Preparing the hospital and protocols is as important as technical expertise in catheter-directed thrombolysis, Dr. Jeffrey Wang said.

**Catheter-Directed Tx in The Community Setting**

**BY SHERRY BOSCHERT**
Elsevier Global Medical News

**F**ew, if any, specialists are aggressively treating massive or submassive pulmonary embolism with catheter-directed thrombolytic therapy at community hospitals, but it is feasible and can have good outcomes with proper planning and preparation, according to Dr. Jeffrey Wang.

Catheter-directed thrombolytic therapy for massive or submassive pulmonary embolism (PE) can shorten stays in the ICU and the hospital, reduce or eliminate the need for home oxygen therapy, and help restore right heart function, he said. However, catheter-directed interventions for these patients is rare outside of academic or tertiary-care settings, probably because of a lack of randomized trials, little retrospective data, and lack of expertise, he said.

For physicians considering this treatment at their own community hospitals, Dr. Wang emphasized that preparing the hospital and protocols is as important as technical expertise in doing the procedure. The fluoroscopy suite must be available on an emergency basis, for example.

“In our institution, we use the same protocols for call-in and transport to the cath lab as for ST-elevation myocardial infarction, which allows us to get the patient up and into the fluoroscopy suite within 30 minutes,” said Dr. Wang of Shady Grove Adventist Hospital, Rockville, Md.

Before doing his first case, he made sure that protocols were in place in the emergency department, in the ICU, and with the hospitalist team for the early detection of deep vein thrombosis and PE, notification of the appropriate staff, and posttreatment care of patients.

Systemic anticoagulation has been the mainstay of PE treatment, but the American Heart Association and the American College of Chest Physicians have recommended more aggressive treatment for massive and submassive PEs, Dr. Wang said. Up to 60% of patients with massive pulmonary embolism with catheter-directed thrombolytic therapy for massive or submassive PE can be done on outpatient basis.

**Desensitization Restores Aspirin’s Benefit in AERD**

**BY NEIL OSTERWEIL**
Elsevier Global Medical News

**ORLANDO –** Aspirin sensitivity can be a real headache for patients and clinicians, but a safe and effective aspirin desensitization protocol can bring the analgesic and anti-inflammatory benefits of aspirin therapy to patients with aspirin-exacerbated respiratory disease, reported a clinician at the annual meeting of the American Academy of Allergy, Asthma, and Immunology.

Patients with AERD who undergo aspirin desensitization have fewer bouts of sinusitis, show improvement in both asthma symptoms and sense of smell, and use less corticosteroid, compared with those who don’t undergo desensitization, said Dr. Katharine M. Woessner, who is program director in the division of allergy, asthma, and immunology at Scripps Clinic in San Diego.

Aspirin desensitization also blunts the response to other NSAIDs like ibuprofen and naproxen, which, like aspirin, inhibit the cyclo-oxygenase-1 (COX-1) enzyme, Dr. Woessner said. Aspirin and other NSAIDs induce rhinitis and asthma attacks in patients with AERD, and the disease is progressive even when patients are careful to avoid all NSAIDs.

Only 3 of 1,400 consecutive patients with AERD that was treated with aspirin desensitization at Scripps experienced systemic reactions, and all of those responded to a single dose of intranasal epinephrine, she said.

“I don’t know why aspirin desensitization works, but we clearly have a therapy that’s easy to use and is quite effective in managing these patients,” she said.

**NCCN: Screen High-Risk Smokers**

**BY DIANA MAHONEY**
Elsevier Global Medical News

The benefits of routine lung cancer screening in high-risk individuals outweigh the potential risks, according to members of a National Comprehensive Cancer Network guidelines panel that recommended low-dose helical CT screening of high-risk groups.

Lung cancer, she noted, is the only one of the top four deadliest cancers (lung, prostate, breast, and colorectal) that is not currently subject to routine screening.

Dr. Reid and her colleagues on the National Comprehensive Cancer Network (NCCN) Guidelines Panel for Lung

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KEYSTONE, COLO. – Chronic bronchitis and gender might provide more clinically meaningful clues to phenotyping patients with chronic obstructive pulmonary disease than does lung function, recent findings from the COPDGene study suggest.

“These are a lot of important features of COPD that we don’t capture by FEV₁, and we need additional clinical features and radiographic information so we can tailor our therapies more even in the future,” COPDGene investigator Dr. Barry J. Make, FCCP, said at a meeting on allergy and respiratory diseases.

Researchers with the ongoing COPD gene study used the ATS (American Thoracic Society) questionnaire to identify chronic bronchitis in 1,061 patients with GOLD stage 2-4 COPD. In all, 290 patients had chronic bronchitis, defined as cough and sputum on most days of 2 or more consecutive days, and 771 did not have chronic bronchitis.

The researchers found that chronic bronchitis is a predictor of future COPD exacerbations, said Dr. Make, codirector of the COPD program and medical director of respiratory care services at Denver’s National Jewish Health, which sponsored the meeting. The chronic bronchitis-positive group had 1.21 exacerbations/patient per year, compared with 0.63 exacerbations/patient per year in the chronic bronchitis-negative group (P < 0.07). In addition, more patients in the chronic bronchitis-positive group reported severe exacerbations (26.6% vs. 20%; P = 0.04).

“We’re concerned about exacerbations, because if you’re hospitalized with an exacerbation of COPD, your mortality within the first year after you get out of the hospital is 20%,” he said.

COPD patients with chronic bronchitis were younger, smoked more, were more often current smokers, and had more nocturnal and perennial awakenings caused by cough and dyspnea. Dr. Make pointed out that the ATS questionnaire is validated to check for cough and sputum, but also emphasized the importance of using CT in assessing patients with COPD.

Notably, patients who have chronic bronchitis have thicker airways on chest CT, compared with the chronic bronchitis-negative group, as indicated by a higher mean segmental wall area percentage (63.2% vs. 62.6%; P = 0.13). Their percent gas trapping and lung emphysema were similar (Chest 2011;140:626-33).

A second COPDGene study in 1,002 COPD patients reported that each 1-mm increase in bronchial wall thickness on quantitative CT is linked with a 1.84-fold increase in annual COPD exacerbations after multivariate analysis that adjusted for lung function, Dr. Make said. The analysis also found that for patients with 35% or greater total emphysema, each 5% increase in emphysema was linked with a 1.18-fold increase in annual exacerbation rate (Radiology 2011;261:274-82).

Thus, COPD patients with chronic bronchitis and emphysema have more exacerbations, and “from CT exam, we can predict a patient’s future exacerbations,” he said.

Dr. Make pointed out that a history of chronic bronchitis and at least one COPD exacerbation requiring systemic corticosteroids and/ or hospitalization were among the inclusion criteria for two pivotal trials that led to the 2011 approval of the phosphodiesterase-4 inhibitor roflumilast (Daliresp). Pooled data from the multicenter trials demonstrated a significant 17% reduction with roflumilast in the rate of moderate or severe exacerbations per patient per year among adult outpatients with COPD (Lancet 2009;374:685-94).

Gender Differences

Women with COPD are known to have more exacerbations than men, to have lower lung function than men with the same cigarette exposure, and to have more symptoms than men with the same lung function. In addition, more women die of COPD, compared with men. Yet, data are limited regarding gender differences in lung anatomy that might explain this troubling paradox, at least in part. Dr. Make highlighted a recent study that identified gender differences in airway dimensions in 1,021 male and 1,026 female smokers in the COPDGene cohort (COPD 2011;8:285-92).

Multidetector CT scans of the chest revealed that in all airways measured, women smokers had higher wall area percentage but smaller luminal area, internal diameter, and airway wall thickness than did male smokers. Gender remained one of the most significant predictors for these differences on multivariate analysis, even after researchers adjusted for age, body size, and other confounders.

Dr. Make reported ties to several pharmaceutical companies and the National Heart, Lung, and Blood Institute.
ONLY inhaled prostacyclin analogue approved as an add-on to oral PAH monotherapy

- 52% of patients improved 6MWD by greater than 20 m
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  - One plastic ampule per day—no need to replace ampule for each treatment session
  - About 5 minutes a day for device preparation—once in the morning, and the device is ready to go all day
- Treatment timing can be adjusted for planned activities

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, headache, throat irritation/pharyngolaryngeal pain, nausea, flushing, and syncope

STUDY DESIGN: TRINITY 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.

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.

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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.


Dr. Woessner said. AERD usually begins in patients in their 30s or 40s who have a prior history of tolerance to aspirin and other NSAIDS and who are more than 5% overweight and likely to occur in women, and tends to be more severe in women than in men. Patients develop chronic congestion, rhinitis, anosmia, and nasal polyps, often followed by asthma 1-5 years after the onset of rhinitis. The disease is characterized by chronic eosinophilic rhinosinusitis and nasal polyposis that are initially intermitent but evolve into chronic, hyperplastic eosinophilic sinusitis that often requires surgical intervention, Dr. Woessner said.

The asthma that develops in patients with AERD is persistent, usually moderate to severe, and related to the severity of sinus disease. However, “asthma is not necessarily a prerequisite to make a diagnosis of aspirin-exacerbated respiratory disease,” she noted.

Aspirin Challenge
The clinical standard for AERD diagnosis is an oral aspirin challenge. Patients typically can experience a 20% or greater decline in FEV1 or FEV1/FCFV40% measured over the first minute of aspirin exposure, and a nsaoprocal reaction, but purely upper airway or lower airway reactions can also occur. Patients may also have a partial asthma reaction, with a 5%-15% decrease in FEV1, and related to the severity of sinus disease. However, “asthma is not necessarily a prerequisite to make a diagnosis of aspirin-exacerbated respiratory disease,” she noted.

AERD Precautions
Aspirin challenge and desensitization in the outpatient setting can be safely performed with a few caveats. The patient should have stable asthma within 10% of the best prior value and an FEV1 of at least 60%-80% of predicted, or an output of at least 1.5 L. The patient should be on inhaled steroids and a long-acting beta-agonist, and 2-4 weeks before desensitization should be started on montelukast or another leukotrienoid modifier. The advent of leukotrienoid inhibitors has made aspirin desensitization a routine outpatient procedure, session moderator Dr. Mariana C. Castells noted in an interview.

“We used to do aspirin desensitization in the intensive care unit because the reactions were scary and we didn’t know how to control them. In the last 10 years, we started to use montelukast [Singulair] and Zyflo [zileuton], less than 15% of patients are in an intensive care unit,” said Dr. Castells of the division of rheumatology, immunology, and allergy at Brigham and Women’s Hospital in Boston.

Patients are asked to not use antihistamines for 72 hours before the procedure so that their nasso-ostral responses can be observed. Patients with nasal polyps may require debulking surgery prior to the procedure.

“We had recommended in the past that intravenous access be available, but we have data now that it may not be necessary,” Dr. Woessner said.

On day 1 of sensitization, patients take 20-40 mg of aspirin at 8 a.m., 40-60 mg at 11 a.m., and 60-100 mg at 2 p.m. On day 2, the respective doses at the same times of day are 100-160 mg, 160-250 mg, and 325 mg.

