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A disturbing photograph or graphic depicting the dangers of tobacco use will be included on cigarette packages.

HHS Rule to Require Graphic Warnings

BY ALICIA AULT
Elsevier Global Medical News

The Department of Health and Human Services issued a sweeping new tobacco control strategy that would require cigarette makers to place photographs and graphic depictions of the harms of smoking prominently on the packages or in advertising.

The graphic warnings – which will be regulated by the Food and Drug Administration – were part of a proposed rule issued by the agency. They were required by the Family Smoking Prevention and Tobacco Control Act and are the centerpiece of the 66-page strategy released by the HHS.

"Every day, almost 4,000 youth try a cigarette for the first time and 1,000 youth become regular, daily smokers," HHS Secretary Kathleen Sebelius said in a statement. "Today marks an important milestone in protecting our children and the health of the American public."

The HHS estimates that 443,000 Americans die from tobacco-related diseases each year, with 50,000 of those deaths caused by secondhand smoke. Some 8.6 million Americans have smoking-related chronic diseases.

FDA Commissioner Margaret Hamburg said, "When this rule takes effect, the health consequences of smoking will be obvious every time someone picks up a pack of cigarettes."

The agency will require a disturbing photograph or graphic to take up half a package of cigarettes or be prominently placed in an ad, and include one of the following warnings: "Cigarettes are addictive," "Tobacco smoke can harm your children," "Cigarettes cause fatal lung disease," "Cigarettes cause cancer," "Cigarettes cause strokes and heart disease," "Smoking during pregnancy can harm your baby," "Smoking can kill you," "Tobacco smoke causes fatal lung disease in nonsmokers," and "Quitting smoking now greatly reduces serious risks to your health."

See **Warnings** • *page 8*

Start E-Prescribing Now to Avoid Incurring Penalty

Faxing a prescription does not count.

BY SUSAN LONDON
Elsevier Global Medical News

VANCOUVER, B.C. – The Centers for Medicare and Medicaid Services is currently offering providers a bonus for e-prescribing, or electronically transmitting prescriptions to pharmacies. But soon, providers will instead be hit with a penalty if they don't get on board with this practice.

"They are really promoting this," Michael K. McCormick, a practice administrator at the DuPage Medical Group in Winfield, Ill., said at CHEST 2010, the annual meeting of the American College of Chest Physicians. But by transitioning from a bonus to a penalty over several years, "they are giving you time to get going on it."

The Medicare Electronic Prescribing (eRx) Incentive Program, which began in 2009 and runs through 2013, provides bonus payments for e-prescribing when certain eligibility criteria are met, with bonus percentages being reduced over the span of the program, according to Mr. McCormick, a registered respiratory therapist.

But the CMS also will start financially penalizing providers who do not begin e-prescribing in 2011. The penalty for failing to e-prescribe will be 1%, 1.5%, and 2% of all Medicare Part B charges in the years 2012, 2013, and 2014, respectively.

The bottom line is to "e-prescribe at least 10 times in the first 6 months of 2011 so you won't be penalized in 2012," Mr. McCormick recommended. "You really need to start doing this in 2011."

The 2010 reporting criteria require that health care providers report e-prescribing for at least 25 eligible patient encounters (which can include

See **Penalty** • *page 18*

INSIDE

Postop Outcomes Worse in COPD

BY SUSAN LONDON
Elsevier Global Medical News

VANCOUVER, B.C. – Patients with chronic obstructive pulmonary disease are more likely to die after surgery than are those without COPD, even after controlling for comorbidities and type of surgery, according to a cross-sectional study of nearly half a million patients undergoing surgery in the United States.

The researchers found that patients with COPD were 29% more likely to die and 35% were more likely to experience complications, compared with similar patients without the disease, said presenting investigator Dr. Prateek K. Gupta, a surgeon at Creighton University in Omaha, Neb.

In addition, hospital length of stay was four times longer for the COPD group.

"Knowledge of the increased risk associated with COPD may improve patient selection and the informed consent process," he said at CHEST 2010, the annual meeting of the American College of Chest Physicians.

See **Outcomes** • *page 10*

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AHA Cardiopulmonary Resuscitation Guidelines Revised

Two randomized, controlled trials found no statistically significant differences in survival.

BY ROBERT FINN
Elsevier Global Medical News

The American Heart Association guidelines for cardiopulmonary resuscitation have been changed to advocate starting chest compressions before and perhaps without starting rescue breathing.

The AHA's previous CPR guideline advised rescuers to clear the victim's airway, breathe into the victim's mouth, then start giving chest compressions. Modifying the CPR recommendations that had stood for more than 40 years, the new guidelines recommend that bystanders undertaking CPR focus on performing chest compressions, as any delay in chest compression increases the risk of death (Circulation 2010;122[suppl 3];S640-56).

The AHA guideline change comes after two independent, randomized, controlled trials, published this past summer, found no statistically significant differences in survival between patients in cardiac arrest who are given standard CPR with chest compression and rescue breathing, compared with those given chest compression alone.

The studies both concluded that when performed by laypeople, CPR with chest compression alone was at least as effective as compressions plus rescue breathing, while also being simpler to teach and to perform.

These randomized, controlled trials confirm and extend the conclusions of earlier studies. In one of the recent studies, dispatchers in London and in two counties in the state of Washington randomly delivered compression-only or standard CPR instructions to 911 callers (999 in London). That study, led by Dr. Thomas D. Rea of the University of Washington, Seattle, eventually enrolled 1,941 patients, of whom 981 received chest compression alone and 960 received chest compression plus rescue breathing. Among those patients, 12.5% who received chest compression alone and 11.0% who received compression plus rescue breathing survived to hospital discharge. The difference was not statistically significant (N. Engl. J. Med. 2010;363:423-33).

One difference between the two groups approached – but did not reach – statistical significance. Patients who had a cardiac cause of arrest were somewhat more likely to survive to discharge if they received compressions alone (15.5% vs. 12.3%, $P = .09$).

In the other study, investigators randomized 1,276 patients who were the subjects of calls to the 18 emergency medical dispatch centers in Sweden. At the direction of dispatchers, 620 received compression-only CPR and 656 received standard CPR. Dr. Leif Svensson of the Karolinska Institute, Stockholm, and his colleagues found that the rate of 30-day survival was 8.7% in the compression-only group and 7.0% in the group receiving standard CPR (N. Engl. J. Med. 2010;363:434-42).

Several subgroup analyses also failed to reveal significant group differences. The survival rates did not differ significantly with age, with the interval between the call and the first EMS response, or with the interval between the call and the first cardiac rhythm.

Dr. Svensson and his colleagues also pointed to studies showing that laypeople have difficulty providing adequate ventilation using rescue breaths. CPR guidelines call for the two rescue breaths to take 1.5-2 seconds/breath. But in one study, people not trained in CPR took 16 seconds on average to deliver the two breaths.

In addition, a new meta-analysis by Dr. Michael Hüpfl of the department of anesthesiology at the Medical University of Vienna and his colleagues pooled data from three randomized trials (the two previously described plus one other [N. Engl. J. Med. 2000;342:1546-53]). They found that chest compression–only CPR performed by bystanders under directions from a telephone dispatcher was associated with an improved chance of survival, compared with standard CPR performed by the same (14% vs. 12%) in adult patients experiencing cardiac arrest outside a hospital. The absolute increase in survival was 2.4%, with the relative chances of survival increased 22% by chest compression–only CPR (Lancet 2010 Oct. 15 [doi:10.1016/S0140- 6736(10)61454-7]).

In a secondary meta-analysis of seven observational cohort studies, the researchers saw no significant difference between the compression-only and standard CPR arms.

Compression-only CPR, the investigators concluded, should become the default instructions for dispatchers to give to bystanders. "The pooled effect size of about 22% might seem small, but rates of survival after out-of-hospital cardiac arrest have been about 4%-8% for the past few decades, so our result could represent important progress," they wrote.

In the United Kingdom, compression-first CPR is already the standard recommendation for treating sudden adult cardiac arrest; guidelines since 2005 have reduced (but not eliminated) the recommended amount of mouth-to-mouth or mouth-to-nose ventilation. The Resuscitation Council UK, which makes CPR guidelines widely followed in the United Kingdom and the rest of Europe, has new guidelines for bystanders in the works that do away with the recommendation for rescue ventilation.

"If people have not been trained, they should be no doubt doing compression only," said Dr. Jerry P. Nolan of the Royal United Hospital NHS Trust in Bath, England, and an author of existing Resuscitation Council guidelines. However, for trained professionals, standard CPR with ventilation remains preferable, he said. Compression-only CPR "works for only about the first 4 or 5 minutes. The whole thing comes down to what is ideal for the bystander's level of training," Dr. Nolan said.

The Washington/London study was funded by the Laerdal Foundation for Acute Medicine. Two investigators received defibrillators and funding from Philips Medical Systems and Physio-Control; their institutions received funding from the Medtronic Foundation. The Swedish study had funding from Stockholm County Council, SOS Alarm, and the Swedish Heart-Lung Foundation. The Vienna study received funding from the U.S. National Institutes of Health and the American Heart Association. ■

Michele G. Sullivan and Jennie Smith contributed to this report.

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Spontaneous reports of serotonin syndrome have been reported with the coadministration of ZYVOX and serotonergic agents. If signs or symptoms of serotonin syndrome, such as cognitive dysfunction, hyperpyrexia, hyperreflexia, and incoordination occur, discontinuation of one or both agents should be considered.

Myelosuppression (including anemia, leukopenia, pancytopenia, and thrombocytopenia) has been reported in patients receiving ZYVOX. In cases where the outcome is known, when ZYVOX was discontinued, the affected hematologic parameters returned to pretreatment levels. Complete blood counts should be monitored weekly, particularly in patients who receive ZYVOX for longer than 2 weeks.

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Clostridium difficile associated diarrhea has been reported with use of nearly all antibacterial agents, including ZYVOX, and may range in severity from mild diarrhea to fatal colitis.

Lactic acidosis has been reported with the use of ZYVOX. Patients receiving ZYVOX who develop recurrent nausea, vomiting, unexplained acidosis, or a low bicarbonate level should receive immediate medical evaluation.

Peripheral and optic neuropathy have been reported primarily in patients treated with ZYVOX for longer than the maximum recommended duration of 28 days. If patients experience symptoms of visual impairment, prompt ophthalmic evaluation is recommended.

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

The most commonly reported adverse events in adults across phase 3 clinical trials were diarrhea, nausea, and headache.

*Methicillin-resistant *Staphylococcus aureus*.

References: 1. Rubinstein E, Cammarata SK, Oliphant TH, Wunderink RG; and Linezolid Nosocomial Pneumonia Study Group. Linezolid (PNU-100766) versus vancomycin in the treatment of hospitalized patients with nosocomial pneumonia: a randomized, double-blind, multicenter study. *Clin Infect Dis.* 2001;32(3):402-412. **2.** Wunderink RG, Cammarata SK, Oliphant TH, Kollef MH; for Linezolid Nosocomial Pneumonia Study Group. Continuation of a randomized, double-blind, multicenter study of linezolid versus vancomycin in the treatment of patients with nosocomial pneumonia. *Clin Ther.* 2003;25(3):980-992. **3.** Boselli E, Breilh D, Rimmelé T, et al. Pharmacokinetics and intrapulmonary concentrations of linezolid administered to critically ill patients with ventilator-associated pneumonia. *Crit Care Med.* 2005;33(7):1529-1533.

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Meta-Analyses Link Asthma to Higher Lung Ca Risk

BY BRUCE JANCIN
Elsevier Global Medical News

DENVER – Asthma may be a risk factor for lung cancer, according to two new meta-analyses.

The public health implications of such an association would be enormous. Asthma affects at least 15 million Americans, 40% of them children. Its prevalence has been climbing steadily for decades in developed countries, more than doubling in the United States during a recent 20-year period. And lung cancer is the second most common noncutaneous malignancy in this country, with 10% of lung cancer deaths not attributable to smoking, said Chanis Mercado at the annual meeting of the American Public Health Association.

One of the two meta-analyses she performed as a Ph.D. candidate in public health at the Ponce (P.R.) School of Medicine involved 17 high-quality case-control studies with a total of 54,238 subjects. The conclusion was that individuals with asthma had 34% greater odds of having lung cancer, compared with matched controls without asthma.

A separate meta-analysis that included 16 high-quality cohort studies and 1,384,824 subjects showed that those with asthma were 46% more likely to develop lung cancer than were subjects without asthma.

These results were statistically robust. Eliminating any individual study didn't substantially change the results. Tests for the existence of publication bias proved reassuringly negative.

One possible mechanism for the observed asthma–lung cancer link is that the persistent chronic inflammation that is a defining feature of asthma causes DNA damage to cells in the airway. Another is that asthma patients have defective clearance of toxins in the bronchioalveolar epithelium, resulting in prolonged local exposure to carcinogens, she said. ■

PAH Index for Pediatric Patients Approved by Panel

BY ELIZABETH MECHCATIE
Elsevier Global Medical News

ADELPHI, MD. – A Food and Drug Administration advisory panel voted 7 to 6 that a specific hemodynamic measure of response to drugs approved for pulmonary arterial hypertension in adults could be used to demonstrate the drugs' efficacy in children with the disease, as well as to determine dosing in children.

Members of the FDA's Cardiovascular and Renal Drugs Advisory Committee who voted positively said that while that measurement – the pulmonary vascular resistance index (PVRI) – had limitations, its use as an end point in studies of drugs in children would help get effective drugs approved for the pediatric pulmonary arterial hypertension (PAH) population and would be more useful than the 6-minute walking test in this population, which is used as a clinical end point in adult studies. The pulmonologists and the pediatric cardiologist on the panel explained that while there were some differences, they said they believed PAH in children was similar enough to the disease in adults – including hemodynamic manifestations – that PVRI results could be used to extend the adult indication to children.

The FDA is considering making the PVRI a basis for expanding the indication of drugs approved for PAH in adults to children with PAH. Currently, none of the drugs approved for treating PAH in adults is approved in children with the disease.

In adults, sildenafil and other drugs for PAH have been approved based on studies that demonstrated improvements in exercise capacity associated with treatment. But exercise testing in children, particularly among those under age 7 years, is difficult to perform, and another way to objectively measure responses to treatment in this population is needed.

At the meeting, Pfizer Inc., the manufacturer of the phosphodiesterase-5 inhibitor sildenafil, which was approved for adult PAH in 2005, presented data from adult studies and a pediatric study that showed improvements in exercise capacity were associated with improvements in PVRI. (Pfizer markets sidenafil as Revatio for PAH and as Viagra for erectile dysfunction.)

In 2001, the FDA issued a written request to Pfizer to conduct a pediatric study of sildenafil for pediatric PAH. In response, the company conducted a study of 234 patients, which was started in 2003 and used exercise testing as the main end point. However, because of the difficulty performing exercise testing in children, the company has requested that hemodynamic data in children also be included. The panel was asked to vote on whether they thought the available hemodynamic data should be included, but declined because of insufficient data to make the decision.

Pfizer was planning to file for approval of sildenafil for PAH in children, if the panel had voted that the hemodynamic data could be included. A statement issued by the company after the meeting said that the company was encouraged by the panel's discussion about "establishing a path forward for conducting clinical trials for pediatric patients" with PAH, and that it planned to continue to work with the agency to evaluate the findings of the pediatric PAH study, with the goal of gaining approval for this population.

