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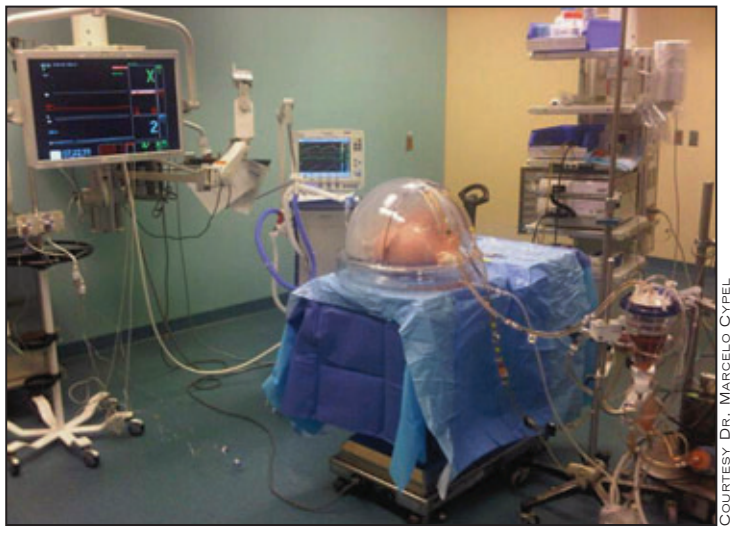

COURTESY DR. MARCELO CYPEL

Post-transplant survival at 1 year was 86% for the EVLP group and 87% for the traditional transplant group.

Ex Vivo Perfusion Widens Transplant Pool

BY DAMIAN McNAMARA
Elsevier Global Medical News

SAN FRANCISCO – Additional research has shown good outcomes with a new process that allows successful transplantation of lungs that might otherwise be deemed unacceptable.

Researchers at the Organ Regeneration Laboratory at the University of Toronto evaluated and repaired 58 donor lungs over 4-6 hours in a process called normothermic ex vivo lung perfusion (EVLP). In all, 50 of these lungs were successfully transplanted into patients, for a final utilization rate of 86%, Dr. Marcelo Cypel reported at the annual meeting of the American Association for Thoracic Surgery.

The current study builds on a previous report on initial experience with EVLP from the same research team (N. Engl. J. Med. 2011;364:1431-40). "As we all know, one of the major problems in doing lung transplantation is the organ shortage and the low utilization rates. Only 17% of the lungs from brain death donors and 2% of the lungs from cardiac death donors are used currently," Dr. Cypel said. EVLP lungs accounted for 20% of the transplantations at Toronto General Hospital in 2011.

The EVLP lungs came from 32 brain death donors and 26 cardiac death donors. Dr. Cypel and his colleagues compared the outcomes of these EVLP procedures to another 253 conventional lung transplantations performed at their institution from September 2008 to December 2011.

EVLP patients received a significantly higher percentage of lungs from cardiac death donors, which are generally considered less desirable than lungs from brain death donors. They also received a higher percentage of high-risk lungs from brain death donors (PaO_2/FIO_2 below 300 mm Hg) and more lungs with chest x-ray abnormalities, such as signs of pulmonary edema, compared with patients in the conventional group.

"Donor lungs in the EVLP

See **Ex Vivo** • *page 2*

ACCP: High-Risk Smokers Warrant CT Screening

New guidelines call for annual exam.

BY M. ALEXANDER OTTO
Elsevier Global Medical News

SAN FRANCISCO – Patients aged 55-74 years who have at least a 30 pack-year smoking history should be offered annual low-dose CT lung cancer screening, even if they have quit within the past 15 years, according to new clinical practice guidelines from the American College of Chest Physicians and the American Society of Clinical Oncology.

A systematic review forms the basis of the new ACCP/ASCO lung cancer screening guidelines. The recommendations are based largely on the 53,454-patient, randomized NLST (National Lung Screening Trial), which found that for every 1,000 high-risk smokers, three rounds of annual CT screening saved approximately three lives over about 7 years, which is comparable, at least, to the absolute benefit of screening mammographies in older women (N. Engl. J. Med. 2011;365:395-409).

The risks – including misdiagnosis and unnecessary surgery – and potential benefits should be explained to patients before they opt for screening. "People need to know [that] 19 out of 20 positive results are going to be false positive. A positive screen does not equal a diagnosis of lung cancer," coauthor Dr. Michael K. Gould, FCCP, assistant director for health services research at Kaiser Permanente of Southern California, Pasadena, said at an international conference of the American Thoracic Society.

In addition, "CT screening should not be performed" in the smokers and ex-smokers who fall outside of the high-risk group, or in those with

See **ACCP** • *page 8*

ARDS Redefined by Hypoxemia Severity

BY SHERRY BOSCHERT
Elsevier Global Medical News

SAN FRANCISCO – A proposed new definition of acute respiratory distress syndrome describes categories based on mild, moderate, or severe hypoxemia that correlate increasing severity with significantly increased mortality or increased time on mechanical ventilation among survivors.

The draft definition, created under a consensus process by an international panel of experts, was refined by empirical testing in a meta-analysis of data on 4,457 patients in two large data sets from seven centers. The risk of mortality from acute respiratory distress syndrome (ARDS) was 27% with mild disease, 32% with moderate ARDS, and 45% with severe ARDS, Dr. Niall D. Ferguson and Dr. Gordon D. Rubenfeld reported at an international conference of the American Thoracic Society.

The median duration of mechanical ventilation in survivors was 5 days in patients with mild ARDS, 7 days with

See **ARDS** • *page 9*

INSIDE

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With EVLP, More Lungs Usable

Ex Vivo • *from page 1*

group were significantly more injured at baseline; however, the outcomes were comparable," said Dr. Cypel, a member of the surgical faculty in the Division of Thoracic Surgery at Toronto General Hospital University Health Network.

For example, post-transplant survival at 1 year was 86% for the EVLP group and 87% for the traditional transplant group in this retrospective study; at 3 years these rates dropped to 70% and 72%. There were no significant differences in survival for patients who received lungs from brain death or cardiac death donors.

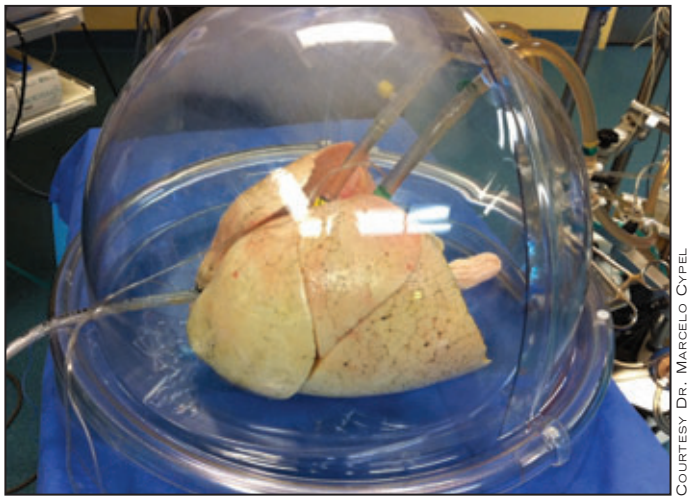
Other findings included no significant difference in the rate of primary graft grade 3 dysfunction at 72 hours between groups according to International Society for Heart and Lung Transplantation criteria. In addition, the EVLP patients had a trend toward a decreased length of hospital stay, compared with conventional transplant recipients, Dr. Cypel said.

"Again, you and your colleagues have demonstrated the safety and efficacy of using EVLP in the transplantation of lungs that previously would not have been used by your group," remarked study discussant Dr. R. Duane Davis, who is director of transplant services at Duke University Health System in Durham, N.C. "Using this technology, we may be able to start applying lung transplant more practically for societal needs."

Dr. Davis asked Dr. Cypel how surgeons at Toronto General Hospital achieved an 86% EVLP utilization rate compared with the 54% rate observed in the U.S. trial and comparable rates in the United Kingdom and elsewhere.

"Our experience with the procedure and extensive laboratory research prior to starting the clinical trial" explain the difference, Dr. Cypel replied. Donor selection criteria also could play a role.

"The important thing is, it is taking some of the adventure out of lung transplantation," study coauthor Dr. Shaf Keshavjee, FCCP, said during a separate presentation at the meeting. "Ex vivo lung perfusion is clinically feasible. We can do a long-term perfusion of lungs outside the body without injuring them. It is possible to keep lung 12 hours outside the body and normothermic.



COURTESY DR. MARCELO CYPEL

EVLP has allowed the overall number of transplants in Toronto to remain steady at the same time that organ donation rates have decreased, Dr. Marcelo Cypel said.

"We are developing ways to figure out which lungs need a fix and to target treatment to lungs that need treatment," added Dr. Keshavjee, director of the Toronto lung transplant program and chair of the division of thoracic surgery at the University of Toronto. Examples include resolution of pulmonary edema and infections through EVLP.

Treating infected lungs with lavage and high-dose antibiotics may make these organs acceptable for transplantation one day, even in cases of pneumonia.

The goal is to double or triple the overall number of lung transplants using the EVLP technique in the United States, said Dr. Davis. EVLP comprises 20% of transplants in Toronto, but the overall transplant volume has not increased.

EVLP has allowed the overall number of 100 transplants or so per year in Toronto to remain steady at the same time that organ donation rates have decreased, Dr. Cypel responded.

"The major contribution of EVLP will not be for the large transplant centers like Duke or Toronto, which already use 40% of the organs and for whom a marginal increase is not that large," Dr. Cypel said. "Look at the majority of lung transplant centers that use 10% or less of the offered lungs; that is where we can have a major impact by increasing the number of organs available."

Vitrolife supported the clinical trial. Dr. Cypel and Dr. Keshavjee reported no other relevant disclosures. Dr. Davis said he received research support from Vitrolife for a U.S. study. ■

Dr. Steven Q. Simpson, FCCP, comments: Normothermic ex vivo lung perfusion is perhaps the most significant single advance in lung transplantation since its inception. This study extends previous pilot data reported in the New England Journal of Medicine and extends it by providing long-term follow-up. The technique allows surgeons to transplant organs that are not being used in other centers – for example, edematous lungs or those obtained from cardiac death donors – and to do so with results as good as those obtained with more "pristine" lungs. Widespread adoption of this technique would allow significantly more patients to have lung transplant.

IN THIS ISSUE

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CHEST PHYSICIAN is available on the Web at www.chestnet.org/accp/chest-physician.

Dr. W. Michael Alberts, FCCP, is Medical Editor in Chief of CHEST PHYSICIAN.

CHEST PHYSICIAN

CHEST PHYSICIAN, the newspaper of the American College of Chest Physicians, provides cutting-edge reports from clinical meetings, FDA coverage, clinical trial results, expert commentary, and reporting on the business and politics of chest medicine. Each issue also provides material exclusive to the members of the American College of Chest Physicians. Content for **CHEST PHYSICIAN** is provided by International Medical News Group, an Elsevier company. Content for NEWS FROM THE COLLEGE is provided by the American College of Chest Physicians.

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For PAH (WHO Group 1) patients on oral monotherapy

TYVASO: the ONLY inhaled prostacyclin analogue approved for 4x-daily dosing[1]

Short treatment sessions: just 2 to 3 minutes each[2]

ONLY inhaled prostacyclin analogue approved as an add-on to oral PAH monotherapy[1]

- 52% of patients improved 6MWD by greater than 20 m[3]
- Improvement in 6MWD at peak (20 m) and trough (14 m) exposure[3]

Dosing regimen fits into patients' schedules

- Short treatment sessions: just 2 to 3 minutes, 4x daily[2]
- Set up once daily[1,2]
  - —One plastic ampule per day—no need to replace ampule for each treatment session[1]
  - —About 5 minutes a day for device preparation—once in the morning, and the device is ready to go all day[2]
- Treatment timing can be adjusted for planned activities[1]

Adverse events

- The most common adverse events seen with Tyvaso in ≥4% of PAH patients and more than 3% greater than placebo in the placebo-controlled clinical study were cough, headache, throat irritation/pharyngolaryngeal pain, nausea, flushing, and syncope[1]

STUDY DESIGN: TRIUMPH I was a 12-week, randomized, double-blind, placebo-controlled, multicenter study of patients (N=235) with PAH who were receiving a stable dose of bosentan or sildenafil for 3 months before study initiation. Patients were administered either placebo or Tyvaso in 4 daily treatment sessions with a target dose of 9 breaths (54 mcg) per session over the course of the 12-week study. Primary endpoint was change in 6MWD at 12 weeks. Secondary endpoints included time to clinical worsening, Borg dyspnea score, NYHA functional class, trough 6MWD at week 12 (obtained at least 4 hours after study drug administration), peak 6MWD at 6 weeks, quality of life as measured by the MLWHF questionnaire, and PAH signs and symptoms.[3]

INDICATION

Tyvaso is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%).

The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities.

While there are long-term data on use of treprostinil by other routes of administration, nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration.

IMPORTANT SAFETY INFORMATION

- Tyvaso is intended for oral inhalation only. Tyvaso is approved for use only with the Tyvaso Inhalation System
- The safety and efficacy of Tyvaso have not been established in patients with significant underlying lung disease (such as asthma or chronic obstructive pulmonary disease) and in patients under 18 years of age. Patients with acute pulmonary infections should be carefully monitored to detect any worsening of lung disease and loss of drug effect
- Tyvaso may increase the risk of bleeding, particularly in patients receiving anticoagulants
- In patients with low systemic arterial pressure, Tyvaso may cause symptomatic hypotension. The concomitant use of Tyvaso with diuretics, antihypertensives, or other vasodilators may increase the risk of symptomatic hypotension
- Hepatic or renal insufficiency may increase exposure to Tyvaso and decrease tolerability. Tyvaso dosage adjustments may be necessary if inhibitors of CYP2C8 such as gemfibrozil or inducers such as rifampin are added or withdrawn
- The most common adverse events seen with Tyvaso in ≥4% of PAH patients and more than 3% greater than placebo in the placebo-controlled clinical study were cough (54% vs 29%), headache (41% vs 23%), throat irritation/pharyngolaryngeal pain (25% vs 14%), nausea (19% vs 11%), flushing (15% vs <1%), and syncope (6% vs <1%)
- Tyvaso should be used in pregnancy only if clearly needed. Caution should be exercised when Tyvaso is administered to nursing women

Please see brief summary of Full Prescribing Information on following page. For more information, please see Full Prescribing Information, Patient Package Insert, and the Tyvaso Inhalation System Instructions for Use manual. These items are available at www.tyvaso.com.

6MWD=6-minute walk distance. MLWHF=Minnesota Living With Heart Failure. NYHA=New York Heart Association. WHO=World Health Organization.

References: 1. Tyvaso [package insert]. Research Triangle Park, NC: United Therapeutics Corporation; 2011. **2.** Tyvaso [patient package insert]. Research Triangle Park, NC: United Therapeutics Corporation; 2011. **3.** McLaughlin VV, Benza RL, Rubin LJ, et al. Addition of inhaled treprostinil to oral therapy for pulmonary arterial hypertension: a randomized controlled clinical trial. *J Am Coll Cardiol*. 2010;55(18):1915-1922.

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PROSTACYCLIN MADE PRACTICAL

Public Lacks Awareness of Palliative Care

BY BRUCE JANCIN
Elsevier Global Medical News

DENVER – More than three-quarters of the general public have no idea what palliative care is, according to a national survey. And that, as it turns out, is actually excellent for the field's future growth prospects, according to one of the nation's top palliative care specialists.

"This is good news for us. We can create the cognitive frame where there isn't one already in place," said Dr. Diane E. Meier, director of the Center to Advance Palliative Care and professor of geriatrics and internal medicine at Mount Sinai School of Medicine, New York.

While the public is largely a blank slate with regard to palliative care, nonpalliative care physicians and other health care professionals tend to believe that palliative care is simply end-of-life care. Many don't understand that palliative care is actually about relieving the pain, symptoms, and stress of serious illness in patients of any age and at any stage of disease, and that palliative care can be delivered alongside curative or life-prolonging therapies, Dr. Meier said at the annual meeting of the American Academy of Hospice and Palliative Medicine.

The consumer survey sponsored by the Center to Advance Palliative Care and the American Cancer Society involved 800 adults; 70% indicated they were "not at all knowledgeable" about palliative care, and another 8% had never heard of the term. Only 5% were categorized as "very knowledgeable" about palliative care.

Once they were informed about what palliative care truly is, however, survey participants were very positive about it.

For example, once they were educated about palliative care, 95% of those surveyed said it's important for patients with serious illnesses and their families to learn about palliative care. Most (92%) indicated they would likely consider it for themselves or a loved one, and an equal percentage said it's important that palliative care services be available at all hospitals, Dr. Meier reported.

She and other leaders in the palliative care field are now seeking funding for an ambitious 5-year, multimillion-dollar social marketing campaign to increase public awareness regarding palliative care.

"We've recognized that we're not going to see policy change without public support," Dr. Meier said.

Among the policy changes she and her colleagues seek is a big boost in the palliative care workforce, which at present is so small as to constitute a major barrier to access. While there is one oncologist for every 145 patients in the United States with a new cancer diagnosis, and one cardiologist for every 71 patients who have an MI, there is just one palliative care specialist for every 1,300 people with a serious illness. Postgraduate training in palliative care is widely unavailable.