During desensitization, FEV1 should be measured every hour, and should be at least 1.5 L and greater than 60% of predicted. When a patient has a reaction and that reaction is the provoking dose, should be repeated, and if
Airway Abnormalities May Represent Preclinical RA

BY BRUCE JANCIN
Elsevier Global Medical News

SNOWMASS, COLO. – Where does rheumatoid arthritis hang out in the body preclinically during the years following autoantibody formation but before symptomatic joint involvement?

Increasing evidence suggests that RA is smoldering in the lungs during this preclinical stage, which can last a decade or more. Indeed, bronchiolo-associated lymphoid tissue may actually be the site where tolerance is broken and RA-related autoimmunity and systemic inflammation are generated, according to Dr. William FC. Rigby, professor of medicine and professor of microbiology and immunology at Dartmouth Medical School, Hanover, N.H.

He credited the discovery of the existence of a lengthy preclinical seropositive phase of RA to landmark studies involving U.S. military personnel with centrally stored blood samples that were available for many years prior to their being diagnosed with RA (Ann. Rheum. Dis. 2008; 67:801-7). The existence of this years-long preclinical lag time has since been confirmed in multiple other populations.

Recently, investigators at the University of Colorado at Denver, Aurora, identified the lung as an early site of autoimmune-related injury in subjects with what is being called preclinical seropositive RA (Arthritis Rheum. 2011 Dec. 19; [doi:10.1002/art.34344]).

“This is a great paper, profound in its implications,” Dr. Rigby commented at a symposium sponsored by the American College of Rheumatology.

By conducting mass screenings at an annual Colorado health fair, the investigators identified a cohort of 45 subjects with preclinical RA (defined by elevated anti-cyclic citrullinated peptide antibodies and/or two or more rheumatoid factor isotypes, along with no evidence of arthritis on a 68-joint examination). Earlier work with the Armed Forces cohort had established that this serologic profile is 96% specific for RA.

All 45 subjects underwent chest CT with blinded scan readings. So did 16 seronegative healthy controls matched for age, sex, and smoking status, as well as 12 patients with early RA diagnosed less than 1 year before.

The prevalence of airways disease on CT (air trapping, bronchial wall thickening, bronchiectasis, and/or centrilobular opacities) was 77% in the autoantibody-positive preclinical RA group, compared with 31% of controls. Moreover, none of the subjects with clinical RA subjects with CT lung abnormalities had any evidence of synovitis of their joints on MRI, indicating that RA isn’t smoldering preclinically in their joints for a long time prior to the time they show up in a rheumatologist’s office with joint symptoms.

The prevalence of CT airways changes in the early RA group was similar to that in the preclinical seropositive group.

Of note, none of the subjects with preclinical RA had CT evidence of interstitial lung disease, it was all airways disease, Dr. Rigby observed.

The lung is quite plausible as the site where tolerance is broken (that is, autoantibodies against self-proteins such as cyclic citrullinated peptides are first formed), in light of the fact that smoking is a well-established environmental risk factor for RA, associated with a greater than fivefold increased risk of the rheumatologic disease in epidemiologic studies. Infectious respiratory illness could also hypothetically serve as a trigger for the breaking of tolerance, the rheumatologist said.

Some research groups are homing in on the gut or periodontal colonization by Porphyromonas gingivalis as possible key sites where tolerance is broken in individuals who will years later be diagnosed with RA. At this time, however, Dr. Rigby considers the evidence for the lung as the major player to be further along and more persuasive.

He reported having no financial conflicts.

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In a 66-year-old man with RA, chest radiograph (A) shows multiple lung nodules bilaterally. CT images of the upper thorax (B) and mid thorax (C) show bilateral lung nodules with a random distribution. CT scans 1 year later (D, E) show an increase in number and size of lung nodules. Surgical lung biopsy revealed necrotic (rheumatoid) nodules (F).
A panel of 10 serum biomarkers for lung cancer could offer more accurate interpretation of nodules detected on CT, avoiding invasive biopsies and radiographic follow-up.

"CT screening detection of an indeterminate pulmonary nodule is nonspecific but frequent finding in high-risk subjects with a smoking history, creates a diagnostic dilemma," wrote William L. Bigbee, Ph.D., and colleagues.

"Although the biomarker model we described could not detect every lung cancer, it offers a significant clinical improvement over CT imaging alone... Also, patients with nodules not identified as cancer by the model would continue to receive follow-up clinical monitoring. One would be biopsied if the nodules grew in size, which is the current standard of care," (J. Thorac. Oncol. 2012;7:698-708).

Dr. Bigbee of the University of Pittsburgh and his colleagues cite results of the National Lung Screening Trial (NLST), published in June 2011, which showed for the first time that low-dose CT screening of heavy smokers could reduce lung cancer mortality by 20%. But, as the researchers note in the current study, the "vast majority" of positive results in the NLST program turned out to be false after diagnostic evaluation. Moreover, smaller nodules are least likely to be malignant and least likely to be considered for biopsy or surgery.

For the current study, the researchers initially looked at a "training" set of 56 patients with non-small cell tumors in the University of Pittsburgh Cancer Institute Georgia Cooper Lung Research Registry. These cases were matched with 56 controls from the Pittsburgh Lung Screening Study (PLuSS), the 160,000-person trial that found an 89.2% accuracy when confronted with early- vs. late-stage tumors. Among stage I/II lung tumors, the 10-biomarker panel classified 15% of stage II/IV lung cancer patients correctly compared to 50% of the stage III/IV tumors, suggesting the model performs well in discriminating early-stage lung cancer," they wrote. "With a specificity of 94.8%, the 10-biomarker model was 89.2% [accurate] in stage I/II disease." The authors conceded that the biomarker panel presented here would not suffice for general population screening. However, in a clinical context, among high-risk patients, the model "may provide clinical utility in guiding interpretation of screening CT scans, even in tobacco-exposed persons with COPD or emphysema," they wrote. "Formal validation in larger patient cohorts will be needed to confirm these initial findings."

This study was funded by grants from the National Cancer Institute. There were no personal disclosures.

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New NCCN Guidelines

Cancer Screening presented the update at the NCCN annual conference. The revised guidelines recommend annual low-dose helical CT screening for the following two groups of high-risk individuals:

► Those aged 55-74 years with a minimum smoking history of 30 pack-years who are current smokers or quit within the past 15 years.

► Those aged 50 years or older with a minimum smoking history of 20 pack-years plus one additional lung cancer risk factor.

Evidence from the randomized, controlled National Lung Screening Trial (NLST) suggests that early detection via screening reduced lung cancer-specific mortality in the former risk group, which characterizes the NCCN guideline population. Specifically, 1 in 100 high-risk individuals enrolled in the study screened positive on their first low-dose CT exam, and one life was saved for every 320 high-risk individuals screened over 2 years (three screens) (N. Engl. J. Med. 2011;365:395-409). The NCCN recommendation for this group is category 1, the highest level. The recommendation for annual screening in the second high-risk group is based on less robust evidence and a nonuniform consensus of the NCCN panel members. Dr. Reid said.

As such, it is a less-empiric category 2B recommendation. The NCCN screening recommendations have been deemed by some experts to be premature in the absence of cost-effectiveness analysis, particularly because of the high false-negative rates seen in both the CT group (94.4%) and the radial group (94.5%), as well as the potentially harmful effects of radiation exposure associated with low-dose CT scanning.

In addition to recommending appropriate candidates for routine screening and the proposed frequency of the scans, the new NCCN guidelines outline lung cancer risk factors, address the risks and benefits of screening as well as screening accuracy, and offer an algorithm for the evaluation and follow-up of positive scans.

Specifically, the guidelines recommend the following:

► Basing the frequency of low-dose CT in high-risk patients on the size and status (solid, nonsolid, part-solid, ground-glass, ground-glass opacity) of the nodule on baseline CT.

► Excising all nodules that increase in size or become solid or partially solid during follow-up.

► Considering PET with CT for nodules 8 mm or larger at baseline.

► Performing biopsy or excision of nodules that are suspicious for lung cancer, based on PET with CT findings.

► Reexamining within 1 month any solid endobronchial nodules with low-dose CT immediately after vigorous coughing.

► Counseling smokers to quit.

The NCCN is the first professional organization to recommend routine low-dose CT screening for individuals who are considered to be at high risk for lung cancer, according to Dr. Reid. Last summer, the International Association for the Study of Lung Cancer issued a call for physicians to discuss lung cancer screening with patients with a high-risk smoking history.

Dr. Reid disclosed no financial conflicts of interest. Disclosures of the NCCN Guidelines Panel for Lung Cancer Screening are online.
For patients with severe COPD associated with chronic bronchitis and a history of exacerbations

COPD EXACERBATIONS

are serious events...
Reducing Patient Risk Is Critical

INDICATIONS AND USAGE
DALIRESP is indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. DALIRESP is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

Please see Important Safety Information and Brief Summary of full Prescribing Information on the following pages and at www.DALIRESP.com.

COPD=chronic obstructive pulmonary disease.
For patients with severe COPD associated with chronic bronchitis and a history of exacerbations

DALIRESP® is the first and only selective PDE4 inhibitor to reduce the risk of COPD exacerbations

Moderate exacerbations were defined as those requiring treatment with systemic corticosteroids

Severe exacerbations were defined as resulting in hospitalization and/or death

DALIRESP is not a bronchodilator and is not indicated for the relief of acute bronchospasm

Study design: A pre-specified pooled analysis from 2 identical, 52-week, double-blind, placebo-controlled trials in patients with severe COPD associated with chronic bronchitis and a history of exacerbations (N=3091). Median patient age was 64 years; 76% male, 84% Caucasian. LABAs or short-acting anticholinergics were allowed as concomitant treatment. The reduction in the rate of moderate (requiring treatment with systemic glucocorticosteroids) or severe (resulting in hospitalization and/or leading to death) exacerbations and change in lung function (pre-bronchodilator FEV1) were co-primary endpoints. Each study met both co-primary endpoints.

Mean Number of Exacerbations per Patient per Year

Placebo (n=1554) 1.37 vs DALIRESP (n=1537) 1.14, P=0.0003 vs placebo

Reduction in the rate of moderate or severe exacerbations

17% REDUCTION

• Moderate exacerbations were defined as those requiring treatment with systemic corticosteroids

• Severe exacerbations were defined as resulting in hospitalization and/or death

• DALIRESP is not a bronchodilator and is not indicated for the relief of acute bronchospasm

IMPORTANT SAFETY INFORMATION

Contraindications

DALIRESP is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

Warnings and Precautions

• DALIRESP is not a bronchodilator and should not be used for the relief of acute bronchospasm.

