Pediatric Palliative Care Still Too Rare

By Christine Kilgore

Dr. Stefan J. Friedrichsdorf has a list of “myths” about pediatric palliative care that he presents during lectures. Among them: that the death of a child in the United States is a rare event, that pediatric palliative care is just for children with cancer, and that care starts when treatment stops.

In his lectures – and in his work every day at Children’s Hospitals and Clinics of Minnesota, Minneapolis – Dr. Friedrichsdorf debunks these myths.

In January, he was one of two pediatricians who won national awards from the Hastings Center and a partnering foundation for their contributions to the broader field of palliative care. He and pediatrician Dr. Savithri Nageswaran of Brenner Children’s Hospital at Wake Forest University Baptist Medical Center in Winston-Salem, N.C., joined two geriatricians and an internist in receiving the award.

“The biggest need was to facilitate collaboration between multiple providers,” Dr. Savithri Nageswaran said.

The pain and palliative care program at Dr. Friedrichsdorf’s institution is a relatively long-standing program, but pediatric palliative care is a new subspeciality and is still a relatively new area of pediatric care and of palliative medicine – one for which delivery models and educational pathways are still evolving, and one for which reimbursement is poor and regulatory barriers are challenging.

“It’s truly interdisciplinary, in that people need to really go beyond what they’ve been trained for,” said Dr. Friedrichsdorf, who is medical director of the department of pain medicine, palliative care, and integrative medicine at Children’s. “I’m nothing without my team.”

Pediatric palliative care has been defined and described by the World Health Organization, the Institute of Medicine, the American Academy of Pediatrics, and other bodies as individualized, integrative care that is provided for children with life-threatening conditions.

See Pediatric • page 23

Bariatric Surgery Deaths Tied to Sleep Apnea

Screening for OSA should be standard.

By M. Alexander Otto

HUNTINGTON BEACH, CALIF. – Underrecognized and undertreated obstructive sleep apnea is the most likely cause of unexplained deaths following bariatric surgery, according to results of a small pilot study.

Because of that, continuous positive airway pressure (CPAP) and continuous pulse oximetry monitoring – with alarms to alert nursing staff to hypoxic episodes and rouse oxygen-desaturated patients from sleep – should be included in postoperative care, said Dr. Scott Gallagher, a bariatric surgeon at the University of South Florida, Tampa, where the study was conducted.

In previous work, the researchers found that severe, prolonged, and frequent arterial hypoxemia is common in sleeping bariatric surgery patients. They sought to determine why such patients – who seemed to be doing well after surgery – died suddenly in their sleep, without pulmonary embolism or any other obvious cause. In 15 gastric bypass patients monitored for 24 hours after surgery, they found that the average episode of hypoxemia lasted 21 minutes, and the longest for hours. Blood oxygen saturation fell as low as 60% (J. Surg. Res. 2010;159:622-6).

Right-to-left shunt, diminished inspired oxygen partial pressure, and other textbook causes “didn’t exist in these patients,” Dr. Gallagher said.

That left either postoperative, narcotic-induced hypventilation or obstructive sleep apnea as the most likely explanation. Narcotic pain control is common after bariatric surgery, as is sleep apnea.

See Bariatric • page 20

Once-Daily Drug on Horizon for COPD

By Elizabeth Mechcatie

SILVER SPRING, MD. – The majority of a Food and Drug Administration advisory panel recommended that the inhaled bronchodilator indacaterol be approved for patients with chronic obstructive pulmonary disease, to be taken at a dose of 75 mcg once daily.

Two weeks later, however, the FDA told the drug’s maker, Novartis, that the agency would need 3 more months to complete the review of indacaterol’s research data.

At an initial meeting in March, the FDA’s Pulmonary-Allergy Drugs Advisory Committee voted 13-4 that the data on the safety and efficacy of the 75-mcg dose of indacaterol, as a maintenance treatment, provided substantial evidence to support the drug’s approval at this dose, for the proposed indication: the long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease.

See Drug • page 2

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obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

This majority of the panel agreed that the 150-mcg once-daily dose had not been shown to be effective, largely because of the limited amount of data directly comparing the two doses.

Indacaterol, a long-acting beta, adreno
ergic agonist (LABA) that is adminis
tered in a dry-powder inhaler, has a rapid onset of effect sustained over 24 hours, according to Novartis, which filed for approval of two once-daily doses: 75 mcg and 150 mcg. But in a 12-5 vote, the panel recommended against approval of the higher dose, largely because of the paucity of data directly comparing the two doses and, as panel chair Dr. Peter Terry, FCCP, professor of medicine, Johns Hopkins University, Baltimore, said, “no comp
celling evidence that there was a signif
icant difference” between the two doses.