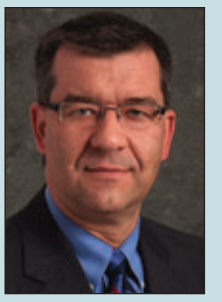
Dr. Meier would like to see an increased number of physician and nurse practitioner fellowship programs established in palliative care. Another priority is to develop a midcareer board certification track in palliative care across all medical disciplines. "We have a lot of people coming in from oncology, surgery, and other fields who are seeking work with meaning and purpose," she observed.

Starting in 2013, the specialty will require fellowship training for board certification in palliative care. "Grandfathering in" will no longer be possible.

Dr. Meier reported having no financial conflicts. ■

COMMENTARY

Dr. Darcy Marciniuk, FCCP, comments: The survey results highlight the low awareness of palliative care, results likely applicable to many colleagues and health care systems. But why wait for further specialists in the field to increase that awareness? There is much we can all do today to both acknowledge and lessen the unmet needs of many of our patients who would benefit from comprehensive and effective palliative care.



Young CF Patients Don't Gain From Hypertonic Saline

BY M. ALEXANDER OTTO
Elsevier Global Medical News

VITALS

Major Finding: When treated with hypertonic saline, the pulmonary exacerbation rate in infants and young children with cystic fibrosis was 2.3 events/person-year, no different from those treated with isotonic saline.

Data Source: The findings are from a randomized trial involving 321 infants and children aged 5 years or younger.

Disclosures: Dr. Rosenfeld disclosed that she is an adviser to Genentech and Vertex Pharmaceuticals, and receives research grants from Vertex. Dr. Dasenbrook is a consultant for Savara and Gilead. Dr. Konstan is an adviser to Aradigm and a consultant for Boehringer Ingelheim, Genentech, Novartis, PARI Respiratory Equipment, Vertex, and several other companies. He receives grants or has grants pending from several companies, and receives speaker's fees from Genentech and Novartis.

SAN FRANCISCO – Inhaled hypertonic saline did not reduce the number of pulmonary exacerbations in infants and children with cystic fibrosis in a randomized trial.

The trial pitted 7% hypertonic saline in 158 pediatric patients against 0.9% isotonic saline as a control in 163 patients. The solutions were nebulized twice daily for 48 weeks, with both groups getting albuterol or levalbuterol beforehand. The patients ranged in age from 4 to 60 months. Adherence was at least 75% in each group, judging from returned study drug ampoules, reported lead investigator Dr. Margaret Rosenfeld at an international conference of the American Thoracic Society.

In the hypertonic saline group, the mean pulmonary exacerbation rate was 2.3 events/person-year (95% confidence interval [CI], 2.0-2.5), and the mean number of total antibiotic treatment days for pulmonary exacerbations was 60 (95% CI, 49-70). In the control group, the mean pulmonary exacerbation rate was 2.3 events/person-year (95% CI, 2.1-2.6), and the mean total number of antibiotic treatment days was 52 (95% CI, 43-61).

No significant differences were seen in secondary end points, including height, weight, respiratory rate, oxygen saturation, cough, or respiratory symptom scores. Adverse event profiles were similar, with cough the most common event in about 40% of each group (JAMA 2012 May 20 [doi:10.1001/jama.2012.5214]).

"There is great interest in the CF [cystic fibrosis] community about developing early intervention strategies to delay or prevent CF lung disease before the bronchiectasis becomes irreversible. From our current evidence, hypertonic saline does not fulfill that role. Based on its inability to reduce the rate of pulmonary exacerbations, we would not recommend that it be used in this age range," said Dr. Rosenfeld, a pediatric pulmonologist and associate professor of pediatrics at the University of Washington in Seattle.

The finding was a surprise because hypertonic saline is known to prevent exacerbations in older children and adults, perhaps by helping the lungs cough out bacteria. There has been hope it would also help very young children, and its use in that population has increased substantially in recent years, Dr. Rosenfeld noted (N. Engl. J. Med. 2006;354:229-40).

"We've been scratching our heads about" why that hope didn't pan out in the trial. "We have a number of hypotheses. The first one is that pulmonary exacerbations may be really different beasts in infants and young children. [Perhaps] they are mostly triggered by viral respiratory infections. Hypertonic saline can't prevent people from getting respiratory viruses," she said at the conference.

Exacerbations might have been too blunt a primary outcome measure, according to an editorial that accompanied the published study in JAMA.

Very young children with CF have not yet developed the outright lung damage that makes older patients particularly susceptible to exacerbations. Perhaps more subtle markers of early disease onset and progression were needed in the trial, wrote Dr. Elliott Dasenbrook, associate director of the Adult Cystic Fibrosis Program at Case Western Reserve University, Cleveland, and Dr. Michael Konstan, director of the school's Cystic Fibrosis Center and chairman of its pediatrics department.

"Although the results of the study suggest that inhaled hypertonic saline should not be used routinely in young children, the final verdict on its use for infants and young children has not been rendered. It would be disheartening if a viable therapeutic option was discarded because of negative study results when more sensitive end points might have detected benefit from the intervention. Testing therapeutic agents in infants and young children may require different end points capable of assessing onset and progression of disease," they wrote (JAMA 2012 May 20 [doi: 10.1001/jama.2012.5853]).

There was one "tantalizing" hint in the trial that hypertonic saline may delay structural damage, Dr. Rosenfeld said. Among the 22 children aged 4-16 months in the hypertonic saline group who had pulmonary function tests, forced expiratory volume in 0.5 seconds ($FEV_{0.5}$) was a mean of 38 mL greater (95% CI, 1-76) than among the 23 children tested in the control group, the only significant pulmonary function difference.

Perhaps that could be a marker in future trials, but "statistically significant difference does not necessarily imply clinical significance," Dr. Dasenbrook and Dr. Konstan noted. "These exploratory end points should be viewed as hypothesis generating, and research exploring the clinical effects of these differences is needed."

That research is likely to happen. "We would like to study [hypertonic saline] further and see if we get a signal if we choose more physiologic end points," Dr. Rosenfeld said. ■

COMMENTARY

Dr. Burt Lesnick, FCCP, comments: Just as children are not just small adults, infants with CF are not just little children. We need to better understand the maturational effects on therapies and how pathophysiology varies by age. This study is a good start.

Pediatric Asthma Admissions Varied Greatly by Neighborhood

BY NEIL OSTERWEIL
Elsevier Global Medical News

BOSTON – Asthma admissions, like politics, are local.

So suggests the wide variability within a single Ohio county in hospitalization rates for children with acute asthma, Dr. Andrew F. Beck, a fellow in general and community pediatrics at Cincinnati Children's Hospital Medical Center, said at the annual meeting of the Pediatric Academic Societies.

A neighborhood-by-neighborhood analysis of pediatric asthma admissions in Hamilton County (Cincinnati and environs), showed that some neighborhoods had admission rates as high as 27 per 1,000 children aged 1-16 years, while others recorded no pediatric asthma hospitalizations at all, Dr. Beck reported.

"Hamilton County had an admission rate double the national average, with profound in-county variation in admission distribution," he noted. "Given this variation, we expect that neighborhood would be a powerful unit of measure that would be easily translatable to members of the community."

Armed with highly localized data, public health authorities could develop more effective interventions targeted at reducing disparities in asthma care, theoretically reducing admissions and saving millions of health care dollars, he explained.

To characterize variations in asthma admission rates among Hamilton County neighborhoods and assess differences in patient- and neighborhood-level characteristics, the investigators drew data from the population-based, prospective, observational Greater Cincinnati Asthma Risks Study.

They looked at 862 sequential admissions of 757 patients for asthma or wheezing from September 2010 through August 2011 of all children aged 1-16 years with addresses within the county.

All of the admissions were at Cincinnati Children's Hospital Medical Center, which accounts for about 95% of all county admissions, according to Ohio public health data. To reduce the likelihood of confounding variables, the researchers excluded children with respiratory or cardiovascular comorbidities.

The mean overall admission rate for the county was 5.1 per 1,000 children; that compares with a national average of about 2.5/1,000, Dr. Beck noted. Neighborhoods whose residents had the highest third of admission rates averaged 17.0/1,000, compared with 7.5 per 1,000 for the middle third and 2.6/1,000 for the bottom third.

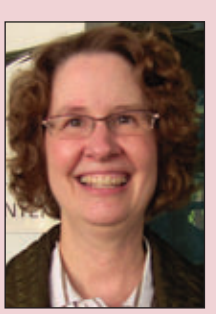
"If the county rate were reduced to that of the lowest tertile, annual admissions would decrease by more than 50% and $2.1 million could be saved," Dr. Beck said.

The researchers used factors chosen from U.S. Census data to determine differences among the three admission-rate groups. They found that lower household incomes, lower levels of education, greater population density, and lower percentage of home ownership within neighborhoods were all significantly predictive of higher asthma admission rates (*P* less than .0001 for all factors).

Other factors significantly associated with a greater chance of admission included patient-reported "difficulty making ends meet," lack of transportation, cockroach infestation, depressive symptoms, and running out of medications (*P* less than .01 for all comparisons).

The study was supported by a National Institutes of Health grant and a National Research Service Award grant. The investigators reported having no relevant financial disclosures. ■

COMMENTARY



Dr. Susan Millard, FCCP, comments: This study could be expanded to communities around the United States. This type of analysis would help asthma coalitions, community leaders, and religious groups focus their respiratory health education efforts on certain neighborhoods and therefore impact the lives of many at-risk children.

Warfarin Self-Testing Ups Time in Therapeutic Range

BY BRUCE JANCIN
Elsevier Global Medical News

CHICAGO – The new oral anticoagulants for stroke prevention in atrial fibrillation may be garnering all the buzz, but don't count out warfarin.

"It's not just a knee-jerk reaction that all patients should be switched to the new agents. It's dependent upon how well you as a physician are managing your patients on warfarin," Dr. Jack E. Ansell said at the annual meeting of the American College of Cardiology.

"Warfarin therapy is all about management. If it's not managed well, you can compare it to anything, and anything is going to be better. And if it's managed very well, then it's very difficult to beat warfarin therapy," said Dr. Ansell, chairman of the department of medicine at Lenox Hill Hospital in New York.

A growing body of evidence indicates that the new standard in high-quality management of warfarin therapy involves patient self-testing of international normalized ratio (INR) at home using a fingerstick blood sample and a portable point-of-care device.

Case in point: Dr. Ansell presented highlights of the new STABLE study, in which he and his coinvestigators conducted a retrospective analysis of the real-world experience of more than 29,000 warfarin-treated patients enrolled in a national commercial comprehensive self-test support service (JACC 2012 March 27 [doi: 10.1016/S0735-1097(12)61865-8]).

Patients who performed frequent self-testing – meaning more than 80% of their self-testing was done on a weekly basis – had a mean time spent in the therapeutic INR range (TTR) of 74%. That's unprecedented, he said.

By comparison, in the pivotal RE-LY randomized trial for dabigatran (Pradaxa), the control group on warfarin had a TTR of 64% (N. Engl. J. Med. 2009;361:1139-51). In the ROCKET-AF trial of rivaroxaban (Xarelto), warfarin controls had a TTR of 55% (N. Engl. J. Med. 2011;365:883-91). And in the ARISTOTLE study of apixaban (Eliquis), an agent expected to soon receive Food and Drug Administration marketing approval, the warfarin control group had a TTR of 62% (N. Engl. J. Med. 2011;365:981-92). In all these major randomized trials involving the novel oral anticoagulants, patients assigned to warfarin were closely managed, but in traditional fashion – home self-testing wasn't involved.

In contrast, in the STABLE study, the overall TTR, including those patients who self-tested variably and inconsistently, was still 69.7%.

"This is important because the cost-effectiveness analyses done with dabigatran and the other new anticoagulants suggest that when you get up to a TTR above 70% with warfarin, the cost-effectiveness of the new agents diminishes and warfarin actually becomes more cost-effective," Dr. Ansell said.

A particularly impressive finding in STABLE was that patients who did weekly self-testing had a 2.3% incidence of critical value INR results, defined as an INR below 1.5 or greater than 5.0. "This is really a phenomenally low result," he commented. It represented a 48% reduction from the 4.4% incidence in patients with variable self-testing frequency.

Participants in the STABLE study tested themselves at home, but their warfarin dosing was managed by their referring physicians or anticoagulation clinics. Thus, an individual's TTR reflected the warfarin management expertise of the referral source.

There are several reasons why home monitoring achieves better TTRs and – as shown in other studies – lower major bleeding and thrombotic event rates than with usual care or anticoagulation clinics not utilizing patient self-monitoring, Dr. Ansell said. Home testing is more frequent, timely, and consistent, and the immediate feedback regarding INR results is likely to promote adherence.

A variant of patient self-testing starting to catch on in the United States is patient self-management. This entails teaching patients how to manage their own warfarin dose on the basis of their home INR measurements.

The most recent American College of Chest Physicians clinical practice guidelines on antithrombotic therapy for atrial fibrillation give patient self-management of warfarin therapy a class 2B recommendation, stating, "For patients treated with vitamin K antagonists who are motivated and can demonstrate competency in self-management strategies, including the self-testing equipment, we suggest patient self-management rather than the usual outpatient INR monitoring" (CHEST 2012;141[2 suppl]:e531S-75S).

Session cochair Dr. Samuel Z. Goldhaber, FCCP, agreed that warfarin still has a place in anticoagulation. The fact that it costs as little as $4 per month while dabigatran, for example, retails for 60 times that amount, is not to be shrugged off. Plus, warfarin is a known quantity backed by decades of clinical experience.

"Even though warfarin can cause horrible complications, there are no more surprises left about what warfarin can do," observed Dr. Goldhaber, professor of medicine at Harvard Medical School and director of the venous thromboembolism research group at Brigham and Women's Hospital, Boston.

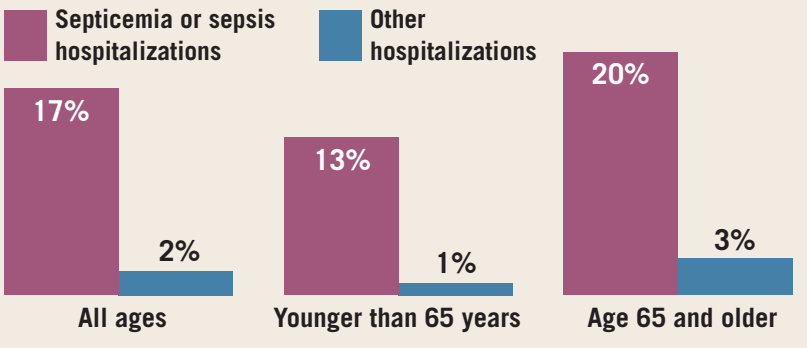
The STABLE study was funded by Alere Home Monitoring. Dr. Ansell is a consultant to the company. Dr. Goldhaber has served as a consultant to numerous pharmaceutical companies developing cardiovascular medications. ■

COMMENTARY

Dr. Jun Chiong, FCCP, comments: This study finds that many patients who take warfarin can benefit from INR self-monitoring. Although some might not be able to monitor themselves, self-monitoring is a great idea if patients are carefully selected. Patients with atrial fibrillation now can switch to antithrombin agents that do not require blood monitoring, and they have shown significant reduction in stroke and systemic embolism over warfarin alone. People with mechanical valve replacements face a significant risk of stroke from blood clots and will still be on warfarin. This is where lifetime self-monitoring is very beneficial, as tight monitoring is required in this population and getting frequent blood tests is inconvenient, time consuming, and costly.

DATA WATCH

Patients With Septicemia or Sepsis More Than Eight Times as Likely to Die in the Hospital



Note: Based on data from the 2008 National Hospital Discharge Survey.
Source: Centers for Disease Control and Prevention

IMNG Medical Media

Reduced TPA Regimen Safely Treats Pulmonary Embolism

BY MITCHEL L. ZOLER
Elsevier Global Medical News

CHICAGO – A reduced-dose regimen of tissue plasminogen activator and parenteral anticoagulant safely led to improved outcomes in hemodynamically stable patients with a pulmonary embolism in a pilot study with a total of 121 patients treated at one U.S. center.

None of the 61 patients treated with the regimen, which halved the standard dosage of TPA and cut the dosage of enoxaparin or heparin by 20%-30%, had an intracranial hemorrhage or a major bleeding event, compared with a historic 2%-6% incidence of ICH and a 6%-20% incidence of major bleeds in hemodynamically unstable pulmonary embolism patients who receive the standard, full dose of both the thrombolytic and anticoagulant, Dr. Mohsen Sharifi said at the annual meeting at the American College of Cardiology.

While he acknowledged that the results need confirmation in a larger study, "in our experience treating deep vein thrombosis [with a similarly low dosage of TPA], we are comfortable that this amount of TPA can be given safely," said Dr. Sharifi, an interventional cardiologist who practices in Mesa, Ariz.

The findings also showed that applying this reduced-dose intervention to hemodynamically stable patients with a PE, who are typically not treated with thrombolysis, substantially improved their long-term prognosis by reducing their development of pulmonary hypertension. After an average of 28 months follow-up, 9 of the 58 patients (16%) followed long term and treated with the reduced-dose regimen had pulmonary hypertension, defined as a pulmonary artery systolic pressure greater than 40 mm Hg, compared with pulmonary hypertension in 32 of the 56 control patients (57%) managed by standard treatment with anticoagulation only.

Current guidelines from the American Heart Association call for fibrinolytic treatment only in patients with a massive, acute PE, or in patients with a submassive PE who are hemodynamically unstable or have other clinical evidence of an adverse prognosis (Circulation 2011;123:1788-830). According to Dr. Sharifi, about 5% of all PE patients fall into this category. He estimated that broadening thrombolytic treatment to hemodynamically stable patients who met his study's inclusion criteria could broaden TPA treatment to an additional 70% of PE patients currently seen in emergency departments.