• Prescribers should advise patients, their caregivers, and families to be alert for the emergence or worsening of insomnia, anxiety, depression, suicidal thoughts or other mood changes, and if such changes occur, to contact their healthcare provider. Prescribers should carefully evaluate the risks and benefits of continuing treatment if such events occur. Before using DALIRESP in patients with a history of depression and/or suicidal thoughts or behavior, prescribers should carefully weigh the risks and benefits of treatment with DALIRESP.

– Treatment with DALIRESP is associated with an increase in psychiatric adverse reactions. In controlled clinical trials 5.9% of patients treated with DALIRESP reported psychiatric adverse reactions vs 3.3% treated with placebo. The most common psychiatric adverse reactions were insomnia (2.4% vs 1.0%), anxiety (1.4% vs 0.9%), and depression (1.2% vs 0.9%). Three patients treated with DALIRESP experienced suicide-related adverse reactions (one completed suicide and two suicide attempts) compared to one patient (suicidal ideation) treated with placebo.

In the same studies:
DALIRESP significantly reduced the rate of exacerbations vs placebo in patients using a bronchodilator¹,³

CONSISTENT EFFECT WITH A CONCOMITANT BRONCHODILATOR¹,³

| DALIRESP with LABAs (Long-acting β₂ Agonists) | ✓ |
| DALIRESP with Short-acting Anticholinergics | ✓ |

The effect with concomitant LABAs or short-acting anticholinergics was similar to that seen in the overall population¹,³

- Patients should have their weight monitored regularly. If unexplained or clinically significant weight loss occurs, weight loss should be evaluated and treatment discontinuation considered.
  - In addition to weight loss being reported as a common adverse reaction (7.5% of patients treated with DALIRESP vs 2.1% placebo), weight was prospectively assessed in two 1-year clinical trials. In these studies that compared DALIRESP to placebo, 20% vs 7% experienced moderate weight loss (5-10% of body weight) and 7% vs 2% experienced severe weight loss (>10% body weight). During the follow-up period after discontinuing DALIRESP, the majority of patients regained some of the weight they had lost.

- Use with strong cytochrome P450 enzyme inducers (e.g., rifampicin, phenobarbital, carbamazepine, phenytoin) is not recommended, as they decrease the exposure and may reduce the therapeutic effectiveness of DALIRESP.

Adverse Reactions
In clinical trials the most common adverse reactions (≥2% and greater than placebo) were diarrhea (9.5% vs 2.7%), weight loss (7.5% vs 2.1%), nausea (4.7% vs 1.4%), headache (4.4% vs 2.1%), back pain (3.2% vs 2.2%), influenza (2.8% vs 2.7%), insomnia (2.4% vs 1.0%), dizziness (2.1% vs 1.1%), and decreased appetite (2.1% vs 0.4%).

Please see Brief Summary of full Prescribing Information on the following page and at www.DALIRESP.com.
**DRUG INTERACTIONS**

A major step in roflumilast metabolism is the N-oxidation of roflumilast to roflumilast N-oxide by CYP3A4 and CYP1A2 [see Clinical Pharmacology (12.3)].

**Drugs That Induce Cytochrome P450 (CYP) Enzymes**

Strong cytochrome P450 enzyme inducers decrease systemic exposure to roflumilast and may reduce the therapeutic effectiveness of DALRESP. Therefore the use of strong cytochrome P450 inducers (e.g., rifampicin, phenobarbital, carbamazepine, and phenytoin) with DALRESP is not recommended [see Drug Interactions (5.4) and Clinical Pharmacology (12.3)].

**Drugs That Inhibit Cytochrome P450 (CYP) Enzymes**

The co-administration of DALRESP (500 mcg) with CYP3A4 inhibitors or dual inhibitors that inhibit both CYP3A4 and CYP1A2 simultaneously (e.g., erythromycin, ketoconazole, fluvoxamine, escin, and etonidine) may increase roflumilast systemic exposure and may result in increased adverse reactions. The risk of such concurrent use should be weighed carefully against benefit [see Clinical Pharmacology (12.3)].

**Oral Contraceptives Containing Gestodene and Ethinyl Estradiol**

The co-administration of DALRESP (500 mcg) with oral contraceptives containing gestodene and ethinyl estradiol may increase roflumilast systemic exposure and may result in increased side effects. The risk of such concurrent use should be weighed carefully against benefit [see Clinical Pharmacology (12.3)].

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

Teratogenic effects: Pregnancy Category C. There are no adequate and well controlled studies of DALRESP in pregnant women. DALRESP was not teratogenic in mice, rats, or rabbits. DALRESP should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

DALRESP induced stillbirth and decreased pup viability in mice at doses corresponding to approximately 16 and 48 times, respectively, the maximum recommended human dose (MRHD) (on a mg/m² basis at maternal doses + 2 mg/kg/day and 6 mg/kg/day, respectively). DALRESP induced post-implantation loss in rats at doses greater than or equal to approximately 10 times the MRHD (on a mg/m² basis at maternal doses + 0.6 mg/kg/day). No treatment-related effects on embryo-fetal development were observed in mice, rats, and rabbits at approximately 12, 3, and 26 times the MRHD, respectively (on a mg/m² basis at maternal doses of 1.5, 0.2, and 0.8 mg/kg/day, respectively).

Nonteratogenic effects: DALRESP has been shown to adversely affect pup postnatal development when dams were treated with the drug during pregnancy and lactation periods in mice. These studies found that DALRESP decreased pup rearing frequencies at approximately 40 times the no adverse effect dose (NAD) (on a mg/m² basis at a maternal dose of 6 mg/kg/day) during pregnancy and lactation. DALRESP also decreased survival and forelimb grip reflex and delayed prena detachment in mouse pups at approximately 97 times the MRHD (on a mg/m² basis at a maternal dose of 12 mg/kg/day) during pregnancy and lactation.

**Labor and Delivery**

DALRESP should not be used during labor and delivery. There are no human studies that have investigated the effect of DALRESP on perinatal outcomes. However, animal studies showed that DALRESP disrupted the labor and delivery process in mice. DALRESP induced delivery retardation in pregnant mice at doses greater than or equal to approximately 16 times the MRHD (on a mg/m² basis at a maternal dose of >2 mg/kg/day).

**Nursing Mothers**

DALRESP and/or its metabolites are excreted into the milk of lactating rats. Excretion of roflumilast and/or its metabolites into human milk is probable. There are no human studies that have investigated effects of DALRESP on breast-fed infants. DALRESP should not be used by women who are nursing.

**Geriatric Use**

COPD does not normally occur in children. The safety and effectiveness of DALRESP in pediatric patients have not been established.

**Drug Interactions**

A major step in roflumilast metabolism is the N-oxidation of roflumilast to roflumilast N-oxide by CYP3A4 and CYP1A2. The administration of the cytochrome P450 enzyme inducer rifampicin resulted in a reduction in exposure, which may result in a decrease in the therapeutic effectiveness of DALRESP. Therefore the use of strong cytochrome P450 enzyme inducers (e.g., rifampicin, phenobarbital, carbamazepine, and phenytoin) with DALRESP is not recommended. [see Drugs That Induce Cytochrome P450 (CYP) Enzymes (7.1) and Clinical Pharmacology (12.3)].

**ADVERSE REACTIONS**

The following adverse reactions are described in greater detail in other sections:

- **Psychiatric Events Including Suicidality** (see Warnings and Precautions (5.2))
- **Weight Decrease** (see Warnings and Precautions (5.3))

**Adverse Reactions in Clinical Studies**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug can be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety data described below reflect exposure of 3,363 patients treated with DALRESP 500 mcg once daily in four 1-year placebo-controlled trials, two 6-month placebo-controlled trials, and two 6-month drug add-on trials [see Clinical Studies (14.1)]. In these trials, 313 and 1,232 COPD patients were exposed to DALRESP 500 mg once daily for 6 months and 7 years, respectively. The population had a median age of 64 years (range 40-91), 73% were male, 92.9% were Caucasian, and had COPD with a mean pre-bronchodilator forced expiratory volume in one second (FEV) of 8.9 to 8.191 predicted. In these trials, 31.5% of the patients treated with DALRESP reported an adverse event, compared with 65.3% treated with placebo.

The proportion of patients who discontinued treatment due to adverse reaction was 4% for DALRESP-treated patients and 9.8% for placebo-treated patients. The most common adverse reactions that led to discontinuation of DALRESP were diarrhea (2.4%) and nausea (1.8%).

**Adverse reactions**

Serious adverse reactions, whether considered drug-related or not by the investigators, which occurred more frequently in DALRESP-treated patients include diarrhea, atrial fibrillation, lung cancer, prostate cancer, acute pancreatitis, and acute renal failure.

**Table 1. Adverse Reactions Reported by ≥2% of Patients Treated with DALRESP 500 mcg daily and Greater Than Placebo**

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>DALRESP (500 mcg)</th>
<th>Placebo</th>
<th>Treatment Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>12/35 (34%)</td>
<td>11/29  (38%)</td>
<td>-5/4 (15%)</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>9/31 (29%)</td>
<td>13/35 (37%)</td>
<td>-4/4 (12%)</td>
</tr>
<tr>
<td>Nystagmus</td>
<td>2/14 (14%)</td>
<td>1/10 (10%)</td>
<td>+1/4 (40%)</td>
</tr>
<tr>
<td>Headache</td>
<td>19/10 (19%)</td>
<td>17/31 (55%)</td>
<td>-8/12 (22%)</td>
</tr>
<tr>
<td>Back pain</td>
<td>6/17 (35%)</td>
<td>10/31 (32%)</td>
<td>-4/4 (12%)</td>
</tr>
<tr>
<td>Migraine</td>
<td>12/24 (50%)</td>
<td>11/24 (46%)</td>
<td>+1/4 (17%)</td>
</tr>
<tr>
<td>Asthma</td>
<td>11/41 (27%)</td>
<td>11/31 (35%)</td>
<td>-1/2 (18%)</td>
</tr>
<tr>
<td>Increased appetite</td>
<td>1/15 (7%)</td>
<td>1/24 (4%)</td>
<td>+1/2 (50%)</td>
</tr>
</tbody>
</table>

Adverse reactions that occurred in the DALRESP group at a frequency of 1 to 2% were rates exceeded in the placebo group include:

- Gastrointestinal disorders - abdominal pain, dyspepsia, gastritis, vomiting
- Infections and infestations - rhinitis, sinusitis, urinary tract infection
- Musculoskeletal and connective tissue disorders - muscle spasm
- Nervous system disorders - tremor
- Psychiatric disorders - anxiety, depression

**Management of Overdose**

In case of overdose, patients should seek immediate medical help. Appropriate supportive medical care should be provided. Since roflumilast is highly protein bound, it is unlikely to be an efficient method of drug removal. It is not known whether roflumilast is dialyzable by peritoneal dialysis.

Manufactured by: Nycomed GmbH, Production Site Oranienburg Lindestrasse 70 – 98 16515 Oranienburg Germany

Manufactured for: FarmaPharmaceuticals, Inc. subsidiary of Forest Laboratories, Inc. St. Louis, MO 63045, USA

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Please also see full Prescribing Information at www.daliresp.com.
Treating PEs Outside Tertiary Care
Community • from page 1

PE die, data suggest, with two-thirds of the deaths occurring in the first hour of embolism formation. Within 30 days of submassive PE formation, 15%-20% of patients die secondary to pulmonary hypopertension and cor pulmonale.

