacco-free environments in school facilities and at school events.

Efforts should be made to eliminate state laws that preempt stronger local tobacco control laws, to reduce illegal sales to minors, and to reduce exposure to tobacco advertising and promotion among 6th-12th graders. Also, federal and state taxes on tobacco products should be increased, the report states.

Healthy People 2020 has been in development since 2007. A panel of health experts drew on input from public and private health officials, preventive medicine experts, representatives from 2,000 health organizations, and thousands of public comments.

The initiative expands upon topics from Healthy People 2010, and will incorporate the Internet and other media in spreading the message. The ultimate goals, according to HHS officials, are to avoid preventable diseases and to promote improved quantity and quality of life.

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*Reports were subjective and recorded in a daily diary form.

Cancer Patients Benefit From Earlier Palliative Care

BY SUSAN BIRK
Elsevier Global Medical News

CHICAGO – Oncologists and others who care for cancer patients can improve outcomes by integrating palliative care into standard treatment earlier—even as early as the time of diagnosis. Dr. Charles F. von Gunten said at the Chicago Supportive Oncology Conference.

Doing so would require clinicians to expand their definition of palliative care far beyond the traditional boundaries of hospice, which begins only toward the end of life when other therapies are no longer working, said Dr. von Gunten of the University of California, San Diego, and provost at the Institute for Palliative Medicine at San Diego.

He called on clinicians to rethink the traditional ‘either-or’ approach to cancer treatment—in which care consists of either therapies aimed at reducing or curing the illness or care designed to ease suffering and improve the quality of life—and to adopt a ‘both-and’ model instead that employs both standard therapies and palliative interventions simultaneously.

Dr. von Gunten noted the growing accumulation of data during the past 20 years demonstrating the effectiveness of palliative care.

One recent study, for example, found that early palliative care significantly improved quality of life and mood among patients with metastatic non-small cell lung cancer as compared with standard care (N. Engl J. Med. 2010;363:733-42).

Although significantly fewer patients in the early palliative care group than in the standard treatment group received aggressive end-of-life care (33% vs. 54%), median survival was significantly longer among patients receiving early palliative care (11.6 months vs. 8.9 months).

“Palliative care delivered by hospice programs in the [United States] is better than standard of care at the end of life,” Dr. von Gunten said. “That has been proven... We should get rid of this language of ‘choice’. Hospice is a choice if you want it; antibiotics are a choice if you want it; chemotherapy is a choice if you want it. We’re past that. This is the standard of care, and it should be advocated that way by all of us.”

But palliative care still has a way to go before it becomes an integral part of cancer treatment, although some progress has been made, he said. According to a recent survey, 98% of NCI-designated cancer centers and 78% of community cancer centers report having palliative care programs (JAMA 2010;303:1054-61).

“This is huge progress from 10 years ago, when they couldn’t even say the word,” Dr. von Gunten said. “However, in most of those places — 92% — it’s just one physician, often part-time.”

More sobering, he said, is a 1998 membership survey by the American Society of Clinical Oncologists in which 90% of oncologists reported “trial and error” as their primary source of information about palliative care. “How enthusiastic would you be about a doctor who was going to take out your anus, and you said, ‘Doctor, how did you learn about this?’ and he said, ‘Oh, trial and error.’” Dr. von Gunten said.

Of those surveyed, 73% said they learned from colleagues and role models. “That’s great, except where did colleagues and role models learn? Trial and error,” he said. And 38% of oncologists said the most significant source of their information about palliative care was a traumatic experience. The underlying message is that no one is teaching palliative care to oncologists, he said.

Dr. von Gunten had no disclosures.
Respiratory Events a Risk After Bariatric Surgery

By Diana Mahoney
Elsiver Global Medical News

LAS VEGAS – Pulmonary complications following bariatric surgery occur infrequently but are associated with significantly increased rates of postoperative morbidity and mortality, according to a national study that also identified modifiable risk factors for poor pulmonary outcomes.

In an analysis of data from the American College of Surgeons’ 2007 National Surgical Quality Improvement Program (NSQIP) – a prospective database comprising more than 200,000 inpatient and outpatient operations done at 183 representative U.S. hospitals – postoperative pulmonary and postoperative respiratory failure were the most common non-\-wound-related complications reported among 12,252 patients who underwent bariatric surgery, together accounting for 26% of the overall 30-day morbidity rate, Dr. Prateek Gupta, Columbia University Medical Center, New York, noted at the annual meeting of the American Society for Metabolic and Bariatric Surgery.

“In comparison, renal complications and cardiac complications accounted for 7% and 2%, respectively, of postoperative morbidity,” he noted. The analysis included patients who underwent Roux-en-Y gastric bypass, adjustable gastric banding, and gastroply.

Specifically, postoperative pneumonia was reported in 72 patients and postoperative respiratory failure (defined as reintubation after extubation or a total ventilator-assisted respiratory period of a period of 48 hours) was reported in 86 patients, said Dr. Gupta of Creighton University in Omaha, Neb.

In patients with postoperative pneumonia, “2.7% died within 30 postoperative days, compared with 0.17% of patients without pneumonia,” Dr. Gupta said, and 10.4% of patients with respiratory failure died within 30 days, compared with 0.12% of patients without respiratory failure.

Patients with these pulmonary complications also had significantly longer hospital stays. The mean length of stay for postoperative pneumonia patients was 14 days, compared with 2 days for patients without pneumonia, and a similar, significant trend was observed in patients with respiratory failure,” Dr. Gupta reported.

In multivariate analyses, a history of heart failure was a major risk factor for postoperative pneumonia, with an adjusted odds ratio of 10.7. “To our knowledge, [heart failure] was not previously shown to be a risk factor for pneumonia,” he noted. The association could be due to perioperative worsening of cardiopulmonary function, although the precise reasons are unclear.

Additional risk factors for postoperative pneumonia included history of stroke with neurologic deficit (OR, 9.8), consumption of more than two alcohol drinks per day (OR, 9.0), history of severe COPD (OR, 4.5), an open wound (OR, 3.8), and higher American Society of Anesthesiologists Physical Status classification (OR, 2.0), Dr. Gupta said.

With respect to postoperative respiratory failure, “patients with a history of myocardial infarction within 6 months prior to surgery had 30 times increased risk for this complication,” he said.

Other preoperative risk factors for respiratory failure included receiving a preoperative transfusion of more than four units of blood within 72 hours of surgery (OR, 2.8), consumption of more than two alcohol drinks per day (OR, 7.8), history of severe COPD (OR, 4.6), and hypertension (OR, 2.4), Dr. Gupta reported.

Patients whose bariatric surgery was canceled as an "elective procedure" were six times more likely to experience respiratory failure than were those who had nonemergent procedures, but the nature of the emergencies was unclear,” Dr. Gupta noted.

The increased morbidity and mortality risks that might lead to pulmonary complications is important for patient optimization and selection prior to surgery, Dr. Gupta stressed.

Patients Met NETT Criteria

Emphysema • from page 1

is the main factor contributing to its underuse. “Most pulmonologists do not support this procedure,” commented Dr. Ginsburg, who directs the division of general and thoracic surgery at Columbia University in New York. “We have some pulmonologists who have had great experiences and continue to send us patients, but I think the vast number of pulmonologists do not send patients.”

His center has had a multidisciplinary LVRS team for 15 years, he noted. Between January 2004 and April 2009, the team performed the surgery on patients with emphysema who strictly met the NETT inclusion and exclusion criteria, as well as all CMS selection requirements.

Only patients falling into NETT group 1 (upper lobe–predominant disease, low exercise capacity and dyspnea index) and NETT group 2 (upper lobe–predominant disease, high exercise capacity) were included, he said. Patients with non-upper lobe–predominant disease (group 4) and high-risk features were excluded.

On average, the 49 patients were 63 years old and had an FEV1 (forced expiratory volume in 1 second) of 25% of predicted, a carbon monoxide diffusing capacity of 50% of predicted, and a maximal workload of 37 watts. They were nearly equally split between group 1 and group 2.

LVRS 'can be performed with very low surgical risk, significant benefit, and fairly predictable results.'

All of the patients underwent bilateral LVRS. Twenty percent had their surgery through a median sternotomy, before 2005, when the center switched to video-assisted thoracic surgery.

“We try to take out anywhere from 30% to 40% of the lung volume to really make room for the remaining lung to ventilate… We have to be fairly aggressive with this operation,” he noted.

“The goal of lung reduction is to really allow the good lung space to take all and overcome the inspiratory restraint that exists in these patients.”

None of the patients died during surgery, their hospital stay, or the first 90 postoperative days, Dr. Ginsburg reported.

They had a median length of stay of 8 days. Most (92%) were discharged to home, while the rest were discharged to an inpatient facility (9%) and less (8%) were discharged to rehabilitation facility. “Of note, 47% of our patients had no major complications,” he commented. By far, the leading major complication was a procedure-related pneumothorax (less than 1% a week), seen in 43%. But these leaks were manageable mainly with Heimlich valves that were removed at follow-up office visits.

“The air leak issue, even though it [is common] and certainly leads to prolonged length of stay in these patients, I think clinically it’s that big of an issue,” Dr. Ginsburg said.

Among other complications, two patients had to be reintubated and receive a tracheostomy, but both were weaned off the ventilator and extubated before discharge. Three patients developed pneumonia.

“The survival after LVRS is excellent with 1-year mortality less than 2%, incidence rates of 98% and 95%, respectively,” he said. “If you think about what you’d expect in actual survival for patients who have a severe restrictive FEV1, of 25% I think in and of themselves these are fairly impressive numbers.”

Among the 44 patients with follow-up data, the BODE index fell from 4.9 preoperatively to 2.6 at 1 year (P less than .0001).

“One of the criticisms of early data for lung reduction was that there was a significant amount of missing data, and missing data was more pronounced in patients with actual benefit to surgery,” Dr. Ginsburg commented.

Therefore, the analysis was repeated with imputation of the worst possible values for the patients with missing data.

LViRs now, in 2010, using the lessons from NETT, can be performed with very low surgical risk, significant benefit, and fairly predictable results,” Dr. Ginsburg concluded.

Dr. Ginsburg reported that he is a consultant for PneumRx.
Experts support nearly universal vaccination for 2010-2011 season.

BY HEIDI SPLETE
Elsevier Global Medical News

WASHINGTON – Of 400 U.S. physicians surveyed online, 97% said they have received flu vaccinations for the 2010-2011 flu season or plan to do so, according to data collected by the National Foundation for Infectious Diseases.

These results are encouraging, because they show that more physicians are practicing what they preach about flu vaccination, said Dr. William Schaffner, president of the NFID, said at a press conference on influenza sponsored by the foundation.