The 150-mcg once-daily dose and a higher dose (300 mcg once daily) of in
dacaterol were approved to treat COPD in the European Union in September 2009, where it is marketed as the Ondre
tbrezhaler; the drug at those doses is now approved in more than 50 countries.

Initially, Novartis had applied for ap
proval of these two doses in December 2008, but the FDA requested that the company study lower doses of the drug, after the agency review concluded that no clinically meaningful advantage had been shown for the 300-mcg dose over the 150-mcg dose, and also because of safety concerns. There were more car
diovascular and cerebrovascular adverse events among patients with COPD treat
ed with indacaterol, when compared with those on placebo and the active comp
parator, formoterol. In studies of in
dacaterol in patients with asthma, there were some deaths, possibly related to in
dacaterol, which raised concerns because treatment with inhaled LABAs as mono
erapy has been associated with severe asthma exacerbations and asthma-
related deaths, described in the boxed warning included in the prescribing in
formation of these drugs. Although the mechanism has not been identified, data from controlled and epidemiologic stud
ies suggest that higher doses may con
tribute to this increased risk, according to the FDA.

In response, the company conducted more studies and analyses, and submi
ted data on the 75-mcg and 150-mcg once-daily doses in about 2,700 patients with COPD, and proposed those two doses for approval, recommending the 150-mcg dose as the starting dose.

At this FDA meeting, Novartis pre
sented the results of five phase III stud
dies of the 75-mcg, 150-mcg, and 300-mcg doses, compared with placebo or active controls in approximately 4,000 mostly white patients with COPD, whose mean age was about 64 years. After 12 weeks, there were no significant improvements in lung function, as measured by trough FEV₁, associated with each dose, when compared with placebo. In the safety database of patients with COPD, the risk of serious cardiovascular events (in
cluding MI, stroke, or cardiac death) was not increased, and there was no increase in acute respiratory events associated with any dose of indacaterol studied, according to Novartis.

FDA reviewers concluded that there was no clinically meaningful difference in efficacy between the 75-mcg and the two higher doses, raising the ques
tion of whether the higher dose was nec
essary. Most of the panelists agreed.

“I do believe that at this dose a sub
stantially number of patients with moderately to severe COPD in the United States will benefit from this medication, without substantial risks,” said one of the panelists, Daren Knoell, Pharm.D., acting head of regulatory affairs at Ohio State University and the Davis Heart and Lung Institute, Columbus. He referred to “consistent” evidence across virtually all trials that the 75 mcg once-daily dose benefited most patients.

Novartis has proposed a risk evalu
ation and mitigation strategy (REMS) to manage the potential risks of the drug, which would include educating health care professionals about the appropriate indications for indacaterol and about the increased risk of asthma-related deaths associated in asthma patients treated with LABAs as monotherapy.

Both doses were approved, inda
caterol would be the first bronchodilator in the United States to be approved at two doses for the treatment of COPD, currently, only one dose of formoterol and salmeterol, which are also LABAs, are approved for COPD treatment.

A final decision on approval is not ex
pected until the summer. In a statement issued in late March, Novartis said that the FDA has asked for a 3-month exten
sion of its review of indacaterol, which is expected to be completed by July.

If approved, the company plans to market indacaterol in the United States as the Arcaipa Neohaler.

Novartis has conducted studies of the drug in patients with asthma, but is not filing for approval for an asthma indica
ation in the United States or elsewhere. Some concern about off-label use of the product in patients with asthma was ex
pressed at the meeting.

The FDA usually follows the recom
mendations of its advisory panels. Panel members have been cleared of potential conflicts of interest by the FDA prior to meetings; occasionally, the FDA grants a waiver to a panelist with a conflict, but this was not neces
sary at this meeting.

Dr. Darcy Marciniuk, FCCP, com
ments: The desire to have an effective once-a-day long
-acting beta, agonist in our C O P D tool kit may soon become a reality. The medication dosing needs to get sorted out—we’ll be watch
 ing closely for the FDA opinion on this issue. The real benefit of this medication may be in future single delivery system combina
tions with other effective inhaled COPD therapies.
Indication
REVATIO is indicated for the treatment of pulmonary arterial hypertension (WHO Group I) to improve exercise ability and delay clinical worsening. Delay in clinical worsening was demonstrated when REVATIO was added to background epoprostenol therapy. The efficacy of REVATIO has not been adequately evaluated in patients taking bosentan concurrently.

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

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

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

In PAH patients, the concomitant use of vitamin K antagonists and REVATIO resulted in a greater incidence of reports of bleeding (primarily epistaxis) versus placebo. The incidence of epistaxis was higher in patients with PAH secondary to CTD (sildenafil 13%, placebo 0%) than in PPH patients (sildenafil 5%, placebo 2%).