Approximately 30% of all 500,000 symptomatic PEs diagnosed each year in the United States lead to death. Even among inpatients who are diagnosed with a PE while in the hospital, the mortality rate is approximately 10%-15%, he said.

Until recently, there was no Food and Drug Administration–approved device for catheter-directed thrombolytic therapy. “There’s also not a purpose-built device to help you with these types of procedures,” Dr. Wang said.

At the annual meeting of the Southern Association for Vascular Surgery, he described treating nine women and three men who had a total of seven massive and five submassive PEs. Catheter-directed thrombolytic therapy was offered to patients with massive or submassive PE if they were hemodynamically unstable or had right heart dysfunction, elevated troponin levels, or pulmonary artery pressures greater than 70 mm Hg, or if they were not being weaned off intubation for oxygen within 5 days, Dr. Wang said. He excluded patients who were actively bleeding or who were not able to tolerate any systemic anticoagulation – “not even aspirin,” he said.

Recent surgery was not a disqualifying factor. “Typically those patients were orthopedic in nature, with a hip or knee replacement,” Dr. Wang said. The patient would develop a big PE, and the orthopedist would give him the green light for aggressive treatment.

All procedures were technically successful. One patient developed hemodynamically significant bradycardia, but all were off supplemental oxygen within 24 hours of the procedure, and there were no bleeding events.

One patient died 14 hours after the procedure, most likely due to a paradoxical embolism to the intestine, Dr. Wang said. The 11 surviving patients were discharged to home within 48 hours of the intervention.

His technique includes accessing the internal jugular vein to get to the pulmonary artery, placing a vena cava filter, and giving tissue plasminogen activator as the lytic agent. All patients had a spiral CT scan before going to the catheterization lab, so pulmonary angiography was not routinely performed.

He reserved mechanical (catheter) thrombectomy for some patients with massive thromboembolism. Instead of being guided by angiography, he determined the duration of mechanical thrombectomy by the patient’s blood pressure, pulse, and oxygen saturation. “I discontinued mechanical thrombectomy once oxygen saturation was above 99%, they’re weaning off their inotropes, and the pulse rate was trending toward normal,” he said.

For some patients who developed sinus arrhythmias due to the wire manipulation within the heart and pulmonary arteries, he removed the wire device, waited for it to resolve, and continued. A minority of patients whose arrhythmias continued to occur during the intervention received calcium block- ade or beta blockade.

Patients who received mechanical thrombectomy developed dark or bloody urine that resolved within 48 hours with hydration.

Follow-up at 2 weeks assessed general function and access sites, and patients had a repeat echocardiogram at 1 month. If they were doing well functionally and pulmonary hypertension had resolved, Dr. Wang offered to remove the vena cava filter. All but one patient accepted. All were to remain on systemic anticoagulation for 6-12 months, and patients with massive PE underwent hematoletic work-ups.

Dr. Wang reported having no financial disclosures.

Rivaroxaban Found ‘Noninferior’ to Standard PE Therapy

BY MARY ANN MOON

Rivaroxaban was noninferior to standard treatment at preventing a recurrence of pulmonary embolism in an international open-label trial reported online in the New England Journal of Medicine and presented simultaneously at the annual meeting of the American College of Cardiology.

Rates of adverse bleeding events with rivaroxaban were similar to those with the more complex standard therapy of enoxaparin plus a vitamin K antagonist, a regimen that requires INR (international normalized ratio) monitoring, said Dr. Harry R. Buller of the department of vascular medicine at the University of Amsterdam and his associates in the EINSTEIN-PE clinical trial.

The study involved 4,832 adults with acute symptomatic pulmonary embolism (PE), with or without deep vein thrombosis (DVT), who were treated at 263 sites in 38 countries in 2007-2011. In all, 2,419 study subjects were randomly assigned to receive oral rivaroxaban (15 mg twice daily for 3 weeks, followed by 20 mg once daily) and 2,413 to receive enoxaparin (1 mg/kg twice daily, which was discontinued when the INR reached 2.0 or greater for 2 consecutive days after at least 3 days of therapy) plus either warfarin or acenocoumarol at a dosage adjusted to maintain an INR of 2.0-3.0.

All study subjects were treated for durations of 3, 6, or 12 months, according to the wishes of their treating physicians and in keeping with current practice. The mean duration of treatment was about 9 months.

In the standard treatment group, the INR was in the therapeutic range 62.7% of the time. The INR was not measured in the rivaroxaban group, but adherence to therapy was high in 94.2% of patients.

The primary efficacy outcome was symptomatic recurrent venous thromboembolism, a composite of fatal and nonfatal PE or DVT. This occurred in 50 patients (2.1%) receiving rivaroxaban and 44 (1.8%) receiving standard therapy, which met the criterion for noninferiority, the investigators said (N. Engl. J. Med. 2012 March 26 [doi:10.1056/NEJMoa1113572]).

During the initial 3-week period of intensive rivaroxaban therapy, the primary efficacy outcome occurred in 18 patients (0.7%) of the rivaroxaban group and in 21 patients (0.9%) in the standard therapy group.

The efficacy results were similar in a per-protocol analysis and in an intention-to-treat analysis.

The primary safety outcome was clinically relevant bleeding, and it occurred in 249 subjects (10.3%) in the rivaroxaban group and in 274 (11.4%) in the standard treatment group.

In particular, major bleeding events occurred in 26 patients (1.1%) taking rivaroxaban and 32 (2.2%) taking standard therapy.

During the initial 3-week period of intensive rivaroxaban therapy, bleeding rates were similar between the two study groups. Over the full course of treatment, “there were fewer episodes of intracranial bleeding or bleeding in critical areas in the rivaroxaban group than in the standard therapy group,” Dr. Buller and his colleagues said.

With regard to other safety outcomes, the rates of acute coronary events were similar between the two study groups, at 0.6% with rivaroxaban and 0.9% with standard therapy. Abnormal findings on liver function tests were seen in 0.2% of both groups.
SLEEP MEDICINE

BY M. ALEXANDER OTTO
Elsevier Global Medical News

PHOENIX – Reducing bedtime stimulation and, oddly enough, restricting sleep both have powerful, relatively fast effects on insomnia, especially when used in tandem.

Among cognitive-behavioral therapy approaches, they have the best supporting evidence and, “happily, are the easiest to do,” said Allison Harvey, Ph.D., director of the University of California, Berkeley, Golden Bear Sleep and Mood Research Clinic.

The goal is to teach insomniacs that their beds are for sleeping, not watching TV, surfing the Internet, eating potato chips, or fretting about not getting enough sleep.

Sleep restriction limits their time in bed to the time they actually sleep. The first step is to discover that ratio by having patients keep a sleep diary for a week or two. Insomniacs are usually about 60% sleep efficient; for every 8 hours in bed, they’ll sleep about 5.

The next step is limiting bed time to 7 or 8 hours. At first, that might cause a bit of sleep deprivation, but that’s a good thing because it builds homeostatic pressure to sleep. Dr. Harvey explained at a meeting on sleep medicine held by the American College of Chest Physicians.

The goal is 85% sleep efficiency: 4.25 hours of sleep, for instance, for every 8 hours in bed, they’ll sleep about 5. Within about 6 weeks, patients should be getting an efficient 7 or 8 hours of sleep per night.

At first, “we never go less than 5 hours a night” and “make the determination of how low we go dependent on safety issues. So, if someone’s a truck driver, we probably wouldn’t do this treatment. If someone has bipolar disorder, I would not go below 6 1/2 hours because sleep deprivation can trigger a manic episode.” Naps are okay if needed, as long as they are before 3 p.m. and are 30 minutes or less, Dr. Harvey said.

Stimulus control reinforces the bed-sleep connection. If patients aren’t asleep within 20 minutes, “don’t let them clock watch. [Tell them to] get up and move to another room, and stay up until they are really sleepy,” she said.

If they want to read, it shouldn’t be something that will keep them up all night. If they want to watch TV, it should be something relaxing, not just channel surfing. If they’re anxious, writing in a journal can help.

“I had one patient who said, ‘Oh, I can get some housework done.’ No. Nothing productive. Other patients say, ‘I can get on my computer and do some e-mail.’ No. [They need] dim light conditions.”

Dr. Harvey said. Flexibility is important. Some patients might want to restrict sleep in the evening, others in the morning. Both are fine. Some patients might worry that 5 hours is too little bedtime, so “start with 7½ – it’s better than 8½. Sleep efficiency will pop up a bit, they’ll get confidence. They’ll come down to 7 hours the next week. Just base it on what makes sense for the person,” Dr. Harvey said.

It might take a few weeks for patients to see benefits, so support is important, too. Troubleshoot their routine for problems, and encourage them to continue the program, she said. It’s uncertain what benefit sedative hypnotics such as zolpidem (Ambien) would add to the approach, she noted.

Dr. Harvey reported having no relevant financial disclosures.

Insomnia Responds to Cognitive-Behavioral Approach

The impact of COPD exacerbations

Patients who experience frequent exacerbations have:

• A faster decline in lung function
• A decline in lung function that can take up to several weeks to return to baseline
• A poorer quality of life
• A higher mortality rate

One exacerbation can lead to the next

A common trigger for exacerbations is infection. It is thought that tobacco smoke and other noxious agents impair certain immune responses, leaving patients increasingly susceptible to infection. The increased incidence of infection may lead to even further inflammation, precipitating an exacerbation. Patients may end up in a cycle of recurring exacerbations, leading to progression of their disease as well as decrease in health status.

This inflammatory process of COPD involves a variety of cells, including neutrophils, macrophages, and fibroblasts. The role played by neutrophils is especially significant. In a study of 64 patients with moderate to severe COPD, neutrophils accounted for approximately 70% of the inflammatory cells in patients’ sputum.
Several First-Line Drugs Available for Insomnia

BY M. ALEXANDER OTTO
Elsevier Global Medical News

PHOENIX – It’s a good idea to remind insomnia patients not to mix benzodiazepine receptor agonists – zolpidem, zolpidem, and eszopiclone – with anti-histamines, antinausea drugs such as promethazine, or alcohol.

Mixing the so-called Z-drugs with those or other sedating agents can trigger sleepwalking, sleep driving, or sleep eating, among other problems, in approximately 1 in 1,000 people. Those affected might “get up in the morning and find the kitchen is a mess and all the food is pulled out of the refrigerator. They’ll have no memory of it,” said Dr. James Parish, FCCP, medical director of the center for sleep medicine at the Mayo Clinic in Scottsdale, Ariz.

When Dr. Parish prescribes a Z-drug, “I warn people about this effect and [that] if this happens, they should stop the drug immediately and not use it again,” he said.

