



CHEST *Physician*

THE NEWSPAPER OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS

The 7% decline in mortality is a “welcome change” from the poor outcomes often associated with sepsis, said Dr. Mitchell M. Levy, FCCP.



LIFESPAN/ROBIN DUNN BLOSSOM

Guidelines Reduced Mortality in Sepsis

BY MICHELE G. SULLIVAN

Elsevier Global Medical News

NASHVILLE, TENN. — A sepsis management protocol that focuses on achieving specific management and resuscitation goals within 6-24 hours of initial diagnosis has reduced the sepsis death rate by 7% in participating hospitals.

The decline from an average mortality of 37% at baseline to 30% translates into a relative risk reduction of 20%, Dr. Mitchell M. Levy, FCCP, said at the annual congress of the Society of Critical Care Medicine.

Although the decrease fell short of the campaign's initial

goal, it still represents a “welcome change” from the poor outcomes often associated with sepsis, said Dr. Levy, medical director of the medical intensive care unit at Rhode Island Hospital, Providence.

“We thought we would get a 25% reduction in mortality,” he explained. “I suspect that some of our detractors will therefore say that this is a negative trial. I also suspect that most of us would say a 7% reduction in sepsis mortality would be a welcome change in clinical practice.”

The Surviving Sepsis Campaign was developed by the European Society of Intensive

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ICU Sedatives Linked to Impaired Brain Function

‘First direct interventional evidence.’

BY MICHELE G. SULLIVAN

Elsevier Global Medical News

NASHVILLE, TENN. — Cognitive outcomes are significantly better in mechanically ventilated patients who are allowed a daily trial of spontaneous awakening and breathing, a finding that has led researchers to conclude that the sedatives used to induce coma in intensive care patients may harm the brain.

“This represents the first direct interventional evidence that sedative exposure independently results in impaired brain function in ICU survivors,” Dr. James Jackson said at the annual congress of the Society of Critical Care Medicine. “Not only did patients [in the intervention group] have significantly better neuropsychological outcomes than [did] those who simply underwent a spontaneous

breathing trial with no reduction in sedation, they did not show any increase in the risk of depressive or posttraumatic stress disorder symptoms—a concern that many clinicians have about reducing sedative exposure in the ICU.”

Dr. Jackson, a neuropsychologist at Vanderbilt University, Nashville, presented a follow-up study of patients included in the Awakening and Breathing Controlled (ABC) trial, a randomized, controlled study of the effect of a spontaneous awakening and breathing protocol on ICU patients.

The trial assigned 336 mechanically ventilated patients in intensive care either to management with a daily spontaneous awakening trial after reduced sedation, followed by a spontaneous breathing trial, or to usual care plus a daily spontaneous breathing trial.

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Cash Incentives Helped Smokers Quit

BY HEIDI SPLETE

Elsevier Global Medical News

Paying people to quit smoking significantly increased smoking-cessation rates, compared with a control strategy that had no financial incentives, according to a workplace-based study of more than 800 employees.

Previous studies of workplace-based financial incentives to help people quit smoking have used small sample sizes and small payments, wrote Dr. Kevin G. Volpp of the University of Pennsylvania in Philadelphia, and colleagues.

In the study, the researchers randomized 442 adult smokers to receive information about smoking-cessation programs, whereas 436 smokers received

information about smoking-cessation programs plus a financial incentive. The participants volunteered for the study after they were identified through a survey about smoking habits. Those who used tobacco products other than cigarettes were excluded (*N. Engl. J. Med.* 2009;360:699-709).

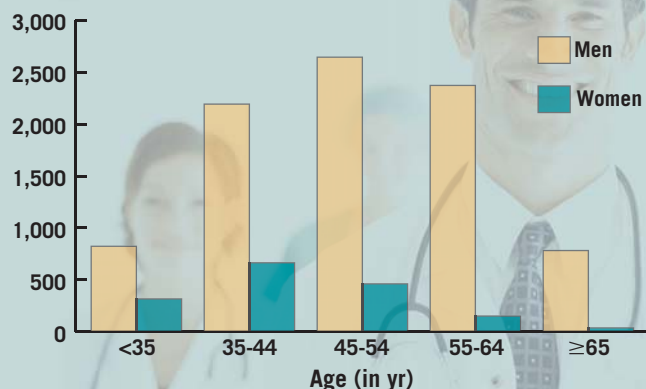
The financial incentive was \$100 to complete a smoking-

cessation program, plus \$250 for confirmed cessation of smoking at 3 or 6 months after entering the study. In addition, participants received \$400 for smoking cessation 6 months after the previous date of confirmed smoking cessation (9 months or 12 months). The participants were also assessed

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VITAL SIGNS

Men Still Outnumber Women in Pulmonology



Note: Age distribution is for 8,818 male and 1,634 female pulmonologists in the United States in 2007.

Source: American Medical Association

ELSEVIER GLOBAL MEDICAL NEWS

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Sleep Institute

American College
of Chest Physicians

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Cognitive Benefits Seen

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Those patients in the intervention group had significantly lower overall exposure both to benzodiazepines and opiates.

Patients in the intervention group spent more days breathing without assistance than did those in the control group (15 days vs. 12 days). They had a shorter ICU length of stay (9 days vs. 12 days) and a shorter hospital stay (15 days vs. 19 days). Patients in the intervention group also had significantly lower mortality (hazard ratio 0.68). For every seven patients treated with the intervention, one life was saved (Lancet 2008;371:126-34).

The study was carried out at four institutions. Dr. Jackson's 1-year follow-up study was performed on the 187 patients recruited from the St. Thomas Hospital in Nashville.

The patients' average age was 67 years. They were seriously ill, with an average APACHE II (Acute Physiology and Chronic Health Evaluation) score of 27.5. None of them had a history of frank dementia, severe stroke, or frank neurologic insult. All patients underwent a full neuropsychological battery

assessing executive function, planning, organization, memory, attention, concentration, language, and symptoms of PTSD and depression. The testing was carried out at discharge and at 3 months and 12 months.

At every time point, patients in the intervention group had significantly better cognitive scores than did patients in the control group. "This was a meaningful and persistent cognitive benefit," Dr. Jackson said.

The prevalence of PTSD and depressive symptoms was similar in both groups, he added, which spoke to the safety of reduced sedation. "We showed

that the risk of depressive and PTSD symptoms was quite high and similar for both groups at all time points, but it didn't matter which group a patient was in," Dr. Jackson explained.

While the follow-up study had no imaging data, Dr. Jackson's colleague, Dr. Wesley Ely, FCCP, of Vanderbilt University, did share some preliminary imaging findings from another group.

"We have ongoing anatomic and functional imaging studies among cohorts of patients who experience delirium in the hospital," he said. The patients go on to develop cortical atrophy and functional MRI changes that display clear evidence of abnormalities in the dorsolateral prefrontal cortex, Dr. Wesley said.

"When they try to draw on memories, the pattern of brain activity we see is very

abnormal for weeks and months after their delirium has resolved," he added. "These findings are not present in those who did not experience delirium." ■

Dr. Stephen M. Pastores, FCCP, comments: *The findings reported by Dr. Jackson underscore the strong association between prolonged sedation and impaired brain function in ICU patients supported by mechanical ventilation. The ABC trial has demonstrated that cognitive function is better when the patient is awakened early after reduced sedation and undergoes a spontaneous breathing trial. ICU clinicians should recognize that less use of sedatives in patients supported by mechanical ventilation not only reduces their time on the ventilator, but also does not increase their risk for post-traumatic stress disorder and depression.*

Secondhand Smoke May Increase Dementia Risk

BY JONATHAN GARDNER

Elsevier Global Medical News

Exposure to second-hand smoke is associated with an increased risk of dementia, according to an English population-based study.

Nonsmokers in the highest quartile of salivary cotinine content were 1.44 times as likely as those in the lowest quartile to show signs of cognitive impairment, according to the study of participants in the Health Survey for England and the English Longitudinal Study for Aging (BMJ 2009 Feb. 13 [doi:10.1136/bmj.b462]).

"Our results provide new evidence to suggest that exposure to secondhand smoke may be associated with increased odds of cognitive impairment," wrote the researchers, led by David J. Llewellyn of the department of public health and primary care at the University of Cambridge.

"Uncovering a link between passive smoking and dementia—the most severe form of cognitive impairment—could have important benefits for public

health," Dr. Mark D. Eisner, FCCP, of the University of California, San Francisco, wrote in an accompanying editorial. He is a pulmonologist and specialist in critical care medicine.

The researchers analyzed data from 4,809 nonsmokers aged 50 years and older who participated in the 1998, 1999, and 2001 waves of the Health Survey for England and also participated in the 2002 wave of the English Longitudinal Study of Aging. Study subjects provided a saliva sample to test for cotinine, a metabolite of nicotine, and also provided a detailed smoking history.

To evaluate cognitive impairment, the researchers used a variety of tests including letter cancellation tasks, time orientation, verbal memory, prospective memory, and calculations.

Researchers found that the cognitively impaired had a higher median cotinine level (0.4 ng/mL of saliva vs. 0.3 ng/mL among the cognitively normal), but also found significant differences in age—as well as ethnicity, education, occupational

class, wealth, and other confounding factors—between the impaired and the cognitively normal participants.

After adjustment for age, sex, education, and testing interval, the highest quartile was 1.68 times as likely to be cognitively impaired as the lowest quartile, the researchers found. Full adjustment for ethnicity, occupation, wealth, smoking history, obesity, alcohol consumption, physical inactivity, and depressive symptoms yielded an odds ratio of 1.44. ■

Dr. Philip Marcus, MPH, FCCP, comments: *Here is yet another reason not to smoke, or certainly to stop as soon as possible: Prevent damage to those around you. Although the study itself could not make a definite connection, there was enough of a suggestion that exposure to environmental tobacco smoke could play a role in the causation of dementia, thus making us think about the environment in which we live. There is nothing redeeming about cigarettes, whether for the person smoking them or for those around them.*

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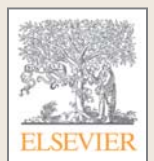
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Legislation Would Expand Patient Access to RRTs

BY DENISE NAPOLI
Elsevier Global Medical News

Newly introduced federal legislation would allow registered respiratory therapists to provide services such as smoking cessation, asthma management, and inhaler training to patients without direct on-site supervision by a physician.

The Medicare Respiratory Therapy Initiative Act of 2009 (S. 343) would give respiratory patients increased access to treatment, explained two of the bill's cosponsors, Sen. Blanche Lincoln (D-Ark.) and Sen. Mike Crapo (R-Idaho). "This access will be very beneficial to the people of Idaho, many of whom live in rural areas, to get the proper health care they need with the expenses being covered by Medicare," Sen. Crapo said in a statement.

Under current law, registered respiratory therapists (RRTs), who have a bachelor's degree but no medical school training, may provide services to patients only under the direct, on-site supervision of a physician.

The new legislation would amend that to allow "general" physician supervision, such that a physician would need to be available to the RRT and patient during care, but not necessarily physically present on-site.

The ACCP plans to post a letter in support of the bill on its Web site for physicians to sign and send to their federal lawmakers. ■

Lynne Marcus, ACCP Vice President, Health Affairs, comments: *It is important that ACCP members write their senators and ask that they cosponsor S. 343, and write their representatives in the U.S. House once a companion bill is introduced. You can keep up to date on this issue and others through the ACCP Legislative Action Center at <http://capwiz.com/chestnet/home>. This Web page offers a quick and efficient way to identify and e-mail your congressional representatives, with one click, about the importance of The Medicare Respiratory Therapy Initiative Act of 2009, as well as other issues of importance to ACCP members and their patients.*

Pay Boosts Smoking Cessation

Smokers • from page 1

for smoking status (but were not paid) after another 6 months (15 or 18 months after study enrollment). The smoking-cessation program was not based at the workplace; instead, participants were advised to use existing programs in the community.