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

Non-arteritic anterior ischemic optic neuropathy (NAION) has been reported post-marketing in temporal association with the use of PDE5 inhibitors for the treatment of erectile dysfunction, including sildenafil.

It is not possible to determine if these events are related to PDE5 inhibitors or to other factors. Physicians should advise patients to seek immediate medical attention in the event of sudden loss of vision while taking PDE5 inhibitors, including REVATIO.

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

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

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

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

The most common side effects of REVATIO (placebo-subtracted) were headache (7%), dyspepsia (6%), flushing (6%), and epistaxis (8%).

Adverse events of REVATIO injection were similar to those seen with oral tablets.

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

Please see Brief Summary of Prescribing Information on the following pages.

Order REVATIO Starter Samples by phone
Contact the REVATIO Sample Fulfillment Program by calling 1-866-833-9559
REVATIO® (SILDENAFIL)

Brief Summary of Prescribing Information

INDICATIONS AND USAGE:
REVATIO® is indicated for the treatment of pulmonary arterial hypertension (PAH) in adults.

DOSAGE AND ADMINISTRATION

Pulmonary Arterial Hypertension (PAH)

REVATIO Tablets
The recommended dose of REVATIO is 20 mg three times a day (TID). REVATIO tablets should be taken approximately 4-6 hours apart, with or without food. In the clinical trial no greater efficacy was achieved with the use of higher doses. Treatment with doses higher than 20 mg TID is not recommended. Dosages lower than 20 mg TID were not tested. Whether dosages lower than 20 mg TID are effective is not known.

REVATIO Injection
REVATIO injection is for the continued treatment of patients with pulmonary arterial hypertension (PAH) who are currently prescribed oral REVATIO and who are temporarily unable to take oral mediation. The dose recommended is 10 mg (corresponding to 12.5 mL) administered intravenously over 3-5 minutes. No cases of syncope or fainting were reported by at least 3% of REVATIO patients treated at the recommended dosage. The adverse drug reactions in Table 1 are reported by at least 3% of patients treated at the recommended dosage (10 mg). Safety data from 2 clinical trials of REVATIO injection in patients with PAH are summarized in Table 4 in the Clinical Trials Experience section.

Syndromes of Hypersensitivity

REVATIO is contraindicated in patients with a known hypersensitivity to sildenafil or any component of the tablet. Rare cases of hypersensitivity have been reported in association with the use of sildenafil including anaphylactic reaction and anaphylactoid reaction. The majority of reported events were non-serious hypersensitivity reactions.

WARNINGS AND PRECAUTIONS

Cardiovascular Effects

REVATIO has vasoactive properties, resulting in mild and transient decreases in blood pressure. Before prescribing REVATIO, carefully consider whether patients with certain underlying conditions could be adversely affected by such vasoactive effects in patients with resting hypotension or in patients who have conditions, which may predispose them to hypotension (e.g., septic cell aneurysm, multiple myeloma, or leukemia). In the event of an erection that persists for more than 4 hours, the patient should seek immediate medical assistance. If priapism (painless erection greater than 6 hours in duration) is not treated immediately, penile tissue damage and permanent loss of potency could result.

ADVERSE REACTIONS

The following adverse reactions are discussed elsewhere in the labeling:

Hypertension (See Warnings and Precautions)
Vision loss (See Warnings and Precautions)
Hearing loss (See Warnings and Precautions)
Pruritus (See Warnings and Precautions)

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Due to the relatively small number of patients in these studies, data from these studies should be interpreted with caution. Safety data were obtained from the 12-week, placebo-controlled clinical study and the open label extension trials, which treated 277 treated patients with pulmonary arterial hypertension. Doses up to 80 mg TID were studied. The overall frequency of discontinuation in REVATIO-treated patients at the recommended dose of 20 mg TID was 2% and was the same for the placebo group.

In the placebo-controlled trial in pulmonary arterial hypertension, the adverse drug reactions that were reported were no more than 2% (REVATIO patients treated at the recommended dosage (20 mg TID) and were more frequent in REVATIO patients than placebo patients, as shown in Table 1. Adverse events were reported spontaneously and mild to moderate in nature.