VITALS

Major Finding: Pulmonary embolism patients receiving reduced dosages of TPA and anticoagulant had a 16% pulmonary hypertension rate versus 57% in controls.

Data Source: Data came from a single-center, randomized study that enrolled 121 patients with hemodynamically stable PE.

Disclosures: Dr. Sharifi and Dr. Crawford said that they had no relevant disclosures.

"Based on the results of this pilot study, you won't get broad acceptance of treating hemodynamically stable PE patients with thrombolysis," commented Dr. Michael Crawford, chief of general cardiology at the University of California, San Francisco. Two larger studies nearing completion are both examining the efficacy and safety of thrombolysis in patients with submassive PE.

Dr. Sharifi said that despite the small study size, he and his associates were convinced enough by their findings to use the reduced TPA dosage tested in this study on a routine basis when they see patients who meet their enrollment criteria.

The MOPETT (Moderate Pulmonary Embolism Treated with Thrombolysis) study enrolled patients with a PE affecting at least two lobar segments, pulmonary artery systolic pressure greater than 40 mm Hg; right ventricular hypokinesia and enlargement, and at least two symptoms, which could include chest pain, tachypnea, tachycardia, dyspnea, cough, and oxygen desaturation. The average age of the patients was 59 years, and slightly more than half were women. Average pulmonary artery systolic pressure at entry was about 50 mm Hg.

Dr. Sharifi and his associates randomized half the patients to receive conventional treatment with anticoagulant only, either enoxaparin or heparin plus warfarin. The other patients received thrombolytic treatment with an infusion of TPA at half the standard dosage, starting in patients who weighed at least 50 kg with a loading dose of 10 mg delivered in 1 minute, and followed by a 40-mg total additional dose administered over 2 hours. Patients who weighed less received the same 10-mg initial dose, but their total dose including the subsequent 2-hour infusion was limited to 0.5 mg/kg. The patients treated with TPA also received concomitant anticoagulation, with either enoxaparin given at 1 mg/kg but not to exceed 80 mg as an initial dose, or heparin at an initial dose of 70 U/kg but capped at 6,000 U, followed by heparin maintenance at 10 U/kg per hour during the TPA infusion (but not exceeding 1,000 U/hour), and then rising to 18 U/kg per hour starting 1 hour after TPA treatment stopped. About 80% of all patients in the study received enoxaparin, and about 20% received heparin.

At 48 hours after starting treatment, average pulmonary artery systolic pressure dropped by 16 mm Hg in the TPA group and by 5 mm Hg in the control patients. By the end of the average 28-month follow-up, average pulmonary artery systolic pressure was 28 mm Hg in the TPA patients and 43 mm Hg in the controls. Dr. Sharifi attributed the efficacy of reduced-dose TPA to the "exquisite sensitivity" of blood clots lodged in a patient's lungs to the drug, a consequence of all the infused TPA passing through the lung's arterial circulation.

Besides showing a statistically significant benefit from TPA for the primary end point, the average duration of hospitalization in the TPA recipients was 2.2 days, compared with an average of 4.9 days in the control patients, a statistically significant difference. At 28 months' follow-up, three patients in the control arm had a recurrent PE and another three had died, significantly more than the no recurrent PEs and one death in the TPA arm. ■

COMMENTARY

Dr. Jun Chiong, FCCP, comments: PE is a commonly encountered disorder with high mortality, and treatment has changed little over the last 30 years. The authors randomized hemodynamically stable patients to receive half the standard dosage of TPA plus conventional treatment with anticoagulant only, either enoxaparin or heparin plus warfarin vs. conventional treatment alone. With a significant decrease in pulmonary pressure, less bleeding, shorter length of stay, and lower mortality, there's a significant need to randomize a similar study on a larger scale and with longer follow-up.

Two Drugs Not Better for Severe Sepsis

BY SHERRY BOSCHERT
Elsevier Global Medical News

SAN FRANCISCO – Treating a new diagnosis of severe sepsis or septic shock with a combination of moxifloxacin and meropenem did not decrease the risk of sepsis-related organ dysfunction, compared with meropenem monotherapy, a randomized, open-label trial showed.

On the contrary, there were statistical hints suggesting that the monotherapy regimen may be safer than the dual-drug strategy, Dr. Tobias Welte and his associates reported at an international conference of the American Thoracic Society.

Mean daily scores on the SOFA (Sequential Organ Failure Assessment) for 551 patients with evaluable data did not differ significantly between groups (a score of 8 in both) during treatment for 7-14 days or until discharge from the ICU or death, said Dr. Welte of Hannover (Germany) Medical School. Subscores on the SOFA for cardiovascular, respiratory, coagulation, renal, or hepatic failure also were similar between groups (JAMA 2012 May 21 [doi:10.1001/jama.2012.5833]).

Among secondary outcomes, mortality rates at 28 days were 24% with the combination therapy and 22% with monotherapy. Mortality rates at 90 days were 35% with combination therapy and 32% with monotherapy. Those differences between groups were not significant, he said.

The combination therapy group had a significantly higher rate of treatment-related adverse events (9%), compared with the monotherapy group (4%).

The investigators had expected that the combination regimen would improve clinical outcomes. Use of empirical therapy with combined antibiotics has been controversial and is more common in the United States than in Europe.

"What we need for the future is a better characterization of patients who are at risk for multiresistant organisms," Dr. Welte said. "If you do it like the Americans do it, every patient is at risk for multiresistancy." With better risk stratification, more than half of U.S. patients with severe sepsis or septic shock might be candidates for monotherapy, he said.

Both groups averaged 8 days of treatment, showing that "8 days of treatment are enough even in patients with severe sepsis or septic shock," Dr. Welte said.

The MaxSep (Treatment of Severe Sepsis and Septic Shock) study included patients from 44 ICUs in Germany in 2007-2010. IV infusions delivered 1-g meropenem every 8 hours plus moxifloxacin 400 mg every 24 hours, or meropenem alone. Follow-up was 90 days.

After treatment, the results were similar between groups in ICU or hospital length of stay, median intervention-free days, and rate of secondary infection.

In previous studies, survival in severe sepsis significantly improved with combination therapy (Crit. Care Med. 2010; 38:1651-64).

The study was funded by the German government. AstraZeneca and Bayer HealthCare provided the study drugs. Dr. Welte reported financial relationships with AstraZeneca, Bayer, and others. ■

COMMENTARY

Dr. Steven Q. Simpson, FCCP, comments: This study showed no effect on organ dysfunction scores or length of stay by the addition of moxifloxacin to meropenem in severe sepsis. The study could be interpreted to indicate that two or more drugs are not necessary. In fact, the variety of infecting organisms in the study and the spectrum of coverage for these two antibiotics would suggest that there should not have been differences in outcome. Before adopting a single-drug strategy for the empiric treatment of patients with septic shock, it is important to understand the local antibiotic susceptibility patterns and to ensure that multiple drugs, when used, are targeted to gaps in coverage. An additional point worth considering is that duration of therapy may be the largest contributing factor to both antibiotic toxicity and microbial resistance.

Screen Only Select Patients

ACCP • *from page 1*

comorbidities that limit life expectancy or preclude curative treatment, according to the guidelines (JAMA 2012 May 20 [doi:10.1001/jama.2012.5521]).

The risks and benefits of screening are just "too close to call" for those patients, said lead author Dr. Peter Bach, director of the center for health policy and outcomes at Memorial Sloan-Kettering Cancer Center in New York.

After doing an extensive literature review, the researchers included eight randomized trials and 13 cohort studies in the final analysis. Although they are confident that screening benefits high-risk patients – based mostly on the NLST, with some added input from smaller trials – they are also concerned about the lack of data on the potential harms of screening, which led to the recommendation to offer screening only to high-risk patients, Dr. Bach said.

For more on the new ACCP/ASCO guideline on CT screening, go to p. 15

Overall, the lack of additional research led the recommendations to be characterized as "weak" under the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach.

The impact of screening even high-risk patients "on smoking cessation, quality of life, and cost-effectiveness is really quite unclear. We don't know in any sense what the frequency should be or the duration," Dr. Bach said.

Also unclear is how screening will play out in settings less experienced and less rigorous than the academic centers where the NLST was conducted. Patient compliance with screening at those centers was 90%, adverse events were rare, and subsequent diagnostic work-ups and interventions were available. To mitigate potential problems, the guidelines recommend that the CT screening be done in similar multidisciplinary settings.

The authors also call for a screening registry "that records each patient's experience [to] help us develop a quality measurement system similar to mammography screening that could maximize the benefits and minimize the harm for individuals who undergo screening," Dr. Bach said.

Given the unknowns, there was a lot of debate at JAMA about whether to publish the review, said journal editor Dr. Howard Bauchner.

"There were many discussions about [if it] would do more harm than good." In the end, the journal opted to publish because 160,000 "people die of lung cancer each year" in the United States, with "little progress over the last decade. This is the first hope we have that we can impact those data," he said.

A supplement to the JAMA article containing the review and guidelines includes a section entitled "Components of a Conversation About CT Screening," which addresses how to talk with patients about these issues.

The American Thoracic Society has also endorsed the guidelines, and the American Lung Association has come to the same conclusion (see story below).

Dr. Bach reported that he has received speaking fees from Genentech. Coauthors reported ties to pharmaceutical companies such as Oncimmune and governmental agencies such as the National Cancer Institute. Dr. Gould and Dr. Bauchner said they have no relevant disclosures. ■

COMMENTARY

Dr. W. Michael Alberts, FCCP, comments: All with an interest in lung cancer were pleased with the results of the NLST trial. Clinicians immediately asked, however, how they should advise their patients. Screen everyone? Screen only smokers? Screen yearly? Screen forever? These are but a few of a myriad of appropriate questions. Fortunately, the ACCP and ASCO has issued guidelines based on systematic review of the benefits and harms of CT screening for lung cancer. These guidelines (and accompanying remarks) should serve as the basis for the development of lung cancer screening programs.

ALA Also Endorses CT Screening for Heavy Smokers

BY MICHELE G. SULLIVAN
Elsevier Global Medical News

The American Lung Association has thrown its weight behind low-dose CT screening of heavy smokers who meet criteria set forth in the National Lung Screening Trial.

The group emphasized that it does not recommend universal screening at this time, and that it believes chest x-rays should not be used for lung cancer screening. It only recommends low-dose computed axial tomography screening – and only for current or past smokers aged 55-74 years, who have smoked at least 30 pack-years and have no history of lung cancer.

'SMOKING CESSATION SHOULD BE CONTINUOUSLY EMPHASIZED AS IT REMAINS THE BEST METHOD OF REDUCING LUNG CANCER RISK.'

"For those who choose to undergo the screening process, smoking cessation should be continuously emphasized as it remains the best method of reducing lung cancer risk," according to an interim report outlining the new guidance.

The document comes from a seven-member Lung Cancer Screening Committee formed to assess the American Lung Association's position in light of the National Lung Screening Trial (NLST) results – the study was the first to show a screening program could reduce lung cancer deaths. The panel's charge was to review current evidence about lung cancer screening that would "offer the best possible guidance to the public and those suffering from lung disease."

The NLST randomized subjects at risk of lung cancer to three annual screenings with either low-dose CT or single-view posteroanterior chest x-rays. Investigators reported that low-dose CT was associated with a 20% decrease in mortality compared with chest x-rays. The false-positive rate was 96%, however (N. Engl. J. Med. 2011;365:395-409).

Since the results were announced, the National Comprehensive Cancer Network (NCCN) has similarly endorsed screening of high-risk smokers, and the International Association for the Study of Lung Cancer (IASLC) has urged physicians to discuss screening with patients who smoke.

Although the landmark trial found solid evidence supporting annual screens in the population studied, the ALA noted it also raised many "personal and public health issues": among them, what to do about false-positive results, the physical and emotional risks of screening and any resultant invasive procedures, cost implications, and equitable access to the CT procedure. The ALA task force sought to provide some guidance around these questions.

"Our hope is that this report will serve ALA well in its mission to guide the public on this very important personal and public health issue," noted committee chair Dr. Jonathan M. Samet, FCCP (Hon), professor and Flora L. Thornton Chair, of the department of preventive medicine at the University of Southern California, Los Angeles, and coauthors.

"We believe that the report and the educational materials that stem from it will be invaluable to the tens of millions of people at risk for lung cancer."

Also among the key points in the interim report are:

► Providers should continue to stress that smoking cessation is the most important way to reduce the risk of lung cancer.

► ALA should produce a patient-focused tool kit that discusses the risks and benefits of screening, including the physical risks of any invasive diagnostic procedure, and the costs – both financial and emotional – of any false-positive result. The tool kit should have information to help patients with chronic lung disease and their health providers to have a detailed discussion about the risks of any subsequent invasive testing.

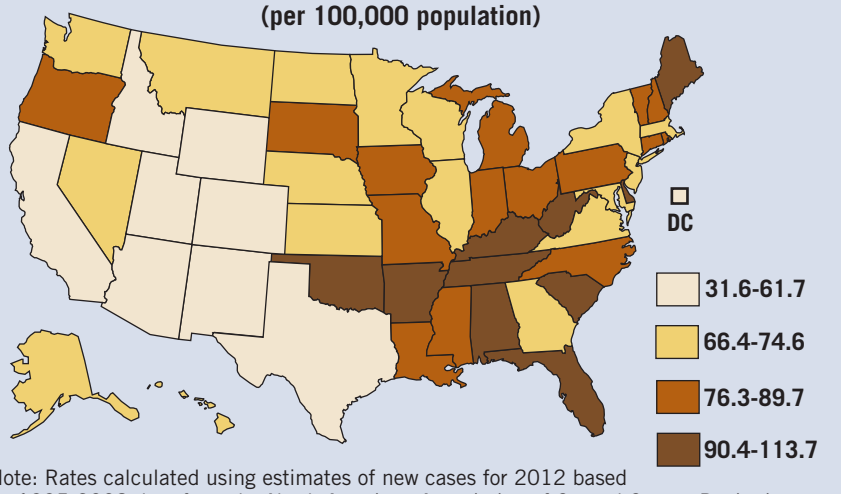
► Since low-dose CT screening is not currently covered by Medicare or private insurance, it should not be used to recruit patients. Doing so would focus care on financially advantaged patients over financially disadvantaged. Hospitals and screening centers should ethically promote the procedure with full disclosure of the risks, costs, and benefits.

► ALA should "strongly advocate" for screening to be linked to "best practice" multidisciplinary clinical teams that can provide complete follow-up for any positive finding.

The group has also created separate "FAQ" sheets for patients and for physicians to help them discuss screening in an objective, accurate manner.

Dr. Samet said he has no relevant conflicts of interest. ■

DATA WATCH



Note: Rates calculated using estimates of new cases for 2012 based on 1995-2008 data from the North American Association of Central Cancer Registries.
Source: American Cancer Society

Stale Secondhand Smoke Impairs Epithelium

BY MARY ANN MOON
Elsevier Global Medical News

Exposure to "aged" secondhand smoke – even to a small amount and even for a brief time – impairs endothelial function, a recent study found.

"Aged" secondhand smoke refers to smoke that lingers in an indoor area 30 minutes or more after a smoker has finished a cigarette, and it is known to be more toxic to the respiratory epithelium than is fresh secondhand smoke, said Dr. Paul F. Frey of San Francisco General Hospital and his associates.

The investigators performed a study to determine whether stale secondhand smoke also impairs endothelial function at the relatively low exposure levels that people are likely to encounter in the community setting. Endothelial dysfunction is a key mechanism in all stages of cardiovascular disease, they noted.

The typical level of aged secondhand smoke found in smokers' homes or in restaurants or other public venues that allow smoking is 100 mcg/m^3 respirable suspended particles (RSPs), and the typical level found in bars or casinos in which smoke is more concentrated is 400 mcg/m^3 RSPs. Dr. Frey and his colleagues assessed the response to 30 minutes of exposure at both of these levels, as well as to filtered smoke-free air, in 33 healthy nonsmoking adults aged 18-40 years.

All participants reported no exposure to secondhand smoke during the month preceding the study. None of them had conditions that could adversely affect endothelial function. Endothelial function was assessed using high-resolution ultrasound to measure maximal percent flow-mediated dilation of the brachial artery.

The study participants were exposed to smoke-free air (11 participants), 100 mcg/m^3 RSPs (11 participants), or 400 mcg/m^3 RSPs (11 participants) in a hooded device attached to a smoking machine. The secondhand smoke was aged for 60 minutes, then routed to the hood for a single 30-minute exposure time. The RSP level was monitored continuously.

Endothelial function was impaired in a dose-dependent fashion at both levels of exposure to aged secondhand smoke. For every 100-mcg/m^3 increase in RSP level, maximal percent flow-mediated dilation of the brachial artery decreased by 0.67%, Dr. Frey and his associates said (J. Am. Coll. Cardiol. 2012;59:1908-13).

"Our research strengthens the evidence that secondhand smoke is detrimental to cardiovascular health even at very short exposures and low particulate concentrations," they noted.

The findings highlight the importance of policies that limit the public's exposure to secondhand smoke, the researchers said. The study conditions may underestimate the effect of aged secondhand smoke in real-world settings, they added.