Members of FDA advisory panels have been cleared of conflicts related to the topic under discussion. ■

COMMENTARY

Dr. Joseph B. Barney, FCCP, commented: In putting this into perspective, I think it's important that standardization of measurements for response to PAH therapy should be as close as possible across the board if the physiology is similar enough between adult and pediatric patients.

STEPHEN I. PELTON, M.D.

PERSPECTIVE

PCV13 Will Further Reduce Disease

The new 13-valent pneumococcal conjugate vaccine (Prevnar 13) is picking up where the 7-valent version left off.

It has been 10 years since the introduction of the 7-valent pneumococcal conjugate vaccine (Prevnar). Overall in the United States, the program has had significant success, with an approximate 65%-70% reduction in invasive disease due to *Streptococcus pneumoniae*. We've also seen substantial reductions in acute otitis media (AOM) and community-acquired pneumonia (CAP).

Nonetheless, in the last few years we've started to see a small but real increase in invasive disease due to nonvaccine serotypes, documented by the Centers for Disease Control and Prevention's Active Bacterial Core surveillance (ABCs) system.

At the same time, there has also been documentation of an increase in AOM and a presumption of increases in CAP due to nonvaccine serotypes. These are harder to document, because data are typically obtained from hospital admissions or insurance claims and not from microbiological testing as is done with the ABCs. However, small studies using tympanocentesis have shown high proportions of nonvaccine *S. pneumoniae* serotypes in children with middle ear disease (Pediatr. Infect. Dis. J. 2007;26:S12-6).

Although we can't determine exactly what proportion of CAP and AOM is due to *S. pneumoniae* at any given time – and the longitudinal data are complicated by the secular changes in AOM definition – we do know that for every 1 case of invasive disease there are about 10 cases of CAP and 100 of AOM. So, we're looking at very clinically significant numbers.

In addition to the shift in serotypes, we've seen the emergence of multidrug-resistant pneumococci, particularly strain 19A. While these strains are usually sensitive to vancomycin, linezolid, and fluoroquinolones, they are resistant to the usual first-line antimicrobials, including amoxicillin, clindamycin, and trimethoprim-sulfamethoxazole, as well as ceftriaxone and other cephalosporins. Thus, both CAP and AOM have become more difficult to treat in children who don't respond to initial therapy.

Licensed earlier this year, PCV13 (Prevnar 13) contains all seven of the PCV7 strains (4, 6B, 9V, 14, 18C, 19F, and 23F), plus six more (1, 3, 5, 6A, 7F, and 19A). The serotypes represent either those that have been increasing in some countries using PCV7 (19A, 7F, 3) or that are globally important (1 and 5). The vaccine was licensed on the basis of immunogenicity for the new serotypes as well as comparability to PCV7 for the seven "old" serotypes and a comparable safety profile.

The 13-valent vaccine is being introduced somewhat differently than was PCV7. The recommendation from the CDC Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians is to administer PCV13 routinely to all children aged 2, 4, 6, and 12-15 months. For children who previously received one or more doses of PCV7, the series should be completed with PCV13. And for children 15 months through 5 years of age who received only PCV7 (or no vaccine), a single dose of PCV13 is recommended.

In contrast, when PCV7 was licensed, the recommended catchup immunization was through 2 years of age and only high-risk children aged 2-5 years. That's because, in general, the risk for invasive pneumococcal disease begins to decline after 3 years of age. However, the data on multidrug-resistant strain 19A suggest that it has been producing substantial disease in previously healthy children up through 5 years of age.

In addition, nasopharyngeal carriage of 19A has been seen frequently in children up to age 5. It is hoped that preventing that carriage will reduce the spread to unvaccinated children less than 4-5 months of age, immunocompromised children who don't respond sufficiently to the vaccine, and adults. Adding indirect protection to a large part of the population should help to reduce the incidence of disease due to the new vaccine serotypes.

Finally, with new conjugate pneumococcal vaccines, are we simply shifting the serotypes that produce disease and not actually preventing it? I would say no. With each new expansion of the vaccine, not only do we add broader coverage, but we expect to see a further reduction in disease. It is anticipated that the six new strains of PCV13 will add another 10%-15% reduction in pneumococcal disease beyond the 65%-70% we've already seen with PCV7, achieving an approximate 80%-90% disease reduction compared with rates in 1998-1999.

However, I don't think we will entirely eliminate pneumococcal disease. A few other important nonvaccine serotypes, including 22F, 33F, and 15B/C, are likely to continue and possibly increase slightly after the introduction of PCV13. Nonetheless, it will help us reduce the burden of pneumococcal disease on child health. ■

DR. PELTON *is chief of pediatric infectious disease and the coordinator of the maternal-child HIV program at Boston Medical Center. Dr. Pelton said he has received research grants from GlaxoSmithKline, Pfizer, Novartis, and Intercell, and has served on advisory boards for those companies and for Sanofi-Aventis.*

ROY S. HERBST, M.D., PH.D.

PERSPECTIVE

Personalized Medicine in Lung Cancer

Tremendous advances have been made in developing targeted therapies for lung cancer, but for the most part, these therapies are still being applied broadly to all comers in the clinic. The BATTLE (Biomarker-Based Approaches of Targeted Therapy for Lung Cancer Elimination) program aims to show that with a well-designed translational research strategy, it is feasible to personalize therapy according to a tumor's molecular profile.

Lung cancer is proving to be a collection of diseases that have highly diverse pathogeneses and molecular characteristics, even within a given histologic tumor type. The numerous pathways and genetic alterations make therapy for this cancer challenging. In particular, it is difficult to discern in advance which patients are most likely to benefit from a given therapy.

For the BATTLE program, based at the University of Texas M.D. Anderson Cancer Center in Houston, we have taken the lab to our clinic so that we can use a tumor's molecular profile to help guide the choice of therapy for a given patient at the time of treatment. In essence, we let the biology of the tumor teach us how to treat it.

The key in setting up the BATTLE program was to link our large, multidisciplinary clinical team with a molecular pathology lab that is dedicated to research and that can provide biomarker profiles within 2 weeks. We streamlined this interaction and the eligibility assessment to reduce barriers to participation for both staff and patients. After an adjustment period, the process worked seamlessly.

Patients were eligible for the initial BATTLE trial if they had non–small cell lung cancer that was chemotherapy refractory and amenable to biopsy. Stable patients with treated brain metastases and patients who had received epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors were allowed to participate because we felt that broad eligibility criteria were important for this trial.

Biopsy of the lung primary tumor or a metastasis was mandated, which made the trial unique among lung cancer trials of similar size. Serum samples were also collected. Whenever possible, multiple core biopsies were obtained from each patient. Some were used to assess the presence of biomarkers for real-time application, whereas others were stored for further discovery analysis. The latter is important because biomarkers that are the focus of research today may not be the relevant ones of the future.

The core biopsy specimens were assessed for 11 biomarkers that reflect activation of the EGFR pathway, the VEGF (vascular endothelial growth factor) pathway, the ras/raf pathway, and the cyclin D1 pathway. The first 100 patients were randomly assigned in equal numbers to one of four treatments: erlotinib (Tarceva), which targets EGFR signaling; sorafenib (Nexavar), which targets ras/raf signaling; vandetanib (Zactima), which targets VEGF and EGFR signaling; or erlotinib plus bexarotene (Targretin), the latter of which targets RXR (retinoid X receptor) signaling.

CT scans at 8 weeks were used to assess disease control, which earlier data from our center suggest is a reasonable surrogate for median progression-free survival and overall survival. We then fed data from these initial patients into an algorithm that allowed us to randomize subsequent patients in an adaptive (preferred) manner, whereby they were more likely to receive the treatment that would benefit them, based on their tumor's molecular profile.

Over 3 years, we enrolled more than 300 patients. Most biopsies were performed with CT guidance; the rest were performed with ultrasound guidance. None was an open surgical biopsy, which was considered too extreme.

The patients' records are annotated with their treatment and clinical outcome, which will provide us with a rich database to use for discovery. Several related studies are exploring the use of various other markers and signatures, including some assessable in blood, so that it may eventually be possible to personalize therapy without the need for an invasive biopsy.

The upcoming BATTLE 2 trial, with a similar patient population, will focus more on combination therapy.

The BATTLE clinical trials program is an important step toward personalizing lung cancer therapy. By using an adaptive trial design and biomarker discovery, we are learning in real time how to treat lung cancer more effectively. In addition, we have created a platform for future clinical trials and biomarker discovery. Without question, such a program requires considerable resources and teamwork. But this is the way that personalized therapy needs to move forward. ■

DR. HERBST *is professor of medicine and chief of thoracic medical oncology, as well as the Barnhart Family Distinguished Professor in Targeted Therapies, at the University of Texas M.D. Anderson Cancer Center in Houston.*

Sex and Race Differences Seen in Small Cell Lung Ca

BY SUSAN LONDON

Elsevier Global Medical News

VANCOUVER, B.C. – Small cell lung cancer presentation varies by sex and race, according to a retrospective analysis of U.S. national data spanning a 32-year period.

Women were more likely than men to have limited disease at diagnosis and had better survival, Dr. Shagun Arora reported at CHEST 2010, the annual meeting of the American College of Chest Physicians. African Americans were younger than whites at diagnosis, and the small cell type made up a smaller proportion of all lung cancers in African American patients than in white patients.

Possible explanations include differences in patterns of smoking and susceptibility to the deleterious effects of tobacco smoke, as well as hormonal factors, according to Dr. Arora of McLaren Regional Medical Center in Flint, Mich.

African Americans are 1.8 times more susceptible than whites to developing small cell lung cancer.

DR. ARORA

Using histologic codes, the investigators identified all cases of small cell lung cancer in the Surveillance, Epidemiology, and End Results (SEER) database among white and African American patients between the years 1973 and 2005.

Analyses were based on 70,886 patients with small cell lung cancer. About 91% were white and 55% were male.

During the study period, the male to female ratio in the proportion of all lung cancers that were of small cell type fell from 2.6 to 0.9, which mainly reflected a rise among women, Dr. Aurora said.

Age at presentation did not differ by sex. But women were more likely to have disease that was limited in stage (that is, confined to one hemithorax) at diagnosis than were men (35% vs. 30%).

And although cancer-specific survival improved for both sexes over time, it was consistently longer for women than for men. At the end of the study period, 2-year survival was approximately 20% among women vs. 15% among men.

"We all know that small cell lung cancer is very closely related to smoking," Dr. Arora commented. Hence, differences between the sexes in smoking patterns may explain some of these findings.

"Females began smoking 20 years after males," she noted, and their smoking rates have been slower to decline. In addition, "females are more prone to tobacco effects: They are 1.5 times more likely to develop lung cancer than males with the same smoking habits."

The study did not use multivariate or stage-stratified analysis, Dr. Arora said; hence, the less-extensive disease of women at presentation may have contributed to their better survival. Nonetheless, this finding "begs the question of a possible hormonal factor."

Study results for race showed that the proportion of all lung cancers that were of small cell type was consistently lower among African American patients than among white patients throughout the study period. As of 2005, the value was 9% compared with 12% for white patients.

Age at presentation was younger among African American patients than among white patients. For example, roughly 50% of African American patients received their cancer diagnosis before age 64, compared with 40% of white patients. But the two racial groups did not differ with respect to the stage at diagnosis or cancer-specific survival.

Here, again, smoking patterns and susceptibility may explain some of the observed differences, according to Dr. Arora.

On one hand, African American smokers smoke fewer cigarettes daily than do their white peers and start smoking later in life, she said. But "because of their lower quit rates, their prevalence of smoking is higher." Also, they smoke more menthol cigarettes, which have higher levels of tar than the nonmentholated kind.

"On top of that, there is a race effect," Dr. Arora noted. "African Americans are 1.8 times more susceptible than whites to developing small cell lung cancer with the same amount of smoking."

Dr. Arora reported that she did not have any relevant financial conflicts. ■

Physicians Can Tip the Balance to Smoking Cessation

BY SUSAN LONDON
Elsevier Global Medical News

VANCOUVER, B.C. – Although physicians might be reluctant to bring up smoking cessation with their patients for many reasons, it is one of the most important preventive activities they can undertake, according to Dr. Arunabh Talwar, FCCP.

Many smokers are ambivalent about smoking, he said at CHEST 2010, the annual meeting of the American College of Chest Physicians. On any given day, their smoking status hangs in balance between one set of factors favoring quitting and another set favoring continuing (BMJ 2007;335:37-41).

"All we need to do is just [tip the balance]," said Dr. Talwar, a pulmonologist at North Shore University Hospital in Manhasset, N.Y.

Indeed, if self-reports are reliable, about 70% of smokers want to stop and 30% try each year. But only 2%-3% succeed.

Referring to the multistage model of behavioral change, he noted that making smokers aware of the link between smoking and end-organ damage is critical in starting the process. "That is the most important thing that physicians do: They move patients from a precontemplation to a contemplation stage and set the stage for the smoking cessation process to occur."

There is compelling evidence of the benefits of smoking cessation, he said. It has been identified as the single most effective step for lengthening and improving patients' lives (BMJ 2004;328:947-9).

"Make no mistake, smoking cessation activity is very cost effective," he added. "I think it is the most cost-effective primary prevention action that a physician can take."

Brief advice to quit costs $338 per year of life saved – or less than 5% of the cost per year of life saved from giving pravastatin for primary prevention of cardiovascular disease, aspirin for secondary prevention of coronary heart disease, or simvastatin for secondary prevention of MI (BMJ 2004;328:397-9).

Still, physicians cite numerous barriers to promoting smoking cessation with their patients, according to Dr. Talwar (J. Smok. Cessat. 2008;3:92-100). A common one is being too busy.

"But studies show us, a minimal intervention – as [little] as 3 minutes of a physician's time – can move patients from 'precontemplation' to contemplation, can help improve quit status," he said. Furthermore, "as you increase the intervention, the success rate will improve."

For example, just 0.3% of smokers succeed in quitting long term on their own, but the value rises to 1.6% when physicians simply ask their smoking status, to 3.3% when physicians ask and provide advice on quitting, and to 5.1% when physicians ask, advise, and give a pamphlet (BMJ 1979;2:231-5).

Busy physicians can streamline efforts by using a team approach. "Some of it can be shared by other health care providers, whether they are nurses, nurse practitioners, physician assistants," Dr. Talwar explained. "We use our respiratory therapists and [pulmonary function test] lab technicians as well; that way, the load gets divided. But also, repeated messages to the patient will help move them along."

Physicians should also consider using telephone "quitlines" (now freely available in all states) and patient support groups in the behavioral modification part of cessation, he advised.

Another barrier physicians cite, lack of expertise, has a stronger negative influence on their smoking cessation activities than lack of interest, time, or materials (Eur. J. Public Health 2005;15:140-5).

Indeed, in a survey of New York City–area health care providers, Dr. Talwar and his colleagues found that only 20% believed their training had adequately prepared them to treat tobacco dependence. And less than 10% were familiar with treatment guidelines. "We are a little bit behind in this, but medical schools have made a change, and most medical schools now make an effort to make sure that standard curricula [on smoking cessation] are there," he said. In addition, comprehensive information is readily available in the ACCP's Tobacco Dependence Treatment ToolKit (http://tobaccodependence.chestnet.org).

Reassuringly, physicians who receive training in this area are 1.5 to 2.5 times more likely to perform smoking cessation tasks (Cochrane Database Syst. Rev. 2000;CD000214).

Physicians also report a lack of financial incentives to be a barrier. Dr. Talwar noted that two CPT codes – 99406 and 99407 – specifically pertain to cessation activities during visits. Physicians can usually bill for this counseling, in addition to routine office visits, four times annually.