“I am optimistic that we are becoming a culture of prevention,” Dr. Schaffner said.

“Plenty of flu vaccine is anticipated for this year,” along with a plentiful supply of antiviral medication, he emphasized, and vaccines are available at pharmacies as well as doctors’ offices.

“Flu vaccination is the best way to protect yourself against the flu,” said Dr. Thomas Frieden, director of the Centers for Disease Control and Prevention. Every year thousands of Americans die from influenza, he said.

For the 2010-2011 flu season, the CDC recommends universal vaccination for everyone aged 6 months and older.

Several vaccination options are available, including a flu shot, a nasal spray, and a high-dose vaccine for older adults, Dr. Frieden said.

Dr. Daniel Jernigan, deputy director of the influenza division in the CDC’s National Center for Immunization and Respiratory Diseases, said that this year’s vaccine contains antibodies against three flu viruses: influenza B, influenza A (H3N2), and influenza A (H1N1).

Approximately 119 million doses of 2010-2011 flu vaccine have already been distributed in the United States, with a total of 160 million doses anticipated, Dr. Jernigan said.

There is no need for a separate H1N1 vaccine this year, he noted.

So far this year, the H1N2 virus has been the most commonly seen, Dr. Jernigan said. While children were disproportionately affected by the 2009 H1N1 virus, “when H1N2 is dominant, we see more illness in children and older adults,” he said.

Another important reason to vaccinate children is that they are incredibly efficient at spreading the flu – to their peers, family members, and others, close contacts, said Dr. Judith S. Palfrey, past president of the American Academy of Pediatrics.

Dr. Palfrey said that children under 9 years of age who have never been vaccinated against the flu should receive two doses this year, given that about four weeks apart. One dose is sufficient for previously vaccinated children, she said. A complete algorithm for childhood vaccination is available at the American Academy of Pediatrics website.

More information about this year’s influenza vaccine is available at the CDC’s flu website cdc.gov/flu.

Although influenza vaccination is recommended for most individuals, some people should not receive the flu vaccine. According to the CDC, individuals who are allergic to eggs or who have had a history of severe reaction to an influenza vaccination should not be vaccinated, nor should anyone who has developed Guillain-Barré syndrome within 6 weeks after receiving an influenza vaccine.

Those with a moderate to severe illness that includes a fever should wait until they recover before getting vaccinated.

And children younger than 6 months of age should not receive any type of flu vaccine.

The press conference was sponsored by the National Foundation for Infectious Diseases in partnership with the National Influenza Vaccine Summit.

The press conference was also supported in part by the Centers for Disease Control and Prevention and by unrestricted educational grants to the NFID from Flu Vaccine Business Practices Initiative (c/o HIDA), Genentech, GlaxoSmithKline, MedImmune, Merck & Co., Novartis Vaccines, Pfizer, Sanofi Pasteur, and Walgreens.

Most Health Care Workers Skipped 2009 H1N1 Vaccine

BY BRUCE JANCIN
Elsevier Global Medical News

VAIIL, COLO. – Acceptance of the pandemic 2009 H1N1 influenza vaccine by U.S. health care workers was, in a word, “terrible,” Dr. Adriana Weinberg declared.

A mere 37% of the physicians and other health care workers were vaccinated against the pandemic virus, Dr. Weinberg reported at the annual conference on pediatric infectious diseases sponsored by the Children’s Hospital, Denver.

Uptake of the vaccine by two notably high-risk patient groups – pregnant women, and children and adolescents aged 6 months to 17 years – was equally poor at 38% and 37%, respectively, said Dr. Weinberg, professor of medicine, pediatrics, and pathology, and medical director of the clinical virology laboratory at the University of Colorado Hospital, also in Denver. These data were provided to the National Vaccine Advisory Committee by the Centers for Disease Control and Prevention.

Among parents and other care providers whose children were younger than 6 months of age, vaccine acceptance was even worse at 14%.

Moreover, only 25% of adults aged 24-64 years with immunosuppression or other chronic conditions placing them at elevated risk for increased flu morbidity got vaccinated. That was essentially the same rate as in the over-all U.S. population, including both high-priority and non-high-priority individuals.

As a result of this low uptake, many millions of soon-to-expire doses of pandemic 2009 H1N1 influenza monovalent vaccine are being destroyed.

In several studies, the main reason cited by health care workers and pregnant women for not accepting the vaccine was fear of side effects, especially Guillain-Barré syndrome, which was an issue with the 1976 swine flu vaccine.

The safety concerns proved baseless this time around, as evidenced by consistently reassuring findings from three separate sources: the Vaccine Safety Datalink, the Vaccine Adverse Event Reporting System, and the Emerging Infections Program.

For example, there were no deaths and no cases of Guillain-Barré syndrome among recipients of 438,376 doses of the vaccine in managed care organizations participating in the Vaccine Safety Datalink. And during surveillance for Guillain-Barré syndrome conducted through the Emerging Infections Program, the rate of cases was 1.92/100,000 person-years among vaccine recipients, compared with 1.21/100,000 person-years among nonrecipients.

That 0.7/100,000 person-years excess of Guillain-Barré syndrome associated with the pandemic H1N1 vaccine is similar to that associated with the seasonal influenza vaccine, according to Dr. Weinberg.

One audience member said the reason a lot more families in his practice didn’t get H1N1 vaccine against H1N1 wasn’t fear of side effects; it was that he and other office-based physicians in his community didn’t get shipments of the vaccine until after the second and as it turned out, final, wave of the 2009 pandemic had passed.

Dr. Weinberg agreed that lack of timely vaccine availability caused by long delays in the cumbersome manufacturing process was a huge problem. A potential solution would be to produce influenza vaccines in cell culture instead of eggs, something the Food and Drug Administration is very reluctant to allow, although one such flu vaccine was recently approved. Another solution would be to identify common epitopes that confer cross-strain protection against all influenza strains, so a new vaccine wouldn’t have to be created in advance of every flu season.

“There has been a big push on this. There are some good candidate epitopes emerging in the last year. We shall see,” the virologist said.

The vaccine manufacturing for the coming 2010-2011 flu season contains antigens for a pandemic 2009 H1N1 influenza virus as well as a seasonal influenza A H3N2 Perth 2009 virus and an influenza B Brisbane 2008 virus. The immunization schedule recommended by the CDC calls for a single dose of the vaccine for adults and children older than age 10 years. Children aged 6 months to 9 years are to receive two doses 21 days apart unless they are in the minority who received the pandemic H1N1 monovalent vaccine last season, in which case they are to get a single dose of the trivalent vaccine.

Despite this recommendation, a recent randomized controlled trial concluded that a single dose may be sufficiently immunogenic in young children (JAMA 2010;303:37-46).

“We do anticipate circulation of the pandemic H1N1 strain in the next flu season, but I have to caution you that in the Southern Hemisphere, where influenza season is going on right now, there is very, very little pandemic H1N1. What predominates are the H1N2 and the B Brisbane,” she said.
Surgeon General: Even One Cigarette Is Harmful

BY ALCIA AULT

WASHINGTON – For the first time, there is evidence of immediate and direct harm done by smoking even one cigarette, according to the 39th annual U.S. Surgeon General’s Office report on smoking.

Surgeon General Regina M. Benjamin said at a press briefing that previous reports from her office have focused on the various diseases that smoking could cause. “This report focuses on how tobacco smoke causes damage to every organ in your body,” she said. When asked why this report could make a difference when so many previous warnings have not convinced all Americans to quit smoking, Dr. Benjamin said that she thinks that the direct evidence of harm will personalize the message.

The 700-page “Report of the Surgeon General: How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease,” determined that tobacco smoke contains 7,000 chemicals, hundreds of which are known to be toxic and 70 of which are carcinogenic, she noted.

The report describes multiple insults to the body from those chemicals, including changes in DNA that can lead to cancer; damage to the lining of the lungs; obstructive pulmonary disease and bronchitis; stress on the vasculature and cardiovascular disease; and an increased risk of heart attack, stroke, and aortic aneurysm.

Smoking also interferes with the effectiveness of chemotherapy and the control of blood sugar and leads to fertility problems, including difficulty conceiving, miscarriage, and preterm birth. Just one cigarette can trigger a heart attack or stroke, she said.

In addition, the report examined the effects of secondhand smoke, finding that even brief exposure can cause cardiovascular disease and can also trigger acute cardiac events, such as heart attack. Babies exposed to secondhand smoke are more likely to die of sudden infant death syndrome.

The report highlights the increasingly addictive properties of today’s cigarettes, many of which are designed to enhance nicotine absorption and its crossing of the blood-brain barrier, Dr. Benjamin said.

Department of Health and Human Services Secretary Kathleen Sebelius said at the briefing that the report shows that “there is no safe level of exposure to tobacco smoke,” and, she added, “If you’re a smoker, the best time to quit is right now.”

John R. Seffrin, Ph.D., CEO of the American Cancer Society Cancer Action Network, agreed. “Today’s report makes it clear, once again, that there is no such thing as a safe cigarette and no such thing as a safe level of exposure to secondhand smoke for nonsmokers,” he said in a statement.

Ms. Sebelius noted that, every day, 4,000 Americans under 18 years old try their first cigarette, and 1,000 become daily smokers. Some 1,200 Americans die every day as a result of tobacco-related causes, she said, and the report is part of the Obama administration’s ongoing strategy to completely eliminate tobacco use.

The Surgeon General’s report is available at www.surgeongeneral.gov. The office has also created a consumer-friendly version of the report and a print-able, one-page fact sheet for physicians to use in discussing the report with their patients.

Manufactured by Amgen Inc.

Loughborough, United Kingdom

Manufactured for Schering Corporation, a subsidiary of Merck & Co., Inc.

Whitehouse Station, NJ 08889 USA

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PULMONARY MEDICINE

JANUARY 2011 • CHEST PHYSICIAN PULMONARY MEDICINE

Dr. Philip Marcus, FCCP, comments: In 1964, the first Surgeon General’s report on the effects of smoking on health was released. In the next 60 years, extensive data from thousands of studies have consistently substantiated the devastating effects of smoking on the lives of millions of Americans and others around the world. Yet today in the United States, tobacco use remains the single largest preventable cause of death and disease for both men and women.

Now, this 2010 report of the Surgeon General explains beyond a shadow of a doubt how tobacco smoke causes disease, essentially validating earlier findings, and expands and strengthens the science behind these findings. Armed with this irrefutable data, the time has come to mount a full-scale assault on the tobacco epidemic. More than 1,000 people are killed every day by cigarettes, and one-half of all long-term smokers are killed by smoking-related diseases. This report should lay the issue to rest at this time, and hopefully there can be a true reduction in cigarette smoking and a concomitant end to the epidemic of smoking-related illnesses.
H1N1 Isn’t Over

T

writer • from page 1

least 90% of the population were vaccinated, herd im-
munity would protect even those people who can’t be
vaccinated, such as infants under 6 months of age and
others with contraindications, Dr. Harrison said.