The subjects remained at rest throughout their exposure to secondhand smoke and were exposed for only half an hour. In real-world experience, people are exposed for much longer durations and may be physically active during their exposure, which increases minute ventilation. Moreover, "our subjects were healthy and may have been less susceptible to decrements in endothelial function than patients with vascular disease."

This study was supported in part by the Tobacco-Related Disease Research Program and the University of California, San Francisco. One coauthor reported ties to companies that develop or market smoking-cessation medications and being a paid expert witness in litigation against tobacco companies. ■

COMMENTARY

Dr. Vera DePalo, FCCP, comments: These data show that "aged" secondhand smoke, even of transient, limited exposure, can provoke physiologic changes. This further underscores that the effects of smoking are not limited to the smoker alone, reach beyond the respiratory system, and raise additional concerns for second-hand smoke exposure during childhood.

'Berlin' Better Predicts Mortality

ARDS • *from page 1*

moderate ARDS, and 9 days with severe ARDS, said Dr. Ferguson, director of critical care medicine at the University of Toronto. The study was published online May 21 (doi: 10.1001/JAMA.2012.5669).

The European Society of Intensive Care Medicine convened the panel of experts in Berlin in 2011 to draft a new definition of ARDS in hopes of improving upon the 1994 definition from the American-European Consensus Conference (AECC), said Dr. Rubenfeld, professor of medicine at the University of Toronto and chief of the program in trauma/emergency and critical care at Sunnybrook Health Sciences Centre, Toronto. Since the AECC definition was adopted widely, issues of reliability and validity have emerged. The American Thoracic Society and the Society of Critical Care Medicine endorsed the 2011 consensus effort.

Under the new Berlin Definition, patients with mild ARDS have mild hypoxemia, defined as a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen of 201-300 mm Hg (PaO_2/FIO_2 = 201-300 mm Hg). Moderate hypoxia (PaO_2/FIO_2 = 101-200 mm Hg) defines moderate ARDS, and severe hypoxia (PaO_2/FIO_2 = 100 mm Hg or less) defines severe ARDS.

The initial draft of the Berlin Definition included four ancillary variables for severe ARDS that were dropped after the meta-analysis found that they did not improve the predictive value for mortality, the speakers and their associates in the study reported. The abandoned variables were radiographic severity, respiratory system compliance, positive end-expiratory pressure, and corrected expired volume per minute.

Dr. Rubenfeld stressed that these variables still are important for clinicians to measure and for understanding ARDS, but they were not included in the definition of severe ARDS because they made the definition more complex while not adding anything to the predictive value of the definition.

He also cautioned that neither the Berlin Definition nor the AECC definition is designed to be a prognostic model; the end point of mortality was used to hone the Berlin Definition.

The Berlin Definition had better predictive validity for mortality than the AECC definition in an analysis using the area under the receiver operating curve (AUROC) in logistic regression models. The Berlin Definition had an AUROC of 0.577, compared with 0.536 for the AECC definition, a statistically significant improvement.

The data for the meta-analysis came from four multicenter clinical studies and three single-center physiological studies, the investigators reported.

Based on the Berlin Definition, 22% met the criteria for mild ARDS, 50% had moderate ARDS, and 28% had severe ARDS. Median ventilator-free days declined with severity of disease, from 20 days with mild ARDS to 16 days with moderate ARDS and 1 day with severe ARDS.

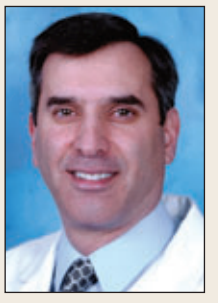
Among patients with mild ARDS at baseline under the Berlin Definition, 29% progressed to moderate disease and 4% progressed to severe disease within 7 days. Among patients with moderate ARDS at baseline, 13% progressed to severe disease within 7 days.

The investigators suggested that this approach of combining consensus discussions with empirical evaluation might be a model for creating more accurate, evidence-based definitions for critical illness syndromes. Previous ARDS definitions relied on expert consensus alone.

Without the empirical evaluation that led to deleting the ancillary variables, a needlessly complex ARDS definition would have been proposed, Dr. Rubenfeld said.

The study was sponsored by the European Society of Intensive Care Medicine, the National Institutes of Health, and the Canadian Institutes of Health Research (CIHR). CareFusion provided in-kind support for the study. Dr. Ferguson was supported by a CIHR New Investigator Award. Dr. Rubenfeld reported having financial relationships with Ikaria, Faron, and Cerus. Some of his associates in the study reported financial relationships with Maquet Medical, Hemodec, Faron, AstraZeneca, U.S. Biotest, Sirius Genetics, Sanofi-Aventis, Immunetrics, Abbott, Eli Lilly, Ikaria, GlaxoSmithKline, Tarix, Apeiron, and/or Novalung. ■

COMMENTARY



Dr. Carl Kaplan, FCCP, comments: This new ARDS definition associated with hypoxemia severity will be of interest to every discipline and clinician associated in the triage, care, and follow-up of critically ill patients with acute hypoxemic respiratory failure. The "Berlin Definition" of ARDS will fundamentally change and simplify our current clinical and research terminology. This hopefully will translate into important and practical changes in clinical bedside practice and improve overall patient-related outcome measures.

Berlin Definition of ARDS

► **Timing.** Develops within 1 week of a known clinical insult or new or worsening respiratory symptoms.
► **Chest imaging.** Bilateral opacities on x-ray or CT scan are not fully explained by effusions, lobar/lung collapse, or nodules.
► **Origin of edema.** Respiratory failure is not fully explained by cardiac failure or fluid overload. Objective assessment (e.g., echocardiography) is needed to exclude hydrostatic edema if no risk factor present.
► **Oxygenation.***
Mild: PaO_2/FIO_2 of 201-300 mm Hg with positive end-expiratory pressure (PEEP) or continuous positive airway pressure (CPAP) of 5 cm H_2O or greater.
Moderate: PaO_2/FIO_2 of 101-200 mm Hg with PEEP of 5 cm H_2O or greater.
Severe: PaO_2/FIO_2 of 100 mm Hg or less with PEEP of 5 cm H_2O or greater.

*If altitude is higher than 1,000 m, the correction factor should be calculated as PaO_2/RO_2 × (barometric pressure/760).

Chest X-Rays Incongruous With Lavage in VAP

BY PATRICE WENDLING
Elsevier Global Medical News

DALLAS – Clinicians frequently perform bronchoalveolar lavage in ventilated trauma patients without radiologic evidence of pneumonia, according to a retrospective analysis.

Among 1,343 chest x-ray reports from 344 patients who all underwent bronchoalveolar lavage (BAL), there was no mention of infiltrates in 11% and no suspicion of pneumonia in 64%, according to a review that used natural language processing to sift through the reports.

"Our indication for BAL includes chest x-ray infiltrates or a change in chest x-rays, so I was very surprised to see that there were so many BALs done without an infiltrate mentioned in the chest x-ray report," said lead author Dr. Heather L. Evans, a trauma and acute care surgeon and surgical intensivist at the University of Washington in Seattle. "I think that this may be something of a soft call when providers are concerned that the patient has increasing secretions, decreasing oxygenation, and worsening sepsis of unknown etiology. Perhaps the chest x-ray is not as firm and fast a rule as we are led to believe."

Indeed, the Centers for Disease Control and Prevention removed the chest x-ray from its new surveillance definition for what is now termed adult ventilator-associated events. The new definition, expected to be implemented in 2013, is not intended for clinical management, leaving physicians in a quandary when making a clinical diagnosis of VAP. Enter natural language processing, a tool that is increasingly being applied in radiology as part of machine learning to aid in text analysis of radiology reports (Med. Image Anal. 2012 [doi:10.1016/j.media.2012.02.005]).

The investigators used natural language processing coding methods to code 1,343 chest x-ray reports from the day prior, day of, and day after BAL among 344 trauma patients ventilated for more than 48 hours at a level 1 trauma center. Two specially trained reviewers coded the reports using the chest x-ray element from the Clinical Pulmonary Infection Score (CPIS) as "no infiltrate," "diffuse infiltrate or atelectasis," or "focal infiltrate" and scored the reports on a three-point scale for suspicion of pneumonia as "no suspicion," "suspicion," or "probable pneumonia."

VITALS

Major Finding: The differences between the BAL-positive and -negative groups regarding the presence or absence of infiltrates were significant only on chest x-ray reports from the day after BAL ($P = .004$).

Data Source: This study was a retrospective analysis of 1,343 chest x-ray reports and bronchoalveolar lavage results from 344 ventilated trauma patients.

Disclosures: The authors reported no relevant conflicts of interest.

The CPIS classifier had a 90% overall accuracy, 93% specificity, 86% sensitivity, and 85% positive predictive value. The suspicion classifier achieved comparable results of 85%, 89%, 78%, and 78%, respectively.

As expected, localized infiltrate was significantly more common in reports from BAL-positive than BAL-negative patients (13% vs. 9%), while no infiltrate was significantly more common in those from BAL-negative patients (15.3% vs. 11.5%). However, 1,013 chest x-ray reports, or 75.4% of the data, fell in-between with diffuse infiltrate or atelectasis and had a 50-50 chance of being diagnosed as VAP, Dr. Evans said at the annual meeting of the Surgical Infection Society.

"Failure to discriminate diffuse infiltrate defines the group where culture data is most useful," she observed.

Radiology reports noting any suspicion of pneumonia were significantly more common in positive-BAL than in negative-BAL patients (45.6% vs. 28%), while reports with no suspicion of pneumonia were significantly more common in BAL-negative patients (68% vs. 60%).

Still, 430 (50%) of the 856 chest x-ray reports with no suspicion of VAP were in patients with BAL-positive results, Dr. Evans pointed out.

To sort out the implications of this finding, the investigators stratified the CPIS data by time and discovered that differences between the BAL-positive and -negative groups regarding the presence or absence of infiltrates were statistically significant only on chest x-ray reports from the day after BAL ($P = .004$).

"Considering the timing of this chest x-ray report information is absolutely crucial and something we will definitely incorporate in the future," she said, adding that future work will involve evaluation of coded chest x-ray report content in VAP risk assessment.

Invited discussant Dr. Addison K. May, chief of trauma and surgical critical care at Vanderbilt University in Nashville, Tenn., asked whether the authors were surprised by the findings given that chest x-ray readings and BAL results correlate only about 40% of the time, and asked why the authors chose to include the radiology report from the day after BAL. Dr. Evans said the lack of correlation wasn't surprising and that chest x-ray report language will be incorporated, along with other available clinical values, into their VAP risk assessment model.

"To exclude the chest x-ray information is to ignore a fundamental piece of diagnostic data that clinicians use all the time," she added. "As much as we don't like to rely on the chest x-ray, I'm currently doing a qualitative study of the diagnosis of ventilator-associated pneumonia at my institution, and I can tell you in the 15 interviews I've done, every single person says the chest x-ray is a fundamental piece that they rely on to make the diagnosis.

"So I think if we're going to remove the chest x-ray from our definition, whether it's from surveillance or from the definition that we use clinically, we have to have data to support that it shouldn't be there."

Dr. Evans said the chest x-ray report from the day after BAL was included to help train the classifier to be accurate, and that the finding of statistical significance only for that day's chest x-ray report data was unexpected and provocative.

She added that although there are many indications for chest x-ray in the ICU, "the days of getting a chest x-ray every morning just because the patient is ventilated are a gross overuse of that imaging modality." ■

COMMENTARY

Dr. Marcos Restrepo, FCCP, comments: This article reviews a series of interesting observations by using a natural language system, a novel technology to review radiology reports and raises concerns about a topic regarding the use of chest radiographs to suspect VAP (or the new term, ventilator-associated events).

The new methodology that is recommended by the National Healthcare Safety Network (the Centers for Disease Control and Prevention health care–associated infections surveillance system) excludes chest radiographs in the criteria algorithm.

Studies are needed to validate this methodology compared with the one used for more than 4 decades of research in patients with VAP.

Shorter Treatment Failed for Ventilator-Associated Pneumonia

BY SHERRY BOSCHERT
Elsevier Global Medical News

SAN FRANCISCO – A phase III clinical trial ended early after preliminary results showed lower cure rates and higher death rates in patients with ventilator-associated pneumonia who were treated for 7 days with doripenem, compared with those who received 10 days of imipenem.

With 274 patients randomized of a planned enrollment of 524 participants, the investigators conducted a modified intention-to-treat analysis of patients with qualifying bacterial organisms confirmed by bronchiolar lavage and culture. Clinical cure rates were 46% for doripenem and 57% for imipenem, and 28-day all-cause mortality rates were 22% for doripenem and 15% for imipenem, Dr. Marin H. Kollef, FCCP, and his associates reported in a late-breaker session at an international conference of the American Thoracic Society.

The confidence intervals for both results crossed the threshold of no greater than a 15% difference between groups that would be required to say the doripenem regimen was noninferior to the imipenem regimen. Multiple overall and subgroup analyses showed trends favoring the safety and efficacy of the imipenem regimen, said Dr. Kollef, professor of medicine at Washington University and director of the medical ICU and of respiratory care services at Barnes-Jewish Hospital, both in St. Louis.

The difference in 28-day all-cause mortality did reach statistical significance in a subgroup of patients infected with *P. aeruginosa*, who were more likely to survive on imipenem therapy, he said.

Doripenem is a carbapenem antibiotic approved in the United States for complicated urinary and abdominal infections but not approved for pneumonia. It is approved in many other countries for the treatment of nosocomial pneumonia, including VAP.

The study, known as the DORI-NOS3008 study, used a higher dose of doripenem than is approved in other countries for pneumonia, the thinking being that a higher dosage might allow shorter treatment. Patients randomized to doripenem received 1 g of doripenem in a 4-hour infusion every 8 hours for 7 days plus a 1-hour infusion of saline placebo every 8 hours for 10 days. The imipenem group received a 4-hour infusion of placebo every 8 hours for 7 days and a 1-hour infusion of imipenem every 8 hours for 10 days.

In the doripenem group, 44% of patients reached a creatinine clearance of at least 150 mL/min, compared with 71% of patients in the imipenem group.

The findings contradict results of a previous phase III study of VAP treated for 7-10 days at the discretion of the investigator. That study, known as DORI-10, reported noninferiority between doripenem and imipenem. In that study, more than 90% of cured patients were treated for at least 8 days, and 35% of patients were treated for at least 10 days, Dr. Kollef noted (Crit. Care Med. 2008;36:1089-96).

The findings suggest that physicians should consider treating VAP for longer than 7 days, Dr. Kollef said.

The study was funded by Johnson & Johnson, which markets doripenem. Dr. Kollef has been a speaker for Pfizer. ■

Dyspnea Effects Similar With IPCs, Talc Pleurodesis

BY SHERRY BOSCHERT
Elsevier Global Medical News

SAN FRANCISCO – Indwelling pleural catheters did not provide greater relief of dyspnea, cause less chest pain, or improve quality of life compared with chest tube and talc pleurodesis in patients with symptomatic malignant pleural effusion, an unblinded, randomized study of 106 patients found.

Patients receiving indwelling pleural catheters (IPCs) had a shorter initial hospitalization (0 days vs. 4 days) but were five times more likely to develop adverse events, Najib M. Rahman, D.Phil., reported at an international conference of the American Thoracic Society.

The study was published online May 20, 2012 (JAMA 2012;307 [doi:10.1001/jama.2012.5535]). The lead investigator of the Second Therapeutic Intervention in Malignant Effusion Trial (TIME2) was Dr. Helen E. Davies of University Hospital of Wales, Cardiff.

The patients from seven UK centers had undergone no prior pleurodesis. In the IPC group, outpatients had the IPC inserted, had a large volume drained, and were educated to do subsequent drainage at home. In the talc group, patients were admitted for chest tube insertion and talc for slurry pleurodesis. All patients were asked to assess their dyspnea daily at the same time each day using a 100-mm visual analog scale (VAS), with 0 mm indicating no dyspnea and 100 mm representing maximum dyspnea.

Dyspnea improved in both groups. Overall, mean VAS scores decreased by 37 mm from baseline with IPC and by 30 mm with talc, which was not significantly different. Dyspnea scores did not differ significantly between groups in the first 42 days, the primary outcome measured. At 6 months, however, there was a statistically significantly greater improvement in dyspnea in the IPC group, with a mean 14-mm lower score than the talc group.

"IPC may be better than talc at 6 months" of follow-up, said Dr. Rahman of the University of Oxford (England).

In the talc group, 22% of patients required further pleural procedures, compared with 6% in the IPC group, a significant difference. Five patients in the IPC group developed pleural infection, compared with one patient in the talc group.

"A lot of chest physicians think talc pleurodesis is more painful, but it turns out that IPC is painful too," he said. Scores for chest pain and for quality of life did not differ significantly between groups.

The study was not powered to assess mortality risk, but no significant differences were seen between groups out to 12 months of follow-up.

"We must not conclude that IPCs and talc are the same" or equivalent, Dr. Rahman said. The investigators are assessing the cost implications of the results, including costs for procedures and complications after the initial treatment.

The results should be interpreted with caution because the study was powered to assess superiority, not equivalence between treatments, Dr. Nick A. Maskell said in an editorial in the same issue (JAMA 2012;307 [doi:10.1001/jama.2012.5543]).

Clinicians for years have debated the best management of malignant pleural effusions. Talc is recommended as first-line treatment of symptomatic patients by international guidelines, said Dr. Maskell of the University of Bristol (England).

Based on the TIME2 study findings, physicians should feel comfortable discussing the advantages and disadvantages of both treatments with patients to help them pick the strategy that best suits them, he said.