Half of physicians still believe that reimbursement is insufficient. "But the situation is much better than 7 or 8 years ago, when it was much more difficult to get reimbursement for these activities," he commented.

Physicians also mention patients' low likelihood of quitting as a barrier to broaching smoking cessation, according to Dr. Talwar. But the irony is that quit rates are influenced in large part by physicians' efforts and the intensity of those efforts.

Discussing the so-called 5 A's of smoking cessation – ask, advise, assess, assist, and arrange – he noted that physicians do fairly well on the first two, but not so well on the others.

For example, a study of 246 community-based primary care physicians found that 67% asked their patients about smoking status and 74% gave advice, but just 35% assisted with smoking cessation efforts and merely 8% arranged for follow-up (Prev. Med. 1998;27:720-9).

It is important to understand that relapses are part of the cessation process, Dr. Talwar stressed; in fact, smokers who succeed in quitting make five to seven attempts, on average, before succeeding. Hence, "you have just to have to be patient with them."

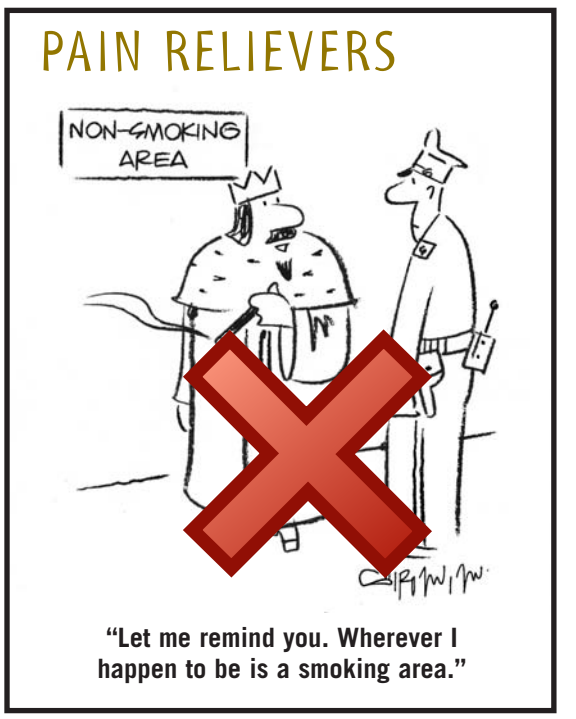
It might also be possible to improve the odds of successful quitting by approaching patients at teachable moments, he further noted. For instance, "admission [to the hospital] is an opportunity to interact, to make the change. Maybe that's the time when you need to approach them."

His own 800-bed hospital generates a list each day of inpatients who smoke. A smoking cessation therapist then visits these patients and invites them to the smoking cessation clinic.

A final barrier is that some physicians themselves are smokers. "It's been shown that physicians who smoke have very little faith in their own ability to promote smoking cessation," Dr. Talwar commented (Prev. Med. 2005;40:595-601).

On the other hand, this group has greater insight into the difficulties of quitting and might be able to draw on their own experiences to assist patients in this endeavor, he added.

Dr. Talwar did not report any conflicts of interest. ■



"Let me remind you. Wherever I happen to be is a smoking area."

'Smoking Can Kill You'

Warnings • *from page 1*

The cancer warning might have a photograph of an obviously terminally ill person in a hospital bed, or a close-up of a mouth riddled with rotting teeth and sores. The heart disease warning might have a photograph of a man clutching his chest, in the throes of a myocardial infarction.

The FDA is seeking the public's input on which graphic depiction to use for each warning. It is accepting comments until Jan. 9, 2011. Then the agency will select one graphic for each of the nine warnings and publish the choices in a final rule to be issued by June 22, 2011. Manufacturers would have 15 months from that time – by October 2012 – to come into compliance. If they do not comply, their product will be banned from sale in the United States.

Public health advocacy groups applauded the HHS plan and the FDA proposal. "The new warnings represent the most significant change in U.S. cigarette warnings since they were first required in 1965," Matthew L. Myers, president of the Campaign for Tobacco-Free Kids, said in a statement.

The American Cancer Society Cancer Action Network said that current warnings are ineffective "because of their inability to attract attention due to their size and placement on the packaging." The group said that the proposal is important and timely. "The FDA has the opportunity to make an enormous impact on effectively informing the public of the actual harms of using tobacco products and inducing the desire to quit among users," the ACSCAN said in a statement.

The HHS strategy paper recommended expanding tobacco cessation services, including through Medicare and Medicaid; accelerating the adoption of smoke-free laws across the country; increasing the number of tobacco-free workplaces and campuses; and adopting evidence-based intervention strategies. Health care providers should receive enhanced incentives for offering interventions and treatments, and federal agencies should increase research into tobacco cessation strategies and treatments and surveillance and monitoring of control efforts, said the HHS strategic paper.

The HHS also called for a national media campaign to prevent kids from smoking, which Mr. Myers characterized as a critical element. "The administration and Congress must now provide sufficient funding for these initiatives if they are to succeed," he said.

According to the HHS, if the agency receives funding and all of the initiatives were to go forward, the country could meet the Healthy People 2010 objective to reduce the smoking rate to 12% of American adults. ■

COMMENTARY

Dr. Philip Marcus, FCCP, comments: Stronger warnings on cigarettes are a long time coming. However, it is unclear whether they will have a significant impact on those experimenting with cigarette smoking. It is certainly a step in the right direction, but better public education must take place as well.

Midlife Smoking Doubled Later Dementia Risk

BY MARY ANN MOON
Elsevier Global Medical News

People who smoked two packs of cigarettes or more a day at midlife were more than twice as likely as nonsmokers to develop dementia and dementia subtypes such as Alzheimer's disease, according to a recent report.

The association between midlife smoking and dementia 2-3 decades later remained robust after the data were adjusted to account for several confounding factors, including stroke. Therefore, smoking "seems to have some independent effect on vascular dementia, beyond acceleration of cerebrovascular disease," said Dr. Minna Rusanen of the department of neurology at the University of Eastern Finland, Kuopio, and her associates.

Few studies have addressed the long-term cerebrovascular consequences of smoking in middle age, and those that have done so had small sample sizes of predominantly white subjects, the investigators noted (Arch. Intern. Med. 2010 [doi:10.1001/archinternmed.2010.393]).

COMMENTARY

Dr. Philip Marcus, FCCP, comments: Lung cancer, COPD, laryngeal cancer, esophageal cancer, wrinkles, and now dementia. One more reason to stop smoking, and even better, to never start smoking. This study provides conclusive evidence of the link between cigarette smoking and dementia and should cause every smoker to think, "wake up and smell the coffee," and finally kick the habit.

Dr. Rusanen and her colleagues used data from a large, multiethnic cohort of more than 33,000 members of the Kaiser Permanente Medical Care Program of Northern California. The study cohort took part in the Multiphasic Health Checkup and were first assessed at enrollment between 1978 and 1985, when they were aged 50-60 years. For the analysis, the medical records of 21,123 people who were still living and in the health plan in 1994 were reviewed for dementia diagnoses.

A total of 5,367 people (25%) were diagnosed by neurologists, neuropsychologists, or internists as having dementia, including 1,136 cases of Alzheimer's disease and 416 cases of vascular dementia.

After researchers adjusted for age, sex, and certain cardiovascular risk factors, they found that people who smoked two or more packs per day at midlife were more than twice as likely as nonsmokers to develop dementia (risk-adjusted hazard ratio, 2.14), Alzheimer's disease (HR, 2.57), or vascular dementia (HR, 2.72) 20-30 years later.

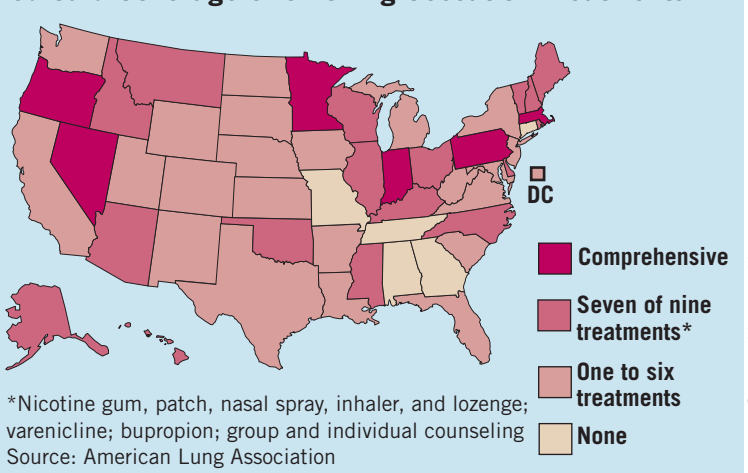
The association between smoking and dementia risk was analyzed separately for people who had stroke because stroke is a robust predictor of dementia and is highly associated with smoking. Midlife smoking remained a robust independent predictor of dementia and dementia subtypes in that subanalysis, the investigators said. Compared with nonsmokers who had a stroke, those who had smoked two or more packs per day and had a stroke were 1.83 times more likely to develop dementia.

The link between midlife smoking and later dementia remained robust when the data were adjusted for patient race, ethnicity, and gender. "The deleterious effects of smoking on risk of dementia seem to be the same for both sexes and across different ethnic groups," Dr. Rusanen and her associates said.

The study was supported by Kaiser Permanente Community Benefits and several national institutions in Finland. One investigator reported ties to Elan Corp., Pfizer, Janssen, and Novartis. ■

DATA WATCH

Medicaid Coverage of Smoking Cessation Treatments



*Nicotine gum, patch, nasal spray, inhaler, and lozenge; varenicline; bupropion; group and individual counseling
Source: American Lung Association

ELSEVIER GLOBAL MEDICAL NEWS

observed in an additional 22 patients 12 to 17 years of age who were treated with

DULERA in another clinical trial. The safety and efficacy of DULERA have not been established in children less than 12 years of age.

Controlled clinical studies have shown that inhaled corticosteroids may cause a reduction in growth velocity in pediatric patients. In these studies, the mean reduction in growth velocity was approximately 1 cm per year (range 0.3 to 1.8 per year) and appears to depend upon dose and duration of exposure. This effect was observed in the absence of laboratory evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression, suggesting that growth velocity is a more sensitive indicator of systemic corticosteroid exposure in pediatric patients than some commonly used tests of HPA axis function. The long-term effects of this reduction in growth velocity associated with orally inhaled corticosteroids, including the impact on final adult height, are unknown. The potential for "catch up" growth following discontinuation of treatment with orally inhaled corticosteroids has not been adequately studied.

The growth of children and adolescents receiving orally inhaled corticosteroids, including DULERA, should be monitored routinely (e.g., via stadiometry). If a child or adolescent on any corticosteroid appears to have growth suppression, the possibility that he/she is particularly sensitive to this effect should be considered. The potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the risks associated with alternative therapies. To minimize the systemic effects of orally inhaled corticosteroids, including DULERA, each patient should be titrated to his/her lowest effective dose *[see Dosage and Administration (2.2)]*.

8.5 Geriatric Use

A total of 77 patients 65 years of age and older (of which 11 were 75 years and older) have been treated with DULERA in 3 clinical trials up to 52 weeks in duration. Similar efficacy and safety results were observed in an additional 28 patients 65 years of age and older who were treated with DULERA in another clinical trial. No overall differences in safety or effectiveness were observed between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out. As with other products containing $beta_2$-agonists, special caution should be observed when using DULERA in geriatric patients who have concomitant cardiovascular disease that could be adversely affected by $beta_2$-agonists. Based on available data for DULERA or its active components, no adjustment of dosage of DULERA in geriatric patients is warranted.

8.6 Hepatic Impairment

Concentrations of mometasone furoate appear to increase with severity of hepatic impairment *[see Clinical Pharmacology (12.3)]*.

10.1 Signs and Symptoms

DULERA: DULERA contains both mometasone furoate and formoterol fumarate; therefore, the risks associated with overdosage for the individual components described below apply to DULERA.

Mometasone Furoate: Chronic overdosage may result in signs/symptoms of hypercorticism *[see Warnings and Precautions (5.7)]*. Single oral doses up to 8000 mcg of mometasone furoate have been studied on human volunteers with no adverse reactions reported.

Formoterol Fumarate: The expected signs and symptoms with overdosage of formoterol are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the following signs and symptoms: angina, hypertension or hypotension, tachycardia, with rates up to 200 beats/min., arrhythmias, nervousness, headache, tremor, seizures, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, hypokalemia, hyperglycemia, and insomnia. Metabolic acidosis may also occur. Cardiac arrest and even death may be associated with an overdose of formoterol.

The minimum acute lethal inhalation dose of formoterol fumarate in rats is 156 mg/kg (approximately 63,000 times the MRHD on a mcg/m^2 basis). The median lethal oral doses in Chinese hamsters, rats, and mice provide even higher multiples of the MRHD.

10.2 Treatment

DULERA: Treatment of overdosage consists of discontinuation of DULERA together with institution of appropriate symptomatic and/or supportive therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdosage of DULERA. Cardiac monitoring is recommended in cases of overdosage.

Manufactured by 3M Health Care Ltd.,
Loughborough, United Kingdom.
Manufactured for Schering Corporation, a subsidiary of
MERCK & CO., INC.
Whitehouse Station, NJ 08889 USA.

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Tuberculosis Rate Falling, But Not Fast Enough

Currently, the annual global decline is estimated at a modest 0.07%.

BY JENNIE SMITH
Elsevier Global Medical News

Though the global incidence rate of tuberculosis is falling, thanks to wide-scale coordination of standardized anti-TB interventions, the goal of eliminating TB by 2050 will not be met without new technologies and approaches, say specialists at the World Health Organization.

The reasons for the slower-than-hoped-for reduction rate of TB incidence, which now holds at less than 1% per year, are economic, geographic, and technological.

Current diagnostic methods in wide use detect only about 60% of TB cases. Vulnerable people in many poor countries still do not have access to affordable treatment or early diagnosis. Meanwhile multidrug-resistant (MDR) TB remains a threat in some regions, particularly Europe; and HIV infection fuels tuberculosis incidence in other regions, particularly Africa. In 2008 there were an estimated 139 incident cases of TB per 100,000 population, or 11 million worldwide, with 1.8 million associated deaths.

In an article on TB interventions published online in the Lancet, Dr. Knut Lönnroth and Dr. Mario Raviglione of WHO's Stop TB program in Geneva, along with colleagues in the United States, Kenya, and India, undertook a broad review of published studies and of epidemiologic data to measure progress on TB reduction goals set by WHO and the United Nations between 1990 and 2000. They also surveyed control policies and health systems in 22 nations that together make up 80% of the world's TB burden, while noting that data reporting in many of the high-burden countries could be subpar or inconsistent.

The WHO and UN goals included halting and beginning to reverse by 2015 the rise in incidence of TB; halving by 2015 the incidence and death rates of 1990; and reducing TB incidence to one case per million people by 2050. The first goal, Dr. Lönnroth and Dr. Raviglione concluded, may have been met as early as 2004. The second will likely be met in most regions, they said, but not all. The third goal may be out of reach without a reconsideration of overall strategy and further technological improvements.

Though some newer technologies, such as preventive therapy with isoniazid, are helping and should be expanded, "we can still wish for a better technology in terms of drug treatment for people with active disease. We want better, simpler diagnostic tools that can be used in peripheral settings, such as rural clinics," Dr. Lönnroth said in an interview. "And the ultimate thing we can wish for is a new and better vaccine."

But Dr. Lönnroth noted that there are countless factors affecting TB rates, not all of which can be addressed with technology. "One thing is not going to help the situation," he said. "It has to be a combination of different types of efforts."