The study population included adults aged 18 years and older who reported smoking at least five cigarettes daily. Demographic traits were similar between the two groups. The participants were followed for at least 12 months, and the study's primary end point was smoking cessation 9 or 12 months after study enrollment.

Overall, the rate of confirmed smoking cessation (based on a cotinine test) at 9 months or 12 months was approximately three times greater in the financial incentive group, compared with the control group (15% vs. 5%). The smoking-cessation rate within 6 months of starting the study was significantly higher in the financial incentive group, compared with the control group (21% vs. 12%). And the cessation rate remained significantly higher in the financial incentive group, compared with the control group at 15 or 18 months (9% vs. 4%).

Significantly more individuals in the financial incentive group than in the control group enrolled in (15% vs. 5%) and completed (11% vs. 3%) a smoking-

cessation education program. Those in the financial incentive group who took part in the smoking-cessation program had higher smoking-cessation rates, compared with controls who took part in the program (46% vs. 21%).

"Targeted payments for smoking cessation have the advantage of being unbundled from health insurance premiums and thus may be more salient to people, thereby having a greater influence on behavior," the researchers said.

The relapse rates between the 9- or 12-month follow-up and the 15- or 18-month follow-up were 36% in the financial incentive group and 27% in the control group.

The study was limited by its majority of white adults (90%) with high levels of income and education, the researchers noted.

The study was supported in part by grants from the Centers for Disease Control and Prevention and the Pennsylvania Department of Health. Dr. Volpp has received lecture fees from Aetna Inc. and grant support from Aetna and Pfizer Inc. ■

Dr. W. Michael Alberts, FCCP, comments: *Paying people to do the right thing would seem to be unnecessary. If one applies a dispassionate cost/benefit analysis, however, to a program as successful as described in this article, paying for cessation may be a win-win.*



The smoking-cessation rate was about three times greater in the financial incentive group.
DR. VOLPP

FDA Panel Votes on Strains For Next Flu Vaccine

BY ELIZABETH MEHCATIE
Elsevier Global Medical News

SILVER SPRING, MD. — The influenza B strain in the current influenza vaccine in the United States should be replaced for the 2009-2010 influenza vaccine, according to a preliminary recommendation by a federal advisory panel, which based its decision on data available on circulating viruses collected to date during this influenza season.

At a Feb. 18 meeting, the Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee voted in favor of replacing the current B component of the vaccine, a B/Florida/4/2006-like virus (a B/Yamagata lineage virus), with a B/Brisbane/60/2008-like virus (a B/Victoria lineage virus).

The panelists unanimously voted to retain the two influenza A strains included in the current vaccine for the next season's vaccine. The influenza A (H1N1) strain in the current vaccine is an A/Brisbane/59/2007-like virus; the H3N2 strain is an A/Brisbane/10/2007-like virus.

The panel's recommendations are not final; they will meet again to discuss the final recommendations later in the influenza season, taking into account data collected on influenza virus activity for the remainder of the season.

The panel's recommendations concur with those of the World Health Organization to retain the two influenza A strains, but to change the B strain to a B/Brisbane/60/2008-like virus, which reflects the B virus that is predominant worldwide.

There are two major circulating lineages of influenza B viruses, Victoria and Yamagata.

Worldwide, B viruses of both lineages (B/Victoria/2/87 and B/Yamagata/16/88 viruses) have cocirculated with H1N1 or H3N2 viruses, according

to Alexander Klimov, Ph.D., chief of the virus surveillance and diagnosis branch, in the Centers for Disease Control and Prevention's influenza division. However, more than 60% of circulating B viruses are from B Victoria lineage, he said at the meeting.

During this season to date, influenza A (H1N1) viruses have predominated in the United States and in many other North American countries and in Asian countries, and the majority of the viruses have been closely related to the H1N1 strain included in the current vaccine, said Dr. Klimov, who is also deputy director of the WHO Collaborating Center for Surveillance, Epidemiology, and Control of Influenza.

Influenza A (H3N2) viruses have been cocirculating with H1N1 and B viruses in many countries, predominantly in most European countries and in Japan. Most have been antigenically similar to the H3N2 strain in the current vaccine, and have been sensitive to the influenza antivirals oseltamivir (Tamiflu) and zanamivir (Relenza), Dr. Klimov said.

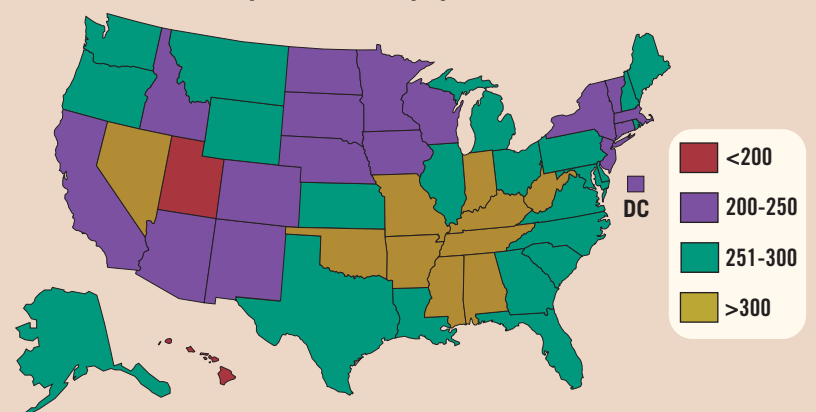
In the United States, oseltamivir-resistant influenza A (H1N1) has predominated this season and has been found in 30 states, said Dr. Joseph Bresee of the epidemiology and prevention branch, in the CDC's influenza division.

Oseltamivir-resistant H1N1 strains were antigenically similar or identical to the strains in the current vaccine. Viruses that have been sensitive to and those resistant to oseltamivir have been antigenically similar, he added.

This was the topic of a health advisory issued by the CDC in December, which recommended that zanamivir or a combination of oseltamivir and rimantadine (Flumadine) are more appropriate options than oseltamivir alone when influenza A (H1N1) virus infection or exposure is suspected. ■

DATA WATCH

Deaths Attributed to Smoking in 2000-2004 (per 100,000 population)



Note: Based on data from the Smoking-Attributable Mortality, Morbidity, and Economic Costs system.
Source: Centers for Disease Control and Prevention

Oseltamivir-Resistant Influenza Strain Takes Hold

BY SHERRY BOSCHERT
Elsevier Global Medical News

The dominant strain of influenza A during the current flu season is nearly completely resistant to oseltamivir because of a mutation that leaves its virulence intact, according to two studies that upset long-held ideas about oseltamivir-resistant influenza A (H1N1) viruses.

Findings from a third study bolster the rationale for widespread flu vaccination.

Taken together, the findings from these three studies should motivate more people to get annual influenza vaccinations, especially health care workers, since treatment options are now more limited, said Dr. Gregory A. Poland, who was not a participant in the studies. He is the American College of Physicians liaison to the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

In the first study, Dr. Nila J. Dharan of the CDC's influenza division in Atlanta, and associates, tested 268 influenza A (H1N1) isolates from the 2008-2009 season, and 99% were oseltamivir (Tamiflu) resistant (JAMA 2009 [doi:10.1001/jama.2009.294]).

Such findings shore up concerns raised by a December 2008 CDC health advisory that reported finding resistance to oseltamivir in 98% of 50 influenza A (H1N1)

viruses from 12 states in the early part of the 2008-2009 influenza season, according to Dr. Dharan and associates. About 55% of influenza types isolated so far by the CDC in the 2008-2009 season are oseltamivir-resistant H1N1.

Previously it was thought that the mutation conferring oseltamivir resistance weakens the ability of the virus to be transmitted from person to person and to sicken or kill people, but Dr. Dharan's study and another by Dr. Jairo Gooskens dispel those notions. In Dr. Dharan's study, 3% of 142 patients whose resistant viruses were tested by the CDC died of influenza.

Dr. Gooskens of Leiden (the Netherlands) University, and associates performed gene sequencing analysis on viruses from four patients in a nosocomial outbreak of oseltamivir-resistant influenza A (H1N1) at one hospital. The virus spread from the index patient to three others (JAMA 2009 [doi:10.1001/jama.2009.297]).

In neither study did the use or overuse of oseltamivir appear to contribute to viral resistance, a fact that "frankly, has caught us with our intellectual pants down," said Dr. William Schaffner, chair of preventive medicine at Vanderbilt University, Nashville, Tenn., and the Infectious

Diseases Society of America liaison to the ACIP. He did not participate in the studies.

At an ACIP meeting held in late February, committee members "acknowledged that we are still a little flummoxed about how it is that these viruses could have spread not only within the United States but globally so rapidly," he said.

If it's true that inappropriate use of oseltamivir is not a root cause of the increasing resistance, "it follows that for this organism and this agent, the most basic 'truth' about anti-infective resistance may be wrong," Dr. David M. Weinstock and Dr. Gianna Zuccotti, both of Harvard University, Boston, wrote in an editorial accompanying the reports.

Oseltamivir-resistant influenza A (H1N1) is susceptible to the other available neuraminidase inhibitor, zanamivir (Relenza), and to the adamantanes amantadine (Symmetrel) and rimantadine (Flumadine). Patients with suspected influenza A (H1N1) infection who are candidates for treatment should receive either zanamivir or the combination of oseltamivir and rimantadine, the CDC's health advisory recommended.

The third study analyzed more than a million active-duty members of the U.S. military during three influenza seasons.



These findings should motivate more people to get annual influenza vaccinations.
DR. POLAND

The trivalent inactivated vaccine (TIV) was more effective than was the live attenuated influenza vaccine (LAIV) or no vaccine in protecting this annually immunized cohort of healthy adults from developing influenza or pneumonia. The LAIV vaccine was as effective as the TIV vaccine only in vaccine-naïve service members (JAMA 2009;301:945-53).

Together these findings point to the need for more research on point-of-care testing to determine what virus a patient has, whether the patient should be treated, and with what, said Dr. Poland, chief of the Mayo Vaccine Research Group and professor of medicine, infectious diseases, molecular pharmacology, and experimental therapeutics at the Mayo Clinic, Rochester, Minn.

The study investigators and Dr. Weinstock and Dr. Zuccotti all reported having no conflicts of interest related to the studies. Dr. Schaffner has been a consultant for, or received funding from, GlaxoSmithKline, Novartis, Sanofi Pasteur, and MedImmune, which make influenza vaccines or treatments. Dr. Poland has been a consultant for, or received funding from, Dynavax, Novavax, Merck & Co., GlaxoSmithKline, Novartis Vaccines, CSL Biotherapies, PowderMed, Avianax, and Protein Sciences. ■

Updates on CDC influenza antiviral recommendations can be monitored at www.cdc.gov/flu/professionals/antivirals.

Sepsis Protocol Compliance Rises

Mortality • from page 1

Medicine, the International Sepsis Forum, and the Society of Critical Care Medicine to standardize and improve the diagnosis, treatment, and management of sepsis. The global initiative's two protocols, called "bundles," offer stepwise evidence-based guidelines to achieve preset goals for resuscitation and sepsis management.

So far, the ongoing campaign has been adopted by 166 facilities in North America, Europe, and Latin America, said Dr. Levy. For the first time, he released the program's 2-year data on mortality and compliance with each of the bundle's objectives. Thus far, 15,000 patients have been treated according to the protocol.