Combining the best of both strategies may be the way of the future, Dr. Maskell added. Some preliminary studies suggest it may be feasible and beneficial to deliver pleurodesis agents via an IPC in the outpatient setting.

The only other randomized controlled trial comparing IPCs with pleurodesis for malignant pleural effusion used doxycycline, which is not as effective as talc, and found similar improvements in dyspnea and quality of life between groups, he said (Cancer 1999;86:1992-9). ■

VITALS

Major Finding: Dyspnea scores for patients with malignant pleural effusion decreased by a mean 37 mm on a 100-mm scale in those treated with IPCs, compared with a 30-mm decrease in patients who got a chest tube and talc pleurodesis. The IPC group had a fivefold increased risk for adverse events.

Data Source: The unblinded, randomized, controlled trial involved 106 symptomatic patients at seven UK centers.

Disclosures: The study was funded by the British Lung Foundation and the Robert Luff Foundation. Dr. Rahman reported being a consultant to Rocket Medical, which supplied the IPCs and drainage bottles for the trial. Some of his associates reported financial associations with Boehringer Ingelheim, Medico, AstraZeneca, GlaxoSmithKline, Chiese, CareFusion, Sequana Medical, Merck, and Gilead. Dr. Maskell disclosed receiving honoraria and grants from Carefusion.

Quality of Dyspnea Directs Diagnosis, Management

BY PATRICE WENDLING
Elsevier Global Medical News

KEYSTONE, COLO. – Understanding the quality of a patient's dyspnea provides insights into the underlying physiologic mechanism and can guide management, according to Dr. James T. Good Jr., FCCP, a pulmonologist at National Jewish Health in Denver.

Complaints that may represent dyspnea can be as vague as fatigue, lack of energy, or simply getting old, but most commonly are a sensation of air hunger, of work or effort to breathe, or of chest tightness. All three sensations are the result of a mismatch or neuromechanical dissociation between ongoing motor signals to the respiratory muscles and incoming afferent information from the lungs, chest wall, and upper airways, Dr. Good said at a meeting on allergy and respiratory diseases.

For the patient who describes air hunger, the sensation can be equated to being held underwater and is often so distressing that patients say they would prefer pain to air hunger. The sensation is mediated primarily through central and peripheral chemoreceptors and stimulated by hypercapnia or hypoxia in the presence of decreased arterial carbon dioxide (CO_2) partial pressure and oxygen partial pressure, Dr. Good said.

In the patient who describes work or effort when breathing, the sensation is stimulated by respiratory motor muscle contraction and muscle fatigue and is mediated through a combination of central motor discharge, chest wall receptors, and metaboreceptors located within skeletal muscle, he said at a meeting on allergy and respiratory diseases, which was sponsored by National Jewish Health.

In patients with chest tightness, the sensation is stimulated by bronchoconstriction and tends to be mediated primarily through rapidly adapting stretch receptors (RARs) and C-fiber receptors in the pulmonary and respiratory tract. Chest tightness can occur with other dyspneic sensations but is fairly specific to asthma and COPD.

The first question to ask patients who present with complaints of an uncomfortable sensation associated with breathing is whether it occurs at rest or with exertion, Dr. Good suggested. Dyspnea at rest implies an acute illness or moderate to severe cardiopulmonary disease. It also is very common in patients with anxiety, with or without underlying disease, and in patients with alterations in the respiratory drive. Dyspnea with exertion is most common in patients with cardiac dysfunction, pulmonary diseases, metabolic disorders, deconditioning, obesity, and anemia.

The next important question to ask is whether the patient with dyspnea has normal oxygen saturation (Sa_{O_2}), he said. A normal Sa_{O_2} implies a mild disorder such as exercise-induced bronchospasm, while an abnormal Sa_{O_2} implies moderate to severe cardiopulmonary disease if dyspnea occurs at rest, mild to moderate cardiopulmonary disease if dyspnea occurs during exercise, or sleep-disordered breathing if it occurs with sleep.

Dr. Good observed that many of his cardiology colleagues routinely obtain an electrocardiogram in their patients who are short of breath, which is an important part of the work-up, but that they overlook spirometry.

"If a patient has dyspnea they need to have spirometry," he said. "You have to start with that. It is absolutely key."

Dyspneic patients with normal spirometry are unlikely to have significant underlying COPD or interstitial lung disease (ILD), but they could have exercise-induced bronchospasm, mild or persistent asthma, or vocal cord dysfunction.

If an obstructive pattern is observed on spirometry, this could be a clue to evaluate for COPD or asthma. A restrictive pattern on spirometry should raise suspicion for ILD, neuromuscular disease, chest wall abnormalities, pleural effusion, or heart failure, he said.

Dr. Good presented several cases that highlighted the importance of a thorough work-up, including that of a 70-year-old retired engineer with increasing air hunger dyspnea on exertion. Spirometry revealed a normal FEV_1 of 2.74 L, or 84% of predicted volume, and FVC of 4.91 L, or 111% of predicted volume. The FEV_1/FVC ratio was 56%, which is low, but not enough to explain the amount of dyspnea the patient was experiencing. Cardiac evaluation proved uneventful, but pulmonary function tests revealed a diffusion capacity of 17.2, or just 53% of predicted value.

"Once the dyspnea evaluation is complete, it is usually possible to determine all factors that are contributing to the patient's breathlessness and direct specific therapy" to the underlying disease process, he said.

Other therapeutic approaches include conditioning, fitness, and weight loss in obese patients with dyspnea, as well as beta-agonists and anticholinergics, theophylline, opiates, anxiolytics, and selective serotonin reuptake inhibitors. Supplemental oxygen usually relieves dyspnea in hypoxemic patients, making vagal afferents unlikely contributors, he said.

Dr. Good disclosed serving as an investigator and speaker for Genentech and as a speaker for GlaxoSmithKline and Merck. ■

COMMENT

Dr. Darcy Marciniuk, FCCP, comments: Perhaps the most common symptom experienced by our patients, dyspnea is exceedingly complex. Clinicians often feel limited in their understanding and treatment options. Dr. Good appropriately captures the wide-ranging causes and outlines a practical approach to its investigation, which if exertional, will often include cardiopulmonary exercise testing.

PRESIDENT'S CORNER: THE MEMBERSHIP SPEAKS...

Changes Are Coming: Know the Facts and Prepare

Coping With the ICD-10 Delay

By Dr. Scott Manaker, FCCP

With the recent announcement of yet another delay in the mandatory implementation of ICD-10 (the International Classification of Diseases, 10th Edition) in the United States, all physicians and their practice staff are now scrambling to cope. The Office of the National Coordinator (ONC) for Healthcare Information Technology has proposed a new implementation date of October 1, 2014, to allow more time for providers and vendors alike to prepare and adopt ICD-10.

But do not be dismayed. This delay yields an opportunity for the wise use of the available time, regardless of how many or few plans characterize your current state of ICD-10 preparation. The bulk of change management in your practice will be leaving the comfort and experiential knowledge base of ICD-9, accumulated over decades of use here in the United States. However, remember that our international colleagues have employed ICD-10 in their practices for many years. So, use the time to proceed with your ICD-10 preparations in a thoughtful and considered manner, rather than the perhaps haphazard or passive approach previously taken. For example, freshly consider being an early adopter, at or before the beginning of the mandate.

The delay provides an opportunity to develop a more comprehensive plan for the impact upon your practice, regardless of your practice size and model (private practice, employed/staff models, or academic plan). Consider each electronic program (application) impacted by diagnosis coding, and include not only your office electronic medical record (EMR) but also your billing systems and diagnostic equipment (both pulmonary function and polysomnography); and also the various systems you use at each hospital where you practice. For example, examine how will a patient's diagnoses flow from hospital inpatient care to your outpatient EMR at the time of discharge.

Purchase an ICD-10 book now, and consider how your common ICD-9 diagnosis codes will change with ICD-10.

Think about training and certification for at least one individual in your practice, and send any coders employed in the practice for ICD-10 training. Do a mock-up of any practice billing sheets used in your office and hospitals with likely ICD-10 diagnosis codes. Coordinate with forthcoming ICD-10 offerings from your vendors, hospital, and the ACCP; and compare notes with your colleagues. Consider the now pending ICD-10 implementation in each of your contracts—with payers, vendors, your hospitals—including hold harmless clauses if you make the conversion on time and they fall behind.

An often overlooked problem will be maintaining both ICD-9 and ICD-10 codes during any period of your early adoption and also to accommodate delayed implementation by other payers.

Finally, and most importantly, use the time to test! Test your EMR, your equipment and systems, and your partners and practice staff to ensure that when the day comes to implement ICD-10, you are ready.

Data Transparency, Physician Performance Improvement, and Reimbursement

By Dr. Richard Hamrick, FCCP

The "Age of Measurement" is upon us. The reporting of quality metrics for acute care hospitals started almost a decade ago with Core Measure submission to the Centers for Medicare & Medicaid Services (CMS) and evolved over a few short years into value-based purchasing with a portion of hospital Medicare revenue (1% in 2012) at risk. Hospitals that score well will do better than the 1% withhold; those scoring poorly will receive less, based on a sliding scale of performance. In addition, hospitals face penalties for excessive readmissions in 2013 over national baseline performance data for the conditions of acute myocardial infarction, pneumonia, and congestive heart failure. COPD exacerbations, as well as other conditions, are projected to follow in subsequent years. Furthermore, penalties for poor hospital performance in hospital-acquired conditions, including "Never Events" (such as retained foreign bodies from surgery, air embolism, or transfusion of incompatible blood), as well as central line-associated blood stream infections, catheter-related urinary tract infections, pressure ulcers, and other disorders come into play in 2016. By 2016, 6% of hospital-base Medicare revenues will depend upon quality metric scores—and most hospitals depend on Medicare for around half of their total revenue.

Similar pilots and programs are underway in the long-term care and home health industries. The same level of scrutiny is forthcoming for

Continued on following page

Health-care Reform: Is Anyone Listening?

In this issue of *CHEST Physician*, a series of three articles will provide our readers with concise and practically relevant information that is likely to affect their clinical practices.

Dr. Scott Manaker, Regent-at-Large, has written the first article on ICD-10. Instead of shirking from this major change in diagnosis and coding of diseases, he recommends a proactive approach based upon gathering facts, training health-care professionals, and testing systems that will be affected by this change.

Dr. Richard Hamrick, Regent-at-Large, comments on how performance metrics are being currently utilized to affect a portion of the Medicare compensation to hospitals. The "at risk" portion of the hospital compensation is expected to be ramped up from 1% this year to as much as 6% by 2016, as "never events" and "hospital readmissions" are added to the list of monitored metrics.

Drs. Mark Metersky, Chair of Guidelines Oversight Committee; and Michael Baumann, President-Designate, collaborate on writing about value-based purchasing. They shed light on the benefits of utilizing evidence-based guidelines in clinical practice but discuss the limitations of this approach, including patient-related factors that obviate application of these guidelines in every case. The expansion of databases and generation of report cards for physicians and hospitals is a concept that is being rapidly put into effect.

The purpose of publishing a compendium of articles on health-care reform is not to paint a picture of gloom and doom to our members. Rather, the intent is to keep them informed, so they can make intelligent decisions based upon facts.

–Dr. Suhail Raoof, FCCP

Note - The views expressed in these articles are those of the authors and do not represent the views of the ACCP, its leadership, members, or staff.

Continued from previous page

physicians, with consequences for reimbursement beginning to emerge from both CMS and commercial insurers.

Medicare is opening its database of 47 million patients to qualifying organizations for detailed study of billing data. These national data can be applied and reported at the specific physician level, facilitating the development of "report cards" for physicians and hospitals alike. Twelve states have formed all-payer claims databases with the potential for similar public reporting of outcome measures for individual physicians on the state level.

For several years, physicians have been eligible for Medicare bonus payments by electronic prescribing and also by submitting quality data via the Physician Quality Reporting System (PQRS). But the most tangible evidence of physician quality being tied to reimbursement resides in the Accountable Care Act (ACA). Under the ACA, by 2015 for some and by 2017 for all physicians, CMS will begin to modify physician Medicare payments via a "value modifier," based on the quality of care and cost efficiency. The manner by which this will be done remains unclear at this time, but the intent is clear.

Anthem in Virginia has notified all primary care physicians that any subsequent reimbursement increases will be based on performance of predetermined quality metrics. And all of the Pioneer Accountable Care Organization (ACO) pilots underway via CMS contemplate some portion of physician reimbursement ultimately based on quality metrics.

Many hospital systems are utilizing sophisticated business intelligence tools, such as Crimson or Premiere, to provide a highly detailed analysis of individual physician performance. These data are then shared with the physician, as well as health-care system performance data. As physicians begin to understand their own individual performance and the performance of their hospitals, this understanding provides a basis to support subsequent performance improvement and prepares physicians for looming changes in data transparency and reimbursement. As one physician has remarked – "If you are going to be naked, you had best be buff."

The Connections? Evidence-Based Medicine, Evidence-Based Guidelines, and Pay for Performance

By Dr. Michael Baumann, FCCP; and Dr. Mark Metersky, FCCP

Evidence-based medicine (EBM) integrates the best available scientific evidence with a health-care provider's clinical expertise (experience) and with a patient's values. Thoughtful application of all three components of EBM is not "cookbook medicine," and can foster achieving the Institute of Medicine's (IOM's) six aims of health care to provide safe, effective, patient-centered, timely, efficient (waste-free), and equitable patient care. Many health-care providers and administrators view appropriate application of EBM as a valuable tool to fill the gap, described by the book *Crossing the Quality Chasm,* between the health care actually provided and the ideal care we should provide to our patients.

However, the three components of EBM are often cumbersome for individual, frontline clinicians. Evidence-based guidelines (EBGs) assist in several of these steps by finding and appraising the evidence and then suggesting recommendations for specific practice situations. Uniform application of EBM can reduce unnecessary variability and potentially the associated costs (not just dollars expended but also the expenses of suboptimal or undesired patient outcomes) of health care. However, EBGs do not answer all potential clinical questions, and even specific areas covered by EBGs may not apply to all patients in similar circumstances. These and other reasons have led to a gap in implementing EBGs. Perhaps more concerning, though, is the often documented, limited adoption of EBG recommendations in specific appropriate patient situations wherein their application should be applied.

Various groups, including the American Medical Association, convened the PCPI (Physician Consortium for Performance Improvement), National Quality Forum (NQF), and other organizations to foster the development of performance measures (PMs). PMs are often developed from EBG recommendations, partly to foster broader, appropriate adoption of guidelines and of best clinical practices. As defined by the IOM, PMs are methods or instruments to estimate or monitor the extent to which the actions of a health-care provider conform to practice guidelines or quality standards. PMs can track processes (frontline care steps such as raising the head of the bed to limit aspiration and potential development of pneumonia) and outcomes (higher level reflections of care, such as death and length of stay). The ACCP is an internationally respected leader in the development of clinical practice guidelines, under the direction of the ACCP's Guidelines Oversight Committee (previously called Health and Science Policy Committee). Many of the ACCP guideline recommendations, most notably the antithrombotic guidelines, serve as the basis for PMs.

The Centers for Medicare & Medicaid Services (CMS) is now charged with interpreting and applying legislation, such as the 2010 Affordable Care Act and earlier federal legislation, that includes pay for performance (also called value-based purchasing [VBP]) expectations. VBP rewards or withholds payment to hospitals based upon their PMs compliance.

The VBP process includes public reporting of these data on the CMS website, Hospital Compare. The Hospital Compare site reports hospital compliance with various PMs and also several outcome measures, including 30-day mortality and readmission rates associated with pneumonia, heart failure, and myocardial infarction. The CMS website, Physician Compare, went live in March of 2011. Public reporting of PM compliance by an individual physician (and other health-care providers) appears forthcoming.

Arguably, VBP as currently designed may improve health-care outcomes. Debate continues, as the current evidence base generally shows only limited improvements associated with financial incentives. The ACCP and other professional societies participate in this debate. Meantime, current application of CMS regulations and both public and Congressional expectations make it critical that hospitals and individual health-care providers understand both the current and proposed VBP processes as health-care reform in the United States continues to evolve. ■

This Month in *CHEST*: Editor's Picks

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

COMMENTARY

▶ **Obamacare's (3) Day(s) in Court.** *By A. R. Moncrieff, JD.*

ORIGINAL RESEARCH

▶ **Short-term Pulmonary Effects of Using an Electronic Cigarette: Impact on Respiratory Flow Resistance, Impedance, and Exhaled Nitric Oxide.** *By Dr. C. I. Vardavas et al.*

▶ **Is Laryngeal Descent Associated With Increased Risk for Obstructive Sleep Apnea?** *By Drs. Y. Yamashiro; and M. Kryger.*

▶ **Role of the $CHADS_2$ Score in Acute Coronary Syndromes: Risk of Subsequent Death or Stroke in Patients With and Without Atrial Fibrillation.** *By Dr. D. Poçi et al.*

▶ **An Intronic Polymorphism in *GRP78* Improves Chemotherapeutic Prediction in Non-small Cell Lung Cancer.** *By Dr. X. Zhu et al.*

NETWORKS

Bronchoscopic LVR, Pulmonary Rehab, TAVR

Interventional Chest/Diagnostic Procedures

Bronchoscopic Lung-Volume Reduction (BLVR)

Lung volume reduction surgery (LVRS) was developed in an effort to provide patients with moderate to severe emphysema with a safe and durable palliation of their dyspnea. Initial experience with LVRS was limited to cases series with no consistent operative approach, widely varying patient selection criteria, and no benchmark for comparison. The National Emphysema Treatment Trial (NETT) was a prospective randomized trial to compare optimal medical treatment (including pulmonary rehab) with optimal medical treatment and LVRS. Between 1998 and 2002, a total of 1,218 patients were randomized. Patients undergoing LVRS had consistent improvements in 6-min-walk-difference, maximal exercise capacity, FEV_1% predicted, and quality of life (disease-specific and overall) over patients treated with optimal medical therapy. In select patients (upper-lobe-predominant emphysema with low exercise tolerance), LVRS afforded a significant long term survival advantage (P=.01), which was also seen in the entire cohort of patients (P=.02), though not as dramatic. Despite all of these benefits, LVRS cases dropped in the years following NETT to only 105 cases in 2006. The failure of LVRS to be adopted has many contributing factors, including a high initial operative mortality vs medical management (7.9% 90-day mortality vs. 1.3%), 58.7% post-operative complication rate and a 90% air leak rate. In the community the perception of LVRS is that is it too costly and is high risk for all patients. Finally, LVRS is limited to specific centers in the country, requires an outpatient pulmonary program, and a group willing to perform the procedure. All of these hurdles, both real and perceived, have hampered the adoption of a procedure with real, quantifiable benefit for patients with moderate to severe emphysema. The role of LVRS in this patient population should be revisited.