Combining different types of efforts is also the basic philosophy of directly observed therapy, short course (DOTS), WHO's standardized package of tuberculosis interventions, which was started in 1995. The key components of DOTS are diagnosis through bacteriology, standardized and supervised treatment, an effective drug supply system, and monitoring and evaluation of performance.

Between 1995 and 2008, a period during which DOTS was implemented in 181 countries (including all 22 of the high-burden countries), 36 million people were cured of TB, with an estimated 6 million more lives saved than if DOTS had not been adopted, wrote Dr. Lönnroth and Dr. Raviglione. TB fatality rates worldwide dropped by half in that period, from 8% to 4%.

However, TB case detection rates, after a period of acceleration, leveled off in 2007 at around 60% globally, short of WHO's goal of 70%. Treatment success under DOTS has proven uneven, with Mediterranean, Pacific, and Southeast Asian countries reporting successful treatment rates as high as 92% in 2007, while Europe and Africa saw 67% and 79% that year, respectively.

Dr. Lönnroth and Dr. Raviglione estimated that detection of incident cases above 70% and treatment rates over 85% would be necessary to produce reductions in the TB rate of 5%-10% per year. Currently, the annual global decline is estimated at a modest 0.07%.

While the European region, notably Russia, continues to struggle with MDR tuberculosis, inadequate treatment success, and high dropout rates from treatment, it is likely the African situation that will cause the 2015 target of halving the 1990 rates to be missed, Dr. Lönnroth and Dr. Raviglione wrote.

HIV infection increases vulnerability to TB coinfection by a factor of 20, and the rapid increase in TB incidence and deaths in Africa during the 1990s was related to the high regional incidence of HIV.

In concluding their analysis, the authors made note of the relationship between poverty and the epidemiology of TB, a relationship underscored in an associated editorial by Dr. Richard Horton, the Lancet's editor in chief, and Dr. Pamela Das, its executive editor. Treatment-related actions alone, Dr. Horton and Dr. Das wrote, "will be insufficient to reach global goals. There is an urgent need to assess interventions for social and economic determinants, such as malnutrition, alcohol use, poor housing, indoor air pollution, and poverty."

Other papers and related comments in the Lancet addressed topics including the interaction of age and immunity with TB, the need to strengthen health systems, and the research priorities for diagnosis, management, and control of tuberculosis.

In a paper on TB vaccines, researchers led by Prof. Stefan H. E. Kaufmann of Max Planck Institute for Infection Biology in Berlin, said that "after decades of inactivity" in research and development for tuberculosis vaccines, 11 candidates are currently in the clinical trial stage. Most of the candidates are intended to replace or be boosters for the recombinant live vaccine (BCG) that is currently in use. The BCG vaccination provides insufficient protection against adolescent and adult TB, and while it is more effective in infants, it has safety issues in those who also have HIV, researchers explained.

The potential for improvement is great, they wrote. A key message of their report is that "new vaccines can contribute to the ambitious goal of reducing the yearly incidence of tuberculosis to less than one new case per million population by 2050." However, the efforts are severely underfunded, and costs are projected to be $2 billion/year over the next 10 years. ■

COMMENTARY

Dr. Mark Metersky, FCCP, comments: As in so many other areas of health care, possessing the knowledge of how to reduce TB rates is not enough. Adequate resources and effective planning and implementation are also necessary.

COPD Surgical Risk

Outcomes • *from page 1*

"Perioperative optimization of these patients may help in improving outcomes and health care costs, and there is a need to study such strategies in multicenter, randomized, prospective trials," he added. These strategies might include giving patients respiratory exercises and encouraging them to quit smoking, he said.

Dr. Gupta and his colleagues used the NSQIP (National Surgical Quality Improvement Program) database, which collects data from more than 250 hospitals, to identify patients who underwent surgery in 2007 and 2008.

They then compared 30-day postoperative outcomes between patients who did and did not have COPD, defined in the database as GOLD (Global Initiative for Chronic Obstructive Lung Disease) stage II, III, or IV or a prior hospitalization for COPD.

Analyses included 468,795 patients who underwent surgery. The types of surgery were typical of those seen in the general population, according to Dr. Gupta, with a predominance of cholecystectomy, appendectomy, hernia repair, and vascular and breast surgeries.

A total of 5% of the patients had COPD. Relative to their unaffected peers, COPD patients had a higher mean body mass index (29 vs. 28 kg/m^2) and older median age (69 vs. 55 years); were more likely to be male (52% vs. 42%), white (82% vs. 72%), smokers (41% vs. 20%), and alcoholics (5% vs. 2%); and were more likely to be on corticosteroids (10% vs. 3%).

The group with COPD also had higher prevalences of more than a dozen comorbidities, especially hypertension (74% vs. 44%), dependent functional status (20% vs. 6%), diabetes (25% vs. 14%), and an American Society of Anesthesiologists score of 3 or 4 (55% vs. 22%).

Median length of hospital stay was much longer for patients with COPD than for their unaffected peers, at 4 days vs. 1 day (*P* less than .0001), Dr. Gupta said. And the 30-day rate of postoperative mortality was higher, at 6.7% vs. 1.4% (*P* less than .0001).

After the investigators took into account more than 50 comorbidities and the type of surgery, patients with COPD still had higher risks of postoperative morbidity (odds ratio, 1.35; *P* less than .0001) and mortality (OR, 1.29; *P* less than .0001).

The odds of nine postoperative complications individually were also elevated for the COPD group, with the greatest increases seen for pneumonia (OR, 1.71), reintubation (OR, 1.54), and failure to wean from the ventilator within 48 hours (OR, 1.45) (all *P* less than .0001).

The study was limited by a lack of detailed information on therapies that patients were receiving, Dr. Gupta acknowledged. "We just know that they had this surgery [and] that they had COPD prior. We don't know what medication or what preoperative optimization they underwent," he said.

COPD 'is associated with increased morbidity, mortality, and length of stay.'

DR. GUPTA

In addition, the study did not specifically assess any influence of the urgency of the surgery (emergency vs. elective) and did not assess the potential impact of mild COPD.

GOLD stage II-IV COPD is "common among patients undergoing surgery and is associated with increased morbidity, mortality, and length of stay," Dr. Gupta concluded. Physicians may be able to use this information to help guide selection of appropriate surgical candidates, counsel patients about risks, and target interventions to improve outcomes, he said.

Dr. Gupta reported having no conflicts of interest related to the research. ■

Initiative Improved COPD Knowledge in Primary Care

BY SUSAN LONDON

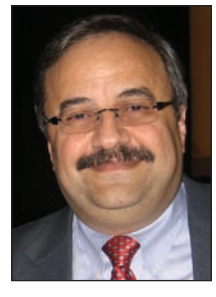
Elsevier Global Medical News

VANCOUVER, B.C. – A live, interactive, case-based educational initiative improved primary care physicians' knowledge of chronic obstructive pulmonary disease, according to study results reported at CHEST 2010, the annual meeting of the American College of Chest Physicians.

In a cross-sectional study of 50 primary care physicians who participated in the initiative and 50 similar nonparticipants, the former were more likely to know that alveolar destruction is a pathophysiologic feature of COPD (94% vs. 74%) and that women have greater susceptibility to the harmful effects of smoking (90% vs. 54%), according to Dr. Nicola A. Hanania, FCCP, and his coinvestigators.

Also, when presented with case vignettes, participants were more likely to recognize COPD in dyspnea patients (90% vs. 74%), reported Dr. Hanania, an associate professor of medicine at Baylor College of Medicine, Houston.

Explaining the need for primary care–focused efforts, he noted that "the majority of COPD patients are [seen] in the primary care arena." But statistics show that "COPD remains under-recognized and underdiagnosed in about 50% of the population out there, not only in the United States but in other countries as well. It also remains undertreated," even though the GOLD (Global Initiative for Chronic Obstructive Lung Disease) guidelines now stress that it is a treatable disease.



The initiative – called Improving COPD Patient Outcomes: Breaking Down the Barriers to Optimal Care – was designed to improve primary care providers' knowledge and competency in the guideline-based diagnosis, staging, and management of COPD, Dr. Hanania said.

It consisted of a series of live half-day meetings conducted over a 3-month period that included short lectures, a video on correct use of inhaler devices, and small-group workshops that incorporated detailed case discussions and demonstrations and practice in the use of spirometry.

A total of 769 physicians attended the meetings. The investigators assessed the initiative's effectiveness with a case vignette–based survey, given to a randomly selected subset of 50 participants and 50 nonparticipants with similar demographics and practice characteristics.

The number of patients with COPD seen weekly was 11 for participants and 15 for nonparticipants. The mean number of years in practice was 28 and 24, respectively. The groups were about equally divided between family physicians and internists.

Participants were 50% more likely than nonparticipants to provide evidence-based, guideline-driven COPD care.

DR. HANANIA

Survey results showed that participants were more likely than nonparticipants to recognize COPD in case vignettes of patients with dyspnea (90% vs. 74%, $P = .007$) and to be aware of the greater susceptibility of women compared with men to the harmful effects of smoking (90% vs. 54%, P less than .001).

Also, when asked which of several pathophysiologic features was one of COPD, participants were more likely to correctly answer alveolar destruction (94% vs. 74%, $P = .007$).

While the groups did not differ significantly in terms of how likely they were to use spirometry for diagnosis and staging of COPD, participants were more likely than nonparticipants to indicate that difficulty in obtaining spirometry results in the office setting was a very significant barrier to COPD management (27% vs. 12%). "Maybe they acknowledged that it is an important tool, but they cannot do it," he commented.

The groups were statistically indistinguishable in their approaches to repeated exacerbations, improving adherence, and maintenance therapy.

The survey also asked about barriers to managing COPD, which may help in designing future initiatives, Dr. Hanania said.

A calculation of the initiative's quality of education index showed that participants were 50% more likely than nonparticipants to provide evidence-based, guideline-driven COPD care, he said.

"We did not attempt to look at long-term [outcomes] – retention of knowledge or practice change – which are very important," Dr. Hanania acknowledged. But a similar, ongoing initiative, being conducted by the ACCP, is currently assessing impact on real-life practice.

That initiative is including not only physicians but also physician assistants and nurse practitioners, Dr. Hanania noted. "In our primary care setting in the U.S., nonphysician extenders – PAs, nurse practitioners – play a major role in encountering COPD," he explained.

The initiative meetings were supported by an educational grant from Novartis Pharmaceuticals. Dr. Hanania had no relevant conflicts of interest. ■

Palivizumab Use Linked With Shorter Hospital Stay

BY PATRICE WENDLING
Elsevier Global Medical News

VITALS

Major Finding: The average length of stay for RSV fell 12.9% after the introduction of palivizumab, versus a decrease of 3.4% for other causes of infant hospitalization.

Data Source: Retrospective cross-section comparison of two time periods.

Disclosures: Dr. Racine reported no conflicts or external study support.

VANCOUVER, B.C. – The introduction of palivizumab as a preventative treatment for respiratory syncytial virus appears to be associated with a shorter length of hospital stay for the disease, one California study showed.

Hospital charges for respiratory syncytial virus (RSV) also increased at a slower pace than for other causes of infant hospitalization, according to a retrospective analysis of California discharges among 3,443,918 infants less than 1 year of age.

The data provide real-world evidence about the impact of palivizumab (Synagis) in the community since its approval in 1998 based on one company-sponsored study, said Dr. Andrew Racine, chief of the general pediatrics section at Albert Einstein College of Medicine in New York City.

"This is important for the following reason: The U.S. sales of palivizumab have gone from about $225 million in 1998 to over $1.5 billion in 2007," he said.

"We're using a lot of this; we might as well know if it's effective," Dr. Racine commented.

Palivizumab costs about $900 a dose, with most at-risk children receiving five doses as prophylaxis. There is no treatment for RSV.

Dr. Racine cautioned that the data are from a single state and were not stratified by risk categories for RSV. In addition, the findings were based on an intent-to-treat analysis and thus may not reflect whether patients actually received the medication. There are plans to link the birth certificate to the hospitalization and to identify gestational age and congenital illnesses.

The researchers used data from the California Patient Discharge Database and individual-level hospitalization records to compare length of stay and hospitalization costs among infants less than 1 year of age during two time periods: before (1995-1997) and after palivizumab (2005-2007).

The mean length of stay for RSV hospitalizations fell 12.9% from 3.95 days before palivizumab to 3.43 days after the drug.

This compares with a decrease of 3.4% for non-RSV hospitalizations, which went from 3.2 days to 3.09. The difference was statistically significant at a *P* value less than .001, Dr. Racine said at the annual meeting of the Pediatric Academic Societies.

Median hospital charges in constant 2007 dollars for an RSV diagnosis increased 20.1% from $16,060 to $19,390 after palivizumab, while non-RSV charges rose 58.6% from $11,901 to $18,857 over the two periods. Again the difference was significant at a *P* value equal to .001.

Session moderator Dr. Esther Chung, a pediatrician with Thomas Jefferson University Hospitals in Philadelphia, suggested that factors in addition to length of stay could be driving down RSV hospitalization costs.

Dr. Racine said that less use of albuterol, corticosteroids, and imaging studies also may have occurred during the second time period, but that these data were not examined and that his own "heartbreaking" experience suggests that these practices continue.

"There are a lot of things we are still doing to these children with this condition that are completely unnecessary and costly," he said.

A study led by Dr. Caroline B. Hall, whose earlier work led to the approval of palivizumab, reported that only 3% of 355 outpatients with confirmed RSV infection received an RSV diagnosis, with 20% of these children diagnosed with bronchiolitis.

Dr. Hall and her associates estimated that RSV infection results in 1 of 334 hospitalizations among children under the age of 5 years (N. Engl. J. Med. 2009; 360:588-98). ■

COMMENTARY

Dr. Christopher Carroll comments: In addition, there are other factors that could be driving down RSV length of stay that are unrelated to palivizumab. These include the increased used of noninvasive ventilation, improvement in hospital care, differences in RSV viral pathogenicity from season to season, and others.

Dr. Carroll of the Connecticut Children's Medical Center in Hartford is a guest adviser for this publication.

Combo Therapy Gives Survival Edge in KPC Bacteremia

Any combination was linked with significantly lower mortality, compared with monotherapy.

BY NEIL OSTERWEIL
Elsevier Global Medical News

BOSTON – Bacteremia secondary to pneumonia caused by carbapenem-resistant *Klebsiella pneumoniae* carries a high mortality rate, but combination antimicrobial regimens involving polymyxins, tigecycline, or carbapenems improve survival compared with monotherapy, according to the findings of an observational treatment study conducted at two medical centers.

Among 41 patients infected with *K. pneumoniae* bacteria that produce *Klebsiella pneumoniae* carbapenemase (KPC), 14-day mortality was 24% and 28-day mortality was 35%, Dr. Zubair A. Qureshi reported at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

Mortality was increased when patients received monotherapy with either colistin (4 deaths among 7 patients) or tigecycline (3 deaths among 5 patients). However, there were no deaths within 28 days among patients treated with either colistin or tigecycline added to any carbapenem, even when the infectious organism was reported to be nonsusceptible to carbapenems, said Dr. Qureshi of the division of internal medicine at the University of Pittsburgh Medical Center.

He noted that the preliminary findings are consistent with a recent review of KPC infections that documented better clinical outcomes with combination therapy compared with monotherapy (J. Antimicrob. Chemother. 2010;6:1119-25).

KPC-type beta-lactamases confer either decreased susceptibility or resistance to virtually all beta-lactam antibiotics, including the carbapenem class agents imipenem, meropenem, and ertapenem.