Otherwise, the Z-drugs have a good safety profile. Sublingual zolpidem (Intermezzo), the most recent entry in the class, has a 2.5-hour half-life and can be used for middle-of-the-night insomnia if patients have at least 4 hours left in bed. Zaleplon (Sonata) has a 1-hour half-life and can also be used in the middle of the night, Dr. Parish said at a meeting on sleep medicine held by the American College of Chest Physicians.

The Z-drugs, along with short- to intermediate-acting benzodiazepines and ramelteon (Rozerem), are first-line options for insomnia, according to the American Academy of Sleep Medicine guidelines (J. Clin. Sleep Med. 2008; 4:487-504).

Benzodiazepines with longer half-lives and active metabolites should be avoided for insomnia, Dr. Parish said. These agents can cause daytime sleepiness and cognitive impairment, among other problems, especially in elderly people less able to metabolize them.

After months or years of long-acting benzodiazepine use, rebound insomnia is an issue, as well. Patients stop the medication and “boom, their sleep is worse than ever for a week or two” before normalizing. The problem can keep “patients taking these drugs for years and years,” Dr. Parish said.

So it’s important to let patients know beforehand about the rebound potential, and tell them “that it’s going to be bad for a while, but don’t panic. Things will [get] better,” he said.

Ramelteon, a melatonin receptor agonist, “is another useful drug,” With no affinity for benzodiazepine receptors, it should not cause daytime drowsiness, he said.

Ramelteon metabolizes in the liver, so it can’t be used in patients with liver disease. It also increases concentrations of alcohol, azole antifungal drugs, and fluvoxamine, and decreases rifampin levels.

“You have to think about how it’s going to affect other drugs. Given that, I think it’s a reasonably effective, reasonably safe drug,” Dr. Parish said.

Because they have anticholinergic and antihistaminic effects, some antidepressants are insomnia options, too, but not as first-line agents and at doses lower than those used for depression.

The tricyclic antidepressant doxepin (Silenor) was approved for insomnia in 2010 at 3-mg and 6-mg doses, but it cannot be used with monoamine oxidase inhibitors.

Follow-up is important with all insomnia agents to assess effect and safety and to monitor for dose escalation. Concomitant cognitive-behavioral therapies – stimulus control and school restriction, for example – are helpful as well, with the goal of tapering patients off sleeping pills as behavior therapy takes effect.

Dr. Parish said he had no relevant financial disclosures.


The federal regulation requiring tobacco companies to display graphic antismoking images on cigarette packs is unconstitutional, a district judge in Washington, D.C., ruled.

"For corporations as for individuals, the choice to speak includes within it the choice of what not to say," Judge Richard J. Leon, district judge for the District of Columbia, wrote in the court memorandum. "The Government may engage in advocacy using its own voice, [but] it may not force others, such as Plaintiffs, to serve as an unwilling mouthpiece."


The Food and Drug Administration unveiled the nine graphic labels in June 2011, after proposed labels and associated regulations were available during a public comment period. Graphic images included a man breathing through an oxygen mask, a cadaver, a woman weeping, a mouth with what appears to be cancerous lesions, and a drawing of a premature baby in an incubator.

Under the regulation, cigarette manufacturers would be required to display one of nine textual warnings on all cigarette packages. Warnings include: "Smoking can kill you" and "Cigarettes are addictive." While the court recognized the government’s right to require certain disclosures for clarity, Judge Leon ruled that "purely factual and uncontroversial information may still violate the First Amendment if they are unjustified and unduly burdensome."

The judge’s ruling spurred vehement reaction from traditional tobacco opponents. "Judge Leon's dangerous ruling blantly ignores significant scientific evidence supporting the effectiveness of larger, graphic warning labels in communicating the health dangers of tobacco use," said a statement by the American Academy of Pediatrics. "If allowed to stand, this ruling would make it impossible to implement any effective warning labels and will therefore harm the health and well-being of millions of children."

The Obama administration vowed to continue pursuit of the warnings.

"This administration is determined to do everything we can to warn young people about the dangers of smoking, which remains the leading cause of preventable death in America," said a statement from the Department of Health and Human Services. "This public health initiative will be an effective tool in our efforts to stop teenagers from starting in the first place and taking up this deadly habit. We are confident that efforts to stop these important warnings from going forward will ultimately fail."

Rep. Henry Waxman (D-Calif.) also criticized the decision.

“These provisions were informed by scientific evidence showing that current warning labels have run their course and that labels with graphic warnings would be more effective in protecting the public’s health from tobacco’s addictive and toxic qualities,” Rep. Waxman said in a statement. “Congress did, in fact, carefully consider the First Amendment issues involved and carefully tailored the legislation to ensure the FDA could act as it has proposed with graphic warning labels for tobacco products.”

Rep. Waxman said he expects the ruling to be appealed and its constitutionality affirmed.

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NOT since the passage of the Medicare in 1965 will there be such sweeping health-care reform as from passage of the Patient Protection & Affordable Care Act (ACA) and the health care provisions of the Health Care & Education Reconciliation Act (HCERA) of 2010, collectively known as the Health Reform Law (HRL), signed into law by President Barack Obama. This legislation covers a huge breadth of health-care topics, including affordability, access, quality, fraud and abuse prevention, tax reform, and the mandate for all Americans to carry health insurance. To date, under the HRL, coverage has been expanded for young adults, increased for drug coverage for seniors hitting the “doughnut hole,” and introduced to provide greater protections against insurance denial related to preexisting medical conditions.

The HRL is also affecting the way in which hospitals conduct and physicians practice health care. Thus, many physicians and the lay public have legitimate concerns about the HRL, as they did in 1965 with Medicare. The behemoth 2,700-page HRL is the largest and most expensive health-care legislation in American history, with the insurance coverage provisions projected to gross $1.762 trillion (net $1.232 trillion) in costs from 2012 to 2022 (Congressional Budget Office, Estimates for the Insurance Coverage Provisions of the Affordable Care Act, March 2012). With its immense scope, size, and cost, and its many sections that are scheduled to be activated in 2014, when the HRL is slated to be fully implemented, it is understandable that a significant number of American patients and physicians are concerned.

While some aspects of the HRL have already been enacted, what follows is a partial list of major changes to the law that will affect hospitals and physicians:

1. Value-Based Purchasing for Physicians, Physician Groups, and Hospitals. Beginning in 2015, the Department of Health & Human Services (HHS) will establish a budget-neutral payment modifier to determine remuneration based on quality of care provided compared with cost. Physicians practicing in rural and underserved areas will be given special consideration. As for hospitals, a percentage of Medicare payments for some common, high-cost procedures (eg, cardiac, surgical, and pneumonia care) will also be bound to cost and quality.

2. Hospital Readmission Reduction Program. Hospitals that participate in the Medicare Inpatient Prospective Payment System (IPPS) will be subject to monetary penalties if their readmission rates exceed a certain threshold. The diagnosis for initial scrutiny of readmission will include myocardial infarction, heart failure, and pneumonia. Hospitals with readmission rates adjusted for high severity, which have not taken steps to reduce their recidivism, will be mandated to establish a Quality Improvement Program via existing patient safety organizations. Hospitals will be required to submit their data to HHS, which will be posted on the HHS website.

3. Quality Reporting for Long-term Care Hospitals, Inpatient Rehab Hospitals, and Hospices. Starting in 2014, these entities will be required to submit certain quality data or else face payment reductions of 2%.

4. Public Reporting of Physician and Hospital Performance: The Physician and Hospital Compare Websites. Starting in 2013, the public will be able to view comparative information on physician performance measures and assessments from the Physician Quality Reporting Initiative; patient health outcomes and functional status; continuity and coordination of care; efficiency; patient experience, as well as engagement of the patient, family, and caregiver; and effectiveness, safety, and timeliness of care. Public reporting of hospital data will be online via the Hospital Compare website.

5. Hospital-Acquired Conditions. Medicare reimbursement penalties will be imposed on hospitals with high rates of conditions or infections acquired while in the hospital, as of FY 2015. (Similar policies will be established for other Medicare providers, such as ambulatory surgical centers, nursing homes, long-term care facilities, health clinics, and others.)

6. Medicare Shared Savings Program. Eligible Medicare providers, including hospitals and vendors, may participate in an Accountable Care Organization (ACO) to reduce Medicare costs by incentivizing collaborative and coordinated care among its providers to increase accountability for quality health outcomes. Federal regulations are being proposed to establish payment models for ACOs. The Department of Justice and Federal Trade Commission are reviewing regulations regarding antitrust laws with respect to ACOs. Internal Revenue Service rules are being amended for ACOs that would be tax-exempt or have 501(c)3 status, and the Office of the Inspector General and OFCCP are reviewing ACOs or doing so. Through a series of incentive and provisions, across Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP).

7. Disproportionate Share Hospitals (DSH). DSH payments help certain hospitals offset costs of care provided to uninsured patients. Beginning in 2014, for some hospitals, the majority of Medicare and Medicaid payment cuts will occur in the form of reductions to DSH payments, as the anticipated number of uninsured patients declines.

8. Market Basket Reductions. The annual market basket payment updates to hospitals, inpatient rehab facilities, nursing homes, home health-care providers, and others will be reduced.

9. CMS Innovation Center. Established in November 2010, the CMS Innovation Center tests health-care delivery and payment systems that support best-care practices and their dissemination, which are aimed at reducing Medicare and Medicaid costs and improving health care. Initiatives include testing of bundled payment models for acute, postacute, and chronic care; reducing hospital readmissions by 20% and nosocomial infections by 40% by 2013; supporting ACO development; fostering primary and patient-centered care; and granting monetary awards for health-care entities that rapidly implement innovative reformed delivery systems.

10. Fraud and Abuse Laws. The Stark and anti-kickback laws are strengthened, along with integrity provisions across Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP).

11. Transparency Reports and Reporting of Physician Ownership or Investment Interests. Beginning on March 1, 2013, and yearly thereafter, manufacturers of drugs or biological or medical supplies that provide payment or other value transfer over $10 to a physician or a teaching hospital will be required to submit reports on these payments/transfers to HHS, which will be publicly displayed on the CMS website. Additionally, manufacturers and group purchasing organizations (GPOs) that deal with the aforementioned items must report certain physician ownership or investment interests in the manufacturer or GPO.

12. Electronic Health Records (EHRs). Under the American Recovery & Reinvestment Act (ARRA) of 2009 comes the Health Information Technology (HIT) & Electronic Health Records (EHR) legislation with its subsequent health-care laws, referred to as the Health Information Technology for Economic & Clinical Health Act (the HITECH Act).

Although not part of the HRL, Medicare-eligible providers also will feel the effects of this legislation. In 2011, the HITECH Act established incentive payments for eligible health-care providers and hospitals to initiate “meaningful use” of interoperable health information technology and qualified EHRs. Eligible providers could receive up to $44,000 over 5 years from Medicare and up to $63,750 over 6 years from Medicaid. Beginning in 2015, Medicare-eligible providers who do not demonstrate “meaningful use” of an EHR will be subject to a payment “adjustment” in their Medicare reimbursement.