Given last year’s experience, that’s not likely to happen. U.S.
health officials hoped to have enough antigen for 229 million
doses. In the end, only 162 mil-

military vaccines in two forms: trivalent, inac-

tivated influenza vaccine (TIV) and live, attenuated in-

fluenza vaccine (LAIV). The TIV vaccine is an
intramuscular injection of killed viruses. It can be giv-

en to anyone over 6 months of age who is not allergic
to the vaccine. Egg allergies are no


Avoid Afluria Flu Vaccine in Children Under 9 Years

BY ROBERT FINN

no other vaccine is available.01_4_6_7_10_13ch11_1.qxp  12/30/2010  1:57 PM  Page 10

children under 5 years of age with reactive airways diseases
such as asthma, anyone with a high-risk medical con-
dition, and pregnant women.

Unlike last year, when two vaccines were

printed on one for seasonal flu and one for H1N1, this year one vaccine
will protect against three strains:

A/California/7/2009 (H1N1), which caused last season’s pandemic.
B/Brisbane/60/2008, the same circulating
strain from last season, which is

Dr. Burt Lesnick, FCCP, comments:

Are at especially high risk from influenza and no other vaccine is available.

CHIL

DE AGED 5-8 YEARS CAN

must not be used in children be-
tween the ages of 6 months and 8 years.

The company’s trivalent influenza vac-

cine (TIV) sold under the trade name
Afluria Unites States was associ-

ated with a large increase in the risk of

fears and febrile seizures in children in

Australia and New Zealand. In April

2010, authorities in those two countries

recommended that physicians suspend
use of CSL’s influenza vaccines in chil-

dren aged 5 years and under. In response, the company voluntarily withdrew its
vaccine from markets in the southern

hemisphere.

In the northern hemisphere, CSL’s in-

fluenza vaccines have been approved for
use in Germany, the United Kingdom, and

the United States. In June 2010, au-
thorities in the United Kingdom recom-

mended that physicians avoid using

CSL’s influenza vaccine in children aged

5 and under.

In making their recommendation, members of the Centers for Disease
Control and Prevention’s Advisory

Committee on Immunization Practices (ACIP) noted that there should be ade-
quately supplies of seasonal influenza vac-
cine even in the absence of Afluria. Other manufacturers are expected to

supply 145-150 million doses of the vac-
cine in the United States; the largest

number of doses ever used in one flu

season was 114 million.

During the course of a teleconfer-

cence sponsored by ACIP, representatives of Sanofi-Aventis, GlaxoSmithKline,
Varicella, and MedImmune all said that

they had adequate supplies of vaccine, and they were willing to increase pro-
duction if necessary to compensate for the 6-12 million doses that CSL had

been expected to provide.

According to the CDC’s medical epi-
demiologist Dr. Tim Uyeki, CSL’s vac-
cine was associated with a ninefold
increase in the risk of febrile seizures,

compared with other manufacturers’
vaccines in children aged 6 months

through 4 years in Australia. The rate

was nine per 1,000 doses in these chil-
dren, compared with an expected rate
of one per 1,000 doses. The rate of febrile

seizures was especially high in children

aged 3-4 years given Fluvarix Junior, one of

CSL’s two versions of this year’s TIV.
The rate in those children was 15 per

1,000 doses.

Febrile seizures occurred an average of
7.2 hours after the child received a
dose of vaccine, with a range of 5.9-8.4 hours. Dr. Uyeki said that no explanation for the

increased risk of fever and febrile seizures has been identified.

Although there was no apparent in-
crease in febrile seizures in children aged

5-8 years, children in that age group did

experience an increase in the incidence of

fever. Sixteen percent of children in that

age group experienced a fever following

a dose of a CSL flu vaccine, compared

with 9% of children receiving another

manufacturer’s vaccine. ACIP members

voted to include chil-

dren aged 5-8 years in their recommen-
dation in order to increase the simplicity

and consistency of the public health

message. Other ACIP recommendations

regarding flu vaccination in children,

both for the seasonal TIV and for pan-
demic influenza A(H1N1), involve chil-

dren aged 6 months to 8 years, and most

members believed it would be confusing
to have this new recommendation
cover children age 6 months to 5 years.

On balance, however, that chil-

dren aged 5-8 years could receive the CSL

vaccine if they were at especially high risk from influenza and if no other vac-

cine was available.

Several committee members voiced

concern about providers who may al-
ready have placed orders for the CSL vac-
cine. Since most vaccine from other

manufacturers has already been allo-
cated, they worried that it would be too
late for some clinicians to change their
orders. In response, a representative from

the American Medical Association rec-

ommended that providers visit the

AMA’s Influenza Vaccine Availability

Tracking System (IVATS) at www.

preventinfluenza.org/ivats. A spread-
sheet at that site lists names and contact

information for distributors who have

vaccine available.

While several members of ACIP dis-

closed that they had relationships with

vaccine manufacturers, only members

with no such conflicts of interest were

permitted to vote.

DATA WATCH

World H1N1 Flu Vaccine Sales, 2009 (in millions/market share)

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>2009 Sales (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pandemrix (GlaxoSmithKline)</td>
<td>$1,190 / 35%</td>
</tr>
<tr>
<td>Focetrix (Novartis)</td>
<td>$950 / 28%</td>
</tr>
<tr>
<td>Humenze (Sanofi Pasteur)</td>
<td>$620 / 18%</td>
</tr>
<tr>
<td>MedImmune H1N1 Intranasal (AstraZeneca)</td>
<td>$365 / 11%</td>
</tr>
<tr>
<td>Panvax H1N1 (CSL)</td>
<td>$160 / 5%</td>
</tr>
<tr>
<td>Celvapan H1N1 ( Baxter)</td>
<td>$50 / 1.5%</td>
</tr>
<tr>
<td>Other</td>
<td>$50 / 1.5%</td>
</tr>
</tbody>
</table>

*Estimated

Note: Based on annual reports of vaccine concerns, trade media coverage, company

Web sites, and medical and government literature.

Source: Kalorama Information
Indication

REVATIO is indicated for the treatment of pulmonary arterial hypertension (WHO Group I) to improve exercise ability and delay clinical worsening. Delay in clinical worsening was demonstrated when REVATIO was added to background epoprostenol therapy. The efficacy of REVATIO has not been adequately evaluated in patients taking bosentan concurrently.

Important Safety Information

Do not use REVATIO in patients taking organic nitrates in any form, either regularly or intermittently. Consistent with its known effects on the nitric oxide/cGMP pathway, sildenafil was shown to potentiate the hypotensive effects of nitrates.

Before starting REVATIO, physicians should carefully consider whether their patients with underlying conditions could be adversely affected by the mild and transient vasodilatory effects of REVATIO on blood pressure. Pulmonary vasodilators may significantly worsen the cardiovascular status of patients with pulmonary veno-occlusive disease (PVOD) and administration of REVATIO to these patients is not recommended. Should signs of pulmonary edema occur when sildenafil is administered, the possibility of associated PVOD should be considered.

Caution is advised when PDE5 inhibitors, such as REVATIO, are administered with α-blockers as both are vasodilators with blood pressure lowering effects.

In PAH patients, the concomitant use of vitamin K antagonists and REVATIO resulted in a greater incidence of reports of bleeding (primarily epistaxis) versus placebo. The incidence of epistaxis was higher in patients with PAH secondary to CTD (sildenafil 13%, placebo 0%) than in patients on bosentan (sildenafil 3%, placebo 2%).

Co-administration of REVATIO with potent CYP3A4 inhibitors, eg, ketoconazole,itraconazole, and ritonavir, is not recommended as serum concentrations of sildenafil substantially increase. Co-administration of REVATIO with CYP3A4 inducers, including bosentan; and more potent inducers such as barbiturates, carbamazepine, phenytoin, efavirenz, nevirapine, rifampin, and ritabutin, may alter plasma levels of either or both medications. Dosage adjustment may be necessary.

Non-arteritic anterior ischemic optic neuropathy (NAION) has been reported post-marketing in temporal association with the use of PDE5 inhibitors for the treatment of erectile dysfunction, including sildenafil. It is not possible to determine if these events are related to PDE5 inhibitors or to other factors. Physicians should advise patients to seek immediate medical attention in the event of sudden loss of vision while taking PDE5 inhibitors, including REVATIO.

Sudden decrease or loss of hearing has been reported in temporal association with the intake of PDE5 inhibitors, including REVATIO. It is not possible to determine whether these events are related directly to the use of PDE5 inhibitors or to other factors. Physicians should advise patients to seek prompt medical attention in the event of sudden decrease or loss of hearing while taking PDE5 inhibitors, including REVATIO.

REVATIO should be used with caution in patients with anatomical deformation of the penis or patients who have conditions which may predispose them to priapism.

REVATIO contains sildenafil, the same active ingredient found in VIAGRA®. Combinations of REVATIO with VIAGRA or other PDE5 inhibitors have not been studied. Patients taking REVATIO should not take VIAGRA or other PDE5 inhibitors.

Patients with the following characteristics did not participate in the preapproval clinical trial: patients who have suffered a myocardial infarction, stroke, or life-threatening arrhythmia within the last 6 months, unstable angina, hypertension (BP >170/110), retinitis pigmentosa, or patients on bosentan. The safety of REVATIO is unknown in patients with bleeding disorders and patients with active peptic ulceration. In these patients, physicians should prescribe REVATIO with caution.

The most common side effects of REVATIO (placebo-subtracted) were epistaxis (8%), headache (7%), dyspepsia (6%), flushing (6%), and insomnia (6%). Adverse events of REVATIO injection were similar to those seen with oral tablets.

The most common side effects of REVATIO (placebo-subtracted) as an adjunct to intravenous epoprostenol were headache (23%), edema (14%), dyspepsia (14%), pain in extremity (11%), diarrhea (7%), nausea (7%), and nasal congestion (7%).
Live, Inactivated Flu Vaccines Equally Cost Effective

Despite recent reports that the intranslative live attenuated influenza vaccine might cause more adverse events in young children than does the inactivated influenza vaccine, the cost-effectiveness of the two approaches remains comparable, according to a recent study.

In a mathematical simulation model, both the live attenuated vaccine and the inactivated vaccine yielded similar cost-effectiveness ratios of less than $40,000 per quality-adjusted life year (QALY) among children under 5 years, which compares well with other well-accepted pediatric interventions, said Lisa A. Presser, Ph.D., of the University of Michigan Health System, Ann Arbor, and her associates (Arch Pediatr Adolesc Med. 2010;164:101).