Given the issues surrounding surgical lung volume reduction (SLVR) discussed above, several trials to achieve bronchoscopic lung volume reduction (BLVR) that have been well tolerated in Europe with promising results are now being initiated at academic centers across the United States. The BLVR systems being studied aim to achieve the clinical effects of SLVR without the morbidity and mortality. A recent randomized study published in the *New England Journal of Medicine* showed that Endobronchial-valve treatment for advanced heterogeneous emphysema induced modest improvements in lung function, exercise tolerance, and symptoms at the cost of more frequent exacerbations of COPD, pneumonia, and hemoptysis after implantation. Additional trials investigating the bronchoscopic placement of coils, biologically active sealants, and one-way valves to induce controlled lung collapse and lung volume reduction are beginning soon. One prior hurdle hindering the success of BLVR is collateral ventilation preventing upper lobe atelectasis. The use of a novel bronchoscopic catheter to identify a subclass of patients with upper lobe predominant emphysema who are more likely to benefit from BLVR is also being investigated. Further studies are needed to ascertain the efficacy of these devices, and centers are encouraged to refer and enroll eligible patients into the upcoming clinical trials for BLVR.

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Dr. David Finley, FCCP, Steering Committee Member; Dr. Momen Wahidi, FCCP, NetWork Chair; and Dr. Lonny Yarmus, FCCP

Allied Health

Pulmonary Rehabilitation – Extra! Extra! – Read All About It!

In the local newspaper is a picture of an elderly gentleman wearing a nasal cannula to deliver his oxygen, pulse oximeter fastened to his finger, lips puckered for pursed lip breathing while he walks on the treadmill during a pulmonary rehabilitation exercise class suggesting that pulmonary rehabilitation is finally getting the publicity and recognition it deserves for the impressive benefits it offers to patients with lung disease. Instead, the picture of the gentlemen is part of a newspaper article announcing the closure of the pulmonary rehab program he attends, leaving 36 patients to find alternatives for their exercise and pulmonary rehab. This has been happening all over the nation due to the decreasing reimbursement for pulmonary rehab from Medicare. With the growing number of people being diagnosed with COPD, there is more of a need now than ever for pulmonary rehabilitation programs. In fact, not having community pulmonary rehab programs is one of the biggest patient barriers we find today in patients not being able to participate in pulmonary rehabilitation. As pulmonary clinicians, we must continue to press forward in working with the Centers for Medicare & Medicaid Services to provide reasonable reimbursement for pulmonary rehabilitation.

Recently, the ACCP joined a coalition of other professional organizations to develop the Pulmonary Rehabilitation Toolkit that is designed to give hospital-based pulmonary rehabilitation programs detailed information regarding payment for pulmonary rehab services of Medicare. Hospitals are struggling with the issues they are facing in dealing with hospital readmissions, patient satisfaction scores, value-based care, and the list goes on and on. They are restructuring this and cutting that and trying to come up with the best value to satisfy the customer and reduce the cost of health care.

If you look at the cost of a hospitalization with or even without complications vs pulmonary rehabilitation… my question then is, "Can we afford *not to* offer outpatient pulmonary rehab?"

Mary Hart, MS, RRT
Steering Committee Member

Cardiovascular Medicine and Surgery

Transcatheter Aortic Valve Replacement (TAVR)

Aortic stenosis is a very common problem affecting up to 4% of people over 80 years of age. A significant

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Lung Cancer Screening: A Multisociety Collaboration

BY SANDRA ZELMAN LEWIS, PHD
ACCP Manager of Evidence-Based Guidelines and Clinical Standards

Lung cancer screening has been a controversial topic for many years but recently received considerable media attention with the publication of the National Lung Screening Trial (NLST) results, which showed the first ever reduction in mortality for a select group of individuals in very specific circumstances. For many years prior to this, and in both editions of the ACCP Lung Cancer Guidelines,[1,2] the ACCP recommended low-dose CT screening (LDCT) only in the context of clinical trials. However, with the publication of the NLST results, patients were clamoring for screening, and physicians were left without evidence-based guidance.

The ACCP and the American Society of Clinical Oncology partnered on the development of guidelines in consultation with the American Cancer Society and the National Comprehensive Cancer Network. *The role of CT screening for Lung Cancer in clinical practice: The evidence-based practice guideline of the American College of Chest Physicians and the American Society for Clinical Oncology* was published online May 20, 2012, in the *Journal of the American Medical Association,* within the larger article on the supporting systematic review.[3] These timely and important guidelines were developed with the intent of providing one set of harmonized recommendations for all physicians who are faced with helping their patients make decisions about screening for lung cancer. In addition to the four organizations that participated in the development process, the American Thoracic Society has endorsed these guidelines.

The recommendations in the article focus on the LDCT screening, but other screening modalities are also being assessed for the 3rd edition of the Diagnosis and Management of Lung Cancer: ACCP Evidence-Based Clinical Practice Guidelines, which are currently in development. There also will be additional reflection on the recommendations put forth in the multisociety publication to provide guidance in circumstances not yet addressed.

The ACCP strives to address important clinical issues for physicians and other health-care professionals employing rigorous evidence-based methodologies to produce trustworthy guidelines. To reduce the number of competing guidelines, multisociety collaborations such as this produce harmonization of recommendations and increased promotion of the guidelines to broader audiences. ■

To access the guidelines, go to http://jama.jamanetwork.com/article.aspx?articleid=1163892. The ACCP press release may be found at www.chestnet.org/accp/article/guideline-lung-cancer-ct-screen. For more information, contact Sandra Zelman Lewis, PhD, slewis@chestnet.org.

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Continued from previous page

proportion of these elderly patients have significant comorbidities making them poor surgical candidates for aortic valve replacement. TAVR involves treating a patient with symptomatic severe aortic stenosis (AS) by displacing and functionally replacing the native aortic valve with a bioprosthetic valve delivered on a catheter via a percutaneous transarterial approach through a peripheral artery (eg, the femoral or subclavian artery), a transaortic approach through a limited sternotomy, or a transapical approach through a limited lower thoracotomy. Two devices, the Edwards' SAPIEN (balloon expandable; approved for clinical use by the FDA in November 2011) and the Medtronic CoreValve (self-expandable) prostheses, are currently in clinical use.

The driving force for TAVR approval in the United States was the PARTNER trial (*N Engl J Med*. 2010;363[17]:1597; *N Engl J Med*. 2011;364[23]:2187).

The trial enrolled 358 inoperable patients (Cohort B) and 699 high-risk patients (Cohort A; 348 TAVR vs 351 surgical aortic valve replacement) with severe symptomatic AS. In Cohort B, TAVR substantially reduced all-cause mortality by nearly 50% and the composite of all-cause mortality and repeat hospitalization by 55% compared with standard therapy at 1-year follow-up. In Cohort A, TAVR was not inferior to surgical AVR for all-cause mortality at 1 year (24.2% vs 26.8%)

The approval of TAVR represents a paradigm shift in the management of aortic valvular heart disease. Its foundational requirement remains a team-based approach to patient care at an institution with sufficient surgical and interventional cardiology experience and expertise and a commitment to the heart team concept.

Dr. M. Fuad Jan; and
Dr. Suhail Allaqaband, FCCP
Steering Committee Member

Chest Infections

New Possible Incentives to Encourage the Development of Much Needed Antibiotics

The emergence of multiresistant organisms as causes of pulmonary infections poses clinical challenges with strains such as the NDM-1 *Klebsiella pneumoniae.* However, pharmaceutical companies are deterred by regulatory hurdles that make antibiotic drug development complex and potentially risky, eg, recent events with inhaled aztreonam. The US Food and Drug Administration (FDA) published updated industry guidelines for both community-acquired bacterial pneumonia (CABP) and health-care associated pneumonia (HAP/VAP) in 2009. These documents did clarify the requirements of the FDA, though not all key issues have been addressed. For instance, in CABP, there is insufficient recognition that published tools such as "patient reported outcome" (PRO) may be useful in demonstrating the value of new drugs (Lamping et al. *Chest*. 2002; 122[3]:920). Also, the efficacy of new antibiotics against atypical pathogens such as *Legionella*, *Mycoplasma,* and *Chlamydophila* is hard to demonstrate, due to difficulty in lab identification of these species. For approval of specific organisms in defined indications, the FDA generally requires >10 such strains. This can be a challenge in clinical trials. Thus, the IDSA has just proposed a new approach to be considered by the FDA as part of the regulatory legislation. This is modeled on "orphan drug" approvals, where a smaller number of patients/isolates would be permitted, with the subsequent drug approval be for Limited Population Antibacterial Drug (LPAD), citing the specific species and indication. LPAD products then would be narrowly indicated for use in small, well-defined populations of patients for whom the drugs' benefits have been shown to outweigh their risks. This novel approach could provide a new incentive to pharmaceutical companies to invest in antibiotics for these pulmonary infections.

Glenn Tillotson, PhD, FCCP
NetWork Chair

CHEST 2011 CENTERS OF EXCELLENCE SERIES

'A Promise to Care': Family Assistance Program

BY JEAN SKELSKEY, RN

As caregivers, we at NorthShore University Health System's ICU have historically focused attention and skills on critically ill patients. However, we have also come to appreciate the importance of family satisfaction with the ICU experience and its potential impact on the well being of the patient. The Critical Care Family Assistance Program, developed in 2002, has dramatically altered our approach to relationships with patients and families.

Because of our success in elevating our values and practice, and proven sustainability of the program, NorthShore was recognized as one of the ten Centers of Excellence at the CHEST 2011. Our ability to optimize multidisciplinary communication and staff efforts to meet specific needs has clearly created an environment of confidence and trust. More important, it is the efforts to fulfill the commitment in the program's name, "A Promise to Care," that here engendered a new degree of staff accountability. This cultural shift has resulted in better patient care, along with increased patient, family, and staff satisfaction.

NorthShore was honored to be recognized for our success in patient/family satisfaction and emotional support. ■

COURTESY ACCP

Pictured above (l-r): Wanda Johanson, CEO-AACN; Kathryn Roberts, President Elect- AACN; Jean Skelskey, RN-NorthShore; Renee Fasanella, RN-NorthShore; Sheryl Brown, RN-NorthShore; and Mary Stahl, President of AACN.

Critical Care Commentary

Cardiogenic Shock: What's Old and What's New

Cardiogenic shock (CS), the syndrome that ensues when the heart is unable to deliver enough blood to maintain adequate tissue perfusion, is a very common reason for ICU admission and is one of the most challenging emergencies for the practicing intensivist. Despite advances in both diagnosis and treatment, mortality remains quite high.

The epidemiology of CS has not changed much over the years; patients susceptible to CS are those with known coronary artery disease (CAD), especially with previous infarction, and have risk factors that make them prone to extensive CAD and left ventricular (LV) dysfunction, including advanced age, diabetes, and peripheral vascular disease. Clinical risk factors include larger infarctions, preexisting LV dysfunction, and loss of compensatory hyperkinesis in myocardial territories remote from the infarction, which usually results from CAD in those territories. The degree of hypotension and tachycardia at hospital presentation with myocardial infarction (MI) predicts the propensity to develop CS, and, unsurprisingly, the factors that predict mortality are reflective of both the severity of the acute insult and important comorbidities. Only one quarter of patients with CS are in shock at hospital presentation; the rest develop shock later on, usually within the first 24 h. Clinical characteristics of patients with early and late shock are similar, except for the extent of CAD; patients with early shock have more single-vessel CAD, whereas patients with late shock, more multivessel CAD. This may be important, because it suggests that early shock in acute MI may be more amenable to revascularization of the culprit vessel, whereas shock developing later may require more complete revascularization.

The incidence of cardiogenic shock had been fairly stable (about 8% of ST elevation myocardial infarction (MI) and 2% of non-ST elevation MI patients), but appears to be decreasing slightly in recent years, as percutaneous interventions for initial treatment of MI become more widespread (Goldberg et al. *Circulation*. 2009:119[9];1211).

The pathophysiology of cardiogenic shock has remained the same, but the importance of recognition of that pathophysiology has increased as more treatment options, both supportive and corrective, become available. Cardiogenic shock is characterized by a downward cascade in which myocardial dysfunction reduces stroke volume, cardiac output, and blood pressure, changes that compromise myocardial perfusion, exacerbate ischemia, and further depress myocardial function, cardiac output, and systemic perfusion. Compensatory mechanisms, such as sympathetic stimulation to increase myocardial contractility and heart rate, and peripheral vasoconstriction, can become maladaptive in the setting of CS, as these mechanisms can increase myocardial oxygen demand and further impair cardiac performance. The interruption of this cycle of myocardial dysfunction and ischemia forms the basis for treatment of CS.

Reperfusion is still the keystone of successful treatment of CS. The randomized SHOCK (Should We Reperfuse Occluded Arteries in Cardiogenic Shock?) trial forms the basis for early reperfusion in CS (Hochman et al. *N Engl J Med*. 1999;341[9]:625). In this trial, patients with CS due to LV failure in acute MI were randomized to emergency revascularization (n = 152), accomplished by either coronary artery bypass graft or angioplasty, or initial medical stabilization (n = 150). Supportive regimens were intensive in both groups, with 86% of patients treated with intraaortic balloon counterpulsation (IABP), and pulmonary artery catheters (PAC) to optimize hemodynamic management were mandated by protocol and inserted in 96% of patients. The primary endpoint, all-cause mortality at 30 days, was 46.7% in the revascularization group and 56% in the medical therapy group, a difference that did not reach statistical significance ($P = .11$), and so a purist might regard this as a negative trial. Virtually nobody does, however, as planned follow-up for the secondary outcomes of 6-month and 1-year mortality, revealed a significant benefit from early revascularization ($P < .03$) (Hochman et al. *JAMA*. 2001;285[2]:190). Emergency revascularization as the standard of care for CS has been given a class I ("just do it") indication in the AHA/ACC guidelines for the management of acute MI (Kushner et al. *Circulation*. 2009;120[22]:2271).

Supportive therapy is a critical adjunct to reperfusion for CS in acute MI, both before reperfusion, and, more critically, after successful reperfusion. Reversible myocardial dysfunction is an important contributor to the pathophysiology of CS. Ischemic myocardium loses contractile function, but even after restoration of normal blood flow, postischemic dysfunction can persist as myocardial stunning. The mechanisms of stunning have been best defined in animal laboratories and appear to involve a combination of oxidative stress, perturbation of calcium homeostasis, and decreased myofilament responsiveness to calcium. Direct evidence for myocardial stunning in humans had been difficult to obtain, but PET scanning has now documented normal blood flow in patients with persistent wall motion abnormalities after percutaneous coronary intervention (PCI). Reversible myocardial dysfunction may also be important in patients with CS in settings outside of acute MI, most notably those with myocardial dysfunction following bypass surgery, fulminant myocarditis, stress cardiomyopathy, and some patients with refractory heart failure.

Supportive therapy for CS includes pharmacologic support, intraaortic balloon counterpulsation, and more complete mechanical circulatory support, which is usually percutaneous in the setting of cardiogenic shock.

The first consideration in pharmacologic support of CS is to avoid medications that are usually indicated in acute MI but whose effects can either initiate iatrogenic shock or worsen ongoing shock. Chief among these are nitroglycerin and ß-blockers; angiotensin converting enzyme inhibitors are just as bad but less frequently used in the acute setting. The classic mistake to is give IV ß-blockers acutely due to failure to distinguish a patient who is tachycardic as a compensatory response to low cardiac output from one whose tachycardia is the cause of the low output.

Maintenance of adequate blood pressure is essential to break the vicious cycle of progressive hypotension with further myocardial ischemia. When arterial pressure remains inadequate, therapy with vasopressor agents, titrated not only to blood pressure but also to clinical indices of perfusion and mixed venous oxygen saturation, may be required. Norepinephrine and dopamine are considered first-line drugs for hypotension in this situation. Dopamine acts as both an inotrope (particularly at low doses) and a vasopressor at higher doses. Norepinephrine acts primarily as a vasoconstrictor, has a mild inotropic effect, and increases coronary flow. A randomized trial comparing dopamine and norepinephrine in 1,678 patients with shock found no significant difference in 28-day mortality in the overall trial, but a prespecified subgroup analysis did find increased mortality with dopamine in the 280 patients with cardiogenic shock (De Backer et al. *N Engl J Med*. 2010; 362[9]:779).