At baseline, the average mortality was 37%. This varied significantly based on the patient's location in the hospital when entered into the study. The baseline mortality rate was lowest among patients recruited from emergency departments (28%), and higher among those in intensive care units (41%) and wards (47%).

Baseline mortality was 26% in those without shock and 30% in those with shock. It was higher in patients who had both elevated lactate levels and hypotension (46%).

Mortality and compliance were assessed quarterly for 2 years. At baseline, only 11% of participating facilities were achieving all the elements of the resuscitation bundle.

By the end of the second year, however, 30% were achieving all the goals. The significant 20% increase followed a

linear improvement, with significant changes beginning in the second quarter. Significant improvements were seen in each of the bundle's elements.

The management bundle showed similar improvements. At baseline, only 18% of facilities were consistently achieving all the bundle's goals. By the end of the study, this had improved significantly, to 36%.

"It took us a little longer to achieve significant changes with this bundle, but by the end of year 1, we were seeing that," Dr. Levy said.

Because the campaign did not collect detailed data about baseline severity of illness, the investigators created a crude severity scale by using data that were available on each patient, including the presence or absence of shock, source of admission (ED or ICU), site of infection, baseline number of organ dysfunction, and the presence of ventilation.

"After adjusting the mortality rates for these factors, the decline was still 5.4%, a significant reduction," Dr. Levy said. ■

A description of the program and access to the manual and database are available at www.survivingsepsis.org.

Dr. Mark L. Metersky, FCCP, comments: *These are promising results; the published results will be eagerly awaited. In particular, given the large number of patients, there may be an opportunity to see which elements of the bundles were most correlated with survival.*

What the Sepsis Bundles Entail

The Surviving Sepsis Campaign, published last year in *Critical Care Medicine* (2008;36:296-327), consists of two bundles.

Sepsis Resuscitation Bundle

Evidence-based goals must be completed within 6 hours for patients with severe sepsis, septic shock, and/or lactate greater than 4 mmol/L (36 mg/dL). The goal is to perform all indicated tasks 100% of the time within the first 6 hours of identification of severe sepsis.

- ▶ Element 1: Measure serum lactate.
- ▶ Element 2: Obtain blood cultures prior to antibiotic administration.
- ▶ Element 3: Administer broad-spectrum antibiotic within 3 hours of emergency department admission and within 1 hour of non-ED admission.
- ▶ Element 4: In the event of hypotension and/or serum lactate greater than 4 mmol/L:
 - a. Deliver an initial minimum of 20 mL/kg of crystalloid or an equivalent.
 - b. Apply vasopressors for hypotension not responding to initial fluid resuscitation to maintain mean arterial pressure greater than 65 mm Hg.
- ▶ Element 5: In the event of persistent hypertension despite fluid resuscitation (septic shock) and/or

lactate greater than 4 mmol/L:

- a. Achieve a central venous pressure of greater than 8 mm Hg.
- b. Achieve a central venous oxygen saturation greater than 70% or mixed venous oxygen saturation greater than 65%.

Sepsis Management Bundle

Evidence-based goals must be completed within 24 hours for patients with severe sepsis, septic shock, and/or lactate greater than 4 mmol/L (36 mg/dL). The goal is to perform all indicated tasks 100% of the time within the first 24 hours from presentation.

- ▶ Element 1: Administer low-dose steroids in accordance with a standardized ICU policy.
- ▶ Element 2: Administer recombinant human activated protein C according to a standardized ICU policy.
- ▶ Element 3: Maintain glucose control greater than 70 mg/dL, but less than 150 mg/dL.
- ▶ Element 4: Maintain a median inspiratory plateau pressure less than 30 cm H₂O for mechanically ventilated patients.

Interested U.S. hospitals can access the Society of Critical Care Medicine's Paragon program. Visit www.sccm.org and click on "Professional Development," followed by "Quality Initiatives."

Use of Nutritional Guidelines Failed to Lower ICU Mortality

BY MARY ANN MOON
Elsevier Global Medical News

Implementing evidence-based guidelines for nutrition in intensive-care patients markedly improved the number of patients who received early nutritional support and the timing of their parenteral feeding, according to a report in JAMA.

However, those improvements did not translate into an expected decrease in mortality, said Dr. Gordon S. Doig of the University of Sydney and his associates.

Early nutritional support of critically ill patients has been estimated to reduce mortality by 8%-13%. "Nevertheless, practice varies widely between ICUs, and up

to 40% of eligible patients may remain unfed after 48 hours in the ICU," the researchers noted (JAMA 2008;300:2731-41).

They undertook a project involving 27 hospitals in Australia and New Zealand that used evidence-based guidelines for ICU nutrition and tested the results against standard ICU practice during a 5-week evaluation period. A total of 1,118 adult ICU patients were enrolled.

In the ICUs that implemented the new guidelines, significantly more patients (94%) were given nutritional support during their ICU stay than were those in control ICUs (73%). Significantly more patients in guideline-following ICUs also were fed within 24 hours of admission

(61%) than were those in control ICUs (37%). Patients in the guideline-following ICUs were fed significantly earlier (within 0.75 days) than were those in the control ICUs (within 1.40 days), and they were fed for a greater proportion of their intensive-care stays. The incidence of clinically significant renal dysfunction was significantly lower in the intervention group (1.5 days per 10 patient-days) than in the control group (2.1 days per 10 patient-days). There were no significant differences between the two groups in dysfunction of other organ systems.

Unfortunately, mortality rates were not significantly different between ICUs that followed the guidelines (29%

mortality rate) and those that followed standard practice (27% mortality rate). Mean durations of ICU stay and hospital stay also were not significantly different.

"The negative findings ... highlight the pressing need for better evidence evaluating the true effectiveness of each individual intervention recommended in this guideline," the investigators said.

The study was supported by the Australian and New Zealand Intensive Care Foundation, which received major support from Novartis, Abbott Laboratories, Nutricia, Fresenius-Kabi, and Baxter Healthcare. Dr. Doig reported receiving academic research grants from Fresenius-Kabi Deutschland and Baxter Healthcare. ■

Respiratory Failure Less Likely In Sepsis Patients With Diabetes

BY HEIDI SPLETE
Elsevier Global Medical News

Sepsis patients with diabetes are significantly less likely to experience acute respiratory failure than are patients without diabetes, according to data from a review of 930 million hospitalizations over 25 years.

Previous studies have shown that sepsis is common in people with diabetes, and that those patients are less likely to develop acute lung injuries as a result of sepsis. But those studies did not compare organ dysfunction in sepsis patients with and without diabetes.

Dr. Annette Esper of Emory University in Atlanta and her colleagues reviewed National Hospital Discharge Survey data for 1979-2003. The researchers used ICD-9 codes to identify cases of sepsis and the sources of the infections.

The researchers identified 12.5 million cases of sepsis,

and 17% of the patients had diabetes. Among the population of patients with diabetes and sepsis, 57% were women, and 64% were white. The average patient age was 68 years.

Overall, patients with diabetes and sepsis were significantly more likely to develop acute renal failure than were patients without diabetes, but were significantly less likely to develop acute respiratory failure (Crit. Care 2009 Feb. 12 [doi: 10.1186/cc7717]).

No other significant differences appeared in the occurrence of other organ dysfunctions or in the average total number of organ dysfunctions in the two groups. However, the difference in acute respiratory failure persisted regardless of the source of infection. Among patients with a respiratory source of sepsis, those who had diabetes were significantly less likely to develop acute respiratory failure than were those without diabetes

(16% vs. 23%). The difference in acute respiratory failure rates was also significant for patients with and without diabetes (6% vs. 10%) who had nonpulmonary sources of infection.

Although the overall fatality rate for sepsis patients with diabetes was significantly lower than for those without diabetes (19% vs. 21%), the fatality rates between patients with and without diabetes who developed acute respiratory failure were not significantly different (52% vs. 48%).

The reasons for the distinction in respiratory failure rates between patients with and without diabetes remain uncertain. Theories include the potential blunted inflammatory response to organ dysfunction in people with diabetes, the investigators said, and the possibility that diabetes patients may be hospitalized for sepsis sooner because they may be more alert to signs of infection. Diabetes medications may play a role, too.

"Pharmacological aspects of [diabetes] may also influence the development of organ dysfunction, because many medications administered to patients with [diabetes], including insulin and thiazolidinediones, are known to have anti-inflammatory effects in addition to lowering blood glucose," the researchers said.

But more research is needed to show the effects of diabetes medications and other factors on respiratory problems in sepsis patients in order to develop more effective treatments, they added.

The researchers had no financial conflicts to disclose. ■

Oral Antibiotics, Walking Cut CAP Length of Stay

BY KERRI WACHTER
Elsevier Global Medical News

WASHINGTON — A clinical pathway involving early mobilization and an early switch from intravenous to oral antibiotics reduced the length of stay for patients with community-acquired pneumonia by more than 2 days, in a randomized study of 401 patients.

The median length of stay was significantly shorter for patients randomized to the clinical pathway, compared with those randomized to standard care—95 hours versus 150 hours, Dr. Jordi Carratalà said at the jointly held annual Interscience Conference on Antimicrobial Agents and Chemotherapy and the annual meeting of the Infectious Diseases Society of America.

The use of the clinical pathway "was effective in reducing the duration of intravenous antibiotic therapy and length of stay without compromising patient outcomes," said Dr. Carratalà of the infectious disease service at the Hospital Universitari de Bellvitge in Barcelona.

The first step of the clinical pathway was early mobilization. This involved getting the patient walking or at least sitting up for at least 20 minutes during the first 24 hours of hospitalization, with progressive periods of walking/sitting upright on successive days.

Then patients were switched from intravenous to oral antibiotics based on objective criteria. They were switched to oral antibiotics when they had a temperature no greater than 100° F (at two measurements at least 3 hours apart), showed improvement or resolution of symptoms, were able to maintain oral intake, and were hemodynamically stable; any

comorbid conditions also had to be stable. After patients were mobilized, on oral antibiotics, and stable, they were discharged.

A total of 401 immunocompetent adults diagnosed with community-acquired pneumonia (CAP) were randomized: 200 to conventional treatment and 201 to the clinical pathway. Patients with shock, aspiration pneumonia, or empyema were excluded. The patients in the two groups were similar in terms of demographic and baseline characteristics.

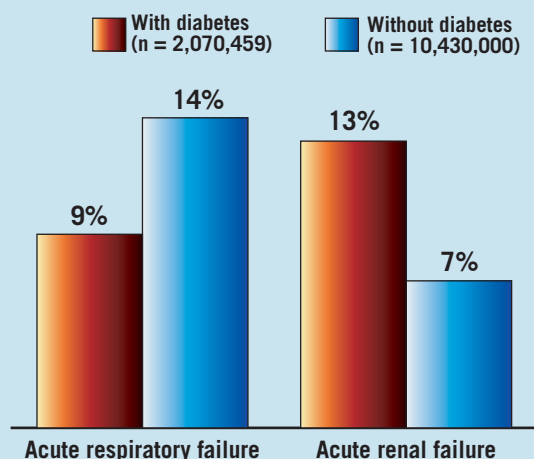
Streptococcus pneumoniae was the most commonly identified organism in both groups (85 patients in the intervention group and 79 in the control group). The causative organism was unknown in many cases in both groups as well (85 patients in the intervention group and 92 patients in the control group). Other identified organisms included *Haemophilus influenzae* and *Legionella pneumophila*.