Investigators at the University of Pittsburgh and St. Luke's–Roosevelt Hospital Center in New York City conducted the single-arm observational study of treatment outcomes in patients with bacteremia due to KPC-producing *K. pneumoniae*. Patients were screened for the presence of KPC by reduced susceptibility to ertapenem, which was confirmed with polymerase chain reaction.

The authors looked at risk factors, antimicrobial therapy, and in-hospital mortality rates. They identified 41 patients (24 women, 17 men) with KPC-producing *K. pneumoniae*, with a median age of 62 years (range 25-90 years). All of the cases appeared to have been acquired in either the hospital (78%) or other health care settings such as long-term care facilities. There were no identified cases of community-acquired infections.

The source of the bacteremia was vascular catheters in 29% of the cases, pneumonia in 27%, urinary tract in 15%, intra-abdominal in 4%, and superficial wounds in 4%. The source was unknown in the remaining patients.

The primary risk factor was immunocompromised status, either from a transplant, malignancy, diabetes, connective tissue disease, chronic renal failure, or HIV infection. In all, 76% of patients had recently received antimicrobial agents, and 41% were nursing home residents.

Death occurred in 7 of 11 patients with pneumonia as the source of bacteremia, 3 of 12 patients with vascular catheters as the source, 1 of 6 patients with urinary catheter-based infections, and 3 of 12 patients whose infections were due to other or unknown sources.

When the investigators looked at 28-day mortality in patients who received definitive therapy, they found that any combination was associated with significantly lower mortality, compared with monotherapy (6% vs. 59%, $P = .002$). The analysis did not include two patients who were lost to follow-up.

VITALS

Major Finding: Combining a carbapenem antibiotic with either colistin or tigecycline improved 28-day survival in patients with bacteremia secondary to pneumonia caused by KPC, compared with those who received monotherapy (6% vs. 59%, $P = .002$).

Data Source: Single-arm observational study.

Disclosures: Dr. Qureshi reported having no conflicts of interest. Several of his colleagues reported receiving consulting fees from AstraZeneca, Merck, Novartis, Leo Pharmaceuticals, Three Rivers Pharmaceuticals, and/or Johnson & Johnson.

The regimens consisted of various combinations of polymyxins, tigecycline, and carbapenems.

"The combination of colistin and carbapenem appears to be superior to any other antibiotic combination, but there is a need for more observation as well as randomized clinical trials to help define the optimal treatment for KPC infections," Dr. Qureshi said. ■

Drug-Resistant KPC Spreading in U.S., Globally

BY ROBERT FINN
Elsevier Global Medical News

VANCOUVER, B.C. – There's a new bad bug on the block, and it appears to be making appearances in long-term care facilities, at least in the Chicago area, according to a recent study presented at the annual meeting of the Infectious Diseases Society of America.

Carbapenem-resistant Enterobacteriaceae, particularly those that produce *Klebsiella pneumoniae* carbapenemase (KPC), are becoming increasingly problematic in the Chicago area, Dr. Mary K. Hayden said during a press briefing. The first case appeared in Chicago in December 2007, but by March 2009 an Internet-based survey of infection preventionists revealed that 26 of 53 facilities (49%) had reported one case, and the mean number of cases per facility was 3.8.

In a subsequent survey in February 2010, 37 of 57 facilities (65%) had reported at least one case, and the mean number of cases per facility was 10.2.

According to the 2009 survey, 81% of the affected patients had been transferred from a long-term care facility or a long-term acute care hospital. In 2010, 75% of patients came from such facilities.

Dr. Hayden, of Rush University Medical Center, Chicago, declined to refer to KPC as a "superbug," a term favored in the popular press, but she did say, "I think it is an organism that should be identified as requiring particular attention. [It] can cause serious, life-threatening infections in hospitalized patients."

These organisms, which are aerobic gram-negative bacilli, produce infections that are particularly difficult to treat because they're resistant to most and sometimes to all available antibiotics.

"This rapid increase in KPC is not unique to the Chicago area," Dr. Hayden said. "KPC was first identified in North Carolina in the late 1990s, and over the next 10 years remained restricted to the East Coast, causing significant morbidity and mortality in areas such as Brooklyn, N.Y. But in the last couple of years, KPC has spread globally, with reports now from multiple areas in the United States and from South America, Europe, and Asia. An extreme example was seen in Israel, which reported a nationwide outbreak of KPC only about 2 years after their first case was identified."

Dr. Hayden said that her team believes their findings point to the need for a regional approach to KPC control. "It will require coordinated collaboration between acute care hospitals, long-term care facilities, and public health [departments]," she said.

The authors had no disclosures. ■

Pulmonary Perspectives

CPR – 50 Years On: Part 2

Although successful return of spontaneous circulation (ROSC) and survival to hospital discharge (STD) depend upon the provision of high-quality CPR, data exist to show that resuscitation quality is often lacking. Researchers from the University of Chicago reported inadequate compression rates by medical house staff in 28% of events, insufficient compression depth (37%), excessive ventilation (61%), and zero compressions for the first 5 min of resuscitations (40%) (Abella et al. *JAMA*. 2005;293[3]:305).

DR ERIC G. HONIG, FCCP

An analysis of outside the hospital cardiac arrest (OHCA) resuscitations in experienced Norwegian emergency medical technician (EMT) personnel showed similar inadequacies in compression depth and excessive hands-off time (Wik et al. *JAMA*. 2005;293[3]:299). Compared with continuous compressions, hands-off no flow time is especially deleterious in animal models of CPR, as coronary and carotid blood flow falls rapidly and rises to much lower levels when compressions are resumed (Steen et al. *Resuscitation*. 2003;58[3]:249). Failure of adequate compressions causes delayed peak blood levels of epinephrine and blunted coronary perfusion pressure (Edelson et al. *Resuscitation*. 2006;71[2]:137). Poor compressions with long preshock pauses are less likely to produce successful defibrillation than are adequate compressions with shorter pauses (Pytte et al. *Resuscitation*. 2006; 71[3]:369). Incomplete release after a compression (also known as "leaning") results in elevated intrathoracic pressure, which will also cause decreased coronary perfusion and decreased resuscitation success. Excessive leaning was demonstrated in 46% of a consecutive series of OHCA resuscitations in Wisconsin (Aufderheide et al. *Resuscitation*. 2005; 64[3]:353). Adequate quality of compressions is a major focus of the newly released 2010 AHA CPR guidelines (Field et al. *Circulation*. 2010;122[183]:S640 or www.Heart.org/CPR).

Though prompt defibrillation is essential in the treatment of shockable rhythms, an analysis of a national registry of inpatient arrests (NRCPR) revealed that defibrillation was delayed more than 2 min in 30% of 6,789 cases reviewed. A dose-dependent reduction in the likelihood of successful ROSC and STD follows increasing delay in defibrillation (Chan et al. *N Engl J Med*. 2008; 358[1]:9).

The 2005 AHA CPR guidelines called for the development of methods to improve the quality of CPR and the implementation of quality improvement processes, including monitoring of CPR quality. A 2007 international expert consensus panel recommended that compression depth, percent of incomplete release, compression rate, compression: relaxation ratio, hands-off no flow time, and the proportions of time with ventilation rate over 15 breaths per minute or zero ventilation be recorded, reported, and tracked (Kramer-Johansen et al. *Resuscitation*. 2007;74[3]:406). The use of newer defibrillators with recording and reporting capability makes collection of these data more feasible.

Cardiocerebral Resuscitation

In consideration of several physiologic principles discussed above, a group in Arizona, led by Gordon Ewy, proposed replacing rescue breathing with continuous oxygen insufflation and continuous compressions. With the addition of postresuscitation hypothermia and aggressive coronary revascularization of survivors, the Arizona system, Cardio Cerebral Resuscitation (CCR) (Ewy and Kern. *J Am Coll Cardiol*. 2009;53[2]:149), produced substantial improvements in survival in several OHCA studies (Kellum et al. *Am J Med*. 2006;119[4]:335).

The early success of the CCR approach prompted the AHA to endorse the 2010 CPR guidelines compression-only resuscitation for OHCA for rescuers without "confident" ACLS skills while continuing to advocate 30:2 rescue breathing by trained rescuers. CCR has been validated only for OHCA ventricular tachycardia/fibrillation (VT/VF) events and has not been studied for nonshockable OHCA rhythms or IHCA events. CCR is not intended for primary respiratory or asphyxic arrests where substantial depletion of body oxygen stores occurs. Continuous compression may potentially increase rescuer fatigue, with deterioration in the quality of compressions.

Mechanical Devices

Cardiac filling occurs during the decompression phase of a CPR cycle. Passive reexpansion of the chest wall generates negative pleural pressure and enhances venous return. This advantage is lost during positive pressure rescue breathing. Addition of an impedance valve into a bag-mask ventilation circuit can block inspiratory airflow during decompression and allow passive chest wall relaxation to generate negative pleural pressure and enhance cardiac filling (Pirracchio et al. *Curr Opin Crit Care*. 2007;13[3]:280). Reviewers for the International Liaison Committee on Resuscitation (ILCOR) described the impedance threshold device (ITD) as "fairly effective," and the AHA gave its adjunctive use a Class IIb recommendation for trained personnel in the newly released CPR guidelines.

Another recent study carried out with mannequins and an audiovisual feedback–capable defibrillator demonstrated rescuer fatigue, manifested by a decrease in compression depth without loss of compression rate, after 90 sec or longer of metronome-guided compressions. It is not clear whether hands-off time associated with a more frequent change of rescuers would offset any advantage gained in compression quality (Sugerman et al. *Resuscitation*. 2009; 80[9]:981). To address problems with rescuer fatigue and inadequate rate and depth of compressions, automated battery-powered compression and compression-decompression devices have been tested. These devices have been associated with improved secondary outcomes (end-tidal CO_2, myocardial blood flow, blood pressure, and coronary and carotid perfusion pressures), but neither device introduced in the last 5 years has produced better survival outcomes, possibly due to the hands-off time required for initial deployment (Perkins et al. *Curr Opin Crit Care*. 2010;16[3]:203). Their routine use was not endorsed in the 2010 AHA guidelines, but they may be considered (Class IIb) by qualified personnel when there are difficulties with manual compression.

The presence of a hard surface (eg, a backboard) has improved the effectiveness of compressions; conversely, the lack of a hard surface has caused recording defibrillators to overestimate the depth of chest compression. Optimal compression depth has been linked to the bed being at the height of the rescuer's knee (Cho et al. *Emerg Med J*. 2009;26[11]:807).

Improving CPR Education

Deficiencies in rescuer performance may indicate a need for improvement in the education and maintenance of resuscitation skills. Knowledge gained from traditional advanced cardiopulmonary life support/basic life support (ACLS/BLS) training deteriorates rapidly. ACLS graduates have been found to perform only 31% of appropriate interventions in real arrest events; skills retention in ACLS-trained nurses may be as low as 30% only 3 months after training.

Frequent refreshers have been demonstrated to improve resuscitation skills retention. Simulation-based ACLS training has resulted in better initial performance than has instructor-only training. Real-time audiovisual feedback from smart defibrillators may improve training effectiveness but may be ignored during the stress of a real arrest event (Seethala et al. *Curr Opin Crit Care*. 2010; 16[3]:196). The use of a weekly, structured debriefing of house staff with a morbidity/mortality format resulted in improvement in CPR quality and a 33% improvement in ROSC but no improvement in STD (Edelson et al. *Arch Intern Med*. 2008;168[10]:1063). An abstract from a group in San Diego reported improved survival outcomes with a resuscitation bundle (simulation-based training, a rapid response team, adherence to the principles of CCR, and feedback defibrillators) (Sell et al. *Circulation*. 2009;120:S1441). In the new 2010 guidelines, the AHA gave Class I recommendations to competency-based assessment in CPR courses, skills retesting within the 2-year certification cycle, the use of videos for consistent training, and emphasis on teamwork and leadership skills, as well as debriefing.

Continued on following page

Dr Marilyn G. Foreman, FCCP
Editor, *Pulmonary Perspectives*

Dr Loren J. Harris, FCCP
Deputy Editor, *Pulmonary Perspectives*

Editor's Insight

This article concludes Dr Honig's apt review of recent advances in CPR, but it does not suffice as a comparison of the 2005 and 2010 guidelines. Please access the 2010 American Heart Association Guidelines for CPR and ECC to review current key recommendations, such as the new sequence for institution of basic life support, a recommended compression depth of 2 inches, a compression rate of at least 100 beats per minute, and compression-only CPR for untrained rescuers, among others (Field, et al. Part 1: Executive summary: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation* 2010;122[183]:S640 or www.Heart.org/CPR).

–Dr Marilyn G. Foreman, FCCP

Continued from previous page

Postarrest Care

The post–cardiac arrest state is associated with 60% to 65% mortality for both OHCA and in-hospital events. Nolan and colleagues (Nolan et al. *Resuscitation*. 2008;79[3]:350) described these clinical problems as the post–cardiac arrest syndrome (PCAS), consisting of anoxic and ischemic brain injury, cardiac dysfunction, and systemic ischemia-reperfusion injury complicated by persistence of the underlying cause of the arrest.

CARDIAC ARREST REMAINS A COMMON AND GENERALLY DEADLY PROBLEM, 50 YEARS AFTER KOUWENHOVEN.

Brain injury is associated with "neuroexcitotoxicity," calcium dysregulation, free radical production, protease cascades, cell death and apoptosis, impaired microperfusion and macroperfusion, and dysautoregulation. Cardiac dysfunction (tachycardia, hypotension, elevated left-sided filling pressures, and decreased cardiac output) is seen in 50% of patients with PCAS. Hypotension, in particular, carries a twofold risk of death.

The cytokine profile associated with ischemia-reperfusion injury in PCAS is similar to that seen in sepsis and has led to suggestions that PCAS may be managed according to similar principles. Mild hypothermia after cardiac arrest (HACA) has been shown to improve survival and neurologic outcomes in select patients with OHCA VT/VF arrests, though the original 2002 reports restricted HACA to only 8% of events (Hypothermia After Cardiac Arrest Study Group. *N Engl J Med*. 2002;346[8]:549).

In the 2010 CPR guidelines, the AHA continues to recommend (Class I) that induced hypothermia be employed for all patients still comatose after ROSC for VT/VF OHCA and considered (Class IIb) for all comatose arrest patients resuscitated from any IHCA and from nonshockable OHCA events.

There is a paucity of clinical data to absolutely support extension of HACA to these other groups, and the potential complications of hypothermia (shivering, bradycardia, electrolyte abnormalities, hyperglycemia, increased infection, and decreased drug clearance) need to be considered (Arrich et al. *Cochrane Database Syst Revs*. 2009; 4:CD004128).

Some groups have integrated HACA and the principles of early goal-directed therapy for sepsis to set protocols for care of patients with PCAS. In addition to HACA, cardiac dysfunction is managed by maintaining a central venous pressure at 8 to 12 mm Hg, a mean arterial pressure of 65 to 100 mm Hg, using dobutamine drip and intra-aortic balloon pump, if necessary. Urine output and lactate levels are reported as being more useful than central venous oxygen saturation.

Hemoglobin value is maintained at 9 to 10 mg/dL. Patients are ventilated to normocapnia. Hyperoxia is avoided; oxygen saturation is kept at 94% to 96%.

Hypoglycemia is considered far more dangerous than hyperglycemia; blood sugars are maintained between 100 and 180 mg/dL.