If tissue perfusion remains inadequate, inotropic therapy should be initiated. Dobutamine, a selective $ß_1$-adrenergic receptor agonist, can improve myocardial contractility and increase cardiac output, and it is the initial agent of choice in patients with a low-output syndrome, provided systolic blood pressure is >90 mm Hg. Dobutamine can exacerbate myocardial ischemia and precipitate arrhythmias, and it can cause hypotension if its vasodilatory effects outweigh the increase in cardiac output.

An IABP reduces systolic afterload and augments diastolic perfusion pressure. In contrast to the effects of inotropic or vasopressor agents, these benefits occur without an increase in oxygen demand. IABPs do not, however, produce a significant improvement in blood flow distal to a critical coronary stenosis; they help to bridge patients through a critical period of shock but are not definitive therapy. It is not surprising that IABPs do not improve mortality when used alone in MI. Retrospective data show that use of an IABP in CS complicating acute MI improves survival at 30 days and 1 year, thereby suggesting efficacy as a stabilizing measure before angiography and prompt revascularization in appropriately selected patients.

Mechanical support with left ventricular assist devices (LVAD) can interrupt the downward spiral of myocardial dysfunction, hypoperfusion, and ischemia in CS, allowing time for recovery of stunned myocardium. In CS after acute MI, percutaneous LVADs may be placed in the catheterization laboratory either as bridges to cardiac transplantation or as bridges to recovery. Two currently approved devices are placed through the femoral artery. Both devices offer complete cardiac support but do require adequate right ventricular function; one device placement involves transseptal puncture while the other does not. These devices augment cardiac output and blood pressure while decreasing myocardial oxygen demand. Known complications of percutaneous LVAD use include limb ischemia and bleeding.

Small randomized trials comparing the use of IABP with one or the other of the devices were combined in a meta-analysis that included 100 patients (Cheng et al. *Eur Heart J*. 2009;30[17]:2102). Hemodynamic benefits for the percutaneous LVADs compared with IABP were shown, with higher cardiac indices and mean arterial pressures, as well as lower pulmonary capillary wedge pressures. However, LVAD use showed no mortality benefit over IABP at 30 days.

For patients with end-stage heart failure and refractory shock, a variety of surgically placed assist devices can be employed for circulatory support. These devices retrieve blood from the

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LV apex and use a pumping device, either continuous or pulsatile, to return the blood into the ascending aorta. Full consideration of these devices is beyond the scope of this article; in CS, they are usually used as bridges, although in other contexts they may be used as destination therapy.

A final consideration in the management of CS is how best to monitor the effects of therapeutic interventions. Echocardiography should be done routinely, as it provides rapid and noninvasive assessment of overall ventricular function, regional wall motion abnormalities, valvular function, and also allows for diagnosis of mechanical complications. However, supportive therapy with vasopressors and inotropic agents is best optimized using hemodynamic measurements. Whether this always needs to be done using a Swan-Ganz catheter is another issue. But unstable patients often have substantial changes in myocardial performance and ventricular compliance over time, so serial measurement of hemodynamic parameters is warranted.

Cardiogenic shock was once regarded as uniformly fatal but is now proving treatable. It remains, however, a prevalent and dangerous condition that requires accurate and efficient diagnosis. The potential reversibility of myocardial dysfunction provides the rationale for supportive therapy to maintain coronary and tissue perfusion until more definitive revascularization measures can be undertaken. Application of a thorough understanding of the essentials of pathophysiology, diagnosis, and treatment of CS can allow for expeditious management and improved outcomes.

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ACCP Inaugural Business of Medicine Course

BY DR. EDWARD DIAMOND, MBA, FCCP,
Business of Medicine Course Director;
AND MARLA BRICHTA, *ACCP Manager, Health-care Practice and Reimbursement*

The financial and managerial challenges and complexities of delivering health care have been growing at an exponential pace. Most physicians are poorly informed about health-care finance, accounting, quality improvement methods, health information technology, general management, and leadership. The ACCP Practice Management Department developed an educational program to address these essentials.

On April 20-21, 2012, the ACCP held the inaugural Business of Medicine (BOM) course at ACCP Headquarters in Northbrook, Illinois. This course was designed to enhance physicians' and practice managers' knowledge of the skills required to run an effective and efficient medical practice.

The agenda included robust presentations and interactive audience response on the following topics:

- Overview of Current Financial Health-care Environment: Health-care Macroeconomic Forces and Trends
- Financial and Managerial Accounting: Getting Behind the Numbers
- Key Drivers for Physician-Hospital Affiliations: Alignment and Clinical Integrations
- Payer Contracting Strategies
- Optimize Technology to Reduce Costs and Increase Effectiveness
- The New Clinical Paradigm: Using EHRs in Your Practice.

At the close of this day and a half meeting, the 16 physicians and 10 practice administrators from all across the United States and Puerto Rico, committed to "Five Things to Try and Implement and/or Talk to my Partner(s)/Staff About When I Get Back to the Office." All agreed that the BOM course should be offered to ACCP members at least once a year.

Some comments from attendees:

"I recently attended the Business of Medicine conference, finding it very worthwhile. In fact, we are in the process of implementing much of what we heard there." Paul Weinberg, MD, FCCP, Lawrenceville, Georgia

"The knowledge obtained was formidable and it is being put to practice as of now. It was my first experience attending one of your seminars and I'm looking forward to many others." Carmen Padro, Practice Administrator, Puerto Rico

"Thanks for a wonderful course and for your dedication to ACCP and docs like us who have benefited from your efforts and hard work." Johnny Wong, MD, FCCP, Richmond, Virginia ■

CHEST 2012: Destination Atlanta

CHEST 2012 is taking place October 20-25 in Atlanta. Plan now to attend for essential updates on patient care and practice management strategies. More than 300 general sessions, using a variety of instructional formats, will be presented. Look for hands-on simulation opportunities, case- and problem-based presentations, small-group interactive discussions, self-study opportunities, and more.

As you prepare for the meeting and begin planning your stay, be sure to allow time to venture into the neighborhoods to experience Atlanta's signature southern charm. The convention and entertainment district, where CHEST 2012 will be held, is home to the Georgia Aquarium, World of Coca-Cola, and Inside CNN Studio Tour. But, if you want to get off the beaten path and go where the locals like to go, check out some of these favorite neighborhoods, recommended by ACCP members who live in Atlanta.

CHEST 2012
October 20 - 25
Atlanta, Georgia

Buckhead

Buckhead is touted for its legendary dining and shopping options. Known as "The Beverly Hills of the East," there are amazing things to do—whether you're looking for indulgent restaurants, posh night clubs, or fabulous shopping. It's populated with stately homes and the Governor's mansion, so you also get a flavor of traditional southern neighborhoods.

Decatur

Located outside Atlanta, Decatur offers a small town feel with great restaurants. On MARTA's east-west rail line, Decatur boasts more than 200 shops, restaurants, galleries, and performance venues along tree-lined streets around downtown and in Oakhurst village, just south of the square. From American to Vietnamese, Mexican to French, dessert to after-dinner drinks, you can find something for every appetite.

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Druid Hills

Druid Hills is a tree-shaded neighborhood of winding streets and small parks. In the early 1900s, Atlanta's wealthiest chose to live in Druid Hills and hired noted architects to design their homes. The result is an eclectic mix of architectural styles nestled along the curving topography of the neighborhood. The National Register of Historic Places recognizes Druid Hills.

Midtown

Every great city has a defining district, the heart that pumps life into the city. In Atlanta, it's Midtown. Home to the city's premier green space, historic neighborhoods and southern landmarks, Midtown is the epicenter for diverse arts and culture, a thriving entertainment scene, abundant shopping, and unparalleled dining selections.

Virginia Highland

Historic Virginia Highland is a popular neighborhood for shopping, dining, and nightlife. Locals and tourists alike mingle here for brunch, cocktails, and innovative cuisine at progressive restaurants and bistros. Virginia Highland is acclaimed for its diverse and unique shopping, featuring trend-setting apparel, classic to kitschy antiques, folk and pop art, whimsical decorative accessories, and so much more. Discovering the unexpected is the attraction in this neighborhood.

Check out other local favorites—go hear live jazz in Castleberry Hill or trek to Little Five Points for alternative shopping, bars, restaurants and even an Elvis shrine at the Star Community Bar. Don't miss Cabbagetown, one of Atlanta's emerging neighborhoods which Travel + Leisure magazine featured in "America's Best Secret Neighborhoods." Bicycle tours of Atlanta offer an up-close experience with beautiful architecture and historic sites and neighborhoods. For a fun, eco-friendly adventure, try ATL-Cruzers, electric car tours exploring Midtown, Downtown and all the hidden history in between.

Thanks to ACCP members Dr. Salim Harianawala, Ellen Hillegass, Dr. Saeid Khansarinia, Dr. Burt Lesnick, Dr. Greg Martin, Dr. Jonathan Popler, and Dr. David Schulman for sharing their favorite Atlanta neighborhoods. Learn more about the city at atlanta.net. And, keep watching for developing details on CHEST 2012 at accpmeeting.org. ■

The OneBreath® Evening at the Georgia Aquarium

Amidst all of the extraordinary learning and networking opportunities at CHEST 2012, attendees can also take an exciting, aquatic trip with friends and colleagues and support a phenomenal cause.

"The OneBreath Evening at the Georgia Aquarium" will be held on Sunday evening, October 21, in support of The CHEST Foundation's OneBreath initiative.

Once inside the world's largest aquarium, guests will be transported through six distinct galleries depicting a collection of aquatic animals, from arctic to tropical, that is second to none.

Situated in the heart of downtown Atlanta, the aquarium is dedicated to being a global leader in research and conservation programs that mirror the unique and amazing animals seen within the facility.

Funds raised at the aquarium event support the OneBreath initiative, inspiring people to take care of their lungs and heart and to never take their next breath for granted.

Secure your spot for this memorable evening in an unforgettable setting, and help enhance the reach of the OneBreath mission.

All guests will feast on sumptuous food prepared in the kitchens of Wolfgang Puck and have access to exhibits throughout the aquarium. Individuals who purchase the VIP Pass will enjoy the additional benefits of an exclusive welcome celebration, entry to the phenomenal Dolphin Tales show, and a delectable dessert reception.

Gallery Tour admission tickets are $150; children (ages 3-11) are $35. VIP Pass tickets are $300; children (ages 3-11) are $50.

Donors to the OneBreath initiative may be eligible for complimentary VIP Pass tickets. Visit wwww.onebreath.org for more details.

OneBreath is also offering chances to win an opportunity to swim with the whale sharks while visiting Atlanta during CHEST 2012. Two four-person prize packages are available. Raffle tickets are $100 each or three for $250. Only 500 tickets are available, making your chances of winning quite good!

Secure your admission and raffle tickets now through the CHEST 2012 registration page at www.accpmeeting.org, or to make a donation to OneBreath, visit www.onebreath.org. ■

Pulmonary Perspectives

Detection of Subclinical Interstitial Opacities in Smokers

High-resolution CT scanning of the thorax (HRCT) has been increasingly utilized in the evaluation, management, or staging of a variety of pulmonary processes, such as lung carcinoma, pulmonary nodules, mediastinal disease, cardiac and pericardial disease, pulmonary infectious and inflammatory diseases, coronary artery calcium determination, trauma, and pulmonary embolism (http://washingtonradiology.com/pdfs/CT_Card_Chest_screening.pdf). This utilization will be impacted as the National Lung Screening Trial has demonstrated that screening of a diverse group of high-risk smokers (ages 55-74 years, ≥ 30 pack-years of smoking, smoking cessation within the previous 15 years, if not actively smoking) with low dose HRCT resulted in a 20% relative reduction in mortality from lung cancer (95% CI,6.8- 26.7), P = .004, in addition to a 6.7% reduction in all cause mortality (95% CI, 1.2-13.6, P = .02) (The National Lung Screening Trial Research Team. *N Engl J Med*. 2011;365[5]:395). However, HRCT in smokers has also been associated with the detection of interstitial abnormalities, such as ground-glass opacities, subpleural micronodules, parenchymal nodules with relatively low attenuation, and dependent areas of increased attenuation (Remy-Jardin et al. *Radiology*. 1993:186[1]:107; Hansell. *Radiology*. 2010;256[3]:695; Lederer et al. *Am J Respir Crit Care Med*. 2009;180[5]:407; Tsushima et al. *Respir Med*. 2010;104[11]:1712; Washko et al. *New Engl J Med*. 2011;364[10]:897). The significance of these opacities and the relationship with emphysema or idiopathic pulmonary fibrosis has been reviewed and debated (King. *N Engl J Med*. 2011;364[10]:968).

To determine if cigarette smoking was associated with subclinical parenchymal lung disease, Lederer and colleagues evaluated a subset (n = 2563) of participants enrolled in the Multi-Ethnic Study of Atherosclerosis (MESA), a population-based, prospective cohort from communities in six states in the United States. MESA is composed of older white, African American, Hispanic, and Asian individuals without clinical cardiovascular disease. These subjects underwent cardiac CT scanning that imaged a sufficient portion of the lungs to allow evaluation for subclinical lung disease, defined as high attenuation areas (HAA) between -600 and -250 Hounsfield units (HU). Spirometric restriction, defined as a forced vital capacity of less than the lower limit of normal according to NHANES III prediction equation (Hankinson et al. *Am J Respir Crit Care Med*. 1999;159[1]:179), was present in 10% (95% CI, 8.9-11.2%) of the subjects and increased by 8% (95% CI, 7-14) for every increase of 10 pack-years in multivariate analysis. Additionally, the volume of these HAAs increased by 1.6 cm^3 (95% CI, 0.9-2.4 cm^3). In adjusted analyses, a higher cotinine level was associated with a greater prevalence of restriction and greater volume of HAAs. HAA increased across categories of pack-years and increased by 2.5 cm^3 for each 10 cigarette pack-years. These findings showed an association between cumulative smoking, spirometric restriction, and high attenuation CT scan abnormalities supporting the hypothesis that cigarette smoking is a risk factor for parenchymal abnormalities other than emphysema.

Evaluating 2,416 HRCTs from the Genetic Epidemiology of COPD: COPDGene Study, Washko and colleagues evaluated the relationship between interstitial abnormalities and HRCT measures of total lung capacity (TLC) and emphysema in a cohort of smokers. Interstitial lung abnormalities were defined as nondependent changes affecting more than 5% of any lung zone. These opacities were found in 194 subjects (8%). Four radiographic patterns were noted: (1) subpleural location of reticular, nodular, or ground-glass opacities (55%); (2) centrilobular and subpleural (mixed) opacities (20%); (3) centrilobular or peribronchial ground-glass opacities sparing the periphery of the lungs (19%); and (4) definite radiologic interstitial lung disease (6%). Compared with subjects without interstitial lung opacities, subjects with interstitial opacities had a greater amount of exposure to tobacco smoke [97 vs 40 pack-years (median) P = .01], were significantly older [64 vs 60 (years) P <.0001], and had a higher BMI 28 vs 27 (median) P = .0006]. Participants with interstitial abnormalities were less likely to have COPD, were more likely to have spirometry that could not be classified according to the GOLD classification at the time of the study ($FEV_1 \leq 80\%$ with and $FEV_1/FVC > 0.7$), and were more likely to have a lower percentage of emphysema. In adjusted models, the odds of a restrictive defect in those with interstitial opacities were 2.3 times the odds of those without the opacities. In adjusted models, participants with interstitial opacities had a 47% decrease in their odds of having COPD. In analyses restricted to subjects with COPD, participants with interstitial opacities had a significantly reduced TLC (-12% vs -7% predicted, P <.0001). Additionally, the magnitude of the reduction in TLC was greater in those with COPD at -950 HU than those without COPD, P = .01 for the interaction between COPD and interstitial abnormalities. The pattern most strongly associated with interstitial abnormalities and current smoking was the presence of centrilobular nodules (OR 4.82, 95% CI 2.47-9.44, P <.0001). Interstitial abnormalities were associated with reduced TLC and less emphysema in approximately 1 in 12 HRCT scans in this cohort of current and former smokers.

The pattern of centrilobular ground-glass opacities and nodules is most consistent with respiratory bronchiolitis, a common incidental histopathologic finding in smokers, characterized by accumulation of pigmented macrophages in the alveoli and alveolar duct (Park et al. *J Comput Assist Tomogr*. 2002;26[1]:13; Niewoehner et al. *N Engl J Med*. 1974;291[15]:755). The subpleural pattern may be seen in elderly, asymptomatic subjects more than 75 years old (Copley et al. *Radiology*. 2009;251[2]:566). The mixed pattern is seen with smoking-related interstitial lung disease (Attili et al. *Radiographics*. 2008;28[5]:1383). The pattern of radiologic interstitial lung disease invokes two concurrent disorders—interstitial pulmonary fibrosis and emphysema. Combined pulmonary fibrosis and emphysema (CFPE), manifested by upper lobe emphysematous changes and lower lobe fibrosis (traction bronchiectasis or fibrosis or honeycombing) has been described (Cottin et al. *Eur Respir J*. 2005;26[4]:586). In this review of 61 cases, subjects exhibited paraseptal emphysema with lower lung zone fibrosis, near normal lung volumes, reduced DLCO, and a significant prevalence of pulmonary hypertension. CFPE has been reviewed in subsequent reports and has been estimated to occur in 5% to 10% of cases of diffuse interstitial lung disease (Zeki et al. *J Autoimmun* 2010;34[3]:J327; Portillo and Morera. *Pulm Med*. 2012;867870: Epub 2012 Feb 9).