The median duration of intravenous antibiotic therapy was also significantly shorter in the intervention group, compared with the controls (48 hours versus 96 hours). A significantly lower percentage of the intervention group had adverse drug reactions, compared with the controls (4.5% versus 16%). There were no differences between the two groups in terms of readmission rates or overall mortality.

"Switching from intravenous to oral therapy as soon as patients are clinically stable can reduce length of stay and lower the associated costs," Dr. Carratalà said. However, there is a high degree of variability in the length of intravenous antibiotic use for the treatment of CAP.

Dr. Carratalà did not report whether he had any potential conflicts of interest. ■

Differences in Organ Dysfunction in Sepsis Patients



Note: Based on a 25-year review of 930 million hospitalizations including 12.5 million cases of sepsis.

Source: Critical Care 2009 Feb 12 [doi:10.1186/cc7717]

Dexmedetomidine Cut Delirium in Ventilator Patients

BY MARY ANN MOON
Elsevier Global Medical News

Compared with midazolam, use of dexmedetomidine did not increase the time ICU patients spent within the target sedation range as researchers had hoped, but it did appear to offer other advantages, Dr. Richard R. Riker, FCCP, reported at the annual congress of the Society of Critical Care Medicine in Nashville, Tenn.

In a prospective randomized trial, ICU patients on mechanical ventilation given dexmedetomidine experienced delirium 20% less often than did those given midazolam, and were removed from mechanical ventilation almost 2 days sooner, Dr. Riker said. The study result, published in *JAMA*, was released online in concert with Dr. Riker's presentation (*JAMA* 2009 [doi:10.1001/jama.2009.56]).

The two agents were compared in 375 patients treated at 68 medical centers in the United States, Australia, Brazil, Argentina, and New Zealand. The study subjects were adult medical and surgical patients who were anticipated to require sedation for at least 3 days of intubation and mechanical ventilation.

Dexmedetomidine currently is approved only at

low doses for up to 24 hours in ventilated patients. The protocol of the study, which aimed to demonstrate the drug's safety and efficacy in longer-term use, called for dosing at up to twice these limits, for up to 30 days. The trial was funded by Hospira Inc., Lake Forest, Ill., which manufactures dexmedetomidine.

The primary efficacy outcome—the percentage of time within the target range of sedation—was not statistically different between dexmedetomidine (77%) and midazolam (75%). So the α_2 adrenoreceptor agonist dexmedetomidine failed to show superiority over benzodiazepines such as midazolam for ensuring light sedation. However, patients given dexmedetomidine were extubated hours to days sooner than those on midazolam. And despite this shorter duration of treatment, patients given dexmedetomidine had a significantly decreased prevalence of delirium (54%) compared with those given midazolam (77%).

Nurses' assessments of patients' ability to communicate, cooperate with treatment, and tolerate the ventilator also was higher with dexmedetomidine, said Dr. Riker of Maine Medical Center, Portland.

Length of ICU stay and 30-day mortality were similar between the two groups, as was the number of adverse events related to treatment. Patients given

dexmedetomidine had a higher incidence of bradycardia (42% vs. 19%), while those given midazolam had higher incidences of tachycardia (44% vs. 25%) and hypertension requiring intervention (30% vs. 19%).

In an editorial comment accompanying the *JAMA* report, Dr. Hannah Wunsch of Columbia University, New York, and Dr. John P. Kress, FCCP, of the University of Chicago said, "as a sedative, dexmedetomidine is notable for its lack of suppression of the respiratory drive and for its potential to provide some analgesia and anxiolysis."

Perhaps more important, this study, together with another recently published clinical trial, "helps to establish dexmedetomidine as a safe alternative to benzodiazepines for long-term sedation of critically ill patients," they wrote (*JAMA* 2009 Feb. 4 [doi:10.1001/jama.2009.24]).

"Taken together, these studies shift dexmedetomidine from a sedative suitable for the occasional patient to one useful for a majority of critically ill patients," Dr. Wunsch and Dr. Kress noted.

Dr. Riker disclosed that he has received honoraria and/or grant support from Aspect Medical Systems Inc, AstraZeneca, Eli Lilly & Co., Hospira, Takeda, and the Academy for Continued Healthcare Learning. Dr. Kress reported serving on the speakers bureau for Hospira, which manufactures dexmedetomidine. ■

FYI

Postmarket Drug Safety Information

The U.S. Food and Drug Administration has created a Web page with a wide variety of safety information about prescription drugs for health care professionals and consumers. The page, www.fda.gov/cder/drugsafety.htm, includes links to information in these categories: drug labeling, professional labeling, and patient package inserts; drugs that have Risk Evaluation and Mitigation Strategies (REMS); and press announcements and safety sheets with the latest risk information.

E-Prescribing Incentive Guide

A new guide from the Centers for Medicare and Medicaid Services explains the e-prescribing incentive program, how eligible professionals can participate, and how to choose a qualified e-prescribing system. By adopting e-prescribing, professionals can save time, enhance office and pharmacy productivity, improve patient safety and quality of care, and earn a 2% incentive from Medicare. To read or print a copy of the guide, visit www.cms.hhs.gov/partnerships/downloads/11399.pdf.

Preventive Services Guide

The Agency for Healthcare Research and Quality has published its 2008 "Guide to Clinical Preventive Services," which highlights recommendations released by the U.S. Preventive Services Task Force. In addition to previous recommendations, the pocket-size guide contains new recommendations released in 2007 on the use of aspirin or NSAIDs for primary prevention of colorectal cancer, screening for carotid artery stenosis, screening for chronic obstructive pulmonary disease using spirometry, screening for illicit drug use, and screening for sickle cell disease in newborns. To obtain a printed copy of the guide, call 800-358-9295 or send an e-mail to ahrqpubs@ahrq.hhs.gov. The guide also can be downloaded at www.ahrq.gov/clinic/pocketgd.htm.

In-Hospital Cardiac Arrests: Survival Not Improved by Rapid Response Team

BY DIANA MAHONEY
Elsevier Global Medical News

Calls for the creation of rapid response teams to reduce rates of in-hospital cardiac arrests may be premature, based on results of the longest follow-up study to date.

Research at St. Luke's Hospital in Kansas City, Mo., included the greatest number of deaths and code events of any rapid response-team study so far. But the hospital's implementation of a rapid response protocol was not associated with a reduction in hospital-wide cardiopulmonary arrest code rates or with improvements in clinically meaningful outcomes related to hospital-wide mortality, reported Dr. Paul S. Chan of the hospital's MidAmerica Heart Institute, and his colleagues.

Although previous studies have linked rapid response teams to a decrease in the rate of cardiopulmonary arrest codes outside of the intensive care unit, the studies' findings may be misleading, the authors wrote. The focus on cardiopulmonary arrests outside of the ICU "may lead to a favorable bias for rapid response teams, because cardiac arrests that occurred after transferring patients with physiological decline to the ICU were not included," they stated. In addition, few if any studies have addressed the potential impact on hospital-wide code and mortality rates of rapid response team undertreatment or underuse (*JAMA* 2008;300:2506-13).

To address those knowledge gaps, Dr. Chan and his colleagues conducted a prospective cohort study at Saint Luke's 404-bed tertiary care hospital comparing hospital-wide cardiac arrest and mortality rates from before and

after the hospital implemented a nurse-led rapid response team.

The team consisted of two experienced ICU nurses and a respiratory therapist charged with responding to all calls for adult inpatients based on standard activation criteria: acute changes in the patient's mental status, respiratory rate, heart rate oxygenation, or blood pressure; and hypoxia, chest pain, or worry from clinical staff. The preintervention period was from Jan. 1, 2004, to Aug. 31, 2005, and the postintervention period was from Jan. 1, 2006, to Aug. 31, 2007.

The primary study outcomes were hospital-wide cardiopulmonary arrest rates per 1,000 admissions and mortality rates per 100 admissions. The researchers also assessed code rate by location and type, and evaluated the degree to which the rapid response team was poorly implemented, the authors wrote.

During the 20-month postintervention period, the rapid response team was activated 376 times, most commonly for altered neurologic status, followed by tachycardia exceeding 130 beats per minute and hypotension. The most common rapid response team interventions were electrocardiogram, additional peripheral intravenous line access, arterial blood gas, and chest radiograph.

Of the patients for whom the rapid response team was activated, 70 died, including 3 during the initial rapid response, 43 in the ICU, 12 in non-ICU wards within 1 week of rapid response intervention, and 12 in non-ICU wards more than a week after intervention.

Although the unadjusted hospital-wide code rates per 1,000 admissions decreased from 11.20 pre-intervention

to 7.53 post intervention, "decreases in non-ICU code rates per 1,000 admissions accounted for the majority of this difference, with little change in ICU code rates," the authors wrote.

Case fatality rates after cardiopulmonary arrest pre- and post intervention were similar, at 77.9% and 76.1%, respectively. In addition, the unadjusted hospital-wide mortality rates per 100 admissions did not change post intervention, although the ratio of deaths to hospital-wide codes increased significantly from 2.88 pre-intervention to 4.11 post intervention, the researchers said.

With respect to potential undertreatment and underuse of the rapid response team intervention, 2 of 24 deaths that occurred after rapid response team intervention in patients without DNR status and not transferred to an ICU would be categorized as response team undertreatment. A total of 20 of 188 codes in the postintervention period in which patients had documented decline within 12 hours of the code but the response team was not activated met the criteria for potential underuse, the authors wrote. Sensitivity analysis determined that correction of those instances would not affect the mortality findings, they added.

Given the lack of "robust outcomes" associated with rapid response team implementation, "well-designed, multicenter, adequately powered, randomized controlled trials with sufficiently long follow-up should be considered to rigorously evaluate the efficacy of rapid response teams prior to endorsing their widespread implementation," the researchers concluded.

The authors reported no relevant financial disclosures. ■

Pulmonary Perspectives

Lung Cancer: Getting Serious About a Serious Disease

Lung cancer is a major health-care issue. It is the leading cause of cancer deaths in men and women, and, in fact, causes more cancer deaths than the next four leading causes of cancer deaths combined. Part of the problem is that we accept sloppy care for patients with lung cancer, because we are nihilistic and think it is the patient's fault for having smoked. However, newer data underscores the importance of taking a serious look at how we care for these patients.

The nihilism about lung cancer is no longer entirely appropriate. Significant advances in outcomes have been made. A lobectomy or pneumonectomy performed thoroscopically makes surgical resection easier to tolerate, even for elderly patients or those with limited pulmonary reserve (Cattaneo et al. *Ann Thorac Surg* 2008; 85:231; Demmy and Nwogu. *Ann Thorac Surg* 2008; 85:S719;

who can be managed with a good quality of life for several years. It is important to note, however, that these results are seen in clinical trials and at specialized centers with organized, multidisciplinary programs. The results from the National Cancer Database are not nearly as good (Jemal et al. *CA Cancer J Clin* 2007; 57:43).

Good patient management starts with an accurate determination of a patient's cancer stage. Multiple studies conducted over 2 decades have documented that a chest CT is notoriously inaccurate in many clinical situations to determine the stage of the mediastinum (Detterbeck. *Semin Thorac Cardiovasc Surg* 2007; 19:217; Detterbeck et al. *Intrathoracic staging*. In: Detterbeck et al, eds. *Diagnosis and treatment of lung cancer: an evidence-based guide for the practicing clinician*. WB Saunders, 2001; 73).

Positron emission tomography is better but still carries unacceptably high false-positive and false-negative rates in many situations (Detterbeck et al. *Chest* 2004; 125:2300). A careful review of the data has produced clinical guidelines, such as those recently being updated by the ACCP, which call for multimodality staging in most patients with NSCLC (Silvestri et al. *Chest* 2007; 132:178S; Detterbeck et al. *Chest* 2007; 132:202S).