The investigators assessed the cost-effectiveness of each of the vaccines and of no vaccination using a mathematical simulation model that estimated the effects on influenza-related health outcomes in a hypothetical cohort of healthy children ages 6 months to 4 years. The live attenuated vaccine was projected to avert more influenza episodes, influenza-related hospitalizations, and deaths than with the inactivated vaccine. However, this benefit was somewhat counterbalanced by an increase in adverse events with the live attenuated vaccine.

Under different conditions, the model showed that cost-effectiveness ratios ranged from $20,000/QALY to $33,000/QALY with the live attenuated vaccine and $21,000/QALY to $37,000/QALY with the inactivated vaccine.

This study was funded by the Centers for Disease Control and Prevention Vaccine and Related Systems. doi:10.1001/archpediatrics.2010.182).
Infant Vaccinations Met Goals of Healthy People 2010

BY DAMIAN MONAMARA
Elsevier Global Medical News

ATLANTA – Vaccination of U.S. infants 19-23 months of age remains high at 90% or greater for routine immunizations, according to results of the 2009 National Immunization Survey released by the Centers for Disease Control and Prevention. This means vaccine coverage in 2009 met or exceeded the 90% goal set by the National Healthy People 2010 initiative.

This survey of vaccinations for 17,313 children nationwide revealed that less than 1% of young children born between January 2006 and July 2008 received no vaccinations (MMWR 2010;59:1171-7).

“Today’s report is generally reassuring, despite concerns we’ve seen in the past about whether parents are continuing to have their children vaccinated, and despite some resurgence in vaccine-preventable diseases in particular areas,” Dr. Anne Schuchat, director of the National Center for Immunization and Respiratory Diseases at the CDC, said during a telebriefing.

Some substantial variation in vaccine coverage between states was again revealed by this announcement, suggesting that there is still work to be done in some communities.

Dr. Schuchat addressed the outbreak of pertussis cases in California, responsible for nine infant deaths since January 2010. The coverage in California for four doses of DTaP the pertussis-containing shot for babies, was 83%, according to state records. “We don’t think it’s the coverage level in babies and toddlers that is leading to that pertussis challenge in California.” Instead, “we think the challenge with those pertussis cases is the increasing vaccination of teens and adults,” she said, although “it continues to be important for babies and toddlers to get their DTaP doses.”

The CDC strongly recommends everyone aged 11 years and older, particularly new parents and those in close contact with young children, receive the vaccination against pertussis. Dr. Schuchat said, “The situation in California is serious, and we are working together with the California health department to really promote uptake of the pertussis vaccine for teens and adults.”

The survey showed national coverage for MMR vaccinations experienced “a significant but not large” drop from 92% in 2008 to 90% in 2009. “That might be a warning sign of larger drops to come or a small change that, because our survey is so large, was statistically significant,” Dr. Schuchat said. Even though national coverage numbers are 90%, “you can still have large pockets of susceptible children.”

Two examples [pertussis and measles] show that we cannot let our guard down,” Dr. Schuchat said.

The survey also revealed a substantial drop in coverage for one vaccine, Haemophilus influenzae B (Hib). A total of 84% of children aged 19-35 months received the three recommended doses in the survey. This represents a decrease of more than 6 percentage points vs. 2008 that “really just reflects the national variation in vaccine uptake,” Dr. Schuchat said. She commended clinicians for following recommendations to drop the booster shot during this shortage, and added that the vaccine is now readily available.

Other survey findings indicate that 44% of children received full coverage for the rotavirus vaccine during infancy. This is the first national survey data to report adoption of the rotavirus vaccine since its U.S. licensure in 2006. “That is really good uptake of this vaccine. Of course, we’re already seeing a very important drop in disease caused by the rotavirus,” Dr. Schuchat said.

In a placebo-controlled fixed dose titration study of REVATIO (starting with recommended dose of 20 mg TID increased to 40 mg TID and then 80 mg TID) as an adjunct to inhaled bronchodilators in pulmonary arterial hypertension, the adverse events that were reported were more frequent in the placebo arm (+4% difference) are shown in Table 2.

Table 2. REVATIO-Induced Adverse Events More Frequent (+4%) than Placebo

<table>
<thead>
<tr>
<th>Adverse Effect</th>
<th>Placebo</th>
<th>Revatio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>34.0%</td>
<td>37.0%</td>
</tr>
<tr>
<td>Edema</td>
<td>13.0%</td>
<td>15.0%</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>14.0%</td>
<td>16.0%</td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>6.0%</td>
<td>7.0%</td>
</tr>
<tr>
<td>Diaphoresis</td>
<td>18.0%</td>
<td>20.0%</td>
</tr>
<tr>
<td>Nausea</td>
<td>2.0%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Nasal congestion</td>
<td>9.0%</td>
<td>7.0%</td>
</tr>
</tbody>
</table>

*Includes peripheral edema.

REVATIO injection Risk:

REVATIO injection was studied in a 616-patient, placebo-controlled study at doses targeting plasma concentrations between 10 and 50 ng/mL up to 8 hours after the dose is expected to affect the adverse events in PAH patients were similar to those seen with oral tablets.

Drug Interactions:

In drug-drug interaction studies, sildenafil (25 mg, 50 mg, 100 mg) and the alpha-blocker doxazosin (4 mg or 8 mg) were administered simultaneously to patients with benign prostatic hyperplasia (BPH) stabilized on doxazosin therapy. In these study populations, mean additional reductions of supine systolic and diastolic blood pressure of 1/7 mmHg, 1/6 mmHg, and 1/4 mmHg, respectively, were observed. Mean additional reductions of standing blood pressure of 6/6 mmHg, 4/4 mmHg, and 3/3 mmHg, respectively, were also observed. There were infrequent reports of patients who experienced symptomatic postural hypotension. These events included dizziness and light-headedness, but no syncope.

Amodipine

When sildenafil 100 mg oral was co-administered with amiodapine, 5 mg or 10 mg oral, to hypertensive patients, additional reduction of standing blood pressure suppression was 5/5 mmHg systolic and 7/7 mmHg diastolic.

Use in Specific Populations:

Pregnancy

Pregnancy Category B

No evidence of teratogenicity, embryotoxicity, or fetotoxicity was observed in pregnant rats or rabbits dosed with sildenafil. There are no adequate and well-controlled studies of sildenafil in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery

The safety and efficacy of REVATIO during labor and delivery has not been studied.

Nursing Mothers

It is not known whether sildenafil or its metabolites are excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when REVATIO is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of sildenafil in pediatric pulmonary hypertension patients have not been established.

Geriatric Use

Clinical studies of REVATIO did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Hepatic Impairment

No dose adjustment for mild to moderate impairment is required. Severe impairment has not been studied.

Renal Impairment

No dose adjustment is required (including severe impairment CLR < 30 mL/min).

Oversedage

In studies with healthy volunteers of single doses up to 800 mg, adverse events were similar to those seen at lower doses but rates and severities were increased.

Cases of sudden decrease or loss of hearing have been reported postmarketing in temporal association with the use of PDE5 inhibitors, including REVATIO. In some of the cases, medical conditions and other factors were reported that may have also played a role in the otologic adverse events. In many cases, medical follow-up information was limited. It is not possible to determine whether these events are related directly to the use of REVATIO, to the patient’s underlying vascular risk factors or anatomical defects, to a combination of these factors, or to other factors (see Warnings and Precautions).

Loss of Hearing

Cases of sudden decrease or loss of hearing have been reported postmarketing in temporal association with the use of PDE5 inhibitors, including REVATIO. In some of the cases, medical conditions and other factors were reported that may have also played a role in the otologic adverse events. In many cases, medical follow-up information was limited. It is not possible to determine whether these events are related directly to the use of REVATIO, to the patient’s underlying vascular risk factors or anatomical defects, to a combination of these factors, or to other factors (see Warnings and Precautions).

Drug Interactions

Nitrates

Concomitant use of REVATIO with nitrates in any form is contraindicated (see Contraindications). Rivaroxaban and other PDE5 inhibitors Concomitant use of REVATIO with rivaroxaban and other PDE5 inhibitors is not recommended (see Warnings and Precautions).

Alpha-blockers

Use caution when co-administering alpha-blockers with REVATIO because of additive blood-pressure lowering effects (see Warnings and Precautions).
CHEST Physician Editorial Advisory Board Gains New Members and a Deputy Editor

Dr Stuart M. Garay, FCCP, is a practicing pulmonologist and Clinical Professor of Medicine at the New York University School of Medicine. He is President of University Physicians Network, a physician founded, owned, and operated organization that is committed to helping member physicians cope with the changes and challenges of the health care business environment. Dr Garay is a member of the Practice Operations Network Steering Committee. In the past, he has served on the ACCP Board of Regents as a Regent at Large; as a member of the CHEST scientific program committee; and on the steering committee of the Clinical Pulmonary Medicine Network. Dr Garay’s clinical and research interests include airway diseases ranging from asthma to bronchiectasis, mycobacterial infections, and sleep apnea. He has participated in numerous clinical trials for asthma and COPD, and he has published more than 50 papers and chapters on various topics in pulmonary medicine. He is co-editor of a text, Tubercolosis.

Dr Darcy D. Marciniuk, FCCP, is a Professor of Medicine and Head of the Division of Respiratory, Critical Care, and Sleep Medicine at the University of Saskatchewan, Saskatoon, SK, Canada. Dr Marciniuk received his Doctor of Medicine from the University of Saskatchewan and had specialty training in internal medicine and respiratory medicine at the University of Western Ontario and at the University of Manitoba. He returned to Saskatoon in 1990, where he assumed his current faculty position with the University of Saskatchewan.

Dr Marciniuk is currently President-Designate of the ACCP, a member of the ACCP Board of Regents, and a Trustee of The CHEST Foundation. He has held a number of leadership positions in the ACCP, including Governor of Saskatchewan; Chair of the Pulmonary Physiology, Function, and Rehabilitation Network; and Co-Chair of CHEST 2005. Dr Marciniuk is Past Chair of the Royal College of Physicians and Surgeons of Canada Evaluation Committee in Respiratory and is a Past President of the Canadian Thoracic Society. He has published more than 90 peer-reviewed publications, chapters, and reviews. His interests in pulmonary medicine include COPD and clinical physiology and exercise.