Electrolytes are normalized as much as possible. No randomized trials are currently available to confirm the utility of PCAS protocols, but two small trials with historical controls demonstrated a doubling of survival for OHCA patients, irrespective of initial rhythm (Sunde et al. *Resuscitation*. 2007;73[1]:29; Gaieski et al. *Resuscitation*. 2009; 80[4]:418).

An organized multisystem approach to the management of PCAS is endorsed and discussed in detail in one of the more important new sections of the 2010 AHA CPR guidelines.

Conclusion

Cardiac arrest remains a common and generally deadly problem, 50 years after Kouwenhoven. We have made progress in our ability to restart stopped hearts, but we can do better.

Improved training, frequent refresher training, feedback, and debriefing should lead to better resuscitation performance and, hopefully, to better outcomes.

Systematic analysis of the quality of our CPR performance should help distinguish the elements of the ACLS and BLS protocols that are truly important. Advances in the systematization of care provided to the post–cardiac arrest patient have the potential to yield greater improvements in our desired end point, which is neurologically intact survival to discharge.

Some of these elements have now been introduced in the 2010 revision of the international CPR guidelines, but the results of systematic quality monitoring and care guided by protocols are not likely to be seen before the 2015 guideline cycle. ■

Dr Eric G. Honig, FCCP
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The CHEST Foundation's new initiative, OneBreath, was announced by Robert G. Johnson, MD, FCCP, Immediate Past Chair of The CHEST Foundation, at the 12th annual Making a Difference Awards Ceremony and Presentation in Vancouver, BC, Canada.

OneBreath is a new public education initiative of The CHEST Foundation. OneBreath integrates the work of The Foundation with the education mission of the ACCP under a common theme by drawing from the professional expertise of ACCP members.

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PAUL A. MARKOWSKI, CAE

FROM THE CEO

Notes From CHEST 2010

As I walked from my hotel to the award-winning Vancouver Convention Centre, the old but true real estate adage of "location, location, location" came to mind. By its sheer setting – along the waterfront, surrounded by mountains, and in the heart of beautiful downtown Vancouver, British Columbia – CHEST 2010 was a success even before the first CME credit was claimed.

Amidst this idyllic backdrop, close to 5,000 attendees descended on CHEST 2010, with the largest number of international attendees (30%) in the history of the meeting. CHEST 2010 was noteworthy in other significant ways. We moved toward "paperless" CHEST meetings by making use of electronic communication tools. The ACCP offered 24/7 access to the most current and late-breaking meeting information and, in so doing, saved considerable printing and paper costs.

New at CHEST 2010, we offered robust online meeting planning tools to allow attendees to search sessions, build a daily itinerary, select session handouts, and download material to various electronic platforms. Other new features at CHEST 2010 included an earlier meeting start day, postgraduate multipass courses, and clinical care–focused tracks. In addition, The CHEST Foundation announced its new OneBreath campaign, and initiatives of the newly formed COPD Alliance were highlighted.

We used social media to help promote CHEST 2010 and generate attendance. A new tool, eventSocial, allowed attendees to check if contacts from their social networks or e-mail accounts were attending the meeting. If not, they could easily use eventSocial to invite colleagues. Overflow rooms were available this year, offering live broadcasts of sessions that were expected to fill to seating capacity. These overflow rooms turned out to be almost as popular as the sessions themselves and were well used.

The ACCP also welcomed worldwide media coverage surrounding the scientific abstracts presented at CHEST 2010. Abstracts generating the most interest were related to a variety of consumer-focused topics, including the link between teens, texting, and sleep disorders; and bronchial thermoplasty as a new treatment for asthma. These abstracts and many others resulted in hundreds of print, broadcast, and online stories around the world.

While we are in the process of analyzing the rich data that we collected from the meeting, several high-level themes emerged from the focus groups that we conducted. For example, many of the research participants who attended CHEST 2010 said that they consider the meeting to be a can't-miss event because the education is more clinically focused than that at other meetings. The enhancements at CHEST 2010 – many of which originated from feedback that we received from members like you – combined with the spectacular physical setting, resulted in what I have been referring to as "an aura of happiness," an energized meeting and superlative attendee experience.

One of the more gratifying moments for me occurred after the meeting on my return flight from Vancouver. A passenger who attended CHEST 2010 animatedly described the meeting to a fellow passenger. In particular, the keynote address, *Percussing the Chest in the Era of Homo Technologicus,* by the best-selling author, Abraham Verghese, MD, moved this attendee. Dr Verghese provided thoughtful insight into taking the history and physical exam of the patient and asserted the importance of this ritual in the era of the "iPatient."

The attendee compared the keynote to his participation in the ACCP Simulation Center, where he gained experience in health-care systems that provide tele-ICU services. Tele-ICU is a growing part of critical care practice, with 10% of adult patients receiving critical care services in the United States now supported by off-site providers. These two very different, yet valuable, experiences struck this attendee and speak to the tremendous breadth of high-quality clinical education that CHEST offers.

I welcome your comments and suggestions for CHEST 2011. Plans are well underway for this meeting that will be held October 22-27, 2011, in Honolulu, Hawaii, which will feature opportunities for the local community to present best practices in "Centers of Excellence," and for attendees to learn about the public policies affecting practice, experience additional CME on neighboring islands, and much, much more.

Missed CHEST 2010? Abstracts of original investigations and case reports presented at CHEST 2010 are now available online at http://chestjournal.chestpubs.org.

On behalf of the ACCP, aloha, and best wishes for a happy and healthy New Year! ■

MR MARKOWSKI *is Executive Vice President and Chief Executive Officer of the American College of Chest Physicians.*

PRACTICE MANAGEMENT RESOURCES

Strong Presence at CHEST 2010

BY DIANE KRIER-MORROW, MBA, MPH, CCS-P; AND MARLA BRICHTA

The ACCP Practice Management Department has provided two unique educational opportunities for attendees for the past 5 years at the annual CHEST meeting.

One-on-One Practice Management Consultations

Diane Krier-Morrow, MBA, MPH, CCS-P, the ACCP's coding and reimbursement consultant, met with 31 attendees to discuss practice management, coding, and/or billing issues pertinent to their specific practices. Diane saw physicians, practice managers/administrators, nurse practitioners, physician assistants, RRTs, RNs, and industry representatives. All participants expressed their appreciation at being given the opportunity to speak with our consultant on the issues of interest to their particular practices.

The consultations were as varied as the types of practice situations that exist. Topic samples of the discussions included the following:

- A practice was opening a four-bed sleep lab and discussed durable medical equipment (DME) payment for non-Medicare third-party payers.
- A nurse practitioner in a pediatric pulmonary practice discussed nonphysician provider billing for endoscopic evaluation of swallowing.
- An attendee wanted to discuss documentation by physician extenders in the ICU and in the inpatient units.
- An attendee wanted to talk about implementing PQRI (now termed PQRS) into the practice. This person returned the next day to discuss selection of specific codes to report for PQRS.
- Two different attendees came to discuss when it is appropriate to report critical care services codes. One of these attendees was concerned about underreporting critical care services (reporting only about 20%), and one was checking to make sure he was not overreporting critical care services (reporting about 80%).
- Three individuals working in the same state (an NP, an RRT, and an administrator new to the practice) met with Diane sequentially to discuss PQRS. Diane encouraged these attendees to keep in touch and continue the dialogue that began at CHEST on PQRS.
- A new solo practitioner brought sample E/M documentation to discuss. Scott Manaker, MD, FCCP, joined this discussion and enhanced the information provided to the attendee.
- An attendee wanted to talk about problems with Medicaid and had not realized that CPR **92950** could be reported (if documented appropriately), in addition to critical care reporting, CPT codes **99291** and **99292**.
- Two industry representatives discussed their devices and how to proceed with development of CPT codes.

Practice Management Roundtable Discussions

Informal discussions led by members of the Practice Management Committee and the Practice Operations NetWork took place on Tuesday and Wednesday in the Lung Health Lounge during the lunch hour. Topics included:

- **Coding and Reimbursement Issues:** Facilitated by Alan Plummer, MD, FCCP; and Diane Krier-Morrow, MBA, MPH, CCS-P
- **Using Nonphysician Providers in Your Practice:** Facilitated by Joseph Austin, MD, FCCP; Michael McCormick, RRT; Irby Williams, MBA; and Tom Syverson, CMPE
- **Electronic Health Records:** Facilitated by Kim French, MHSA

Attendees at CHEST 2010 had many diverse practice management issues they were able to address in the forums provided by the ACCP Practice Management Department. Throughout the various meetings, attendees were encouraged to purchase the 2011 edition of *Coding for Chest Medicine*. Ms Krier-Morrow, in particular, emphasized that *Coding for Chest Medicine 2011: Pulmonary, Critical Care, Sleep* addresses almost every type of inquiry she had during her one-on-one consultations and at the roundtable discussions. This publication is an invaluable practice management resource tool that is a "must have" in every pulmonary, critical care, and sleep medicine practice in the United States. It should be noted that in addition to *Coding for Chest Medicine 2011,* the ACCP is selling the AMA's professional edition of *CPT® 2011*. Order both resources today at https://accp.chestnet.org/storeWA/StoreAction.do?method=view&pcrNum=23.

Take advantage of one-on-one consultations and practice management roundtables at CHEST 2011 next October in Hawaii. ■

Pages 16a—16b

Breathe Strong

BY SANA RAOOF

In the 2009-2010 academic year, I had the pleasure of lecturing on the benefits of regular cardiovascular exercise, especially running, and the dangerous bodily effects of smoking cigarettes.

In the New York Jericho School District (where I grew up), health and social workers, as well as every middle and high school health teacher, worked with me to coordinate 2 weeks (1 in the winter and 1 in the spring) during which I could teach the health classes about the theme of "breathing strong."

SANA RAOOF

After 35 classes, I was overwhelmed by positive feedback and sincere responses from students across the spectrum—grades 7 through 12, all demographics, athletic and unathletic, and smokers and nonsmokers included. I would like to discuss some of the smoking-related components of my presentation.

Having graduated from high school only 2 years ago, I remember the classic smoking education in health class quite clearly, as well as the degree of detachment and desensitization that my classmates and I felt with regards to the health warnings.

In response to this phenomenon, my presentation intentionally represented a stark departure from traditional health lectures. Every minute or so, I kept attention and enthusiasm alive by asking students questions, for example: (1) What are some ingredients in cigarettes? (2) Who can trace the pathway from breathing smoke all the way to nicotine getting to your brain? (3) Which sports do you play? How would your performance in that sport be changed if tar clogged your bronchioles? My questions were meant to make the students imagine their private lives with smoking added in—which uniformly led to sincere responses and personal stories.

By challenging the students themselves to construct the physiologic pathways by which tar clogs bronchioles and nicotine stimulates the brain, I allowed the students to use the biology they already knew to extrapolate the effects of cigarettes on their own bodies.

I believe this approach created a deeper level of understanding among the kids, which is critical to their actual belief that cigarettes will definitely cause them serious bodily harm.

After establishing a personal connection to the students' hypothetical lives as smokers, including their prospects for sports teams, friends, expenditures, and lifestyles, I moved to graphic case studies of smokers dying of various diseases and had students read a long list of all the diseases that smoking can cause.

One image that evoked startling reactions was that of a 32-year-old man, looking muscular and healthy in one photo with his toddler son, oblivious to his lung cancer, and a photo of him 2 months later, lying like a skeleton on a hospital bed, supported by a respirator and his son by his side.

By prompting the students repeatedly to apply concepts we had discussed to different scenarios such as this one, I am confident that the message became quite real and personal to them.

I segued into the running component of my presentation by juxtaposing an image of a 16-year-old female runner and a 16-year-old, unathletic female smoker. I asked which girl was likely to have more friends. Although the kids uniformly chose the runner, I explained that both girls at the same age are statistically likely to have similar numbers of friends, but the runner's friends are likely to be nonsmokers and to look like her (fit and athletic), whereas the smoker's friends are probably smokers and unathletic, as well.

The message was diplomatic enough to be received well by both the fit and the unfit, and the smokers and the nonsmokers in the room.

I am fortunate to be continuing the program throughout the Jericho School District again this year and am incredibly eager to deliver it in other districts, states, and regions. If readers envision this program being given in their local schools, please contact me at sraoof@fas.harvard.edu, and I will be excited to come to your district. ■

SANA RAOOF is a 20-year-old junior at Harvard University, studying chemistry and physics. She participates in debate and track at Harvard, both of which influenced her in her efforts to persuade kids to run and not to smoke.

PCCSU Lessons For December

PCCSU
PULMONARY, CRITICAL CARE, SLEEP UPDATE

▶ **Management of Alcohol, Sedative-Hypnotic, and Opioid Withdrawal in the ICU.** *By Dr Harman S. Paintal; and Dr Geoffrey K. Lighthall, PhD*

▶ **Home Sleep Apnea Testing.** *By Dr W. McDowell Anderson, FCCP; and Dr Christopher P. Karcher*

www.chestnet.org/accp/pcsu

This Month in *CHEST*: Editor's Picks

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

▶ **Are Airflow Obstruction and Radiographic Evidence of Emphysema Risk Factors for Lung Cancer? A Nested Case-Control Study Using Quantitative Emphysema Analysis.** *By Dr F. Maldonado et al.*

▶ **Diagnostic Yield of Electromagnetic Navigation Bronchoscopy Is Highly Dependent on the Presence of a Bronchus Sign on CT Imaging: Results From a Prospective Study.** *By Dr L. M. Seijo et al.*

TRANSPARENCY IN HEALTH CARE

▶ **The Value of Adding a Verbal Report to Written Handoffs on Early Readmission Following Prolonged Respiratory Failure.** *By Dr D. R. Hess et al.*

RECENT ADVANCES IN CHEST MEDICINE

▶ **Recent Advances in Testing for Latent TB.** *By Dr N. W. Schluger and Dr J. Burzynski.*

www.chestpubs.org

Introducing The COPD Alliance

BY BRIAN W. CARLIN, MD, FCCP
Chair, COPD Alliance

The American College of Chest Physicians and four other international medical societies have announced their formal partnership in the fight against chronic obstructive pulmonary disease. The COPD Alliance, composed of the ACCP, the American Academy of Nurse Practitioners, the American Academy of Physician Assistants, the American College of Osteopathic Family Physicians, and the American College of Osteopathic Internists, represents 200,000 primary care and specialty clinicians and proposes to use a focused awareness and education campaign to bring about significant change in the recognition, diagnosis, and treatment of patients suffering from COPD.

Although COPD awareness programs are not new, the COPD Alliance is taking a unique approach to COPD education by targeting primary care clinicians. This is significant because it is estimated that 24 million Americans may have COPD, with only 50% having been diagnosed.

In 2010, the total economic cost of COPD is expected to be $49.9 billion. This figure includes $29.5 billion in direct health-care expenditures and $20.4 billion in indirect costs.

The burden of the morbidity and mortality associated with COPD has a significant negative impact on the quality of life of the patients and their families and society as a whole.

The Alliance will be using its pooled resources to engage a broad range of primary care clinicians to step forward in the fight against COPD. Primary care clinicians will be asked to integrate the routine use of validated screening measures for patients at risk for the development of COPD, to use spirometry to confirm the diagnosis, and to manage these patients with the best available evidence-based therapy.

To keep COPD information at clinicians' fingertips, the COPD Alliance has launched www.COPD.org, a central, Web-based repository of new and existing COPD tools readily available and accessible for free. COPD.org will serve as an electronic tool kit supporting the efforts of health-care providers, as well as patients and caregivers. A variety of outreach and promotional strategies will be used to access members of the partner organizations.