Many population-based studies, however, have documented that pretreatment staging is extremely limited for the majority of patients. For example, in an analysis (Little et al. *Ann Thorac Surg* 2005; 80:2051) involving the majority of resections for early-stage NSCLC performed in the United States in 2001, preoperative mediastinal staging involved only a chest CT in the majority of patients. Another recent large study (Farjah et al. *J Thorac Oncol* 2008; January 19, Epub ahead of print) also found that the vast majority (77%) of patients with NSCLC underwent a chest CT as the only staging test.

Furthermore, even when additional staging interventions are done, data from population-based studies suggest that they are done poorly. For example, in the 2001 study of NSCLC resections (Little et al. *Ann Thorac Surg* 2005; 80:2051), not even a single biopsy of a lymph node was performed in a large proportion of those patients who underwent mediastinoscopy. Thus, despite extensive data and clearly articulated clinical guidelines, what actually occurs leaves much to be desired.

A recent study by Farjah and colleagues

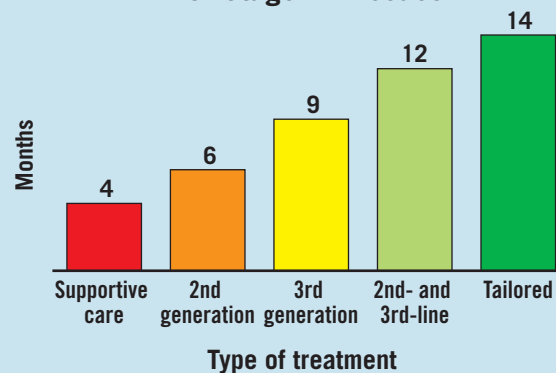
(*J Thorac Oncol* 2008; January 19, Epub ahead of print) documented that the impact of such poor staging is huge. Survival was twice as good in patients who had two or three staging interventions than those undergoing CT alone. The dramatically improved outcome in patients undergoing more extensive staging was consistent in various secondary analyses (eg, stage-specific and lung cancer-specific survival) that were aimed at uncovering an artifactual reason for the difference.

Furthermore, the dose-response nature of the data suggests the effect is real. Thus, the benefit of better staging exceeds by several fold the benefit seen from so-called "breakthrough" advances in treatment (Detterbeck. *J Thorac Oncol* 2009 [in press]). This is corroborated by studies of outcomes related to case volume, in which a review (Hillner et al. *J Clin Oncol* 2000; 18:2327) concluded that, "across studies, the benefit from care at high-volume centers exceeds the benefits from breakthrough treatments."

Lung cancer is too serious of a health-care issue for us not to draw consequences from these data. Given the magnitude of the impact, we must make our practices consistent with clinical guidelines, evidence-based, and of high quality. Care delivered in an unorganized, haphazard way according to local traditions is so markedly inferior that it can no longer be acceptable. This opinion is written from the perspective of a lifelong student of the disease of NSCLC, as well as from that of a practicing thoracic surgeon and someone who has been involved in developing guideline recommendations.

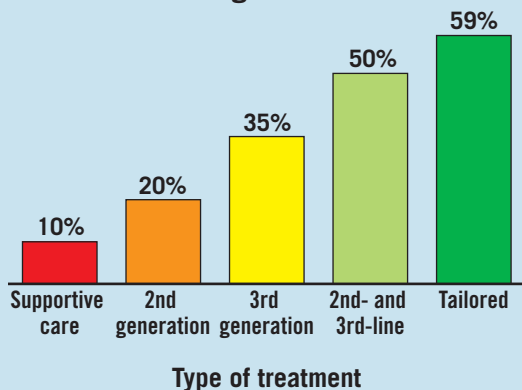
But what exactly should we do? It is not simply a matter of motivation, because physicians want good outcomes for their patients already. We have to face up to the fact that doing the best we can do in the current structure really isn't good enough. Part of the problem is that much of the care of patients with lung cancer occurs in smaller centers by physicians that care for many different kinds of patients and diseases. Examples include general or cardiac surgeons who also do some thoracic surgery, general medical oncologists, and general pulmonologists. Such physicians and centers often don't have the volume of cases to foster the development of a structured, evidence-based approach when functioning only in their own community.

Median Survival Time Among Patients With Stage IV Disease



COURTESY DR. DETTERBECK

1-Year Survival Rates Among Patients With Stage IV Disease



COURTESY DR. DETTERBECK

Demmy and Curtis. *Ann Thorac Surg* 1999; 68:194). Despite surgical resection performed in older and sicker patients, mortality in specialized thoracic surgery centers has decreased to 2% (Boffa et al. *J Thorac Cardiovasc Surg* 2008; 135:247; Allen et al. *Ann Thorac Surg* 2006; 81:1013). Modern three-dimensional and four-dimensional radiotherapy allows escalation of the radiotherapy dose and its effectiveness while maintaining limited toxicity (Socinski et al. *Cancer* 2001; 92:1213; Socinski et al. *J Clin Oncol* 2004; 22:4341).

Significant advances have been made for patients with stage IV disease (Fig 1, 2) (Simon et al. *J Clin Oncol* 2007; 25:2741; Socinski et al. *Chest* 2007; 132:277S). The advent of third generation chemotherapy, targeted therapy, and second- and third-line treatment now makes it no longer unusual to see patients with stage IV non-small cell lung cancer (NSCLC)

Dr. Gene L. Colice, FCCP
Editor, *Pulmonary Perspectives*

We have generally not developed organized health-care systems in which smaller centers are integrated in structured processes of care developed together with larger, specialized centers. Clearly, we have much work to do to find effective solutions to these hurdles.

It is time for us to get serious about treating lung cancer. The data show that we can't afford to be sloppy or unorganized. Nihilism about this disease is also no longer appropriate. There are more lifelong never-smokers who develop lung cancer, and half of patients diagnosed with lung cancer quit smoking 5 to 30 years ago (Visbal et al. *Ann Thorac Surg* 2004; 78:209; Garces et al. *Chest* 2004; 126:1733).

We must begin to seriously examine the quality of our care and develop systems to organize it in ways that provide better outcomes for our patients. ■

Dr. Frank C. Detterbeck, FCCP
Professor and Chief, Thoracic Surgery
Surgical Director
Yale Thoracic Oncology Program
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New Haven, CT

Editor's Insight

Dr. Detterbeck is a thoughtful surgeon who is committed to improving the care of the lung cancer patient. His points about the value of lung cancer staging are extremely important. Health-care professionals involved in the care of lung cancer patients should carefully consider the importance of thorough staging from both the individual and the system perspectives. We have to do a better job of internalizing recommended approaches for managing lung cancer into our everyday practice and holding our systems accountable for ensuring high-quality care.

SLEEP STRATEGIES

Long-Term Outcomes of OSA and Disturbed Sleep

Many fascinating insights into the long-term effects of untreated sleep apnea have been discovered in recent years. Indeed, the past 5 years have yielded an abundance of major research in this area. Some of the most interesting findings have been in elucidating the association of obstructive sleep apnea (OSA) with cardiovascular disease. A summary of what we currently know from the literature is included in this article.

Several convincing studies have laid the foundation for this area of research, including the Wisconsin Sleep Cohort Study (Finn et al. *Sleep* 1998; 21:701) and the Sleep Heart Health Study (SHHS). These studies have convincingly demonstrated a relationship between sleep-disordered breathing (SDB) and increased mortality associated with hypertension, diabetes mellitus, coronary artery disease, and cerebrovascular disease, but a direct physiologic role remains to be established. A recent study (Marshall et al. *Sleep* 2008; 31:1079) on a Western Australia cohort, the Busselton Health Study, adds to the evidence that OSA is an independent risk factor for cardiovascular mortality. In this study, moderate to severe OSA was associated with 33% mortality over a 14-year period compared with 6.5% and 7% mortality in people with mild or no OSA, respectively. The results are even after correction for mean arterial pressure, total cholesterol, high-density lipoprotein, body mass, diabetes, angina, and smoking status.

Cardiovascular Disease

There are several mechanisms that seem to form the basis for increased cardiovascular and cerebrovascular mortality in patients with SDB. Sympathetic nervous system output increases dramatically during rapid-eye movement (REM) sleep and especially during phasic REM sleep, which is more prominent during the latter half of the night. The increase in sympathetic activity increases myocardial oxygen demand and can lead to cardiac ischemia especially in patients with significant coronary artery disease.

OSA also is associated with endothelial dysfunction, systemic inflammation, increased levels of endothelin, hypercoagulability, and stimulation of the renin-angiotensin system, possibly promoting atherosclerosis and systemic hypertension. Sleep deprivation appears to disrupt the hypothalamic-pituitary-adrenal axis with prolonged periods of cortisol secretion and decreased cortisol clearance.

Patients with untreated OSA typically have disturbed sleep with significantly reduced sleep efficiency and excessive daytime somnolence. It is now recognized that short sleepers suffer from an increased prevalence of hypertension,

specifically in those sleeping less than 6 hours per night (Gottlieb et al. *Sleep* 2006; 29:1009). This study included 2,813 men and 3,097 women aged 40 to 100 years from the SHHS cohort. A self-reported questionnaire (Sleep Habits Questionnaire) was used to assess total sleep duration. This study provides a basis for insight into the "U-shaped" curve of sleep duration and prevalence of cardiovascular disease. The picture that is emerging is that a statistically significant increase in the prevalence of hypertension and cardiovascular disease exists in people sleeping <7 h or >8 h. For example, patients sleeping 7 to 8 h had lower systolic blood pressure and antihypertensive medication use compared with people sleeping <7 or >8 h. The odds ratios of having hypertension were 1.25 and 1.86 in patients sleeping 6 to 7 h and <6 h, respectively. This difference was statistically significant and persisted even after adjustment for age, race, apnea-hypopnea index (AHI), and body mass index, and for people sleeping >8 h.

Another fascinating observation has been reported on the relationship of daytime somnolence with SDB and hypertension. A provocative finding from the SHHS has been reported in a recent paper. Kapur and colleagues (*Sleep* 2008; 31:1127) compared patients with OSA and an AHI of ≥ 30 or AHI <1.5 and found the odds ratio for hypertension was 2.8 in patients who were frequently sleepy vs 1.2 in patients who reported less frequent sleepiness. This observation was supported by the finding of a smaller decrease in blood pressure in nonsleepy patients with SDB treated with continuous positive airway pressure (CPAP) than in patients with SDB but who were not sleepy (Barbe et al. *Ann Intern Med* 2001; 134:1015).

There also has been extensive research on the interaction of sleep apnea and congestive heart failure (CHF). Exaggerated fluctuations in intrathoracic pressures (up to -60 cm of water) during obstructive events have been proposed as the underlying mechanism for worse outcomes in patients with CHF and untreated OSA compared with patients without OSA. Under experimental conditions, vigorous inspiratory efforts in the presence of acute airway occlusion cause elevation of left ventricular peak systolic pressure, left ventricular end systolic volume, decreased venous return, and stroke volume. The mechanism is increased afterload during the apnea event. Elevated serum natriuretic peptides are associated with ventricular dysfunction and elevated filling pressures and logically should be associated with SDB. However, one study (Patwardhan

et al. *Sleep* 2006; 29:1301) failed to identify an association of natriuretic peptides with indices of OSA despite significant oxygen desaturations and correction for body mass index.