Table 1: REVATIO All Causality Adverse Events in ≥ 3% of Patients and More Frequent (≥ 1%) Than Placebo

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Placebo</th>
<th>REVATIO 20 mg TID (n=69)</th>
<th>REVATIO Subtracted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epistaxis</td>
<td>1</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>Nasal/paros</td>
<td>36</td>
<td>46</td>
<td>10</td>
</tr>
<tr>
<td>Dizziness</td>
<td>7</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>Flushing</td>
<td>4</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>Cyanosis</td>
<td>1</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Rhinitis</td>
<td>6</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

not otherwise specified

At doses higher than the recommended 20 mg TID, there was a greater incidence of some adverse events including flushing, diarrhea, myalgia and visual disturbances. Visual disturbances were identified as mild and transient, and were predominately color vision to vision, but also increased sensitivity to light or blurred vision. The incidence of these adverse reactions at the recommended sildenafil dose (20 mg TID) dose was 1.4% versus 0% placebo and for all sildenafil doses studied was 1.9% versus 0% placebo. The incidence of eye hemorrhage at the recommended sildenafil dose (20 mg TID) was 1.4% versus 0% placebo and for all sildenafil doses studied was 1.9% versus 0% placebo. The patients experiencing these events had risk factors for hemorrhage including concurrent anticoagulant therapy.
Diversity and Inclusivity

FROM THE CEO

A t CHEST 2010 held in Vancouver, I an- nounced the creation of a Presidential Task Force on Diversity. The Task Force on Diversity has been meeting and working hard to provide the ACCP with recommenda- tions to ensure optimal integration of diversity and inclusivity throughout the activities and structure of the College.

The task force has committed and dedicated members who are proud to have and who should receive our thanks in advance for taking on this very important initiative.

While it is important to have created and engaged this task force, its mem- bers agree that it is a whole new ballgame. This initiative needs champions at all levels, including at the top of the ACCP. We have that enthusiastic spirit within the ACCP leadership, and I’m here to tell you that you have it in me, your EVP and CEO. I decided this initiative needed to be added to my plate of strategic activities.

I have recently participated in one of the top conferences in the professional association world and have come away with one of the most profound learning experiences of my career.

Working with the Institute for Nonprofit Research, Education, and Engagement at North Carolina State University, the American Society of Association Executives (ASAE) commis- sioned research resulting in a white paper on “Enhancing Diversity and Inclusion in Membership Associations” (www.asaecenter.org/foundations/documents/ncusdivincreport.pdf). This research paper was the basis for the conference I attended.

It was determined that diversity can lead to better organizational perform- ance but only if it is effectively man- aged. Associations with strong D&I emphasis and priorities are characterized as having a high level of comfort with conflict and change. They are associ- ations that empower others and take a long-term view. They are associations that consider costs and benefits to the participants and institutionalized policies and practices. There is no one-size-fits-all approach. Associations must carefully determine the specific approach that will work for their organization.

Finally, strong associations see D&I as aligned with their mission and values. So, how does the ACCP measure up to the characteristics identified above? Where would we be ranked in compar- ison with the other organizations with which you may personally be involved?

I have no idea where the past 24 years of my association career, I can see room for improvement at the ACCP. Yet, we should not see ourselves as behind, because, in fact, we are very comparable to many other associations. But, that is where we want to be! The ACCP is the leader in many areas. Why not be the leader in D&I?

So, I would like to ask every one of you to be a champion for D&I at the ACCP. We need everyone to embrace this initiative. It is not only good for the ACCP as an association and business, it is good for you as the caring practitioner you are for your patients.

PCCSU Lessons for April

Update on the Evaluation of Intravascular Fluid Status in Critically Ill Patients. By Dr. Sumit Singh and Dr. Geoffrey K. Lightboll.

The Value of Bronchoalveolar Lavage in the Diagnosis and Management of Intestinal Lung Disease. By Dr. Keith C. Meyer, FCCP.
PQRS Incentive Program and Noncompliance Penalty

BY DIANE KRIER-MORROW, MBA, MPH, CCP-S; AND MARLA BRICHTA

The Physician Quality Reporting System (PQRS), formerly known as the Physician Quality Reporting Initiative (PQRI), is a Medicare reporting program that offers an incentive payment to physicians and (other eligible professionals) who satisfyfully report data on quality measures during a specified reporting period. PQRS reporting is voluntary for 2011-2014, though practices not participating are missing available incentive payments. A penalty for not participating in PQRS will begin in 2015, with a proposed 1% reduction in all Medicare fee-for-service payments and a reduction of 2.0% in 2016. The penalty for noncompliance will continue to 2016. The base incentive payment for 2011 is 1% Medicare Part B physician fee-for-service payment (PFS) allowed charges for all covered professional services (0.5% for each year, 2012-2014). An additional incentive payment of 0.5% for participating in the new Maintenance of Certification Program (MOCP) is available for 2011-2014.