In 2011, each organization will be developing and delivering educational strategies for its members. These strategies will be tailored to that organization's particular membership. In addition, clinicians-in-training will be targeted through these educational strategies, for few training programs currently offer any comprehensive training in COPD management for residents or fellows.

The goal of these efforts is to improve clinician acumen in the early recognition and appropriate diagnosis of COPD, as well as to develop strategies to more effectively treat patients who have this chronic illness.

Currently available tools, such as the COPD Population Screener, the Tobacco Dependence Treatment Toolkit, the GOLD recommendations for the diagnosis and treatment of COPD, and case-based COPD video vignettes will be used as part of the Alliance's strategy.

The COPD Alliance was officially launched at the American Osteopathic Association annual meeting in October and at CHEST 2010. Further launches are planned for the AANP, AAPA, and ACOI meetings early next year. ■

CMS Rules Changing in 2011

Penalty • *from page 1*

multiple encounters for a single patient) and that Medicare account for at least 10% of the provider's payer mix.

"I think that's probably not a problem for most pulmonary/critical care physicians, that at least 10% of your patients [have] Medicare," he commented.

The bonus returned to providers for 2010 is 2% of the total Medicare Part B Physician Fee Schedule allowed charges for services for the entire year; it will be 1% in 2011 and 2012, but only 0.5% in 2013.

The e-prescribing system used must meet certain criteria – for example, it must generate complete lists of all medications a patient is taking; provide information related to any lower-cost, therapeutically appropriate drugs; and, most notably, transmit prescriptions to pharmacies electronically.

Faxing of the prescription does not count, even if a computer system autogenerates the fax, Mr. McCormick cautioned. The prescription "must basically go from your computer to the pharmacy's computer, not through a fax," he specified.

To obtain the bonus, providers can report their use of e-prescribing in any of three ways. "Probably the easiest way to get started is the claims-based reporting," he said, which entails simply adding the G8553 code to the other codes.

Alternately, providers can use registry-based reporting or electronic health record (EHR)–based reporting.

The list of patient encounters considered eligible for e-prescribing is "pretty comprehensive," including all outpatient office visits (those having 992xx codes), home health visits, nursing home visits, and psychiatric care visits, he said. However, inpatient visits are not eligible.

A noteworthy caveat is that providers will not be able to earn both the e-prescribing bonus and another bonus for implementing the EHRs that the CMS is offering, because e-prescribing is among the 15 core measures of EHR implementation.

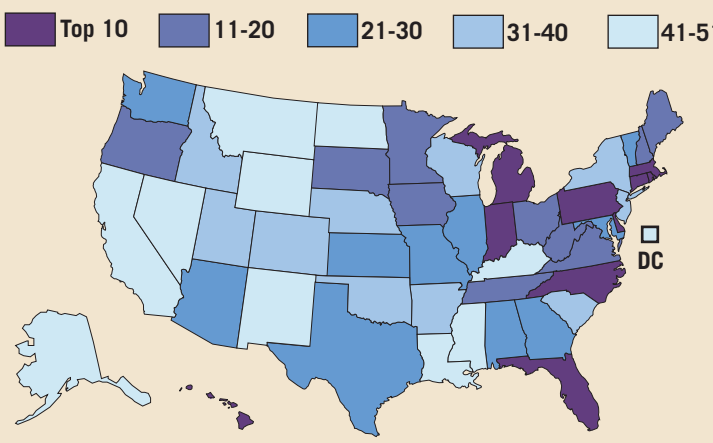
Put another way, "there is no double-dipping, starting in 2011," Mr. McCormick said. "So if you are going to go for that [EHR] bonus, which is a lot more money – $44,000 per provider paid over 5 years – you can't put in for the eRx bonus as well."

Certain providers will be exempt from the penalty, he added: those who generate fewer than 100 claims with eligible eRx patient codes, those for whom less than 10% of patient encounters are eligible (e.g., hospital-based physicians), and those facing relevant hardships, namely, practicing in a rural area with limited high-speed Internet service or a limited number of pharmacies able to receive prescriptions electronically.

The program's rules, which change annually, can be found online (www.cms.gov/erxIncentive). ■

DATA WATCH

Massachusetts Ranked First in E-Prescribing in 2009



Note: Rankings based on an equal-weight analysis of prescription benefit, medication history, and prescription routing transactions within each state.
Source: Surescripts

Elsevier Global Medical News

Antitrust Measures Not Aimed at Collaborative Care

BY SUSAN BIRK

Elsevier Global Medical News

CHICAGO – Contrary to common perception, "the nation's antitrust laws allow – even encourage – doctors to collaborate in ways that lower costs and improve patient care," said Jon Leibowitz, chairman of the Federal Trade Commission, at the annual meeting of the American Medical Association House of Delegates.

If doctors join forces to fix prices, the FTC will stop them, but if they work together to deliver affordable, high-quality care, "not only will we leave you alone, we'll applaud you. And we'll do everything we can to help you put together a plan that avoids antitrust pitfalls," Mr. Leibowitz said in a speech that sought to dispel any stereotype that physicians might have of the commission as being run by "fastidious bureaucrats" and "surreptitious socialists" determined to keep doctors from charging fair prices.

"Too often, I believe, our antitrust enforcement actions are portrayed as a barrier to improved care," he said.

The relationship between organized medicine and the FTC has become strained recently by physician opposition to the "Red Flags Rule" that requires small businesses, including medical practices, to develop policies to detect and prevent identity theft.

The American Medical Association, the American Osteopathic Association, and the Medical Society of the District of Columbia filed suit against the FTC in May to block it from enforcing the rule against physicians. The "bureaucratic burden" imposed by the rule "outweighs any benefit to the public," Cecil B. Wilson, then AMA president-elect, said in a statement.

Mr. Leibowitz said the commission agrees with physicians that the rule is overreaching, and has urged Congress to provide a legislative fix for the issue as soon as possible.

Mr. Leibowitz cited several areas for potential cooperation between physicians and the FTC, all stemming from the Affordable Care Act. The use of health information technology to improve work flow and monitor populations and individuals; clinical integration; and accountable care organizations (ACO) are among the areas that hold potential for collaboration to improve quality and lower health care costs, he said.

Although they are not "a free pass to fix prices," he said that health information technology systems "can be an important tool" to make patient care more effective and affordable. The FTC recently issued three favorable advisory opinions on HIT use by health care providers.

In the area of clinical integration, the FTC provides guidance to providers in the form of advisory opinions regarding joint ventures. The FTC will analyze a proposal and, where feasible, provide an opinion on whether it would recommend an enforcement action if the proposal were implemented, he said.

With regard to ACOs (integrated health systems that will be responsible for providing care to defined populations), "there is already talk of their moving into the private sector," and "we want to work with you moving forward" to avoid competition issues, he said. "As long as the government purchases the services and unilaterally sets payment levels and terms, there won't be an antitrust issue." ■

Loss of Consult Codes Reducing Medicare Access

BY MARY ELLEN SCHNEIDER
Elsevier Global Medical News

Medicare's decision to eliminate consultation codes has resulted in a loss of revenue for many physicians and forced some to cut back on appointments with Medicare beneficiaries, according to a survey commissioned by the American Medical Association and several other medical specialty societies.

In January, officials at the Centers for Medicare and Medicaid Services discontinued the use of inpatient and outpatient consultation codes when billing Medicare, except for telehealth codes. Physicians instead were asked to use new or established office visit codes, initial hospital care codes, or initial nursing facility care codes. At the time of the policy change, CMS officials said they could no longer justify paying physicians more for a consultation when they had reduced so much of the documentation required to bill for these consultations. The agency also said that eliminating consultation codes would reduce the confusion around the definitions of consultations, transfers, and referrals.

However, many specialists believe that the approach is flawed and is hurting both their financial bottom line and patient access to care.

In an online survey of about 5,500 physicians, 72% said that not being able to bill for consultations had decreased their total revenues by more than 5%, with about 30% reporting their revenues had fallen more than 15%.

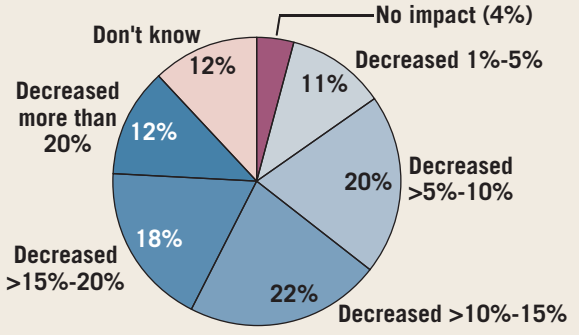
The loss of revenue has in turn had an impact on physicians' practices. For example, 20% of respondents said they have already reduced the number of new Medicare patients seen in their practices. Additionally, 39% said they will hold off on purchasing new equipment or health information technology.

The policy change may also undermine efforts to improve patient care coordination. About 6% of responding physicians said they have stopped providing primary care physicians with written reports following consults with Medicare patients, and another 19% said they plan to do so.

In a letter to the CMS, officials from more than 30 medical specialty societies, including the American College of Physicians, the American College of Gastroenterology, the American Geriatrics Society, and the Society of Thoracic Surgeons, urged the agency to revise the policy when they issue a final regulation on the 2011 Medicare Physician Fee Schedule this fall. The organizations suggested that the CMS consider paying consulting physicians for providing the referring physician with a comprehensive report.

They also said the CMS could ease some of the financial pressure on physicians by revising its guidelines for prolonged visits to allow for reimbursement for services provided outside of the face-to-face visit, such as reviewing charts and communicating with families and other health care providers. ■

How Has the Elimination of Consult Codes Affected Your Practice's Revenue Stream?



Notes: Based on about 5,500 completed reponses to a survey conducted April 12-30, 2010; 0% of physicians selected a response involving increased revenue. Figures have been rounded.
Source: AMA

ELSEVIER GLOBAL MEDICAL NEWS

COMMENTARY

Dr. Philip Marcus, FCCP, comments: The wholesale elimination of reimbursement for consultations has hurt many physicians who provide no procedural services but spend a significant amount of time with a complex patient. The reactions expressed in the survey, viz., limiting Medicare patients and eliminating reports, will likely increase. Also, it is likely that other insurers will follow Medicare's lead. Unless this situation is remedied, the entire scope of consultations as we knew it will change forever.

New Assay Stratifies Risk in Pulmonary Embolism

The highly sensitive TnT assay identifies patients who warrant closer long-term follow-up.

BY BRUCE JANCIN
Elsevier Global Medical News

STOCKHOLM – New-generation, highly sensitive troponin T assays provide added value in the form of improved early risk stratification of normotensive patients with acute pulmonary embolism, according to a prospective head-to-head study.

"I think the most important finding of this study is that with this new highly sensitive troponin T assay, we could safely identify those patients who have a low 30-day risk of adverse events, with a sensitivity of 100% and also a negative predictive value of 100%," Dr. Mareike Lankeit said at the annual congress of the European Society of Cardiology.

In contrast, the conventional troponin T assay had a negative predictive value of only 50%. It would have missed half of the patients who experienced an adverse event (defined as death, endotracheal intubation, need for catecholamines, or cardiopulmonary resuscitation).

Moreover, of the three biomarkers studied, including N-terminal prohormone brain natriuretic peptide, only baseline highly sensitive troponin T (hsTnT) was a significant predictor of mortality risk during long-term prospective follow-up of nearly 3 years, added Dr. Lankeit of Georg-August University Göttingen (Germany).

Recent guidelines emphasize the need for early risk stratification of patients with acute pulmonary embolism. Consensus exists that patients who present with refractory hypotension or shock are at very high risk of early mortality and should undergo urgent recanalization.

Strategies for non–high-risk patients (that is, those who are normotensive on admission) remain controversial. Dr. Lankeit's hypothesis was that the use of more-sensitive laboratory biomarkers in the emergency department would result in improved prognostic assessment of these normotensive patients with acute pulmonary embolism. Patients who were identified in this way as low risk might be possible candidates for home treatment.

She presented a prospective study of 156 consecutive normotensive patients with confirmed acute pulmonary embolism in which she compared the prognostic value of baseline hsTnT, conventional TnT, and NT-proBNP testing.

An hsTnT cutoff value of 14 pg/mL, which 64% of the patients met or exceeded, had a 100% prognostic sensitivity and negative predictive value for 30-day adverse outcomes.

The NT-proBNP assay performed equally well, but the conventional TnT assay, using the cutoff value of 0.03 ng/mL, would have misclassified 50% of patients with an adverse early outcome as being at low risk.

An elevated baseline hsTnT alone was associated with a twofold increased risk of adverse 30-day outcomes. An elevated NT-proBNP was associated with a 2.3-fold risk. But when an hsTnT of at least 14 pg/mL was associated with evidence of right ventricular dysfunction on echocardiography, the 30-day adverse outcome risk was increased to 11.9-fold.

The prognostic power of echocardiographic evidence of right ventricular dysfunction plus an NT-proBNP of at least 1,000 pg/mL was even more impressive, with an associated 17.8-fold increased risk of an adverse 30-day outcome.

In contrast, the conventional TnT assay didn't provide additive prognostic information when it was combined with evidence of right ventricular dysfunction.

During a median follow-up of almost 3 years, 14.4% of the patients died. The only baseline variables that were significantly associated with increased long-term mortality risk were an elevated hsTnT, malignancy, and heart failure. Thus, a baseline hsTnT of 14 pg/mL or greater identifies a subgroup of patients with acute pulmonary embolism who warrant closer long-term follow-up, according to Dr. Lankeit.

She said that in her hospital, where hsTnT is now part of the routine diagnostic laboratory panel that is administered in the emergency department to patients presenting with acute pulmonary embolism, the hsTnT results come back within 30 minutes.

Several of Dr. Lankeit's coinvestigators have received research funding and honoraria for lectures from Roche Diagnostics, which markets the hsTnT assay. Dr. Lankeit declared that she has no financial conflicts. ■

Incidence, Risks for Thoracic Aneurysm in AAA Defined

BY RICHARD M. KIRKNER
Elsevier Global Medical News

NEW YORK – About one in four patients with abdominal aortic aneurysm may be at risk for thoracic aortic aneurysm, judging by results of a single-center retrospective study of more than 1,000 patients.

Dr. Rabih Chaer, a vascular surgeon at the University of Pittsburgh, and his colleagues found that, among 1,082 patients diagnosed with abdominal aortic aneurysm (AAA) who had chest CT at follow-up, 23.4% had some sort of thoracic aneurysm afterward.

"Despite the clinical associations that have been observed between AAAs and peripheral aneurysms and thoracic aneurysms, screening for other common aneurysms continues to be controversial," Dr. Chaer said at the annual meeting of the Eastern Vascular Society.

Therefore, they conducted the study to quantify the risk for thoracic aortic aneurysm in these patients and to identify risk factors that could provide screening parameters, he said. The researchers defined an aneurysm as a greater than 50% increase in the adjacent aorta diameter or a 3 cm or larger increase in the setting of AAA, Dr. Chaer said. Thoracic aneurysms were categorized into two subgroups: synchronous (occurring within 2 years of initial AAA diagnosis) and metachronous (occurring 2 years or more after diagnosis). About 11% of patients had the former, and 12.6% the latter, Dr. Chaer said. The average time to diagnosis was 2.3 years, he said.

In all, the researchers considered 2,196 patients diagnosed with AAA between 2000 and 2008, but only 49% (1,082) had chest CT that qualified them for further analysis, Dr. Chaer noted. The chest studies were conducted for suspected pulmonary disease in 74% of patients, for chest screening in 15%, and for miscellaneous reasons in 11%.