Although hypoxemia is one of the strongest stimuli for pulmonary artery constriction, OSA is associated with only modest elevation in pulmonary artery pressures and is associated with right ventricular failure only in the presence of another cardiac and/or pulmonary disease. OSA, in the absence of another underlying lung disease, is not a cause of severe pulmonary hypertension. However, treatment of OSA with CPAP does reduce mean pulmonary artery pressure.

Preliminary studies found that patients with CHF and central sleep apnea obtained improvement in ejection fraction and other markers of heart failure with CPAP therapy. The Canadian Continuous Positive Airway Pressure for Patients With Central Sleep Apnea and Heart Failure study (CANPAP) by Bradley and colleagues (*N Engl J Med* 2005; 353:2025) was undertaken to prove this theory by randomizing patients with CHF and central sleep apnea to receive CPAP therapy or placebo CPAP therapy. The results of the study were unfortunately disappointing. The CPAP group reported increased mean nocturnal oxygen saturation, left ventricular ejection fraction, and submaximal exercise performance, but no difference in overall mortality or transplant-free survival. One limitation of the study was that the effectiveness of CPAP therapy was not confirmed in this study by poly-somnography. A *post hoc* analysis looked at those patients who had successful suppression of central apneas with CPAP therapy vs those who did not have suppression of central apneas. This analysis suggested that suppression of central apneic events to an AHI <15/h by CPAP improved left ventricular ejection fraction and transplant-free survival. The emergence of the servo-assist mode of positive pressure therapy provides another interesting option for treating patients with heart failure and central sleep apnea. Several preliminary studies have shown some promising results, but longer-term randomized controlled studies are needed.

Diabetes Mellitus and Metabolic Syndromes

Diabetes and dyslipidemia are major risk factors for atherosclerosis and have been associated with increased cardiovascular mortality. In animal models, continuous hypoxic exposure of a 2 h duration is associated with elevated fasting insulin levels. Hypoxic pulmonary disease is associated with impaired glucose tolerance that improves

with oxygen supplementation (Hjalmarsson et al. *Diabetes Metab* 1996; 22:37; Jakobsson et al. *Clin Physiol Funct Imaging* 2006; 26:271). Sympathetic nervous system activation in OSA promotes glucagon and cortisol secretion and lipolysis in adipose tissue, which plays a role in impaired glucose tolerance.

Spiegel and colleagues (*J Appl Physiol* 2005; 99:2008) reported an increased incidence of metabolic syndromes, such as hypertriglyceridemia, hyperglycemia, and increased abdominal obesity, in both short and long sleepers. Ghrelin is a peptide produced predominantly by the stomach and stimulates appetite, whereas leptin is a hormone released by the adipocytes that suppresses appetite. A sleep time of <4 h for two consecutive nights was associated with an increased ghrelin/leptin ratio and cravings for a high-calorie, carbohydrate-rich diet. Abdominal obesity and elevated glucose were strongly associated with short sleep duration (<7 h/night) in another study (Hall et al. *Sleep* 2008; 31:635). A study on 2,656 patients (Stamatidis et al. *Sleep* 2008; 31:1018) found an association of fasting hyperglycemia and hypopneas associated with oxygen desaturation between 2% and 4%. There was a stronger association with glucose intolerance in patients who slept <6 h compared with 6 to 7 h.

Health-care Utilization

There is a reported increase in health care expenditure 5 years preceding the diagnosis of OSA that reverses or plateaus 5 years after initiation of treatment with CPAP (Albarrak et al. *Sleep* 2005; 28:1306). However, obesity-related diagnoses, including metabolic, musculoskeletal, and digestive diseases, continue to increase 2 years after treatment with CPAP. Another study (Kapur et al. *Sleep* 2002; 25:289) reported increased health-care utilization associated with severe SDB but a more significant association with hypoxemic burden as measured by percent of sleep time with oxyhemoglobin saturation below 90%.

Summary

Many studies support the concept that OSA is a significant contributing factor associated with increased mortality from cardiovascular and cerebrovascular disease. OSA adversely affects the cardiovascular system via several pathways and mechanisms. Further studies and discussion on the topic are forthcoming and awaited anxiously by sleep practitioners to enhance our understanding of this important disease. ■

Dr. Vipin Malik, FCCP
Medical Director
Critical Care Unit
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Harrisonburg, VA

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PRACTICE MANAGEMENT UPDATES

Societies Collaborate on Reimbursement, QI Issues

Working with the American Thoracic Society (ATS), the Society of Critical Care Medicine (SCCM), the American Association of Critical-Care Nurses (AACN), and the National Association for Medical Direction of Respiratory Care (NAMDR), the American College of Chest Physicians has helped the Department of Health and Human Services (HHS) respond to a Congressional mandate that the department identify hospital-acquired conditions that should never occur while caring for Medicare patients.

Care for these conditions, Congress decided, would not be reimbursable—a change to improve patient health by giving hospitals and health-care professionals a large financial stake in following treatment guidelines that would protect patients from unnecessary complications.

Although the five societies believe strongly that health-care teams should reduce the incidence of conditions suggested by HHS as “never events,” they convinced HHS that, in fact, the four conditions that were commented on can occur even when health-care providers adhere to best clinical practices. The four conditions are ventilator-associated pneumonia, iatrogenic pneumothorax,

deep vein thrombosis/pulmonary embolism (outside orthopaedic procedures), and delirium in the critically ill.

The ACCP and the other associations, which represent approximately 150,000 health-care professionals, have publically indicated that they, and the professionals they represent, have an obligation to reduce to the lowest possible level the incidence of these four conditions.

“It is unrealistic to presume that these four conditions are completely preventable, even when the most thorough patient care is delivered,” said Dr. James A. L. Mathers, Jr., FCCP, President of the American College of Chest Physicians. “However, we recognize the impact that these conditions have on patient safety and health-care costs and have indicated to HHS our commitment to work to reduce hospital-acquired conditions.”

“The goal of identifying ‘never events’ is laudable, both in terms of saving lives and in terms of restraining health-care expenditures,” said Jo Rae Wright, PhD, president of the ATS, “but none of the four conditions is entirely preventable, so it would be unfair to penalize health-care providers and institutions trying to restore very ill patients to health.”

Of the four hospital-acquired condi-

tions, ventilator-acquired pneumonia (VAP) is the most common and the most deadly. Approximately 25% of all patients on mechanical ventilation support develop VAP and many will die from the infection.

For this reason, the five medical organizations have formed the Critical Care Workforce Partnership HAI Collaborative, a permanent working group, to initially study VAP. Chief among the issues the group will explore are the need to define the condition more precisely; research priorities for VAP prevention, detection and treatment; and the role of various federal agencies in addressing these research issues.

“Our common interest in VAP and the other conditions goes beyond ensuring that our members are treated fairly when providing care to the sickest patients in the hospital,” said Dr. Mitchell Levy, president of the SCCM. “We want to help find a solution so that VAP, if it cannot be eliminated, is reduced to as close to zero as possible through consistency of bedside care.”

Last year, the five societies, along with Society of Hospital Medicine, also worked together on a ruling by the Office for Human Research Protections

(OHRP) following publication of a 2007 report in the *New England Journal of Medicine*, by Dr. Peter Pronovost of Johns Hopkins, containing his “ICU checklist” initiative to prevent catheter infections in Michigan hospitals.

After indicating that the Johns Hopkins Internal Review Board (IRB) made a mistake in indicating that the initiative did not require patient consent, OHRP revised its thinking, in part because of the arguments of the ACCP and the five other societies.

The OHRP agreed with the societies that “quality improvement initiatives that implement scientifically effective therapies for the sole purpose of improving patient outcomes do not require IRB review” and that “IRBs may waive consent in quality improvement research” if all patients receive the standard of care. The latter situation could occur when researchers want to test the most effective way to implement the standard of care.

“While every health-care professional must respect patient privacy and safety, we must also recognize the importance of quality improvement initiatives and make every effort to ensure that these initiatives are not hindered,” said Dr. Mathers. ■

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EDUCATION INSIGHTS

The AQuIRE Registry Addresses Health-care Evolution

BY JOYCE BRUNO
REITZNER, MBA, MIPH

The ACCP AQuIRE Registry is a quality improvement tool for chest physicians developed by chest physicians. The AQuIRE Registry is designed to help chest physicians meet increasing demands placed upon them by the public, credentialing bodies, regulatory agencies, payers, and the institutions in which they practice. The question still standing is the following: *What tangible value will participating in AQuIRE bring to me?*

ACCP members may or may not have identified a reason or need to monitor their practice data to date. Some have indicated that subjective assessment of their personal practices is sufficient and renders no obvious future need for more objective appraisal. However, when continuously monitoring your real data becomes compulsory for participation in recertification, reimbursement programs, privileging, CME activities, etc, which data platform will you use?

ACCP President James A. L. Mathers, MD, FCCP, recently published an article¹ that outlined a number of

external forces impacting ACCP members. In this article, Dr. Mathers introduced the ACCP AQuIRE Registry as a tool to simplify chest physicians' ability to react to these environmental changes.

This past February, the ACCP initiated the pilot phase of the AQuIRE Registry's first clinical modules on diagnostic and interventional bronchoscopy. Ernst and colleagues² discussed the design and intent of the registries in *CHEST*. AQuIRE will provide participants the ability to enhance their practice through the application of useful data reports and peer comparisons. Pulmonary, critical care, and sleep physicians will now have a tool to more easily monitor their practices, understand how they compare among their peers, and provide direction in the development of indications, which will someday be used to determine reimbursement.

The AQuIRE platform will provide users with a dashboard that will enable them to gauge their practice across 12 different indicators, eg, diagnostic yields and resource utilization, as they relate to specific procedures and techniques. While those involved in the pilot phase will help identify which indicators are most useful to physician practice, the

aim of these indicators is to help monitor and compare performance, resource use, efficiencies, and outcomes. The dashboard will eventually monitor and manage state licensure requirements, recertification efforts, CME, and changes in performance as a result of engaging in educational interventions.

As the AQuIRE platform matures, participants will be able to use their AQuIRE privileges as a gateway for satisfying external practice requirements. Users will have the ability to submit data directly to the American Board of Internal Medicine for maintenance of certification and the Centers for Medicaid and Medicare Services for reporting to the Physician Quality Reporting Initiative (PQRI).

► **Understanding Resource Utilization.** Leveraging AQuIRE data with existing hospital, practice, and national data will provide a monitoring tool to identify thresholds where maximum quality care can be rendered with a more efficient consumption of resources. It also will provide a mechanism for examining the impact of practice changes and new technologies on patient care and consumption.

► **Evidence of Performance.** Payers and consumer groups have developed programs that rate physicians based on quality and cost efficiency indicators. These ratings influence patients' medical choices, physician reimbursement, and public perception. The AQuIRE Registry will provide participants with objective data reports featuring relevant quality, outcome, and cost indicators both at the individual level and benchmarked to peers. These data reports serve as statistical aids to clarify ratings and negotiate contracts.

► **Ongoing Professional Practice Evaluation.** As a result of recent changes in Joint Commission standards, health-care organizations must establish a means to assess the performance of all physicians with privileges on an ongoing basis rather than at the 2-year reappointment process. The AQuIRE Registry will provide chest physicians with measures and indicators relevant to them, which can be monitored in real time and provide evidence of engaging in ongoing self-assessment and performance improvement activities.

► **Research and Publication.** In academic settings, professional reappointment, promotion, and tenure are based on the physician's ability to conduct research and publish findings in peer-reviewed journals. The AQuIRE Registry will provide participants with the unique ability to develop research projects based on real world data not available through randomized controlled trials or other studies.³ Additionally, physicians who contribute data to the AQuIRE Registry will have the opportunity to be

recognized in manuscripts that are based on AQuIRE Registry data and published for dissemination in the public domain.