Dr Marcos I. Restrepo, MSc, FCCP, is an Assistant Professor of Medicine in the Division of Pulmonary/Critical Care Medicine at the University of Texas Health Science Center at San Antonio. He is the Director of the Medical Intensive Care Unit at the South Texas Veterans Health Care System, Audie L. Murphy Division. He completed his residency in internal medicine and fellowships in infectious diseases, pulmonary disease, and critical care medicine at the University of Texas Health Science Center at San Antonio. Dr Restrepo is an investigator for VERDICT, which aims to translate medical evidence into clinical practice. He has been an author or co-author of more than 60 journal articles and 7 book chapters and has lectured nationally and internationally. Dr Restrepo serves on the ACCP Respiratory Care Network Steering Committee and previously was on the Chest Infections Network Steering Committee. He serves as a reviewer for 14 journals, including CHEST, Critical Care Medicine, and American Journal of Respiratory and Critical Care Medicine. Dr Restrepo’s primary research interests include immunomodulation in sepsis and pneumonia, appropriate application of interventions to prevent and treat critically ill patients with severe infections, and improving health outcomes and quality of care of patients in the ICU with pneumonia and sepsis.

Dr W. Michael Alberts, FCCP, has agreed to assume the Deputy Editor in Chief role for CHEST Physician and work with Dr Selecky during the final year of his term in 2011. Dr Alberts will then take over as Editor in Chief from 2012 through 2015. We thank Dr Alberts for his continued leadership service to CHEST Physician.
Guidelines Moving Forward

In ongoing efforts to strengthen its internationally recognized guideline development, publication, and dissemination, the ACCP has hired two new employees with notable backgrounds contributive toward this end.

Rebecca Diekemper, MPH, comes to the ACCP from BJC HealthCare in St Louis, where she served as a clinical epidemiologist. In addition to reviewing guidelines and the primary evidence, Rebecca has performed systematic reviews and developed a tool to assess systematic reviews, which has been compared to the Guyatt-Osman and other such tools. She will be primarily working on the lung cancer guidelines, managing the Policy and Procedures Subcommittee, and assisting with the full HSP Committee.

Joe Ornelas, DC, MS, MA, is working toward completing a PhD in health policy and administration at the University of Illinois School of Public Health. In various jobs in academic and hospital settings, he has conducted extensive literature reviews, performed probability-based decision analyses for cost-effectiveness and cost-utility evaluations, and worked on many projects requiring data management and analysis. Joe will work primarily on the antithrombotic and immunosuppressives guidelines and will manage the HSP Guidelines Subcommittee.

New HHS/CCSC Awards Program Announced

Reducing the incidence of healthcare-associated infections (HAIs) is a priority for the ACCP. A new national awards program, Achievements in Eliminating Healthcare-Associated Infections, cosponsored by the US Department of Health and Human Services (HHS) and the Critical Care Societies Collaborative (CCSC), will annually recognize teams of critical care professionals and health-care institutions that achieve excellence and notable, sustained improvements in preventing HAIs, specifically infections involving critical care. The awards program intends to motivate the health-care community to achieve wide-scale reduction and elimination of HAIs and further motivate other clinicians, hospital executives, and facilities to improve clinical practice through utilization of evidence-based guidelines. The ACCP actively participates in the CCSC, along with the American Association of Critical-Care Nurses, American Thoracic Society, and Society of Critical Care Medicine. The initial phase of the awards program will emphasize success related to reducing and eliminating central line–associated bloodstream infections and ventilator-associated pneumonia. Applications are due January 29, 2011. For questions, contact awards@aac.org.

This Month in CHEST: Editor’s Picks

By Dr Richard S. Irwin, Master FCP
Editor in Chief, CHEST

Effects of Bronchoconstriction, Minute Ventilation, and Deep Inspiration on the Composition of Exhaled Breath Condensate.
By Dr J. S. Dehley et al.

Interpreting Lung Function Data Using 80% Predicted and Fixed Thresholds Misclassifies More Than 20% of Patients.
By Dr M. R. Miller et al.

Factors at Admission Associated With Bleeding Risk in Medical Patients: Findings From the IMPROVE Investigators.
By Dr H. Decousus et al.

Beneficial Effects of Treatment With Anti-IgE Antibodies (Omalizumab) in a Patient With Severe Asthma and Negative Skin-Prick Test Results.
By Dr M. van den Berge et al.

SPECIAL FEATURE

By Dr O. Lababede et al.

AMERICAN COLLEGE OF CHEST PHYSICIANS

2011 Education Calendar

Sleep Medicine 2011
January 27-30
Tempe, AZ

Celebration of Pediatric Pulmonology 2011
April 8-10
Ft. Lauderdale, FL

ACCP Critical Care Medicine Board Review 2011
August 26-30
San Antonio, TX

ACCP Sleep Medicine Board Review 2011
August 26-29
San Antonio, TX

Lung Pathology 2011
August 26-29
San Antonio, TX

Mechanical Ventilation 2011
August 30
San Antonio, TX

ABIM Critical Care Medicine and Pulmonary Disease SEP Modules
August 30
San Antonio, TX

ACCP Pulmonary Medicine Board Review 2011
August 31-September 4
San Antonio, TX

CHEST 2011
October 22-27
Honolulu, Hawaii

Basic and Advanced Bronchoscopy Skills
February 11-13
Orlando, FL

Mechanical Ventilation
February 25-27
Chicago, IL

Difficult Airway Management
March 18-20
Chicago, IL

Critical Care Echocardiography
September 24-25
Chicago, IL

ACCP Simulation Program for Advanced Clinical Education

Ultrasonography:
Fundamentals in Critical Care
April 15-17
Baltimore, MD

Focused Pleural and Vascular Ultrasound
September 22-23
Chicago, IL

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Sepsis, Acute Kidney Injury, Sleep Disorders, Flu

**Critical Care**

The Kansas Sepsis Project

Severe sepsis is a common cause of mortality, representing the most common cause of death in noncoronary ICUs (Bone et al. Chest. 1992;101[6]: 1644). Sepsis is rapidly increasing in incidence, projected to affect over 1,000,000 patients per year in the United States by 2020 (Angus et al. Crit Care Med. 2001;29[7]:1303-1310). Rural patients develop severe sepsis in similar proportion to urban patients, yet access to critical care services in rural areas is limited.

Telemedicine can help to bridge the gap between the mostly urban supply of intensivists and underserved rural patients and their local physicians (Marcin et al. J Pediatr. 2004;144[3]:375). Various techniques have been utilized to address this need, ranging from video consultation to teleICU, with reasonable evidence that such care is comparable to hands-on ICU care (Hersh et al. BMC Medical Informatics and Decision Making. 2001;1:5). To further explore uses of telemedicine in the specialty of critical care medicine, a CME/performance improvement project dealing with improving care of patients with sepsis in rural Kansas was implemented via the Eli Lilly Distinguished Scholar Award of The CHEST Foundation. An objective of the project is to empower rural physicians to appropriately care for their own patients with sepsis, as an alternative to real-time telemedicine consultation.

The Kansas Sepsis Project brings CME and performance improvement to rural Kansas areas via telemedicine in both educational and advisory roles. The project provides a novel method for rural medical practitioners to obtain CME credit while performing sepsis quality improvement projects that are eligible for maintenance of board certification. The overall goal of the project is to demonstrate a statewide reduction in sepsis mortality through widespread provider participation, paving the way for similar projects in other rural states.

*Dr. Lucas R. Pitts; and Dr. Steven Q. Simpson, FCCP, Network Vice-Chair and Third Eli Lilly and Company Distinguished Scholar in Critical Care Medicine*

**Cardiovascular Medicine and Surgery**

*Risk of Acute Kidney Injury With Same Admission Cardiac Catheterization and Cardiac Surgery*

Acute kidney injury (AKI) after open cardiac operations is associated with increased morbidity and short-term and long-term mortality. Prevention of AKI during and after surgery is of paramount importance. The Acute Kidney Injury Network definition of AKI is a 0.3 mg/dL or 50% increase in baseline creatinine value. It is common practice to provide diagnostic cardiac catheterization and cardiac surgery in the same admission. This practice may lead to a higher risk of AKI with attendant increased risks for a higher morbidity and mortality. The question, therefore, remains as to the optimal timing of cardiac surgery following cardiac catheterization. A recent prospective study from the Northern New England Cardiovascular Disease Study Group looked at the incidence of AKI after cardiac catheterization in 688 patients undergoing non-emergent cardiac surgery during the same hospital admission (367 patients) or a later admission (301 patients) (Kramer et al. Am Thorac Surg. 2010; 90[5]:1418).

The incidence of AKI was 50.2% in the same admission group vs 33.7% for the later admission group. The difference was highly significant (P < 0.009). Patients undergoing surgery at a later admission had a 45% reduction in AKI. The authors concluded that “it is safe and possibly beneficial in terms of renal protection, to send patients home after cardiac catheterization with a plan for surgery during subsequent admission.”

*Dr. G. Hovsepian Abmassi, FCCP, Network Vice-Chair*

**Allied Health**

*Sleep Disorders Specialty Exam Accredited*

The National Board for Respiratory Care (NBRC) invested several years developing an examination for respiratory therapists specializing in sleep disorders and therapeutic intervention. Candidates must be certified respiratory therapists with clinical experience in the testing, monitoring, diagnosis, and treatment of patients with sleep disorders. Successful candidates will demonstrate overall competency in sleep care, which may require alternative approaches.

The specialty examination was developed in accordance with stringent psychometric and other standards put forth by the National Commission for Certifying Agencies. This body also accredits the registered polysomnographic technologist (RPSTG) examination offered by the Board of Registered Polysomnographic Technologists (BRPT). Both the RPSTG and sleep disorders specialty (SDS) examinations were developed based on job content identified by national job analysis research.

Test specifications for the NBRC’s SDS examination can be reviewed and printed by accessing the NBRC Web site at nbrc.org and clicking on the “Examinations” tab. An online, full-length, free practice examination is also available.

The new specialty examination was developed in response to requests from the NBRC’s sponsors. The Board of Trustees is pleased to announce the new examination was accredited by the National Commission for Certifying Agencies (NCCA), continuing a long tradition of NCCA accreditation for all of the NBRC’s credentialing programs. The NBRC was one of the first four organizations to have its examinations accredited in 1977 when the NCCA was formed, and it is the only organization to continuously maintain accreditation of its credentialing programs for more than 30 years.

*Gary A. Smith, CRT, PAARC Network Steering Committee Member*

**Chest Infections**

*Influenza: Brief Comments on the Recent 2009 Influenza A(H1N1) Epidemic and Observations on Vaccine*

Sporadic outbreaks of highly virulent avian H1N1 influenza virus and the subsequent outbreak of a pandemic A(H1N1) virus have heightened concerns about the eventual emergence of a particularly deadly pandemic virus. Influenza A virus represents one of the most prominent viral pathogens of modern times. Infection with this microbe results in an estimated 36,000 deaths1 and over 200,000 hospitalizations2 in the United States annually, with a projected total economic burden in excess of 80 billion US dollars per year. According to the Centers for Disease Control and Prevention, the incidence of influenza virus infection in the US may reach 20% during a typical flu season; however, this figure can increase substantially during periods of pandemic influenza. Although influenza is typically a self-limiting disease, serious complications can occur, including primary viral pneumonia, secondary bacterial pneumonia, myocarditis, and neurologic syndromes. The risk of mortality and disease complications is elevated for certain populations, including the young, old, immunosuppressed, and immunocompromised.