To qualify for the PQRS incentive, the correct numerator Quality-Data Code must be reported on at least 90% of the claims eligible for each selected measure when reporting PQRS data using Claims-Based Reporting (effective Jan 1, 2011; previously was 80%). A claim is considered “eligible” in PQRS when the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis and the CPT® Category I evaluation and management (E/M) codes on the claim match the diagnosis and encounter codes listed in the denominator criteria of the measure specification. Note that several measures allow the use of CPT II modifiers. For 2011, there are approximately 19 individual measures and 2 measures groups that are relevant to ACCP members. The two measures groups are the community-acquired pneumonia (CAP) and asthma (new this year) measures groups. The CAP measures group bundles H56 Vital Signs, H57 Assessment of Oxygen, H58 Assessment of Mental Status, and H59 Empiric Antibiotic Prophylaxis. The asthma measures group bundles H53 Asthma Pharmacology Therapy, H64 Asthma Assessment, #2311 Asthma: Tobacco Use Screening – Ambulatory Care Setting, and #2321 Asthma: Tobacco Use Intervention – Ambulatory Care Setting.

PQRS data submission is as simple as adding a code to existing claims that have specified ICD-9-CM diagnostic codes and E/M codes in the appropriate CPT II. The ACCP recommends beginning PQRS reporting even further. For example, if all quality actions for the applicable measures in the CAP measures group (H56-H59) have been performed for a patient, just add to the existing claim forms G6550 with $0.00 in the payment field. The ACCP is working toward retaining new measures groups relevant to its members for the coming years.

Each measure has a reporting frequency requirement (called a “measure tag”) for each eligible patient seen during the reporting period for each individual physician. The reporting frequency is found in the instructions section of each measure specification. Ensure that all members of the team understand and capture this information in the clinical record.

The ACCP recommends beginning implementation of PQRS participation as soon as possible, if your practice has not already done so. We recommend referencing chapters 1, 2, and 27 of Coding for Chest Medicine 2011 to provide the above to assist practices that have not yet begun PQRS implementation.

For assistance, contact the ACCP coding and reimbursement consultant staff, Diane Krier Morrow, MBA, MPH, CCP-S, at (447) 677-9464 or diane.kriermorrow@chestnet.org or contact QualityNet Help Desk qnetupport@sdps.org or (866) 288-8912.

Steps to PQRS Participation

1. Select an employee to lead implementation.
2. Review all Centers for Medicare & Medicaid Services (CMS) specifications and decide which performance measures (at least 3 individual) or group measures (at least 1) (CAP and/or Asthma) to report.
3. Augment current charge capture and other practice processes to incorporate PQRS measures – eg, revise encounter form to include selected measures (include relevant HCPCS Category II codes or G performance measure codes), and prompt providers to document performance of the measure.
4. Select the reporting period: Claims-based registry with a Jan 1 or July 1 start date; EHR-based, eRx, and group practice reporting options have a Jan 1 start date.

5. Report $0.00 in the payment field.
6. Audit the claim forms to ensure correct reporting before submission. Have practice (coding, billing, or supervisory) staff regularly and routinely monitor that the providers reporting PQRS measures are reaching appropriate thresholds – changed from 80% to 90% of the applicable population of patients with the diagnoses of asthma, COPD, or pneumonia (when using claims-based reporting).
7. Have practice staff monitor and follow up on Medicare Summary Notices (MSNs) to verify the presence of the N365 code, which indicates process and transmission of the Quality-Data Code.
8. Review each of the steps at monthly departmental meetings.

FROM THE DESK OF THE PRACTICE MANAGEMENT COMMITTEE


BY DR. ROBERT DEMARCO, FCCP, CHAIR; AND DONNA KNAPP BYBEE, MA, PACMP, VICE-CHAIR

Current Procedural Terminology (CPT®) is a listing of descriptive terms and identifying codes for reporting medical services and procedures. CPT was developed in 1966 by the American Medical Association (AMA) to standardize documentation and communication between health-care providers, third parties, and patients. It is now the most commonly accepted medical terminology used to report procedures and services to public, (ie, Medicare, Medicaid) and private insurers. The AMA publishes an updated CPT coding book annually. These are three categories of CPT codes. Category I codes report a procedure or service; eg, new for 2011 is CPT 31634 for balloon occlusion. For a procedure or service to be reimbursed, the correct Category I code needs to be submitted to the payor. Category II codes are supplemental tracking codes that can be used for performance measures, with the purposes of decreasing the need for chart review and manual data collection. The Physician Quality Reporting System (PQRS) codes are included in CPT Category II. Category III are temporary tracking codes for new and emerging technologies, eg, five new codes for 2011 are 0243T-0244T for acoustic PFTs and 82590-82593 for multichannel PFTs.

The main purpose of Category III codes is to facilitate assessment of new services and procedures.