► **Fellows-in-Training and Competency Assessment.** The AQuIRE Registry provides fellows-in-training the opportunity to assess their own practices and demonstrate competency over time. It also will allow them to identify gaps in their knowledge and practice, engage in targeted educational interventions, and develop performance improvement projects that can be used toward Accreditation Council for Graduate Medical Education (ACGME) requirements.

► **Helping the ACCP Increase Opportunities for Your Reimbursement.** On the national level, there are strong incentives to develop measures and indicators for use in reimbursement programs. While bronchoscopy is a common procedure performed by chest physicians, there are no existing measures that would allow participation in such incentive programs. AQuIRE will provide chest physicians the ability to collaborate with national measure developers using objective data to develop meaningful measures for physicians performing bronchoscopies. As with the success realized with the Society of Thoracic Surgeons' (STS) National Database, AQuIRE will provide the ACCP with the ability to assess true resource costs associated with individual bronchoscopy CPT codes and leverage the data to negotiate objectively determined reimbursement rates. ■

For more information, contact Joyce Bruno Reitzner, MBA, MIPH, at jbruno@chestnet.org.

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By Karl Olov Fagerström, PhD
- **21st Century Agricultural Respiratory Hazards**
By Jane Hoppin, ScD

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NETWORKS

Antismoking Funds, End-of-Life Care

Occupational and Environmental Health**Antismoking Funds at Risk**

Smoking cessation and smoking prevention are among the most challenging tasks facing health-care providers.

Recent information from the Campaign for Tobacco-Free Kids suggests this work will continue to be difficult and the campaign's funding continually limited.

In 1998, 46 states joined Mississippi, Texas, Florida, and Minnesota to complete what was called the Master Settlement Agreement (MSA) against our nation's major tobacco companies. This landmark settlement attempted to limit the marketing of tobacco products and, especially, provide a windfall of funds to the states. Most states pledged to use these dollars on youth smoking prevention programs and provide assistance for addicted smokers to quit.

State-sponsored tobacco control programs, which rely on funding from the MSA, have been proven to help patients. Recent information from the Centers

for Disease Control and Prevention shows that these programs significantly reduce smoking rates, tobacco-related deaths and other diseases. State data from Maine show that this state was able to reduce smoking among high



school students by 64% over a 10-year period. They also estimate a future health-care cost savings of more than 400 million dollars. There are other states with similar encouraging data, but these reductions in smoking rates are directly correlated with the money spent on tobacco control.

However, all of the news is not good. None of our 50 states are funding tobacco prevention programs at a level suggested by the Centers for Disease Control and Prevention. In fact, 41 states fund tobacco programs at less than half of the recommended levels, and some states are virtually unfunded. Currently, less than 3% of the MSA money is targeted for tobacco prevention. Many states funnel MSA money directly into a general fund, undesignated for health-care

expenses. Our current economic crisis with massive budget shortfalls will only add to this temptation. We already are seeing cuts in tobacco prevention funding in California, Ohio, Minnesota, Massachusetts, and other states. A reduction in funding has been shown to blunt the decline in smoking cessation. The current average smoking rate for United States high school seniors is approximately 20%, a figure that has not changed over the last 5 years.

A concerted action involving health-care professionals, citizens, legislators, health-care agencies, and others will be required to safeguard antitobacco funding. If this is accomplished, many lives will be saved and we will advance our goal of reducing health-care expenses.

*Dr. Daniel Gerardi, FCCP
NetWork Vice-Chair*

Further Reading

► Campaign for Tobacco-Free Kids, American Heart Association, American Cancer Society Network, et al. *A Decade of Broken Promises: The 1998 State Tobacco Settlement Ten Years Later*. Washington, DC: Campaign for

Continued on following page

Product of the Month**Coding for Chest Medicine 2009**

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Tobacco-Free Kids, 2008

► Centers for Disease Control and Prevention. Best Practices for Comprehensive Tobacco Control Programs—2007. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2007

Palliative and End-of-Life Care Educating Pulmonary/Critical Care Trainees About Palliative and End-of-Life Care

For many types of postgraduate training programs, education in palliative and end-of-life care (PEOLC) is required by the Accreditation Council for Graduate Medical Education (ACGME).¹ These programs include internal medicine, oncology, and geriatrics programs, whose graduates must often deal with patient symptoms near the end of life. Some of the programs have developed in-house curriculum materials for PEOLC or have used the excellent learning resources available from organizations, such as the Center to Advance Palliative Care and the End-of-Life Physician Education Resource Center.^{2,3} There is consensus on the key competencies in PEOLC: communication skills, management of

pain and other symptoms, ethical and legal principles, psychological and family aspects of grieving, understanding health systems, and interdisciplinary team processes.^{4,5} The ACCP has contributed to this consensus and has published recommendations on PEOLC education.⁶ However, ACGME requirements for pulmonary/ICU fellowships mandate very little explicit instruction in palliative care and have no explicit requirement for a clinical experience in end-of-life care.¹ This is despite the fact that an estimated 20% of deaths in the United States occur following an ICU admission. Pulmonary/ICU training programs have not, in general, embraced this education mission. This may be due to their emphasis on the physiology and technology needed to manage acute disease, and also because the relevant literature is published outside its specialty journals. Fellows who train in a program deficient in the domains of PEOLC education may lack skill in conducting a family meeting or palliating symptoms near the end of life. The Palliative and End-of-Life Care NetWork has embarked on a data-gathering project to identify these deficiencies. An e-mail survey will ask fellowship directors and their trainees about their PEOLC education methods and trainee competence in these domains. We expect this will serve as a needs assessment and

help identify gaps in PEOLC training for pulmonary/ICU trainees.

Dr. Paul Richman, FCCP
NetWork Steering Committee Member

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Private Practice

Many questions arise when a person is considering future employment in pulmonary, critical care, or sleep medicine. How do academic practices compare with private practices in reference to work schedule, salary and benefits, and professional development? What items should an employment contract contain? Is hospital employment better than employment in a group? These are just a few of the questions you must be able to answer to select the practice opportunity best suited to your needs. Unfortunately, very few programs prepare their fellows to adequately answer these questions; however, the answers will determine the direction their lives will

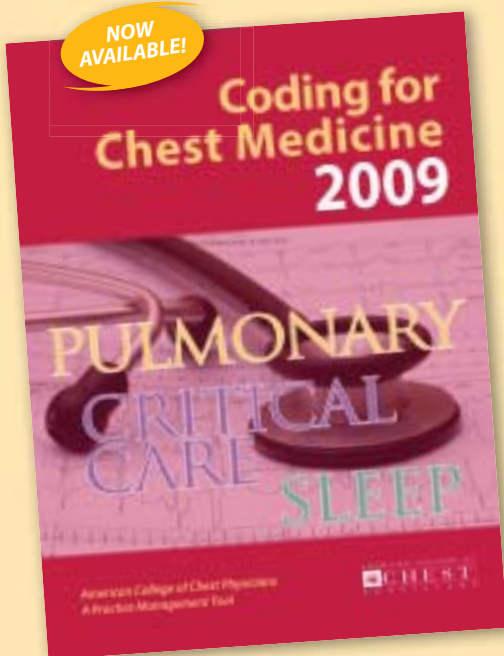
take for many years to come.

The ACCP has always been supportive of its affiliate members through educational activities at the annual CHEST meeting, board review courses, and the ACCP Simulation Center for Advanced Clinical Education. As a continuation of these efforts, the Private Practice NetWork is working in conjunction with the Affiliate NetWork and the Practice Management Committee to further assist affiliate members. The members of these NetWorks are currently cooperating in the development of a multifaceted presentation, which will be reproduced on DVD for widespread distribution. This tool will provide affiliates with the skills to help identify and evaluate potential job prospects. The goal of the project is to provide affiliates with some of the answers to the aforementioned questions and help them identify their ideal practice. Individual NetWork members have volunteered to produce separate presentations, which will then be combined for the final product. The NetWorks hope to have the DVD available for distribution by CHEST 2009.

The Private Practice NetWork also has two NetWork Highlights accepted for CHEST 2009, "Billing Strategies in Critical Care To Maximize Reimbursement" and "Incorporating Pulmonary Rehabilitation Services Into Private Practice: The How's, Why's and Why-Not's." Both sessions are applicable for private and academic practitioners. They are especially pertinent in this era of declining reimbursement and the decision by the Centers for Medicare and Medicaid Services to support rehabilitative services. We hope to see you there! ■

Dr. Michael Nelson, FCCP
NetWork Steering Committee Member

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This Month in CHEST— Editor's Picks

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

► **Clinical Characteristics of Subjects With Symptoms of α_1 -Anti-trypsin Deficiency Older Than 60 Years.** By Dr. M. A. Campos, et al.

► **Helium-Hyperoxia: A Novel Intervention To Improve the Benefits of Pulmonary Rehabilitation for Patients With COPD.** By Dr. N. D. Eves, et al.

► **Health-care-Associated Pneumonia Among Hospitalized Patients in a Japanese Community Hospital.** By Dr. Y. Shindo, et al.

► **Prevalence of Pulmonary Embolism in Acute Exacerbations of COPD: A Systematic Review and Metaanalysis.** By Dr. T. Rizkallah, et al.

► **Uncharted Paths: Hospital Networks in Critical Care.** By Dr. T. J. Iwashyna, et al.

► **CME GUIDELINE COMMENTARY**
The American College of Chest Physicians Evidence-Based Educational Guidelines for Continuing Medical Education Interventions: A Critical Review of Evidence-Based Guidelines.

By Dr. G. Norman
► **SUPPLEMENT**
Effectiveness of Continuing Medical Education: American College of Chest Physicians Evidence-Based Educational Guidelines.



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Helical MDCT Revealed Smaller Pulmonary Emboli

BY DAMIAN McNAMARA
Elsevier Global Medical News

PALM BEACH, FLA. — Helical multidetector computed tomography increases the detection of smaller segmental and subsegmental—but not central—pulmonary emboli following cancer surgery, according to the results of a database review.

In the study of almost 300 cancer surgery patients at a single center, MDCT increased the detection of PEs fourfold because of the ability to diagnose subsegmental PEs. MDCT did not increase the detection of central PEs.

“Diagnosis of pulmonary embolism in most major hospitals has changed, mostly because of the MDCT scan,” said Dr. Yuman Fong, chair of the department of surgery at Memorial Sloan-Kettering Cancer Center, New York, where the study was conducted. “There is increased sensitivity and the ability to get these scans much faster—in a single breath hold.”

MDCT has replaced ventilation/perfusion lung scans as the test of choice for detecting PE in most institutions, he noted at the annual meeting of the Southern Surgical Association.

Dr. Fong and his associates reviewed a prospective database of 47,601 patients who had abdominal, pelvic, thoracic, or soft-tissue major surgery at the cancer center. A total of 1,441 patients had a CT angiogram to rule out PE from January 2000 to December 2005. During this time, use of the contrast-enhanced, high-resolution MDCT scans of the chest

within 30 days of surgery increased at the center from 5 per 1,000 patients in 2000 to 45 per 1,000 in 2005. The researchers sought to determine if patient outcomes changed as a result, said Dr. Fong, who is also vice chair of the technology department at the center.

They identified 311 patients who had a PE within 30 days of surgery. In all, 17 of the patients had a PE but no malignancy, and were excluded from the analysis; the remaining 294 cancer patients were assessed further.