During the most recent pandemic, infection with disease was witnessed in unique populations, such as pregnant women and children, with substantial mortality observed. Elderly individuals were not as predisposed, reflecting previous serologic evidence of prior exposure to similar influenza virus strains. The epidemic demonstrated differences in treatment efficacy for drugs; potential utilities of intensive support, including alternate ventilatory modes such as extracorporeal membrane oxygenation; and difficulties in administering and allocating resources. Interactions among physicians, health-care delivery systems, and administrations were needed. The ability of influenza A virus to infect millions of people each year speaks to the resilient nature of this pathogen and to the necessity for developing improved methods of disease prevention and treatment.

Although commercial influenza vaccines have been available since the mid-1990s, a number of key challenges continue to limit the efficacy of these vaccines. The rapid mutation rate of immunodominant glycoproteins on the virus surface necessitates annual revision of the vaccine and requires a broad network of laboratories to cooperatively perform surveillance on circulating influenza virus strains throughout the year. Importantly, current strain-specific vaccines are only 30% to 50% effective in preventing hospitalization and pneumonia in the elderly and are about 70% effective in preventing illness in healthy adults. Most recently (late 2010), several groups have observed disturbing trends of mistrust of vaccine formulations (individual components), which have resulted in refusal of vaccination by health-care persons of all types, including physicians.

Despite the extensive variability in strains of seasonal influenza, some research investigations have indicated the potential for developing universally protective immune responses against influenza viruses. Over the past decade, an array of conserved influenza virus epitopes have been identified, and the ability of both cell-mediated immune components and humoral immune components to elicit cross-protective immunity to heterologous influenza A viruses have been documented. Moreover, the improvement of influenza vaccine immunogenicity via inclusion of molecular adjuvants and modification of vaccine modality has been widely reported but rarely within the context of a universal influenza vaccine. Top results of a maximally efficacious vaccine in pri-

*Further research is necessary to refine approaches to management of influenza, both in prevention and treatment.*


4. Molecular cardiac surgery and Dr. Joel F. Aldrich; and Dr. Richard E. Winn, FCCP, Network Steering Committee Member
Optimal management requires collaboration with a dentist trained in dental sleep medicine.

Although the first reported case of oral appliance use was by Pierre Robin in 1934, recognition of the effectiveness of these devices in treating sleep-disordered breathing did not gain momentum until the early 1980s. As oral appliances have evolved and dentists have gained expertise in their use, these devices have become an important part of the management of patients with sleep-disordered breathing. At present, oral appliances are recommended as second-line management for patients with obstructive sleep apnea (OSA) who have mild to moderate disease and who prefer an oral appliance or are intolerant of continuous positive airway pressure (CPAP) therapy.

The American Academy of Sleep Medicine’s practice parameters for oral appliance management of OSA notes that oral appliances are indicated in patients with mild to moderate OSA who prefer the use of an oral appliance to CPAP.

Oral appliances are also recommended for those patients who do not respond to CPAP, who are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP. Oral appliances should be fitted by qualified dentists who are trained and have experience in the care of oral health. These appliances improve sleep-disordered breathing and subjective measures of sleepiness when compared with no treatment or placebo. Although CPAP is more effective at improving sleep-disordered breathing than oral appliances, oral appliances produce significant improvements in measures of sleep-disordered breathing, blood pressure, and quality of life. Of note, oral appliances outperformed upper airway surgery in a head-to-head trial.

Oral appliances have been identified by several names, including mandibular repositioning appliances (MRAs), mandibular repositioning devices (MRDs), mandibular advancement splints (MASs), mandibular advancement devices (MADs), and tongue repositioning or tongue retaining devices (TRDs).

These appliances are divided into two categories: those that advance the mandible (MRA, MAS, MRD, and MADs) and those that reposition and retain the tongue in a forward position (TRDs). Since TRDs are not FDA-approved and have not been extensively studied, they will not be discussed further here.

For clarity, the term “mandibular repositioning appliances” will be used in this discussion. MRAs are viewed by the US Food and Drug Administration as class 2 medical devices. MRAs are typically made in two pieces (upper and lower) and then connected. They can be rigid (monobloc) or adjustable (duobloc), with the upper and lower portions attached by a hook or screw assembly or by elastic bands. They are most often made of acrylic resin and well adapted to the teeth for retention purposes.

Adjustable devices are more popular and effective, as they can incrementally advance the lower jaw forward and downward. Many adjustable devices allow for lateral movements of the mandible. This attribute is especially beneficial for patients with OSA who experience bruxism. Devices made of thermoplastic (also known as “boil and bite”) are not considered custom-made appliances and do not perform as well.

How MRAs Work

MRAs work by moving the mandible downward and forward, which opens the posterior airspace and pulls the tongue forward. Mandibular protrusion by means of an MRA results in a significant increase in the airway diameter, especially in the oropharyngeal cross-sectional area, in both obese and nonobese subjects. This increase in airway caliber results in increased airflow, reduced snoring, and improved sleep-disordered breathing.

Side Effects and Contraindications

Side effects of MRAs include temporomandibular joint and facial pain or discomfort, temporomandibular joint noises, minor tooth movement, changes in occlusion, and skeletal changes, including increased facial height. Although oral appliances can be used successfully in patients who grind their teeth, use of an MRA that allows for adequate lateral and anterior-posterior movement may be less likely to exacerbate temporomandibular joint pain.

Most side effects that with MRAs are minor and temporary and do not significantly affect appliance use. Contraindications to the use of MRAs include severe temporomandibular joint pain, insufficient teeth to retain the appliance during usage (eight teeth is probably the minimum), teeth that are compromised by periodontal disease, and a limited mandibular range of motion.

Oral Appliance Management of the Patient With OSA

Oral appliances are an important part of the armamentarium for OSA management. Optimal management of patients with sleep-disordered breathing requires collaboration between a sleep physician and a dentist who is well trained in dental sleep medicine.

When evaluating a patient with OSA for an oral appliance, the dentist does a dental sleep workup, which includes a thorough review of the medical history, an evaluation of the nasal cavity, and an in-depth evaluation of the oral cavity and the temporomandibular joints and associated structures. Impressions for study and working models are taken, as well as a panoramic radiograph or other imaging.

After an appliance is inserted, the dentist needs to follow up with the patient on a weekly or biweekly basis to assess if the appliance is having an effect. If the appliance is not having an effect, it is then titrated (by moving the mandibular, or lower unit, forward) until it does or it is determined that it is not going to work.

A maximum titration of 75% of the patient’s protrusion is generally considered the endpoint for titration. A repeat sleep study is recommended to assess the efficacy of the appliance, once it has been titrated, but it is the author’s experience that this happens rarely.

Once efficacy of the appliance is confirmed, continued follow-up by the dentist is essential in order to assess tooth movement and other side effects. The patient is generally seen every 6 months for the first year and at least one year thereafter.

The ACCP Sleep Medicine Network collaborated with the American Academy of Orofacial Pain to produce a printable patient education brochure about oral appliances. This is available on the ACCP Web site at www.accp.org/oral/organization/patients/oralAppliances.pdf.

References


Oral Appliances for the Treatment of Patients With Obstructive Sleep Apnea


Dr Elmer A. Villalon, DMD
Oral Pain and Dental Sleep Medicine
Pueblo, CO

Dr Barbara Phillips, MSPhD, FCCP
Professor, Division of Pulmonary, Critical Care and Sleep Medicine
University of Kentucky College of Medicine
Lexington, KY
Progress and Congratulations

Dr David D. Gutterman, FCCP

CHEST Journal App

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ONE Breath

Make The Most Of It

The CHEST Foundation is pleased to introduce its new One Breath campaign, an exciting public-facing campaign that incorporates its three pillars: education, care, and community. One Breath: Make The Most Of It emphasizes that living well means breathing well and inspires people to take care of their lungs and heart, never taking their next breath for granted.

The Foundation’s mission remains the same: to provide prevention and education programs and valuable resources in cardiopulmonary and critical care medicine. The four focus areas of tobacco prevention and cessation, humanitarian service, clinical research, and critical care end-of-life care, continue to be the core programming elements.

Support One Breath and Learn More onebreath.org
Poster Contest Spreads Message To Love Your Lungs

“Love Your Lungs” Poster Contest winner Bailey Selecky’s winning design was displayed on T-shirts for participants of the CHEST 2010 5K Walk/Run held on Tuesday, November 2. "Being healthy and breathing strong is very important to me as I am a student athlete and need to be in great physical shape in order to compete and play to the best of my ability,” says Bailey. She also thanks the Ambassadors Group for letting her help spread the important message to “Love Your Lungs.” Each year, the Ambassadors Group sponsors the poster contest, which is open to all youth, ages 8 to 14. Contact dflulton@chestnet.org for 2011 entry forms or more information.

The winning poster in the “Love Your Lungs” Poster Contest was created by Bailey Selecky, a student athlete who enjoys “being healthy and breathing strong.”

Product of the Month

COPD Alliance Spirometer Giveaway

Registered Respiratory Therapist and asthma educator Diane Rhodes of San Antonio was the winner of the COPD Alliance spirometer giveaway during CHEST 2010. Members of the newly launched COPD Alliance presented Ms. Rhodes with a new Ndd spirometer as part of the Alliance’s mission to encourage the early diagnosis of COPD. Ms. Rhodes plans to use the spirometer for screening the employees of the school district where she works; doing community screenings at clinics in the San Antonio area; and monitoring lung function in more than 200 children with asthma who she counsels.

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www.chestnet.org
Volunteers Reach Out to Children During Annual Meeting

The CHEST Foundation and the ACCP Industry Advisory Council 2010 Community Outreach Event

On Monday, November 1, during CHEST 2010, more than 40 ACCP- and Ambassadors Group-member volunteers attended a training session and then boarded a bus to Laura Secord Elementary School in Vancouver. This was the 12th year that volunteers from both the US and international locations reached out to children in the annual CHEST meeting’s host city to present about lung health and the dangers of tobacco. Approximately 100 6th graders interacted with the presenters and “student buddies” during this program, which utilizes different aspects of The Foundation’s Lung Lessons™ program. Comments gathered after the program indicate that the message made it to the young listeners and included:

“I learned a lot more about how smoking affects your lungs. I will never smoke, so I can stay healthy and live longer.”