CPT is maintained by the CPT Editorial Panel, which is composed of 17 members: 11 representing medical specialty societies, two nominated by insurance companies, one by CMS, one by hospitals, and two by nonphysician providers. The CPT Editorial Panel is authorized to revise, update, or modify CPT codes. This committee controls the code numbers, code descriptions, and code categorization but is not in charge of code valuation. That responsibility is held separately by the AMA/Specialty Society RVS Update Committee (RUC).

The CPT Editorial Panel is supported by the CPT Advisory Committee, which is much broader, having representatives from all national medical specialty societies who are also represented in the AMA House of Delegates. Dr. Steven G. Peters, FCCP is the ACCP representative on the CPT Advisory Committee, and Dr. Michael E. Nelson, FCCP is the Alternate ACCP CPT Advisor.

The ACCP Practice Management Committee (PMPC) represents ACCP members’ interests regarding the CPT processes. The ACCP PMPC proposes new CPT codes, recommends revisions to existing CPT codes, comments on relevant submissions from other specialty societies, and also reviews and chooses whether or not to endorse proposals from drug and device manufacturers. The ACCP PMPC represents ACCP in several other ways in addition to CPT, such as representing ACCP members’ interests regarding RUC. ACCP members may submit CPT proposal suggestions to the ACCP PMPC by e-mailing Marla Brichta at MBrichta@chestnet.org.

In May’s CHEST PHYSICIAN, we will be explaining the work with the AMA/Specialty Society Relative Value Scale (RVS) Update Committee (RUC) that recommends values to Medicare for new and revised CPT codes.
The CHEST Foundation 2011 Awards Program

Don’t miss this opportunity! Application deadline is May 4, 2011.

The CHEST Foundation offers ACCP members opportunities to apply for awards in the areas of clinical research, leadership in end-of-life care, and humanitarian service.

New for 2011! OneBreath™ Clinical Research Award in Lung Cancer

This $100,000 award ($50,000 each year for 2 years) supports an ACCP member’s project that is focused on medical and/or surgical detection, or treatment of lung cancer based on clinical/translational research. It is available to an ACCP member (Affiliate Members eligible) who has completed at least 2 years of pulmonary or critical care fellowship or a thoracic surgery residency and is within 7 years of completing training.

The CHEST Foundation and the Respiratory Health Association of Metropolitan Chicago Clinical Research Award in Women’s Lung Health

This $10,000 award supports a clinical research project related to women’s lung health, which may include research on gender differences in various lung diseases, such as COPD and lung cancer. It is available to an ACCP member holding the degree of MD, DO, MB, BCh, PharmD, PhD, or equivalent.

Similar efficacy and safety results were observed in an additional 28 patients 12 to 17 years of age who were treated with DULERA in another clinical trial. The safety and efficacy of DULERA have not been established in children less than 12 years of age.

Clinical studies have shown that inhaled corticosteroids may cause a reduction in growth velocity in pediatric patients. In these studies, the mean reduction in growth velocity was approximately 1 cm per year (range 0.3 to 1.8 per year) and appears to depend upon dose and duration of exposure. The potential for “catch up” growth following discontinuation of treatment with orally inhaled corticosteroids has not been adequately studied.

The expected signs and symptoms with overdosage are those of excessive beta-agonist stimulation and/or exacerbation of any of the following signs and symptoms: angina, hypertension, nervousness, headache, tremor, seizures, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, hypokalemia, hyperglycemia, and insomnia. Metabolic acidosis may also occur. Cardio arrest and even death may be associated with an overdose of inhaled corticosteroids.

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

Inhalation of excessively high concentrations of inhaled corticosteroids can produce systemic effects. The potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the risks associated with alternative therapies. To minimize the systemic effects of orally inhaled corticosteroids, including DULERA, each patient should be titrated to his/her lowest effective dose (see Dosage and Administration [2.2]).

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

This $25,000 award supports research focused on COPD and AAT deficiency. Research projects primarily in usual COPD (not associated with AAT deficiency) are allowed. Projects focusing on AAT deficiency are encouraged. ACCP members, including Affiliate Members, holding the degree of MD, DO, MB, BCh, PharmD, PhD, or the equivalent are eligible.

D. Robert McCaffrey, MD, Master FCCP Humanitarian Awards

Multiple awards totaling up to $50,000 are given for community-based projects supported by the pro bono work of ACCP members worldwide. Projects must show a clear impact on the community and have the potential for long-term sustainability and replicability. Award funds are paid to the nonprofit or nongovernmental organization where the ACCP member donates time and medical service. All ACCP members, including Affiliate Members and Allied Health Members, are eligible to apply, but applicants must be a current member for at least 2 years.

Learn more about the 2011 awards at OneBreath.org, or go to the submission site at mc.manuscriptcentral.com/chest2011. Contact Lee Ann Fulton at fulton@chestnet.org with questions.
Pulmonary Perspectives

The Rigid Bronchoscope: A Pulmonologist’s ‘ Forgotten Tool’?