13. Challenges to the HRL Before the Supreme Court. On March 26, 2012, the Supreme Court began to hear arguments regarding the constitutionality of the HRL minimum coverage requirement (ie, the mandate for every person to obtain health insurance).

Related to this is whether the Supreme Court must wait until the first penalty is charged against an individual who does not comply with this mandate, or whether the Court can decide the mandate’s constitutionality now. If the Court invalidates the mandate for minimum coverage, it must also decide whether the rest of the act, a portion of the act, or none of the act should be invalidated with it. Finally, the Court will need to decide on whether the states are being unconstitutionally coerced by the HRL mandate to expand ‘Medicaid coverage’

In a legislative era of perpetual changes, uncertainty surrounds the HRL and, in turn, how physicians should respond to it, especially given this presidential election year and the anticipated decisions from the Supreme Court. Where does that leave us? It is like sailing in a fog as thick as pea soup, with the wind blowing in one direction and the tide ripping in another, and we attempt to navigate uncertain waters, trying to dodge ledges that are seemingly everywhere, all the while hoping to site a beacon of light to guide us safely to our anticipated destination—higher quality health care, more efficient and nonburdensome for us to deliver and for our patients to receive, and just compensation for our services.

The ACCP, through the work of our standing committees, is taking an active role to ensure that the chest physician’s perspective is represented. We welcome and greatly encourage your participation and feedback.

Health-care Reform: Is Anyone Listening?

This is the second in the series of articles focused on health-care reform (HCR). It focuses on legislative and regulatory changes that confront physicians, hospitals, health-care providers, and patients.

The authors are: Dr. Robert Aranson, Chair of the ACCP Chest Medicine Affairs Committee; Dr. Alan Fein, ACCP Governor for New York State; and Ms. Sharmi Mahajan, LL.M, JD, MPH, Senior Policy Analyst at the ACCP. It is truly a monumental task to distill the essentials of this reform into one page of easily assimilable facts, and the authors must be commended for doing so. Through a series of seven monthly articles, scheduled to appear in CHEST Physician, the ACCP will attempt to provide its members as much information as possible about these changes, some of which are already instituted and others that will be immediately enforced.

—Dr. Suhail Raoof, FCCP
The movie “Field of Dreams” (1989, Universal Studios©) portrays a fantasy story of how a novice farmer builds a baseball field in rural Iowa at the behest of legendary baseball ghosts. Presumably, from the ghosts he hears statements “build it and he will come,” “people will come,” and the closing scene suggests “build it and they will come” because cars are lined up into the horizon. There are significant financial challenges faced by this agrarian family, so the closing scene alluding to reward based on the central message of having faith in building something and reaping benefits without a plan might resonate with many. Electronic medical record (EMR) systems, in general, and specifically, tele-ICU programs that have taken an approach similar to “build it and they will come” have not seen significant outcomes, in contrast to robust process re-engineering implementations.

Tele-medicine is defined as the diagnosis and treatment of patients in remote areas using medical information, as radiographs or television pictures, transmitted over long distances, especially by satellite. Logically, tele-ICU systems provide off-site critical care expertise via video and audio conferencing equipment, facilitating optimal utilization of informational, technological, and clinical systems. Most tele-ICU systems have unidirectional or bidirectional video and audio communications, an EMR, and some might use severity-adjusted benchmarking models. Tele-ICU systems have been described since the 1970s and generally can be grouped into three models. A reactive implementation would include consultations provided by remote clinicians only when solicited, and this model would use unidirectional or bidirectional video and audio and some mechanism to re-educate physicians and laboratory values. An intermediate model could include robotic-controlled audiovisual cues and concurrent access to local EMR resources. Robotic cars have limited video functionality due to a combination of Wi-Fi networks and a lower profile that might disallow optimal patient viewing. The most implemented model includes clerical and expert critical care clinical staff at a dedicated location with multiple tele-ICU workstations. Proprietary systems include a unique EMR, early alert analytic systems designed to detect physiologic instability, bidirectional video and audio communication pathways, and help buttons conveniently located in each ICU room.

Nearly all current tele-ICU programs utilize a proprietary system that, as of 2010, accounted for over 5,500 critical care beds at over 200 hospitals, caring for about 12% of the critically ill in the United States (www.nehr.net/uploads/full_report/teleicu_critical_care_critical_choices.pdf). There are at least two major driving forces promulgating tele-ICU programs. Hospitals are under increasing pressure from regulatory agencies and payers to adopt an ICU physician staffing (IPS) program as described by the Leapfrog Group (www.leapfroggroup.org/medic/file/Leapfrog_ICU_Philosophy_Fact_Sheet.pdf; accessed March 9, 2012). There is general consensus that adopting MIPS standards will decrease mortality, morbidity, and costs associated with caring for critically ill patients (Dimick et al. Crit Care Med. 2001;29[4]:753; Pronovost et al. Crit Care Med. 2004;32[6]:1247). Many smaller hospitals are unable to afford a dedicated intensivist team but, more importantly, they are not able to recruit intensivists, partly due to shortages. Therefore, many hospitals are adopting tele-ICU programs to help mitigate issues by on-site intensivist deficits. The other major factor relates to mixed but favorable evolving tele-ICU outcome literature.

To date, there have been over 100 unique literature contributions pertaining to tele-ICU (Young et al. Arch Intern Med. 2011;171[6]:498), however, only 14 could be considered at least level two studies. Young and colleagues performed an extensive literature search of published studies on tele-ICU programs and found 13 studies that had acceptable rigor. None of the published study designs had a concurrent control arm, and all were preimplementation and post-implementation comparison variants. About half of those studies contained both ICU and hospital mortality and length of stay (LOS) outcome measures. The pooled data represented 35 ICUs, over 15,000 and 25,000 baseline ICU and tele-ICU patients, respectively. Their findings suggest that ICU mortality is statistically lower (p<0.80, 95% confidence interval [CI] 0.66 to 0.97) and that there is a trend toward lower hospital mortality (OR 0.82, 95 CI 0.65 to 1.03). LOS data are less robust; however, ICU LOS significantly decreased by a standardized mean difference (SMD) of –1.26 days (95% CI –2.21 to –0.3), and there is a trend toward decreased hospital LOS SMD by –0.64 (95% CI –1.52 to 0.25). After excluding studies with vendor affiliation, ICU mortality significance erodes but still trends favorably (OR 0.90, 95% CI 0.70 to 1.08), and ICU LOS advantage abates (SMD 0.05, 95% CI 1.05 to 0.16).

An extensive review article (Lilly and Thomas. J Intensive Care Med. 2011;26[1]:16) discloses less rigorous data representing 26 ICU before and after study designs. Standardized mortality ratios (SMR) and LOS were calculated on individual and pooled data using Acute Physiology and Chronic Health Evaluation III (APACHE III) scoring systems. A total of 88% of tele-ICU implementations saw improved LOS, and 81% saw at least a 10% reduction in SMR. A more recent unblinded step wedge trial design tele-ICU study found significantly improved processes of care, decreased complications, and improved adjusted mortality and LOS (Lilly et al. JAMA. 2011;305[21]:2175). When a tele-ICU program is implemented at an academic medical center as an additional tool for a described critical care delivery model (McAuley and Irwin. Chest 2006;130[5]:1571), Lilly and colleagues found: (1) adjusted hospital mortality significantly decreased (OR 0.40, 95% CI 0.13 to 0.89); (2) higher rates of practice adherence for prevention of deep vein thrombosis (DVT) (OR 15.4, 95% CI 11.3 to 22.1) and prevention of stress ulcers (OR 4.57, 95% CI 3.91 to 5.77) and cardiovascular protection (OR 30.7, 95% CI 19.3 to 49.2) and prevention of ventilator-associated pneumonia compliance (OR 2.20, 95% CI 1.79 to 2.70); (3) lower rates of ventilator-associated pneumonia (OR 0.15, 95% CI 0.09 to 0.23) and catheter-related bloodstream infection (OR 0.50, 95% CI 0.27 to 0.93); (4) shorter hospital LOS (hazard ratio for discharge 1.44, 95% CI 1.33 to 1.56). In summary, there is a growing body of literature suggesting that tele-ICU implementations are associated with ICU and hospital mortality decreases, ICU and hospital LOS decreases, and that these effects might be attributed to increases in best practice adherence, earlier detection of physiologic instability, and complication decreases.

It is important to note that not all implementations have experienced improved outcomes; in fact, some have experienced either no change in SMR or LOS or have seen increased SMR ratios and increased LOS. Two larger controlled trials failed to show statistical significance in their primary outcomes (Morrison et al. Crit Care Med. 2010;38[1]:2-8; Thomas et al. JAMA. 2009;302[24]:2671); however, many feel that these two studies failed because the intervention was used in less than 40% of patients. What is lacking in the literature is any indication as to which specific elements of tele-ICU programs are critical to success. One would post that video and audio communications would be integral, but this is not known. Is it early detection of physiologic instability or reengineering processes to increase best practice adherence that infer decreased complications or some other factor? Many opinions abound, and a recent research agenda was proposed by the Critical Care Societies Collaborative that recommends a Donabedian framework dissecting out structure, process, and outcome components (Kahn et al. Crit Care 2011; 140[1]:120).

Tele-ICUs are likely here to stay, largely, in part, due to financial pressures, intensivist staffing challenges, and evolving data supporting improved ICU and hospital mortality and probably LOS. However, a cautionary note must be employed—implementations using a “Field of Dreams” approach will likely prove to be an expensive failure.

Dr. John McIwhine, FCCP eICU Program Director Associate in the Department of Critical Care Geisinger Health System Danville, Pennsylvania
improving the transition of care for the patient with COPD from hospital to home and reducing the 30-day rehospitalization rates following exacerbations are strategies that have matured from a "think tank" status to an operating reality for many American healthcare systems. The Hospital Protection and Affordable Care Act of 2010 has dramatically increased the emphasis on managing a patient's transition from the hospital to home environment. Respiratory therapy plays a pivotal role in managing this transition for a patient with COPD.

One program, available in Western Pennsylvania (DASH Discharge + Assessment + Summary @ Home), focuses on high touch, intensive respiratory services for patients with COPD following their hospitalization for COPD exacerbations. This program was designed to incorporate various critical components (eg, physical/c clinical assessment, environmental assessment, medication management, equipment management, education, establishment of motivational goals, and measurement of outcome indicators) to help manage such patients.

The program is implemented prior to hospital discharge and incorporates over 20 points of contact over the first 30 days following hospital discharge. The key to the program is face to face visits by a respiratory therapist in the patient’s home. During these visits, the therapist helps the patient to understand risk factors, teaches self-management skills, reviews medication use, establishes physician follow-up and rehabilitation appointments, titrates oxygen during home activities, measures clinical/ motivational attributes, and tracks use/adherence data.