“I learned that rat poison is in cigarettes.”

“All cigarettes are bad, even if they (advertisers) say it’s good.”

The ACCP Industry Advisory Council presented a $10,000 grant to Vancouver School District 39, which includes Laura Secord Elementary School. The funds will be used for health education classes and other enrichment activities.

Monir Almassi (left) and Dr Norma Braun present tips for good lung health to elementary schoolchildren.

Many Winners at CHEST 2010—Congratulations!

ACCP Honor Awards
- Soffer Award for Editorial Excellence
  Armin Ernst, MD, FCCP
- Alton Ochsner Award Relating Smoking and Health
  Jerome S. Brody, MD
- $10,000 Humanitarian Award
  Robert C. Hyzy, MD, FCCP
- $1,250 Ambassador Group Humanitarian Recognition Award
  Lata R. Casturi, MA
- American Lung Association and The CHEST Foundation Asthma Clinical Patient Care Research Award
  Shamsah Kazi, MBBS
- Roger C. Bone Advances in End-of-Life Care Award
  Dee W. Ford, MD, FCCP
- Alpha-1 Foundation and The CHEST Foundation Clinical Research Award in COPD and Alpha-1 Antitrypsin (AAT) Deficiency
  Ann E. Tilley, MD
- Association of Specialty Professors and The CHEST Foundation of the ACCP Geriatric Development Research Award
  Jessica Y. Chia, MD
- The CHEST Foundation California Chapter Clinical Research/Medical Education Award
  Hlibert Chen, MD, FCCP

Canadian Thoracic Society Awards
- CTS Annual Christie Memorial Lecturer
  Jerome A. Dempsey, PhD
- CTS Institute of Circulatory and Respiratory Health Distinguished Lecturer in the Respiratory Sciences
  James C. Hogg, MD, PhD, FCCP

The CHEST Foundation Awards
- Third GlaxoSmithKline Distinguished Scholar in Respiratory Health
  Sandra G. Adams, MD, FCCP
- D. Robert McCaffrey, MD, Master-FCCP Humanitarian Award
- $1,000 Humanitarian Award
  Robert C. Hyzy, MD, FCCP
- $7,500 Humanitarian Awards
  Margaret A. Clark, RRT
  Kevin R. Flaherty, MD, FCCP
  Syed S. Naqvi, MD, FCCP
  C. Sola Olopaede, MD, FCCP
- $5,000 Ambassadors Group Humanitarian Recognition Award
  Lata R. Casturi, MA

Young Investigator Award Winners
- $2,000 award winners
  Takahiro Nakajima, MD
  Mary Cataletto, MD, FCCP
  Matthew J. Schuchert, MD
- $1,250 award winners
  Laura Barber, MD
  Michelle Kompere, MD
  Tony Abed, MD, FCCP

Case Report Award Winners
- Thomas C. Iden III, MD
  Adiya Gupta, MBBS
  Rupesh K. Dave, MD
  Nishant Gupta, MD
  Jarrod T. Bruce, MD
  Ankur Kalra, MD
  Abhitab A. Raval, MD
  David Wallace, MD
  Heba Ismail, MBChB
  Jamie L. Bessich, MD
  Jorge E. Guerrero Espinoza, MD
  Garrett Bird, MD
  Kritika Ramachandran, MD
  Sonali Bose, MD
  Nichole T. Tanner, MD
  Sunita Mulipuri, MD
  Jessica E. Freyer, MD
  Arvind Ponnambalam, MD
  Leon C. Bass, MD
  Anushua Chelvanathan, MBChB
  Muhammad T. Akbar, MD

Winners at CHEST 2010 Bingo

CHEST Challenge Winners
- First Place: National Capital Consortium Pulmonary and Critical Care Fellowship Program
  CPT Matthew Aboudarab, LT Gregory Fuhrer, MC, USN
- Second Place: Maimonides Medical Center
  Prashant Ghandre, MBBS
  Anjan Madhavan, MBBS
  Kavan Ramachandran, MBBS
- Third Place: Baylor College of Medicine
  Somai Jyoithula, MBBS
  Amarjib Mattewal, MD
  Visal Sawhney, MD
Humanitarian Award Winners, Outgoing Chair Honored

The CHEST Foundation’s 12th Annual Making a Difference Awards Ceremony and Presentation during CHEST 2010 focused on the D. Robert McCaffree, MD, Master FCCP Humanitarian Award winners. This year’s award winners and their projects were:

- Margaret A. Clark, RRT, Not One More Life Asthma Clinic, Atlanta, GA
- Dr. Kevin R. Flaherty, FCCP, Faith Medical Clinic, Pinckney, MI
- Dr. Robert C. Hyzy, FCCP

Humanitarian Award Winners (L-R): Margaret A. Clark, RRT; Dr Kevin R. Flaherty, FCCP; Dr Robert C. Hyzy, FCCP; Dr Syed S. Naqvi, FCCP; and Dr C. Sola Olopade, FCCP.

The Ambassadors Group Humanitarian Award winner was Lata R. Casturi, MA, Project S.I.E.S.T.A. (Students Involved in the Education About Sleep Hygiene for Teen Adolescents), Houston, TX.

Each award winner prepared a video clip of their project, and these will be posted on The Foundation’s YouTube channel very soon. We encourage you to take the time to view them (www.youtube.com/user/ChestFoundation).

The CHEST Foundation was proud to have the following corporate partners sponsor this year’s dinner: AstraZeneca LP; Boehringer Ingelheim Pharmaceuticals, Inc.; Eisai, Inc.; Genentech and Novartis; Gilead Sciences, Inc.; Merck & Co., Inc.; Ortho-McNeil Janssen Pharmaceuticals; Pfizer, Inc.; sanofi-aventis, US.

Another highlight of the evening was a tribute to outgoing Chair of The CHEST Foundation Board of Trustees, Dr Robert G. Johnson, FCCP. A tribute video was shown depicting Dr Johnson’s long career as ACCP’s Past President (2000) and the many accomplishments during his tenure on The Foundation’s Board (2000-2010). Close friends and colleagues took the opportunity to participate in this farewell tribute by sharing some of their own humorous stories.

Dr Johnson’s contributions to The CHEST Foundation include the formation of a Development Committee responsible for the oversight of fundraising and establishing endowments, as well as the reorganization of the Awards Committee to become a repository for all College awards. The Foundation is pleased that Dr Johnson has accepted the role of Chair of the OneBreath™. Make The Most Of It initiative and will remain a resource to The CHEST Foundation as it launches this important initiative.

Glimpses of CHEST 2010 in Vancouver

CHEST Challenge winners from the National Capital Consortium Pul/CC Fellowship Program.

Dr Alfred Soffer, Master FCCP, takes a turn at virtual reality learning in Experience ACCP.

Meeting attendees appreciated the chance to learn new procedures through simulation.

There was plenty of activity at Experience ACCP in the exhibit hall.

The Cyber Café gets more popular among meeting attendees with every passing year.

Home Testing for Sleep Apnea Not Inferior

BY SUSAN LONDON
Elsiever Global Medical News

VANCOUVER, B.C. – Recent research on the use of home testing for the diagnosis of obstructive sleep apnea and initiation of therapy suggests that “home testing is here to stay,” Dr. Charles W. Atwood Jr., FCCP, said at CHEST 2010, the annual meeting of the American College of Chest Physicians.

For more than 30 years, physicians have relied on the traditional polysomnography performed in the sleep laboratory to diagnose sleep apnea, according to Dr. Atwood. But with growing awareness of the condition and its prevalence, the number of people needing testing could overwhelm capacity.

“If you take the millions and millions and millions of people in the United States alone who have sleep apnea and try to feed them through the relatively small funnel of traditional sleep labs, then you are going to have big bottlenecks,” he said, adding that such bottlenecks already exist in some areas.

However, home-testing devices must meet certain key requirements before they are ready for widespread use. For example, they have to be simpler than those used in the lab. “Perhaps we can get with fewer [physiological] signals, but we need to understand what the key signals are,” commented Dr. Atwood, a pulmonologist and sleep medicine specialist with the VA Pittsburgh Healthcare System and the University of Pittsburgh Medical Center.

Home testing devices will also need to be accurate, with high sensitivity and specificity, and “there is no single device I would say today that is perfect in both these regards,” he noted. Finally, they must be easy to use and durable, given the demands of in-home use.

“Roughly 95 studies conducted between 1990 and 2006 evaluated home testing (also called portable monitoring) for the diagnosis of obstructive sleep apnea. Collectively, they have some limitations, such as their single-site nature, small and usually homogeneous populations, and varying degrees of rigor in design.

And they frequently focused on the highest-risk groups: Those were middle-aged men who were overweight, snored, and were sleepy, so [they were] very low-hanging fruit for typical sleep apnea,” Dr. Atwood said.

These studies showed some mixed results when it came to the diagnostic performance of home testing relative to lab testing. “There is no perfect study, at least so far, in this area, but some have come pretty close,” he commented.

Three more-recent studies suggest that home testing is at least not inferior to lab testing for sleep apnea diagnosis and initiation of continuous positive airway pressure (CPAP) therapy, according to Dr. Atwood.

In the first study, conducted in 68 people with a high likelihood of sleep apnea, the apnea-hypopnea index on CPAP and Sleep Apnea Quality of Life Index scores at 3 months did not differ significantly between a sleep lab and an ambulatory approach (Ann. Intern. Med. 2007;146:157-66). The rate of adherence to treatment was similar to the latter.

In the second study, which involved 102 patients with sleep apnea symptoms and no major comorbidities, all of a variety of sleep and quality of life outcomes, after 4 weeks of CPAP were similar with a standard lab diagnosis and treatment approach vs. a home approach (Chest 2010;138:257-63).

The third study, the Veterans Sleep Apnea Treatment Trial (VISTA), was the largest study of home testing in North America to date, according to Dr. Atwood, one of the principal investigators.

“The VA is ill equipped to manage sleep apnea in a conventional way because we have relatively few numbers of traditional sleep labs,” he noted.

“Our study differed from basically all of the other studies in the literature in that we had lenient inclusion criteria and very nonrestrictive exclusion criteria,” Dr. Atwood noted. For example, patients with comorbidities could participate as long as their condition was stable.

Patient randomized to self-testing or home testing, followed by initiation of CPAP for those with positive results. Among the 223 who were started on CPAP, the home and lab groups had similar demographics. The average apnea-hypopnea index was 41 for the former and 45 for the latter. The Functional Outcomes of Sleep Questionnaire (FOSQ) total score was about 15 in each group.

Results showed that the mean adjusted improvement in FOSQ total score between baseline and 3 months was identical in the two groups, at 1.79 points. And within each group, patients had significant improvements in the total score as well as its individual components.