Since its first reported use to remove a foreign body from the airways by Gustav Killian in 1897, rigid bronchoscopy (RB) has been used successfully for other airway diseases. Airway visualization by bronchoscopy was a technique initially performed almost exclusively by surgeons until the introduction of the flexible bronchoscope in 1966. The flexible bronchoscope replaced the use of rigid bronchoscopes and defined the modern era of pulmonary medicine. In the early 1980s, physicians realized that there were advantages to rigid bronchoscopy for interventional procedures, such as the endobronchial management of lung cancer, critical airway obstruction, and other airway diseases. Furthermore, new indications and modalities are still being developed. Despite the advantages of rigid bronchoscopy; only 4% of pulmonologists who responded to a survey reported that they used a rigid bronchoscope in their practice (Coll et al. J Bronchol. 2000;7:8), though interventional pulmonologists, thoracic surgeons, and otolaryngologists use rigid bronchoscopes on a regular basis. Unfortunately, many pulmonologists finish their training with insufficient knowledge about the indications and uses of rigid bronchoscopes. Different interventional pulmonology programs and bronchoscopy organizations are trying to encourage the use of rigid bronchoscopes by creating fellowships and sponsoring hands-on courses. However, due to the complexity of this procedure and the methods of teaching needed, some will not gain this proficiency. It is the goal of this article to heighten the interest of the pulmonary community to explore and learn more about this ‘old’ instrument.

History and Equipment

Manuel Rodriguez Garcia, a Spanish singer and music teacher, was the first to perform an ‘in vivo’ visualization of the airways by studying his own larynx in 1855. Johann Czermak perfected the technique for indirect laryngoscopy in Germany in 1858. The first use in America was by Horace Green, the ‘father of laryngology,’ to make laryngeal applications of silver nitrate (Bryce et al. The American Laryngological Association 1878-1978: A centennial history. Washington, DC: The Association; 1978).

It was not until 1895 in Germany that Alfred Kirstein performed the first direct examination of the larynx by using a rubber tube with an electric bulb. One of his pupils, Gustav Killian, subsequently performed the first rigid bronchoscopy to remove a foreign body from a patient who had aspirated a bone into his right main bronchus (Zollner F. Arch Otolaryngel 1965;82(6):656). Later, Killian was named the ‘father of bronchoscopy.’ Around the same time, Chevalier Jackson, an American laryngologist from Pennsylvania, started to develop his own endoscopes with distal illumination, he used them initially with dogs and inanimate models. He published his book, Tracheobronchoscopy, Esophagology and Bronchoscopy, in 1907; later, he was considered the ‘father of American bronchosophagology’ (Jackson. The life of Chevalier Jackson: an autobiography. New York, NY: MacMillan; 1938).

E. Broyles introduced the telescope optic for bronchoscopy in Baltimore in 1940, followed by the optical forceps (1948). Shigeto Ikeda from Japan, who later developed the flexible fiberscope, introduced glass fiber illumination for the rigid bronchoscope in 1962. Hopkins, in England, developed a rod-lens telescope system that considerably improved the lighting and imaging through the rigid bronchoscope (1954). This technology was adopted by K. Storz as a cold light illumination source for his rigid bronchoscopes in 1961 (Bolliger et al. Interventional bronchoscopy. Basel, Switzerland: S Karger Publishers; 2000).

Fig 1. A rigid bronchoscope (top) has openings in the distal end to allow ventilation to the contralateral lung; a tracheoscope (bottom) lacks these holes.

Tracheobronchoscopy, Esophagology and Bronchoscopy, in 1907; later, he was considered the ‘father of American bronchosophagology’ (Jackson. The life of Chevalier Jackson: an autobiography. New York, NY: MacMillan; 1938).

Though minor adjustments have been made to the equipment since then, today’s rigid bronchoscopes are similar to those used in the days of Jackson. They are stainless steel, tapered tubes with a flared and beveled distal tip. The proximal end of the bronchoscope consists of a central opening and several side ports that are used for ventilation tubes and instrumentation. The typical ‘light carrier’ is a thin glass rod (telescope) connected to a proximal light source through a fiberoptic cable. Bronchoscopes have slit-like openings in the distal end that allow ventilation to the contralateral lung, while tracheoscopes lack these side holes and are shorter. The diameter of rigid bronchoscopes ranges from 9 to 14 mm, which allows the passage of multiple instruments simultaneously, such as suction catheters, laser fibers, forceps, and flexible bronchoscopes, among others (Figs 1-3).