One predisposing factor for thoracic aneurysm was the type of AAA, Dr. Chaer explained. "Those patients who had a thoracic aneurysm component were more likely to have a suprarenal or juxtarenal aortic aneurysm, and those patients who did not have any thoracic aneurysm were more likely to have had an infrarenal aneurysm," he said. (See box.)

The median age of patients who had a thoracic aneurysm vs. those who did not was 76 years vs. 74 years, he said.

Other predictors for thoracic aortic aneurysm included African American race, family history of thoracic aneurysm, personal history of obesity hypertension, and an AAA diameter more than 5 cm on presentation, he said. Factors that conferred a protective effect were a diagnosis of diabetes mellitus, infrarenal AAA location, and – "counterintuitively" – a history of smoking.

"We propose that routine or targeted screening with chest CT at the time of aortic aneurysm diagnosis may be indicated, not only to really define the natural history of disease, but more importantly to try to prevent late aortic events," Dr. Chaer said.

But Dr. James Black, of Johns Hopkins University in Baltimore, questioned the cost effectiveness of routine screening. At his institution, chest CT would add about $3,000 per patient, he said. "If you took a chest CT at diagnosis of AAA for 100 patients, 90% of the scans would be negative for thoracic aneurysm, at a rough cost in our institution of about $300,000 a year," he said.

Cost of routine chest CT is an issue, Dr. Chaer acknowledged, although the chest CT could be done in the same scan as the abdominal CT.

"It would be nice to have a surrogate marker for thoracic aneurysm," Dr. Chaer said. "Although we found that a thoracic aneurysm was more common in patients who had a juxtarenal aneurysm, those numbers were not hard enough to confidently say that the juxtarenal component is always predictive of a surrogate marker of thoracic aneurysm development. It is something that could be the subject of future studies."

In addition, there is a need to identify risk factors. "We are trying to identify a high-risk group of patients in whom it would be more cost effective to screen," he said. "That would bring down the number significantly and therefore the cost."

Dr. Chaer noted that the heterogeneous population and the retrospective nature were limitations of the study. He reported no disclosures relevant to the presentation. ■

Demographics of Abdominal Aortic Aneurysm Patients

Demographic	AAA without thoracic aortic aneurysm (n = 829)	AAA with thoracic aortic aneurysm (n = 253)
Average age	74.1	76.3
White	92.4%	86.2%
Black	6.4%	12.6%
Female	30.5%	41.5%
Family history AAA	2.2%	5.9%
Family history TAA	0.2%	1.6%
AAA location		
Juxtarenal	2.8%	8.3%
Infrarenal	94.8%	77.1%
Suprarenal	2.4%	14.6%
Comorbidities		
Diabetes mellitus	22.1%	12.2%
Hypertension	72.3%	81.8%
COPD	36.1%	39.1%
Smoking	79.2%	72.7%
Obesity	17.4%	22.5%

Source: Dr. Chaer

Pages 20a—20b

Home Oxygen Safe for Some Bronchiolitis Patients

Only 6% of children discharged on home oxygen therapy had to be admitted at a later time.

BY SUSAN LONDON
Elsevier Global Medical News

VANCOUVER, B.C. – Selected children with bronchiolitis seen in the emergency department can be safely managed with home oxygen therapy and thereby avoid hospital admission, according to Dr. Sarah M. Halstead and her coinvestigators.

In a retrospective study of more than 5,000 pediatric cases of bronchiolitis with hypoxia seen in the emergency department (ED), only 6% of children sent home on oxygen had to be admitted to the hospital at a later time, with none having adverse outcomes or requiring intensive care or placement of an advanced airway.

COMMENTARY

Dr. Burt Lesnick, FCCP, comments: The authors of this study practice at altitude in the state of Colorado. Care should be taken in generalizing these results to other populations.

Moreover, the ED's overall rate of hospital admission for children with bronchiolitis fell by about a third from historical levels before the home oxygen protocol was used, based on results reported at the annual meeting of the Pediatric Academic Societies.

"To improve clinical care, we hope that this data, which does support the safety of a home oxygen program for patients with bronchiolitis seen in the ED, will encourage other institutions to consider similar home oxygen protocols," Dr. Halstead and her coinvestigators said in a poster.

"Increasing ED overcrowding and boarding of inpatients makes the development and analysis of this and other novel outpatient care strategies imperative," they said.

The investigators used electronic medical records to assess outcomes among children aged 1-18 months seen in the emergency department with bronchiolitis during the 2005 through 2009 bronchiolitis seasons, a period when the ED had a home oxygen protocol in place.

Children with cardiopulmonary conditions who required oxygen at baseline were excluded.

"Prior to discharge on home oxygen, we observed patients in the ED for 8 hours," explained Dr. Halstead, a pediatrician at the Children's Hospital in Aurora, Colo.

"If they had oxygen saturations of greater than 90% on half a liter or less of nasal cannula oxygen, they were able to maintain adequate hydration without frequent deep suctioning, they had no signs of respiratory deterioration, and both the caregiver and the attending were comfortable with discharge home, then a follow-up appointment was arranged and … home oxygen was supplied for the family," Dr. Halstead said.

VITALS

Major Finding: The overall rate of admission for bronchiolitis fell from about 40% before implementation of the home oxygen protocol to 28% afterward.

Data Source: A retrospective study of 5,065 cases of bronchiolitis seen in the ED of a tertiary-care children's hospital, 13% of whom were managed with home oxygen therapy.

Disclosures: No conflicts were reported.

The study results were based on data from 5,065 patients with bronchiolitis seen in the emergency department, 13% of whom were discharged on home oxygen therapy.

Within this group, only 6% had to be admitted at a later time – a value that did not differ significantly from the 4% seen among children discharged on room air.

The leading reason for admission after a discharge on home oxygen was an increased oxygen requirement (51%), followed by increased work breathing (46%), parental concern or compliance issues (24%), need for intravenous fluids (8%), and difficulties with home oxygen therapy (5%).

"There were no adverse outcomes, ICU admissions, or need for advanced airways in any of these patients," Dr. Halstead reported.

The ED's overall hospital admission rate for bronchiolitis (which captured both children initially admitted and children admitted after initially being sent home) was 28% during the 2005-2009 study period—substantially lower than the 39%-40% seen historically before implementation of the home oxygen protocol.

Because some children sent home on oxygen may have been admitted later to outside institutions, the admission rate found in the study may be an underestimate, Dr. Halstead said.

She attributed the success of the home oxygen protocol in large part to support from respiratory therapists and primary care providers.

"We have respiratory therapists available in the ED 24 hours a day, 7 days a week. They perform home oxygen teaching and arrange for oxygen to be delivered to the family," Dr. Halstead pointed out.

"We also have support from the [primary care providers] in the community who have made themselves available for follow-up within 24 hours of discharge. They are comfortable caring for their patients on home oxygen, including weaning them off oxygen in an outpatient setting," she said. ■

Severe Asthma's Economic Toll Exceeds $10 Billion

BY HEIDI SPLETE
Elsevier Global Medical News

NEW ORLEANS – Children's school absences and their parents' absences from work represented the greatest economic burden of impairment in children with severe asthma, according to data from an observational study of more than 600 children.

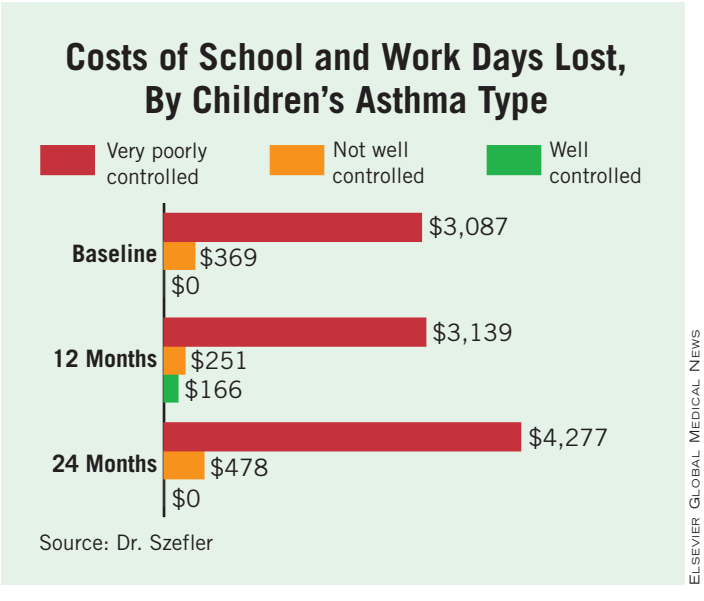
"Asthma costs in the United States have exceeded $10 billion," said Dr. Stanley J. Szefler of National Jewish Health, Denver, and his colleagues. That figure includes $4.6 billion in indirect costs, such as mortality and lost school and work days, and $6.1 billion in direct costs, such as medications and hospital stays.

Dr. Szefler and his colleagues examined whether improvements in asthma impairment in young children reduced the cost burden of asthma. The study was the first to assess the economic burden of asthma in children aged 6-12 years with severe or difficult-to-treat illness as defined by the National Heart, Lung, and Blood Institute (NHLBI) guidelines, the researchers said. The results were presented in a poster at the annual meeting of the American Academy of Allergy, Asthma, and Immunology.

The study included 628 children aged 6 years and older with severe or refractory asthma. At baseline, 386 children had very poorly controlled (VPC) asthma, 219 had not well-controlled (NWC) asthma, and 23 had well-controlled (WC) asthma. The children were a subgroup of the TENOR study, a large observational study that assessed patients with severe and difficult-to-treat asthma. Asthma impairment status was determined using the NHLBI guidelines. On the basis of the guidelines, 62% of the children were classified as VPC, the researchers noted.

The investigators compared the cumulative costs for patients who were consistently VPC at baseline, 12 months, and 24 months with the costs for patients who improved over the 24-month study period. Primary outcomes included school days lost, cost of asthma medications, unscheduled doctor visits, overnight hospital stays, and emergency department visits.

Overall, the costs of school and work days lost in the VPC group at baseline, 12 months, and 24 months were $3,087, $3,139, and $4,277, respectively. Those costs were significantly higher than for the NWC group ($369, $251, and $478, respectively) and the WC group ($0, $166, $0, respectively). The costs of school absences were measured using gender-specific dollar amounts to represent a parent's lost work day and adjusted to 2002 dollars.



Medications were the next largest contributor to cost burden. Medication costs in the VPC group at baseline ($2,117), 12 months ($2,312), and 24 months ($2,298) were significantly higher than in the NWC group ($1,949, $1,987, and $1,995, respectively) and the WC group ($1,861, $1,640, and $1,605). The costs were measured using the average recommended daily dose.

"Significant reduction in cost was observed for patients whose impairment status improved after baseline," the researchers noted. "The highest costs were associated with patients whose asthma impairment status remained consistently VPC," they wrote. Cost reductions associated with improved impairment status occurred in measures of fewer hospital overnight stays, fewer unscheduled physician visits, and fewer emergency department visits.

The likelihood of a patient changing from VPC to WC is small, but the results suggest that even an improvement from VPC to NWC could have a noticeable impact on the costs of asthma care, the researchers said.

The study was sponsored by Genentech. Dr. Szefler received funding from several organizations that are sponsored by the National Institutes of Health, as well as from several pharmaceutical companies. ■

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Over 80% of Inpatients Have High Risk of OSA

BY LEANNE SULLIVAN
Elsevier Global Medical News

VANCOUVER, B.C. – A significant number of hospitalized patients are at high risk for obstructive sleep apnea, but few have been evaluated for OSA, Dr. Sunita Kumar reported at CHEST 2010, the annual meeting of the American College of Chest Physicians.

Because OSA has been shown to increase the risk of adverse outcomes such as stroke and heart failure, screening inpatients might help prevent complications. However, Dr. Kumar noted, the diagnosis and treatment of OSA in hospitalized patients have not been previously shown to affect outcomes.

Of 195 inpatients surveyed over a 24-hour period at Loyola University Medical Center in Maywood, Ill., 157 (81%) were found to be at high risk for OSA. Of those, 41 had undergone a previous sleep study, and of the 41 patients who had been evaluated, 31 were found to have OSA, said Dr. Kumar of the division of pulmonary and critical care medicine at Loyola.

In comparison, 5% of the general population is estimated to have sleep apnea.

The patients had a mean age of 62 years, and 82% were older than 50 years. Their mean body mass index was 28 kg/m^2, with 14% having a BMI over 35. More than half (59%) were men. Of the 31 patients with a previous diagnosis of OSA, 17 were using continuous positive airway pressure (CPAP), 1 had undergone surgery, and 13 were not receiving treatment, generally because of nontolerance of CPAP.

The patients were screened using the STOP-BANG questionnaire, which has high sensitivity for detecting a high risk of sleep apnea but is not very specific, Dr. Kumar said. It has also not been validated in inpatients, which was a limitation of the study. However, the STOP-BANG (snoring, tiredness, observed apnea, high blood pressure, body mass index, age, neck circumference, and gender) questionnaire has been reported to be of high quality for predicting OSA (Can. J. Anaesth. 2010;57:423-38). When these patients were evaluated using only the STOP portion of the survey, 65% were found to be at high risk.

The few previous studies that looked at OSA in hospitalized patients found the prevalence to be as high as 77% (J. Clin. Sleep Med. 2008;4:105-10; Sleep Breath. 2008;12:229-34).

The take-home point of the recent study might be that it is safer to make a presumptive diagnosis of OSA in inpatients, commented session moderator Dr. Rochelle Goldberg, FCCP, president and chief medical officer of the American Sleep Apnea Association.

Also at the session, Dr. Dennis Auckley, FCCP, presented his study on the frequency of complications in 217 hospitalized patients divided into three groups: those with known OSA (36 patients, 17%), those determined to be at high risk using the STOP and Berlin questionnaires (106 patients, 49%), and those at low risk (75 patients, 35%) based on the questionnaires.

The patients' mean age was 50 years. Those with known OSA had a mean BMI of 44, the high-risk patients had a mean BMI of 32, and the low-risk patients had a mean BMI of 28.

Dr. Auckley of Case Western Reserve University, Cleveland, and his colleagues undertook their 4-month, prospective observational study to explore earlier findings that patients with OSA experience more adverse outcomes in the perioperative setting (Chest 2008;133:1128-34).

In their study, 38% of those with diagnosed OSA, 22% of those at high risk, and 14% of the low-risk patients experienced complications. Hypoxemia was the most frequent complication. The difference in complication rate between the known OSA patients and the low-risk patients was significant, even after researchers controlled for age, diagnosis, and comorbidities.

Patients with sleep apnea more commonly experience complications, especially hypoxemia, while hospitalized, Dr. Auckley concluded. The questionnaires have not been validated in hospitalized patients, and the patients were not monitored by oximetry, which were two limitations of the study, he noted.

Dr. Kumar reported that she had no relevant financial conflicts. Dr. Auckley disclosed receiving support from ResMed and Cephalon and equipment from Cleveland Medical Devices, but his current study received no funding. ■

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- 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

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References: 1. Solomkin JS, Mazuski JE, Bradley JS, et al. Diagnosis and management of complicated intra-abdominal infection in adults and children: guidelines by the Surgical Infection Society and the Infectious Diseases Society of America. *Clin Infect Dis*. 2010;50:133-164. **2.** May AK, Stafford RE, Bulger EM, et al. Treatment of complicated skin and soft tissue infections. *Surg Infect*. 2009;10:467-499. **3.** TYGACIL® (tigecycline) Prescribing Information, Wyeth Pharmaceuticals Inc.

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