The reports from Washko and colleagues and Lederer and colleagues support the hypothesis that, in addition to emphysema, cigarette smoking is associated with the development of interstitial lung opacities, restrictive impairment, reduction in lung volume, and less radiographic evidence of emphysema. In contrast to idiopathic pulmonary fibrosis, these opacities are not primarily located in the expected lower lobe distribution. The significance of these opacities and whether they resolve spontaneously or resolve with smoking cessation remain to be determined. We look forward to the results of longitudinal studies in these individuals.

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Atlanta, Georgia

Guest Editor's Comments

Cigarette smoking is associated with several diffuse parenchymal lung diseases, including respiratory bronchiolitis interstitial lung disease (RB-ILD), desquamative interstitial pneumonia (DIP), pulmonary Langerhans' cell histiocytosis (PLCH), and idiopathic pulmonary fibrosis (IPF). In addition, combined lower lobe pulmonary fibrosis and upper lobe emphysema (CPFE) has been reemphasized as a distinct entity. Recently, the potential importance of subclinical interstitial lung abnormalities (ILA) is being recognized in two settings—aging and smoking. ILAs are present in over half of asymptomatic elderly individuals (>age 75 years) who have no pulmonary function deficit, and these CT scan findings are absent in younger individuals (<age 55 years) (Copley et al. *Radiology*. 2009;251[2]:566). As noted in this commentary, subclinical smoking-related ILAs have been found in several CT screening trials. Further, subclinical smoking-related ILAs have been found in surgical specimens (Kawabata et al. *Histopathology*. 2008;53[6]:707; Katzenstein et al. *Hum Pathol*. 2010;41[3]:316).

The presence of these clinically occult radiologic and histopathologic interstitial abnormalities raises many issues for clinicians. In particular, how aggressive should we be in evaluating patients with these abnormalities and how should we manage these patients? Answers to these questions require additional studies. Importantly, it appears that many of the subclinical ILAs in smokers are reversible, usually after smoking cessation. Patients with persistent or worsening ILAs have them largely because they continue to smoke or are found to have one of the defined, smoking-related interstitial lung diseases.

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Shedding Light on the Physicians Sunshine Payment Act

BY SHARMI MAHAJAN, LLM, JD, MPH
ACCP Senior Policy Analyst

One of the underlying goals of the Affordable Care Act of 2010 (ACA) is to increase transparency in health-care decision-making. The Physician Payment Sunshine Act (PPSA) is a clear example of this goal. The act was coauthored by Senator Chuck Grassley (R-IA) and Senator Herb Kohl (D-WI). Embodied in the ACA, the PPSA attempts to deter conflicts of interests in relationships between physicians and teaching hospitals ("covered recipients") on the one hand and certain medical manufacturers on the other. Annual public reporting requirements are imposed on these manufacturers and certain group purchasing organizations.

SEVERAL ORGANIZATIONS PROVIDED COMMENTS TO CMS ON BEHALF OF PHYSICIANS, INCLUDING THE AMERICAN COLLEGE OF CHEST PHYSICIANS.

In December 2011, the Centers for Medicare & Medicaid Services (CMS) requested feedback on its proposed regulations implementing the PPSA. Several organizations provided comments to CMS on behalf of physicians, including the American College of Chest Physicians (ACCP) and the American Medical Association (AMA). Listed below are some of the proposed rule highlights that physicians should consider.

Covered Payments, Transfers of Value, and Financial Relationships
The PPSA specifies that any direct payments or transfers of items of value to covered recipients, greater than ten dollars, are reportable to CMS. There are some exclusions, such as patient educational materials, product samples, and discounts (including rebates). However, in some cases, CMS proposed rules have included reporting on indirect payments, as well. For example, CMS contemplates manufacturers' reports on indirect payments made by third parties to covered recipients when the identity of the recipient is publicly available. That interpretation would capture payments made to continuing medical education (CME) providers who, in turn, provide travel, meals, and transportation reimbursement to faculty physicians. As an accredited CME provider, the ACCP opposes this requirement. In comments to CMS' proposed rule, the ACCP has clearly expressed that accredited medical professional societies rigorously protect against financial conflicts of interest that may bias accredited and nonaccredited education that they provide to physicians. Manufacturers that fund some of these offerings have no input into educational content or physician faculty involved. As such, reporting requirements are redundant in these instances.

Applicable manufacturers and certain group purchasing organizations (GPO) must also report ownership or investment interests held by physicians or their immediate family members in these entities.

Who Submits the Reports to CMS?
Manufacturers of Medicare-, Medicaid-, and CHIP-covered drug, device, biological, or medical supplies.

Information to Be Reported
Among other specifics, manufacturer reports must identify the recipient, recipient business addresses, specialty and National Physician Identification (NPI) number. The amount, form, and date of payment or transfer of value must be indicated along with any associated drug, device, biological or medical supply. A breakdown of payments or other transfers of value into 'nature of payment' categories must also be provided. These include travel, food, speaking engagements, consulting, and research.

Physician Review of Reports
The proposed rule provides physicians 45 days to review and dispute reports prior to publication on the CMS website.

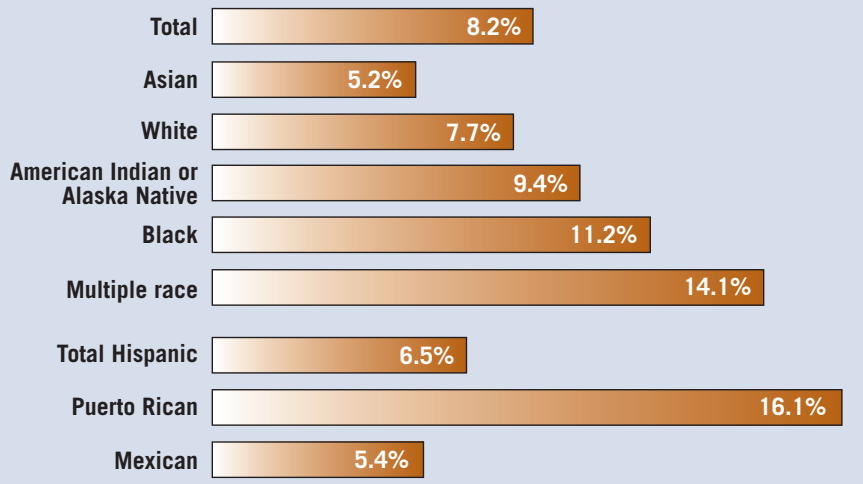
When Will PPSA Implementation Begin?
Many anticipated a delay in data collection until mid or late 2012. However, due to the overwhelming number of stakeholder comments received on the proposed regulations, CMS has delayed implementation until January 1, 2013. Recognizing the complexity of the issue, CMS is composing a work group to clarify issues and make refinements.

Further clarification of the above reporting requirements is anticipated in a final CMS rule later this year. ■

DATA WATCH

U.S. Asthma Prevalence by Race/Ethnicity

(average annual, 2008-2010)



Note: Based on data from the National Health Interview Survey.
Source: National Center for Health Statistics

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ACCP Leaders Bring OneBreath® Outreach to NY

On Friday, May 4, 18 members of the ACCP's Board of Regents (BOR) travelled to the Daniel Carter Beard Junior High School in Flushing, New York, for a very special OneBreath® outreach event. Held in conjunction the ACCP's first BOR regional meeting, held in New York City, the school visit reached more than 120 sixth graders for classroom presentations of The CHEST Foundation's Lung Lessons℠ curriculum.

"It was so meaningful to provide young people with engaging education regarding the importance of lung health and the hazards of tobacco use," said Dr. Stephanie Levine, FCCP, President, The CHEST Foundation Board of Trustees and ACCP BOR member. "Outreach events like this provide prevention resources to children and adolescents so that they can be empowered health advocates. We want to prevent a lifetime of addiction."

The administrators and teachers at the school welcomed the Board's visit, expressing that information about positive choices from outside professionals and experts has a meaningful impact on children at the junior-high level. Post-survey comments from the students indicated their understanding and new learning. Among the many comments, students said they learned that "tobacco is a highly addictive drug," "smoke can trigger asthma," and "tar stays in your lungs forever."

Dr. Sabiha Raoof, FCCP, Ambassadors for One Breath® Chair, and Dr. Diane Stover, FCCP, provided assistance with the local planning of this event and helped prepare BOR members and additional volunteers with tips and training prior to the event.

Those interested in teaching good lung health to children, teens, and adults can contact The CHEST Foundation for a variety of materials and tools, which include the *Lung Lessons℠: A Presenter's Guide* and a lending library of teaching aids. For more information, visit the "Community" section at OneBreath.org, or contact Lee Ann Fulton at lfulton@chestnet.org. ■

COURTESY ACCP

(L-R) Dr. Curt Sessler, Dr. Suhail Raoof, and Dr. Sabiha Raoof teaching about good lung health at the Daniel Carter Beard Junior High School in Flushing, NY.

Marrying *CHEST*, Books, and You

Coming this July, visit www.chestpubs.org to experience the reimagined CHEST Publications website. The goal is simple: take the high impact clinical research from *CHEST*, the latest in clinical education from the ACCP Board Review e-Books, drop you, the reader, in the CHEST PUBLICATIONS center of this vast information pool, and surface only the most relevant pieces of content, without forcing you to wade through a series of semirelated works. How? Here are some hints: search capabilities targeting concepts not just keywords, collections of content organized by the subject areas most meaningful to you, ACCP guidelines accessible from any page on the site, and recommended readings from within *CHEST* and other trusted medical sources displayed beside every article. But that's only a sneak peak. Look for more information to come on this exciting launch. ■

June 30: Deadline to Avoid E-Prescribing Penalties

BY MARY ELLEN SCHNEIDER
Elsevier Global Medical News

So far, the Centers for Medicare and Medicaid has touted the "carrots" associated with the use of health information technology. Come June 30, it will start using one of its first "sticks."

Physicians have until June 30 to report on the use of electronic prescribing under Medicare Part B or apply for a hardship exemption (see box for details). Those who fail to do either face a 1.5% reduction in their Medicare payments starting on Jan. 1, 2013.

The e-prescribing requirement is not difficult to achieve by itself. Rather, it is one more burden faced by physicians already trying to find the time and money to manage Medicare requirements related to the meaningful use of health IT and quality reporting, according to Neil Kirschner, Ph.D., senior associate for regulatory and insurer affairs at the American College of Physicians.

For those who aren't already e-prescribing, the decision will be whether to find an inexpensive e-prescribing program and submit the information necessary to avoid the penalty, or to invest in the transition to a full-scale electronic health record (EHR) system. For a typical physician with a 2,000-patient panel whose practice is 40% Medicare, the 1.5% penalty could add up to $3,000 to $4,000 in 2013, Dr. Kirschner said.

Dr. Mary Newman, an internist in Lutherville, Md., isn't worried about the e-prescribing penalty. Her multispecialty practice has been e-prescribing since 2005, and they've been doing it as an integrated part of their EHR system since 2007. She writes paper prescriptions just a couple times a month now.

Dr. Newman said she wouldn't go back to paper prescribing. E-prescribing is better and safer, she said. With consent from her patients, she now can see medications prescribed by her patients' other physicians. It helps prevent double prescribing, mis-prescribing, and drug interactions, she noted. There also is less time spent on the phone with the pharmacy. In addition, the electronic system helps improve documentation and record keeping, Dr. Newman said.

But while the system is virtually seamless today, Dr. Newman said she and her colleagues first approached the idea with "trepidation and aggravation."

Dr. Jasdip Brar, an internist in Glendale Heights, Ill., jumped right into e-prescribing through his EHR system, but has struggled since.

Last year, Dr. Brar thought he was well on his way to successful e-prescribing through the Medicare eRx Incentive Program when he got a letter from CMS stating that Medicare was cutting his payments by 1% in 2012 for failure to use e-prescribing.

It turns out that the EHR, which had come free with his billing system, never sent the appropriate G codes. He's still waiting to hear from CMS if it will accept his backup documentation as proof of e-prescribing.

"My experience has been kind of rough," Dr. Brar said. This year, he has switched to a different free EHR system and is being more vigilant about ensuring CMS receives his codes.

But regardless of what happens with the payments, Dr. Brar said he's dissatisfied with the electronic products on the market and the requirement that he must e-prescribe. Dr. Brar said he's still much faster when writing prescriptions by hand. When he uses the EHR, it's as if he's being turned into a "point-and-click data entry clerk," he said, and it's not how he wants to spend his time.

"It really becomes frustrating when you're spending more time dealing with a computer than you are the patient," Dr. Brar said.

Despite the obstacles, a majority of physicians are engaged in e-prescribing, according to a new report from Surescripts, which operates the nation's largest health information network.

By the end of 2011, 58% of U.S. office-based physicians had adopted e-prescribing, compared with about 10% of physicians 3 years earlier.

The federal dollars available through the Medicare and Medicaid EHR incentive programs appear to be one of the driving forces behind the uptick in adoption, according to Seth Joseph, director of strategy and innovation at Surescripts and the lead researcher on the report.

As a result, many physicians are starting to see the use of EHRs and e-prescribing technology as inevitable and a standard of care, he said. Another important factor is the development of less expensive, "cloud-based" EHR products, which are making a comprehensive electronic system a more reasonable investment even in smaller practices, Mr. Joseph said. ■

The Fine Print

Under the Medicare Electronic Prescribing (eRx) Incentive Program, individual physicians and other eligible providers must submit information on at least 10 e-prescriptions on their Medicare Part B claim forms between Jan. 1 and June 30. The information must be submitted using either a qualified e-prescribing program or a certified EHR. The claim form must include the e-prescribing G code (G8553) or it doesn't count.

Small group practices participating in the eRx Group Practice Reporting Option must submit codes for 625 e-prescriptions.

Large group practices participating in the program are required to submit codes for 2,500 e-prescriptions.

Individuals who are unable to submit information on at least 10 e-prescriptions can seek a hardship exemption under a few circumstances:

- If they cannot e-prescribe due to local, state, or federal laws.
- If they will write fewer than 100 prescriptions between Jan. 1 and June 30.
- If they practice in a rural area with insufficient high-speed Internet access (use code G8642).
- If they practice where there are not enough pharmacies that can receive electronic prescriptions (G8643).

Submit hardship requests to CMS via the Quality Reporting Communication Support Page by June 30. If the hardship has an associated G code, submit the request through the Communication Support Page or use the G code on at least one claim before June 30.

Those who successfully reported on 25 e-prescriptions in 2011 need not worry about the 2013 penalty.

COMMENTARY

Dr. Stuart Garay, FCCP, comments: Physicians have until June 30, 2012, to begin implementing electronic prescribing. Almost 60% of office-based physicians have adopted e-prescribing. Those who have not done so will incur a 1.5% reduction in their Medicare reimbursement rates beginning Jan. 1, 2013. If you have not started or are in the middle of fulfilling the basic requirement of 10 e-prescriptions between Jan. 1 and June 30, 2012, begin ASAP. Do not "leave money on the table." Don't get penalized by Medicare.

Medicare Hospital Fund Insolvent by 2024

BY MARY ELLEN SCHNEIDER
Elsevier Global Medical News

The Medicare Hospital Insurance Trust Fund, which covers Part A hospital benefits, will remain solvent until 2024, according to a new report from the program's trustees.

Starting in 2024, the trust fund would also be sufficient to cover about 87% of expenses, with that figure falling to 67% by 2050. These figures are similar to financial projections released in last year's Medicare Trustees report.

The Medicare Supplemental Medical Insurance Trust Fund, which covers physician visits and prescription drugs, has adequate funding for at least the next 10 years, the trustees reported. But costs for the Part B and Part D programs are rising. Costs under Medicare Part B, which covers physician and other outpatient services, are expected to increase annually at 4.9% for the next 5 years. The Part D prescription drug program's costs are projected to rise by 8.8% through 2021.

The projected lower spending growth for Medicare Part B is based on Congress allowing a nearly 31% cut to Medicare physician fees to occur on Jan. 1, 2013. The trustees said they doubt that lawmakers would allow that type of cut to happen. "It's almost certain that lawmakers will override this reduction and that Medicare Part B expenditures will therefore be higher, conceivably as much as 12% higher than is reported in these reports for 2013," said Robert D. Reischauer, one of Medicare's public trustees and the former president of the Urban Institute.

Health and Human Services Secretary Kathleen Sebelius, who also serves as a Medicare trustee, said the Affordable Care Act has added about 8 years of solvency to the Medicare Hospital Insurance Trust Fund in part through provisions that fight health care fraud, help prevent medical errors, and cut excessive payments in the Medicare Advantage program.

Without those changes, she said, the program would have become insolvent by 2016.

Whether the projections of extended solvency will turn out to be accurate depend on whether Congress moves forward with changes to the way Medicare pays physicians and hospitals, Mr. Reischauer said. He added that it will also rely on the ability of physicians to become more efficient and on private payers to join with the government to demand changes in the health care delivery system. ■

COMMENTARY

Dr. Stuart Garay, FCCP, comments: Everyone knows that Medicare will run out of money. The question is when? The latest Medicare Trustees report predicts that Medicare will remain solvent until 2024. There are a lot of assumptions – including that the Affordable Care Act remains intact. Notwithstanding this major unknown, it is apparent that Medicare will be changing how it reimburses physicians and hospitals in the future, if it is to remain solvent.

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