To date, over 550 patients have been enrolled into the program from 23 hospitals. These patients had COPD and required home oxygen therapy following their hospital admission. The overall 30-day readmission rate for the group is 9%, compared with 24.2% in Western Pennsylvania. Analysis of the results of a subgroup of patients who were hospitalized with an exacerbation of congestive heart failure requires home oxygen therapy and enrolled into the program showed a similar 30-day readmission rate of 9%. The results are measured using clinical best practices as promoted by the American Thoracic Society (ATS) and the American Lung Association. Strategies to reduce hospital readmission rates following an exacerbation of COPD will need to be developed in order to provide the best care possible for such patients. Various strategies have been developed throughout the country.

This program has successfully integrated the respiratory therapy team into the transition of care process for such patients.
The work of Dr. Dee Ford, MSCR, FCCP, 2010 recipient of the Roger C. Bone Advances in End-of-Life Care Award, is having a far-reaching impact, from the Medical University of South Carolina (MUSC) to the ACCP Simulation Center at CHEST 2011, and beyond. Her project, “Integrating an End-of-Life Communication Curriculum Into Pulmonary/Critical Care Training,” utilizes the study “Improving Clinical Communication Skills (ICCS)” and is built on adult-learning principles that emphasize experiential learning through interaction with simulated patients to practice communications skills.

At MUSC, where Dr. Ford serves as Associate Professor, she has developed a program to bring together the interprofessional team in the ICU. This systematic approach ensures that physicians and nurses, along with spiritual and psychosocial professionals involved in the care of the patient, “huddle” before an ICU family meeting. "While the ICU can be extremely hectic," Dr. Ford comments, "you should never be too busy to spend time with the family of a critically ill patient. This is especially true when you expect the patient might not survive. The family will remember that the experience of the rest of their lives. The interprofessional professionals at MUSC have embraced making communication an explicit part of their training and strive to integrate effective communication into routine ICU culture to the benefit of families and patients.

The simulation session, “Critical Conversations in Palliative Care: A Comprehensive Approach to Communicating Patient Care,” reached a wide and diverse audience at CHEST 2011. This hands-on learning opportunity is co-chaired by Dr. Ford and Dr. Daniel Ray, FCCP, 2006 Roger C. Bone Advances in End-of-Life Care Award recipient. Dr. J. Randall Curtis, FCCP, recipient of this award in 2001, served as faculty for this session. The session brought together world-renowned experts from various fields, including critical care, oncology, and pediatric palliative care. Through this opportunity, fellows and medical students gained skills needed for optimal patient care and family communication. This essential skills training will be replicated in future courses.

The Roger C. Bone Advances in End-of-Life Care Award was established in 1999 to recognize an ACCP member who demonstrates outstanding leadership in end-of-life care. This award honors the late Roger C. Bone, MD, Master FCCP, who wrote about the ethical and huministic issues surrounding communication among physicians and their patients. For Dr. Ford, receiving this nationally recognized award carries tangible and intangible value. Those who receive this acknowledgment from The CHEST Foundation also receive acknowledgment at their institutions and in their careers. However, first and foremost for Dr. Ford, it is about the work and not the recognition. ‘I was tremendously honored to have received this important award from The CHEST Foundation. Yet, ultimately, the reward comes from the work I do with patients and families and the physicians-in-training who I can influence. Recently, I had an amazing experience where my efforts at training our fellows in principles of end-of-life communication came full circle back to me. A physician from a referring hospital commented to me that one of our recently graduated pulmonary fellows was working at his hospital. He noted that our fellow ‘really knew how to talk to families about end of life’ and that this former fellow responded, ‘It’s one of the most important parts of my job.’"

The Foundation offers ACCP members opportunities to apply for a variety of awards in the areas of clinical research and humanitarian service. The CHEST Foundation awards have supported ACCP members early in their careers, as well as those Distinguished Scholars whose innovations have the potential to transform clinical care and save lives. Learn more about The CHEST Foundation 2012 Awards Program below and at OneBreath.org, or contact Lee Ann Fulton at lfulton@chestnet.org.

Dr. Ford with some colleagues.
I would like to take this opportunity to provide you with an update on the direction of the ACCP and some outstanding programming on which we’ve embarked.

Having just completed our 2012 Spring Leadership Meeting (formerly called the Spring Board of Regents Meeting), I am happy to report some major progress in our leadership development activities and strategic planning.

Under the leadership of your President, Dr. Suhail Raoof, FCCP, and direction of the Leadership Development Task Force, co-chaired by COL Lisa Moores, MC, USA, FCCP, and Dr. Kay Guntupalli, FCCP, we launched the beginning of a newly structured and systematic learning program for our current leadership, potential leaders, and any volunteers who are passionate about guiding the ACCP today and into the future.

Our 2012 Spring Leadership Meeting kicked off with a joint session of all leadership—Board of Regents, Board of Trustees, Chairs, and Vice-Chairs of committees. Dr. Raoof and I provided a “State of the Association”; Mary Byers, co-author of Race for Relevance, enlightened the attendees with a presentation focusing on crucial issues faced today by professional associations, such as the ACCP, and Susan Decker of BoardSource, Inc. provided the group with organizational governance education and guided the attendees through strategic planning. It was an incredible day!

Ms. Byers provided six key points about how to face the future that are relevant to any professional society and to all physicians as members of a practice plan, hospital, or other health-care delivery system. All organizations should be assessing these ideas today.

- Different times require different leadership (leadership skills). Leaders should be discussing issues more, voting less, and assessing their processes, including their committee structure. Focus on the big issues, and don’t get stuck in the weeds.
- Be future-focused. Focus on setting up successful systems for those who follow you. Does your organization have the right resources, including technology? The College is investing in an association management system to better meet member needs. Hospitals are investing in electronic health records. Most importantly, focus on your greatest potential for growth. For the ACCP, that is our educational expertise.
- Govern vs manage. Ideally, your board should be focusing at the 30,000-foot level (management level). Managing is easier as it involves short-term decisions, often involving fewer choices and fewer individuals; governing (the Board’s role) takes greater discipline and requires looking at the big picture to make strategic decisions positively impacting multiple member constituencies.
- Focus on why. When you know the why of what you plan to do strategically, you are more likely to know the way of doing it with greater clarity.
- Focus on sustainability of your organization. How have ACCP members changed over time (your medical staff members)? Think about generational differences—baby boomers vs generation X. Does this mean the ACCP model needs to change? Will the revenue stream change? Will generation Xers participate in the same way as our current volunteers?
- Be radically courageous. Don’t be afraid of letting go of what is not working. Eighty percent of the value of an organization often comes from 20% of the projects being pursued. The greatest potential for growth comes from what you are already doing well. For the ACCP, that is the educational opportunities we provide to you as a valued member.

As you can see, the ACCP is heading into a thought-provoking, new direction on leadership development and governance education. The participants at the Spring Leadership Meeting were fully engaged and actively participated in a long day.

This is just the first step. The Leadership Development Task Force has laid out a plan for the future that will deliver this type of enrichment to many more members and future leaders at forthcoming CHEST meetings and other educational venues.

Stay tuned! More exciting information will follow.

In Memoriam

Dr. Irwin Berlin, FCCP, died in March 30, 2012. His funeral was held Monday, April 2, in New York. Dr. Berlin was Chief, Division of Pulmonary/Critical Care Medicine, Elmhurst Hospital Center, Elmhurst, NY. He was an active ACCP Fellow, serving previously as ACCP Governor for New Jersey and as a member of the former Government Relations Committee from 2001-2010, chairing that group from 2009-2010. He was a current member of the ACCP Chest Medicine Affairs group. Dr. Berlin once noted, “One of the highlights of my career was to represent ACCP at the invitation from the Obama Administration, and participate in the Rose Garden signing ceremony for the Family Smoking Prevention and Tobacco Control Act.”

The CHEST Foundation’s OneBreath® Campaign Updates

Family Activities Toolkit Contest

Our second social media contest is currently taking place and runs through April 30, 2012. Individuals may enter the contest by liking OneBreath on Facebook and completing the contest entry form. The goal is to increase awareness of OneBreath, to encourage exploration of the Family Activities Toolkit, and to highlight the unique content of OneBreath.

OneBreath has gained nearly 500 new Facebook “likes” since the start of this new contest in March. Our current community is nearly 1,700 people and growing.

Content Editors and Contributors

OneBreath is seeking ACCP members who are interested in participating in the campaign as content editors and contributors for the OneBreath.org website. Content editors and contributors will help to enhance, edit, and seek out content related to the nine prevention areas of the campaign.

OneBreath Bloggers Needed

OneBreath is giving ACCP members the opportunity to become guest bloggers on its newly launched blog. Blog postings, 200- to 300-word articles, are meant for a patient audience. If you are interested in joining as a OneBreath content editor, contributor, or blogger, or have a topic suggestion, please contact Kristi Bruno at kbruno@chestnet.org or call (847) 498-8308.

ACCP Board Review.
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Rely on the ACCP, the leader in board review curriculum for more than 25 years, for comprehensive review programs of proven success. World-renowned clinicians present exam-focused content to offer relevant board preparation courses that make the best use of your study time.

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Disaster Response Training, Radon, Asthma Literacy

Disaster Response Training

Disaster Response Training is crucial for preparedness. A simulation exercise is vital in ensuring readiness. The combination of theoretical knowledge and practical skills is key to effective disaster response training. This training helps individuals understand the potential scenarios and the appropriate actions to take in such situations.

Radon

Radon is a naturally occurring radioactive gas that can be found in homes and buildings. It is a known cause of lung cancer, especially in smokers, and can pose a significant health risk. Monitoring and mitigation measures are essential to protect public health.

Asthma Literacy

Asthma literacy is crucial for individuals to effectively manage their condition. It involves understanding asthma triggers, symptoms, and the importance of regular medication, as well as making lifestyle changes to control symptoms.

Women’s Health

Dr. Sheila Goodnight, a valued member of the College, has dedicated her career to advancing women’s health. Her contributions have been instrumental in improving health outcomes for women and promoting gender equality in healthcare.

Emergency Medicine Australasia


Some on a lecture on PPE use and management of chemical victims was given. Performance in intubation, subjective PPE experience, and acute patient management were evaluated. This rapid learning session employed task trainers, human patient simulators, and case-based discussion to improve skills with initial management of acute respiratory decomposition in highly toxic/infectious victims. The course faculty included military instructors, clinicians with global disaster experience, and emergency airway management in critical care. The use of these techniques will have an impact in many critical areas.

Palliative Care

Palliative Care is a multidisciplinary approach that focuses on improving the quality of life for patients and their families. It is a type of care that is provided to patients of all ages whose diagnoses are life-limiting and who are expected to die soon after being told of a terminal illness.

Occupational and Environmental Health

Occupational and Environmental Health is a critical field that deals with the interaction of the environment, workplace, and health. It is essential for preventing workplace injuries and illnesses, ensuring a healthy work environment, and promoting worker health and safety.