Both home and lab groups also had significant improvements on the Epworth Sleepiness Scale (~2.6 and ~2.9, respectively), the mental health component of the 12-item Short Form Health Survey (v2.5 and +3.0), and the Center for Epidemiologic Studies–Depression scale (~1.4 and ~2.2). Neither group improved significantly on the psychosocial task or the physical health component of the 12-item Short Form Health Survey.

When it came to adherence, which was monitored with smart cards, the mean adjusted number of CPAP hours daily was 3.42 in the home group and 2.99 in the lab group, a difference that was not significant. Cost-effectiveness analyses are still ongoing.

“We concluded that the functional improvement with CPAP for sleep apnea is not worse when treated in the home setting vs. the sleep lab,” Dr. Atwood said.

“We believe ... home-based sleep apnea diagnosis and initiation of CPAP therapy is an effective way to treat sleep apnea.”

While home testing won’t entirely replace labor-intensive polysomnography, Dr. Atwood suggested trying to “integrate home sleep testing with full polysomnography in a clinically rational way.”

Dr. Atwood reported that he received research support from Embia, Resmed, and Respironics, and is a consultant to Embia and Itamar Medical, all of which manufacture testing and treatment devices for sleep disorders.

Pulmonary/Critical Care

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Pulmonary/Critical Care

The VA Medical Center in Milwaukee, Wisconsin is a large tertiary care facility affiliated with the Medical College of Wisconsin. Openings exist for pulmonology and critical care physicians to join the section of Pulmonary, Critical Care Medicine and Sleep Medicine. Qualified candidates must be Board certified or eligible in Pulmonary Disease and Critical Care Medicine and have the qualifications for a Faculty appointment at the Medical College of Wisconsin. Fellowship training in sleep medicine is a plus. Professional and academic opportunities exist through the Medical College of Wisconsin and the Department of Veterans Affairs. Interested candidates should send a current Curriculum Vitae, referencing Pulmonary, to: Clement J. Zablocki VA Medical Center, Human Resources Attn: Prudy Kitterman, 5000 W. National Avenue, Milwaukee, WI 53205. prudy.kitterman@va.gov fax to 414-382-5296. Additional inquiries should be directed to Andrea Antonescu, MD at 414-384-2000 X42765 or email to andrea.antonescu@va.gov

Satisfaction With Medicine Low Among U.S. Physicians

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Note: Data collected from 10,320 primary care physicians from February to July 2009. Source: The Commonwealth Fund
CPAP Reverses Left Atrial, Ventricular Remodeling

By Bruce Jancin

SAN ANTONIO – Six months of continuous positive airway pressure therapy markedly improved adverse left ventricular and atrial remodeling in patients with moderate to severe obstructive sleep apnea in a prospective study.

Diastolic as well as systolic abnormalities were reversed, raising the welcome prospect that CPAP is likely to prevent the development of one of the most dreaded complications of severe obstructive sleep apnea (OSA) – chronic heart failure – although this point remains speculative, Dr. Saleh Al-Mutairi said at the annual meeting of the Associated Professional Sleep Societies. He recruited 32 patients with newly diagnosed moderate to severe OSA for the study, which involved serial follow-up, by cardiac magnetic resonance (CMR), echocardiography, and cardiac biomarkers through 6 months of individually titrated CPAP therapy.

The study’s average age of 58 years, with a mean baseline apnea-hypopnea index of 53 events/hr and a body mass index of 34.5 kg/m². None of the participants had known cardiac disease. Adherence for CPAP was good. The patients’ weight didn’t change significantly during the study, and those being treated for hypertension remained on the same medications throughout the follow-up period.

Other studies have shown improve ment in left ventricular dysfunction with CPAP, but they were short-term trials. This is the first study with follow-up as long as 6 months. Dr. Al-Mutairi and echocardiography, said Dr. Al-Mutairi of the University of Minnesota, Winnipeg.

He focused on the CMR results because he considers technology that more reliably the extent of cardiac remodeling, assessing ventricular size and function. The echo findings, however, corroborated the CMR results.

Most of the left ventricular measurements followed during the study were abnormal at baseline. At the 6-month results included a 25% reduction from baseline in left ventricular end-diastolic volume and a 19% decrease in left ventricular end-systolic volume.

Dr. Al-Mutairi noted particular attention to the 30% reduction in left atrial volume index, which he considers highly encouraging. “The treatment of OSA with CPAP may prevent the left atrial remodeling measured by CMR and echo as the left atrial volume index. This is a very important point, given the association between the left atrial volume and cardiovascular events,” he observed.

There was no significant change in C-reactive protein, brain natriuretic peptide, or other cardiac biomarkers during the 6 months of CPAP use. The mechanism of action of CPAP was OSA. It is thought to predispose to heart failure involves an exaggerated negative thoracic pressure in response to the apneic episodes. This presumably leads to increased left ventricular systolic mural pressure, which the left atrium resists, with resultant increased compliance and atrial overtretching, Dr. Al-Mutairi explained.

Dr. Al-Mutairi reported having no financial conflicts.

TIGACIL® (tigecycline) Brief Summary

See package insert for full Prescribing Information. For further product information and current package insert, please visit www.tigecycline.com.

TIGACIL is indicated for the treatment of adults with complicated skin and skin structure infections caused by suitably susceptible organisms, including certain strains of penicillin-resistant strains of Staphylococcus aureus (methicillin-resistant Staphylococcus aureus [MRSA]) and other Gram-positive, Gram-negative, and anaerobic microorganisms (See Table 1). TIGACIL is also indicated for the treatment of adults with complicated intra-abdominal infections (CIAI) caused by suitably susceptible organisms, including certain strains of MRSA and anaerobic microorganisms. TIGACIL is also indicated for the treatment of complicated wounds (infections) including diabetic foot ulcers, signs of infection, or wounds/infected wounds, including fasciitis, osteomyelitis, and osteitis due to suitably susceptible aerobic or anaerobic microorganisms (See Table 1).

TIGACIL is contraindicated in patients with demonstrated sensitivity to tigecycline or any of its components.

The use of tigecycline in patients with chronic renal impairment is indicated (See Table 1).

In patients with severe renal impairment (creatinine clearance CcGFR <30 ml/min), it is recommended to start the first dose at 75% of the recommended dose (75% of the usual dose) followed by 50% of the usual dose every 12 hours.

Key Cardiac Magnetic Resonance Changes Within 6 Months of CPAP

<table>
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<th>Cardiac Magnetic Resonance Change</th>
<th>Baseline</th>
<th>Follow-up</th>
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</thead>
<tbody>
<tr>
<td>Left ventricular end-systolic volume</td>
<td>68 mL</td>
<td>63 mL</td>
</tr>
<tr>
<td>Left ventricular end-diastolic volume</td>
<td>199 mL</td>
<td>150 mL</td>
</tr>
<tr>
<td>Left ventricular mass</td>
<td>184 g</td>
<td>149 g</td>
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<tr>
<td>Left atrial volume index</td>
<td>36.0 mL/m²</td>
<td>34 mL/m²</td>
</tr>
</tbody>
</table>

Notes: Based on a study of 32 patients with moderate to severe obstructive sleep apnea (OSA) The changes are statistically significant.

Source: Dr. Al-Mutairi.
Expanded broad-spectrum coverage is on your side

TYGACIL is indicated for the treatment of adults with:

- Complicated skin and skin structure infections caused by Escherichia coli, Enterococcus faecalis (vancomycin-susceptible isolates), Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus agalactiae, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Streptococcus pyogenes, Enterobacter cloacae, Klebsiella pneumonieae, and Bacteroides fragilis
- Complicated intra-abdominal infections caused by Citrobacter freundiii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumonieae, Enterococcus faecalis (vancomycin-susceptible isolates), Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Bacteroides fragilis, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Clostridium perfringens, and Peptostreptococcus micros
- Community-acquired bacterial pneumonia caused by Streptococcus pneumoniae (penicillin-susceptible isolates), including cases with concurrent bacteremia, Haemophilus influenzae (beta-lactamase negative isolates), and Legionella pneumophila

Important Safety Information

- TYGACIL is contraindicated in patients with known hypersensitivity to tigecycline
- Anaphylaxis/anaphylactoid reactions have been reported with nearly all antibacterial agents, including TYGACIL, and may be life-threatening. TYGACIL should be administered with caution in patients with known hypersensitivity to tetracycline-class antibiotics
- Isolated cases of significant hepatic dysfunction and hepatic failure have been reported in patients being treated with tigecycline. Some of these patients were receiving multiple concomitant medications. Patients who develop abnormal liver function tests during tigecycline therapy should be monitored for evidence of worsening hepatic function. Adverse events may occur after the drug has been discontinued
- The safety and efficacy of TYGACIL in patients with hospital-acquired pneumonia have not been established
- An increase in all-cause mortality has been observed across phase 3 and 4 clinical studies in TYGACIL-treated patients versus comparator-treated patients. The cause of this increase has not been established. This increase in all-cause mortality should be considered when selecting among treatment options
- TYGACIL may cause fatal harm when administered to a pregnant woman
- The use of TYGACIL during tooth development may cause permanent discoloration of the teeth. TYGACIL should not be used during tooth development unless other drugs are not likely to be effective or are contraindicated
- Acute pancreatitis, including fatal cases, has occurred in association with tigecycline treatment. Consideration should be given to the cessation of the treatment with tigecycline in cases suspected of having developed pancreatitis
- Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including TYGACIL, and may range in severity from mild diarrhea to fatal colitis
- Monotherapy should be used with caution in patients with clinically apparent intestinal perforation
- TYGACIL is structurally similar to tetracycline-class antibiotics and may have similar adverse effects. Such effects may include: photosensitivity, pseudotumor cerebri, and anti-anabolic action (which has led to increased BUN, azotemia, acidosis, and hyperphosphatemia). As with tetracyclines, pancreatitis has been reported with the use of TYGACIL
- To reduce the development of drug-resistant bacteria and maintain the effectiveness of TYGACIL and other antibacterial drugs, TYGACIL should be used only to treat infections proven or strongly suspected to be caused by susceptible bacteria. As with other antibacterial drugs, use of TYGACIL may result in overgrowth of non-susceptible organisms, including fungi
- The most common adverse reactions (incidence >5%) are nausea, vomiting, diarrhea, abdominal pain, headache, and increased SGPT
- Prothrombin time or other suitable anticoagulant test should be monitored if TYGACIL is administered with warfarin
- Concurrent use of antibacterial drugs with oral contraceptives may render oral contraceptives less effective
- The safety and effectiveness of TYGACIL in patients below age 18 and lactating women have not been established

Please see brief summary of Prescribing Information on adjacent page.