The overall incidence of PE among cancer surgery patients increased from 2.3 per 1,000 patients in 2000 to 9.3 per 1,000 in 2005, a significant difference. This higher rate resulted from significantly greater diagnosis of subsegmental PEs, which increased from 0.1 per 1,000 patients in 2000 to 3 per 1,000 in 2005. At the same time, MDCT did not increase detection of central PEs, diagnosed in 0.7 per 1,000 patients in 2000 versus 0.6 per 1,000 in 2005.

Increased detection of subsegmental PEs with MDCT “makes sense because it’s more sensitive,” Dr. Fong said. “Subsegmentals are harder to find with VQ [ventilation/perfusion] scan or single-detector CT.”

The researchers also looked at mortality. The annual incidence rate of fatal pulmonary embolism did not change during the study, remaining at 0.4 per 1,000. Not surprisingly, the 30-day mortality rate for patients with the more serious central PE was higher, at 44%, compared with 6% for patients with subsegmental PE. Those with central PE “were more likely to go to the ICU, have

cardiopulmonary arrest, and die in the hospital,” Dr. Fong said.

More than half of the central PE group was symptomatic, whereas “only a few of the peripheral PEs were severely symptomatic,” he said. Shortness of breath, hypoxia, and an elevated heart rate (more than 100 beats per minute) were more common among central PE patients.

All 294 cancer patients with PE were treated with anticoagulants. Of these, 40 patients (14%) developed complications from the treatment. “Given a 14% complication rate with anticoagulation, are we putting some patients at increased risk?” asked Dr. Robert C.G. Martin, a surgical oncologist at the University of Louisville (Ky.).

“At Memorial Sloan-Kettering, when we discover a PE, whether or not it’s central, we anticoagulate them,” Dr. Fong replied. “Surgeons put the patients on [anticoagulants,] and then the oncologists are generally afraid to take folks off anticoagulants, so they remain on semipermanent anticoagulation.” There is a balance to strike between a higher risk of complications and the lower likelihood of metastasizing cancer cells circulating in the blood “being able to stick,” he added.

A meeting attendee asked about the use of mechanical compression devices. Dr. Fong replied that compression devices

are mandatory at Memorial Sloan-Kettering, and clinicians who choose not to use them for a particular patient must justify the reason in the records.

“What we do not know at this time is the optimal treatment of peripheral PEs that are diagnosed,” Dr. Fong said. “This requires future study.” ■

Dr. Keith M. Wille, FCCP, comments:

While multidetector CT has increased detection of peripheral pulmonary emboli (PE), the optimal management of patients with isolated subsegmental PE—specifically, whether or not to anticoagulate—remains unclear. Recent reviews (J. Thromb. Hemost. 2006;4:724-31; Radiology 2005;234:654-8) highlight the limited published data available to resolve this issue. On one hand, patients with adequate cardiopulmonary reserve, no deep venous thrombosis, and low risk for subsequent PE might not require anticoagulation. However, recurrent PE, including fatal events, have been reported despite initial negative CT results.

For now, the decision to treat patients with anticoagulants should be made on a case-by-case basis, with consideration for the risk of bleeding if given anticoagulants and the risk of subsequent PE if not. Future multicenter studies will hopefully provide better guidance for managing this clinical problem.

FDA Approves Bronchial Valve For Postoperative Air Leaks

BY ELIZABETH MEHCATIE
Elsevier Global Medical News

An implantable bronchial valve designed to control prolonged air leaks of the lung after lobectomy, segmentectomy, or lung volume reduction surgery was approved by the Food and Drug Administration.

The IBV Valve System includes the valve, a catheter for inserting it, and a sizing kit to measure the target area for valve implantation, according to the FDA statement announcing the approval. The system is used to treat patients “who have undergone partial or total removal of a lung lobe or lung volume reduction surgery and who experience prolonged air leaks [present 7 days after surgery] or significant air leaks that may become prolonged,” the FDA said.

The catheter containing the valve is passed through a bronchoscope, and the valve is then placed in the affected area of the lung, where it self-expands and redirects air flow from the diseased regions while allowing secretions and trapped air to pass through, according to Spiration Inc., the manufacturer. The valve expands and contracts with breathing and

can be removed during a bronchoscopy.

The valve was approved under the Humanitarian Device Exemption program, which applies to devices for diseases or conditions that affect fewer than 4,000 U.S. patients yearly. Approval was based on successful use of the valve in 58 patients with emphysema and 4 patients with prolonged air leaks, according to Spiration. The company plans to conduct a postapproval study to obtain more safety and efficacy information.

The valve is being studied in a trial of U.S. patients with severe emphysema. Patients aged 40-70 years with predominantly upper lobe emphysema and shortness of breath with exertion who have had inadequate responses to medical treatments and who are either ineligible for or opposed to invasive surgery are being enrolled in the trial, according to Spiration.

The approval “is an extremely important step for patients with emphysema,” said Dr. Robert James Cerfolio, FACS, FCCP, professor of surgery and chief of the section of thoracic surgery at the University of Alabama at Birmingham, who has had significant experience with these valves. He is an investigator in a study of the device. ■

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Supervised Weight Loss Improved Mild Sleep Apnea

BY HEIDI SPLETE

Elsevier Global Medical News

A program for healthy weight loss significantly improved mild obstructive sleep apnea, according to results of a study of overweight adults aged 18-65 years.

Obesity is a known risk factor for obstructive sleep apnea (OSA), but no randomized studies have addressed whether weight reduction improves the condition, noted Dr. Henri P.I. Tuomilehto of the University of Kuopio (Finland), and colleagues.

In the study, the researchers randomized 72 overweight adults with mild OSA to a program that included a very-low-calorie diet and supervised lifestyle modification, or to a program of routine lifestyle counseling.

The intervention included instructions for a very-low-calorie diet and 14 visits with a nutritionist during a 1-year period (including face-to-face meetings and group sessions), as well as recommendations for increasing physical activity. No specific exercise program was included in the intervention.

Improvements in OSA were objectively measured using the apnea-hypopnea index (AHI), and subjectively measured using a quality of life scale

and patient reports of symptom changes. All participants had a body mass index between 28 and 40 kg/m² and an AHI of 5-15 events per hour when they entered the study. Demographic characteristics were similar between the two groups.

At 1-year follow-up, the intervention group achieved significantly greater weight loss on average, compared with the controls (11 kg vs. 2 kg). The average total AHI in the intervention group was 6 events per hour, which was significantly less than the average of 9.6 events per hour in the control group (*Am. J. Respir. Crit. Care Med.* 2009; 179:320-7).

"Changes in AHI during the 12-month follow-up were strongly associated with changes in weight and waist circumference," the researchers wrote. A 5-kg weight loss from baseline body weight was associated with a 2.0-unit reduction in AHI, and a 5-cm reduction in waist circumference was associated with a 2.5-unit reduction in AHI.

In addition, the intervention was associated with improvements in other obesity-related cardiovascular disease risk factors.

During the course of the follow-up period, two of four patients in the intervention group who were taking

oral diabetes medications were able to discontinue the medications, while two of the controls started taking diabetes medications.

In all, 5 of 18 patients in the intervention group were able to discontinue their antihypertensive medications, compared with 2 of 15 patients in the control group.

Patients in the intervention group also reported improvements in quality of life, with scores nearly twice as high as the

controls at the 1-year follow-up point.

Patients in the intervention group also reported greater improvement in symptoms of OSA, including snoring and daytime sleepiness, compared with controls.

The study was limited by the use of a professional nutritionist, so the results may not generalize precisely to clinical practice, the researchers noted.

The researchers had no financial conflicts to disclose. ■

Apnea Risk in Bronchiolitis May Be Lower Than Thought

BY BETSY BATES

Elsevier Global Medical News

DENVER — Apnea risk may be lower than previously believed in otherwise normal infants with bronchiolitis. Early studies included many children with serious comorbid conditions that may have compounded their apnea risk, a systematic review of studies concluded.

Hospitalization rates for children with bronchiolitis have risen 250% in the more than 30 years since publication of a noteworthy article that cited an apnea rate of 20% in children with respiratory syncytial virus (RSV), Dr. Shawn L. Ralston said at a meeting on pediatric hospital medicine.

So pervasive is hospitalization for RSV-related bronchiolitis, in fact, that up to 1 in 5 hospital admissions of infants is due to the diagnosis, she said. However, severity and death rates have not changed since the 1970s, suggesting that some children may be hospitalized unnecessarily.

"I think there's a belief that RSV infection alone, and not just clinical bronchiolitis, increases the risk of apnea," said Dr. Ralston, a pediatric hospitalist at the University of Texas Health Science Center at San Antonio.

She therefore set out to conduct a systematic review of the literature about rates of apnea in children with RSV and bronchiolitis, results of which she presented at a meeting sponsored by the Society of Hospital Medicine, the American Academy of Pediatrics, and the Academic Pediatric Association.

From eight well-conducted, retrospective studies, she identified 3,623 patients as having bronchiolitis.

A total of 310, or 8.5%, were deemed to have apnea either observed or indicated by a parent or health care worker report. In 1,402 cases in which gestational age at birth was clearly documented, just 4.7% of full-term babies (defined as 38 weeks or greater) with bronchiolitis had associated apnea, she reported.

These rates are far lower than those reported in a series of studies, beginning with one published in 1977 by Denver

physician Frederic W. Bruhn (*J. Pediatr.* 1977;90:382-6) that identified apnea in 56 of 274 infants less than 6 months old who were diagnosed with RSV, a rate of 20.4%.

"This study made a big splash," Dr. Ralston said during her oral presentation.

Several other studies followed during the 1980s that had heterogeneous apnea rates ranging from 10% to 20% and left an overall impression that apnea was very common in children with RSV and bronchiolitis.

A closer look at pertinent studies found wide disparities in design, inclusion criteria, and stratification of data, she noted. The most striking methodological problem was the fact that studies with high apnea rates failed to exclude children with underlying illnesses and conditions.

"This is not the typical baby who looks fine but has RSV," she explained, noting that infants included in the studies had diagnoses such as coinfections, pertussis, microcephaly with seizure disorder,

"sleep apnea," and a wide range of chromosomal and metabolic abnormalities.

Some studies published in the 1970s and 1980s included 20%-30% of subjects with complex comorbidities, leading to a "tremendously misleading" impression of apnea risk in normal children, she said.

The studies also tended to de-emphasize the importance of patient age and gestational age at birth, which appear to be very important risk factors.

Apnea rates in the Bruhn study, for example, declined from 20% to 12% in babies born at 38 weeks' gestation or later. The youngest babies were at highest risk.

Although Bruhn's study found higher apnea rates among infants with RSV versus other respiratory viruses, subsequent studies called into question that conclusion as well, said Dr. Ralston.

"The take-home message is apnea happens, but there are no controlled studies suggesting that apnea is more common in RSV than in other viral respiratory infections," she said. "That may sound like heresy." ■



Just 4.7% of full-term babies with bronchiolitis had associated sleep apnea.
DR. RALSTON

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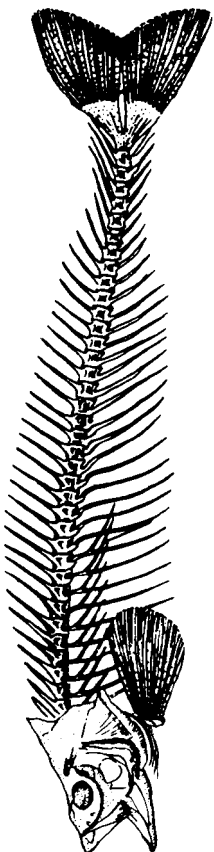
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