Respiratory Care

The Respiratory Care field focuses on the diagnosis and treatment of respiratory conditions. Respiratory therapists are trained professionals who work closely with physicians and other healthcare providers to manage respiratory issues and provide critical care services.

Networking

Networking is an essential skill in any profession. It involves building relationships and making connections that can lead to opportunities for collaboration, career advancement, and personal growth. Effective networking is crucial for professional development and career success.
FROM THE DESK OF THE PRACTICE MANAGEMENT COMMITTEE

February 2012 CPT® Editorial Panel Meeting

BY DIANE KRIER-MORROW, MBA, MPH, CCS-P
ACCP Coding and Reimbursement Consultant

NOTE: Please be aware that these actions are a reflection of the discussions at the most recent Panel meeting. Future Panel actions may impact these items. Codes are not assigned and exact wording is not finalized until just prior to publication. Release of this more specific CPT® code set information is simultaneous with the release of the entire set of coding changes in the CPT publication.

At the February 2012 CPT Editorial Panel meeting, ACCP and ATS were the busiest ever with presenting five proposals. All attending CPT meetings sign confidentiality statements, and historically were not to inform members of panel actions until the AMA CPT book was published. Just recently we became aware that AMA published the results of the February 2012 meeting on its website with the following link: http://www.ama-assn.org/resources/doc/cpt/summary-of-panel-actions-feb2012.pdf.

The membership should be aware of what codes will be added/revised/deleted of interest to pulmonary care, critical care, and sleep medicine physicians in the coming CPT Changes for January 1, 2013.

Tab # | Title of Request | Description of Request | Description of CPT Editorial Panel Action
---|---|---|---
9 | Chest Tube Thoracostomy Revision 32551 | Request for clarification of intent for use of 32551 by 1) adding the word “open” to identify this as an open procedure, 2) to indicate “water seal” as an “e.g.”; 3) to remove diagnosis terminology from the descriptor, 4) to remove references to imaging for this procedure as image guidance is rarely necessary, and 5) to remove the current diagram. | Accepted revision of code 32551 to specify the surgical approach and by deleting the diagnostic references.
10 | Chest Tube Placement | Request for the establishment of four new chest tube placement codes (325X1-325X4); deletion of 32420, 32421, 32422; and the deletion of the 32421-32422 illustration. | Accepted establishment of four new codes for thoracentesis and pleural drainage (325X1-325X4), with deletion of codes 32420-32422.
22 | Bronchography (Deletion of 31656, 31715, 71040, 71060). | Request to delete bronchoscopy code 31656, transbronchial injection code 31715, and bronchography radiological supervision and interpretation codes 71040 and 71060. | Accepted deletion of codes 31656, 31715, 71040, and 71060, as bronchoscopy has now been replaced by use of computed tomography (CT).
70 | Chest Wall Manipulation | Request for editorial revision of the initial and subsequent pulmonary manipulation chest wall therapeutic procedure codes 94667 and 94668 to include reference to another manual technique – frequency chest wall oscillation therapy. | Postponed until time uncertain. Reconsideration is requested and will be addressed at the May Panel meeting.
73 | Pediatric Polysomnography | Request to establish codes 958X1X and 958X2X to report pediatric polysomnography for children 5 years of age or younger. | Accepted; 1) establishment of codes 958X1X and 958X2X to report pediatric polysomnography for children younger than 6 years of age; 2) revision of code 958X08 to include “any age” and codes 95810-95811 to include age specification “age 6 years or older.”
85 | Bronchial Thermoplasty | Request to convert Category III bronchial thermoplasty codes 0276T and 0277T to Category I status (codes 316X1, 316X2). | Accepted conversion of Category III codes 0276T and 0277T to Category I codes 316X1-316X2.

EXECUTIVE COMMITTEE

RUC Related Issues – Issue #1 – Revision of Bronchial Valve Codes

Request to approve 316X1, 316X1B revised placement codes was approved as CPT Category I codes for bronchial valve placement.

Accepted RUC referral to convert one placement code into two placement codes to parallel the removal codes reviewed at the previous meeting.
CHEST 2012: Destination Atlanta

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COPDGene Study Generates New Insights Into COPD

In September 2007, the largest study of COPD in the United States was funded by the NHLBI to broadly address unanswered questions about the causes of COPD. The study was funded as paired projects at National Jewish Health in Denver, Colorado, and Brigham and Women’s Hospital in Boston, Massachusetts, under the direction of Co-Principal Investigators Dr. James D. Crapo, FCCP, and Dr. Edwin K. Silversman, PhD. The ambitious goals of the project were to enroll 10,000 smokers with and without COPD from two ethnic groups, precisely characterize the subjects using spirometry, respiratory symptoms, medical history, 6-minute walk test, and high-resolution CT scans, followed by genome-wide association testing for susceptibility to COPD and COPD-related traits (Regan et al. COPD. 2010;7[1]:32). The extensive clinical, radiographic, and genetic phenotyping would be analyzed to detect novel subtypes of COPD. In addition, the study investigators planned to enhance enrollment of African Americans to address apparent disparities in COPD susceptibility and to potentially discover unique COPD susceptibility genes in this population.

Initially, some skepticism was expressed about the ability to complete enrollment for such a complex project over the 5-year period of funding. Twenty-one clinical centers across the country commenced enrolling subjects in March 2008. Enrollment was completed in just over 3 years due largely to the commitment of a group of investigators and clinical coordinators at each of the sites. CT scans are being analyzed by the Quantitative Imaging Lab at National Jewish, using the VIDA software, for automated measures of emphysema, gas trapping, and airway disease (http://www.vidadiagnostics.com/index.html) and by the Brigham and Women’s Hospital imaging team using an alternative software package (http://www.slicer.org). A separate project to maintain longitudinal contacts was established, and 80% of the cohort has been reporting ongoing health data approximately every 6 months.

More than 30 scientific papers are either published or in preparation with early results from the study. These include a number of genetics papers in which COPDGene GWAS data from an early group of 1,000 subjects was used in combination with other large cohorts to identify or confirm genetic findings, such as associations to FAM13A for COPD affection status (Cho et al. Nat Genet. 2010;42[3]:200), FTO variants to BMI in COPD subjects (Wan et al. Am J Res Cell Mol Biol. 2011;45[2]:304), and smoking behaviors to regions of CYPIA2 and a locus at chromosome 15q25 (Siedlinski et al. Thorax. 2011;66[10]:894).

Intersitial lung disease in the context of smoking was the topic of another study from COPDGene (Wasylko et al. N Engl J Med. 2011;364[10]:897). Using visual read of the CT scans from 2,416 subjects enrolled in COPDGene, the group found 194 subjects (8%) had evidence of interstitial lung abnormalities (ILA). These subjects with CT evidence of ILA had greater smoking exposure, were more current smokers, had lower total lung capacity, and were more likely to fall into the unclassified category of subjects. However, there was a definite overlap of ILA with COPD—63 (32%) of the ILA subjects fell in the GOLD 2-4 group, and these subjects showed less emphysema and lower total lung capacity than subjects without ILA.

A unique group of smokers has emerged from the COPDGene project that is not classified by GOLD criteria but shows significant health effects. These subjects have a normal (>0.7) FEV1/FVC ratio but reduced (<80% predicted) FEV1. They have been termed GOLD unclassified subjects. Early in the recruitment process for COPDGene, it was decided that the study would encompass all smokers with the specified smoking exposure and not exclude subjects who failed to meet the current classification criteria for COPD. The rationale for this was that these subjects had smoking exposure and either represented an alternative control group or potentially a group “at risk” of smoking-related disease.

For purposes of studying genetic associations to COPD, this group represents an important comparison group. The GOLD unclassified subjects constituted 9% of the subjects in COPDGene study (Wan et al. Am J Respir Crit Care Med. 2011;184[3]:37). They showed greater impairment of the 6-minute walk, fewer pack-years of smoking, higher BMI, reduced total lung capacity, more comorbid cardiovascular disease, and lower oxygen saturation. The unclassified group was heterogeneous, with about half of the group having a reduced total lung capacity, slightly more than half of the group is obese with BMI>30, and the group overall has significantly more comorbid disease and worse physical function than the GOLD 1 group. Further study will be done on this group of smokers as the full cohort is analyzed and genetic data become available.

Several groups of investigators have used the early COPDGene data to look at the unique aspects of race and COPD. Using the large population of African American subjects enrolled in this study, investigators found significant differences in quality of life and function (Han et al. Chest. 2011;140[5]:1169). Although African American subjects had similar mean percent predicted FEV1 values compared with non-Hispanic white subjects, they had fewer pack years of smoking exposure and worse 6-minute walk distance (381 meters ±135 vs 298 meters ±119, P <.001). Within COPD subjects who reported exacerbations, African Americans had worse quality of life and more dyspnea.

Another study that addressed differential impacts of race looked at Early Onset COPD (Porem et al. Am J Respir Crit Care Med. 2011;184[4]:414). In this study, the authors found that severe early onset COPD (age < 55 years and FEV1 < 50% predicted) was identified more often in African American subjects (present in 42% of African Americans compared with 14% of the non-Hispanic white group, P < .0001). Women were also overrepresented in the early onset group, and both maternal smoking and maternal history of COPD were significant predictors of early disease.

Chronic bronchitis as a distinct phenotype in COPD was identified by another group (Kim et al. Chest. 2011;140[3]:626). Chronic bronchitis was defined as cough and phlegm production for greater than 3 months, and 27% of the subjects with COPD studied fell into that category. These subjects were younger, had greater pack-years of exposure, were more likely to be current smokers, had more exacerbations, and were more likely to have severe exacerbations than subjects without chronic bronchitis, although their mean FEV1 was the same, and there was no difference in percent emphysema or gas trapping. The subjects with chronic bronchitis did have evidence of greater airway disease with mean segmental wall area percent significantly greater. This group is poised to need directives for reducing smoking and airway mucin production.

The COPDGene study is poised to provide important information about both genetic causes of COPD and the natural history of the disease in the coming years. The investigators hope to obtain additional funding to perform a second evaluation of these subjects in order to determine disease progression over time. The genetic data from the whole cohort are in preparation for analysis. With data on 10,000 well-characterized smokers, we anticipate detecting additional important genetic findings over the next few years that, hopefully, will offer opportunities to improve treatment or reduce the incidence of this disabling disease.

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Guest Editor’s Note

The COPDGene project offers an incredible degree of promise in our efforts to better understand the disease we call “COPD.” The project is already starting to nicely demonstrate that COPD is not merely one homogeneous disease but rather multiple different diseases with some commonality in their presentation. The early data from COPDGene are pointing us in that direction, with evidence supporting some specific phenotypes, such as the restrictive or “unclassified” group, the early-onset group, and the chronic bronchitis group. Additional work will, in all likelihood, identify additional important subgroups, along with genetic or other markers of disease activity and severity. The ultimate goal of this work and other related projects around the world is to prevent, treat, and even cure COPD.

We have come a long way over the last 5 years, but still have a long way to go toward our goal of decreasing the morbidity and mortality of this group of diseases.

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