Anesthesia

Preoperative patient preparation for RB includes restricted oral intake for at least 6 hours before the procedure and correction of coagulopathies. The use of agents to decrease bronchial secretions is not routinely required. Even though the technique for RB has remained almost the same since the late 19th century, the anesthetic technique has changed considerably. Jackson described the use of hypodermic morphine sulfate combined with topical cocaine as adequate to perform RB (Jackson. Bronchoscopy and esophagology. Philadelphia, PA: JB Saunders Company; 1927).

Currently, general anesthesia is preferred for the comfort and safety of the patient. Communication and coordination between the bronchoscopist and the anesthesiologist is crucial before, during, and after the procedure. Anesthesia induction can be done via inhaled sevoflurane (usually in critical airway stenosis) or by administration of IV agents like remifentanil and propofol (Perrin et al. Chest. 1992;102(5):1526). Muscle relaxants, like succinylcholine, are commonly used during the initial stages of anesthesia.

Fig 2. The proximal part of rigid bronchoscope has multiple ports: The ones on the lower side are for ventilation; those on the upper side are for instrumentation.

Fig 3. A rod-lens telescope can be introduced into the rigid scope; a light source connects to inferior part of telescope. Visualization is done through the black port.
Indications and Contraindications

Even though flexible bronchoscopy is indicated in the diagnosis and management of different pulmonary diseases, there are still multiple conditions in which RB is preferred over flexible bronchoscopy, i.e., the management of massive hemoptysis, removal of foreign bodies, and malignant airway obstruction. Moreover, some therapeutic techniques, like the placement of silicon stents for tracheal stenosis, tracheobronchomalacia, and malignant airway obstruction, can only be performed with a rigid bronchoscope.

Since general anesthesia is typically needed, contraindications for RB are related to comorbid diseases that increase the risk of anesthesia. An absolute contraindication includes cervical spine disease, which prevents positioning of the neck (Wain. Chest Surg Clin N Am. 2001;11(4):691).

Complications

In experienced hands, the complications of RB are rare. The most common ones are related to trauma of the upper airways, including the oropharynx and teeth (Ayers and Beamis. Clin Chest Med. 2001;22(2):355). Massive hemoptysis is very rare. Cardiac arrhythmias and respiratory depression can be seen due to anesthesia. Only two deaths were reported after 11,000 rigid bronchoscopies (Caputi et al. Pammunera Med. 1986;28(3):271).

Conclusion

The use of RB decreased after the introduction of flexible bronchoscopy. Despite being a safe procedure and having solid indications in the management of pulmonary diseases, most pulmonologists do not perform RB; furthermore, many of them have no exposure to RB during their training. It is important to stimulate the interest of pulmonologists to prevent RB from becoming a “forgotten tool.”

Dr. Javier I. Diaz-Mendez
Senior Staff Physician
Interventional Pulmonology

Dr. Paul A. Royle, FCCP
Senior Staff Physician
Pulmonary and Critical Care Medicine
Henry Ford Health System
Detroit, MI

Editor’s Insight

This article provides a historical review of rigid bronchoscopy and highlights its importance in the future of pulmonary medicine. The introduction of flexible bronchoscopy brought about a rapid decline in the number of physicians performing and teaching the technique of rigid bronchoscopy. Over the past 20 years, however, the growing field of interventional pulmonary medicine has brought the rigid bronchoscope back from the “brink of extinction” by defining the criteria for certification and indications for use (Ernst et al. Chest. 2003;123(5):1693; and Bolliger et al. Eur Respir J. 2002;19(2):356). This review should serve as a call to action to incorporate rigid bronchoscopy into the basic training of a bronchoscopist, especially at those institutions where high-grade airway obstruction, massive hemoptysis, and stent deployment and removal are commonplace.

Dr. Eric L. Flennaugh, FCCP
Georgia Cancer Coalition’s Distinguished Cancer Clinician & Scholar,
Director of Advanced Diagnostic and Interventional Pulmonary Medicine,
Georgia Cancer Center of Excellence and Morehouse School of Medicine,
Atlanta, GA

Editor’s note: Because I was not trained in rigid bronchoscopy and RB is not performed by me at my institution, commentary for this article was invited and provided by a guest editor.

Centers of Excellence

New at CHEST 2011, in Honolulu, HI, the ACCP will offer selected hospitals, non-hospital-based medical practices, and companies a special opportunity to showcase programs and practices that improve health-care outcomes. We plan to call this space “Centers of Excellence and Non-Hospital-Based Best Practices” (COE).

The COE will be held in a dedicated area adjacent to, but separated from, the Clinical Resource Center (exhibit hall). The COE will contain up to 10 hospitals and non-hospital-based practices, along with 10 “touchdown stations,” for close interaction with attendees, all selected by a special ACCP committee. The touchdown station will serve as a special space, allowing a company to present its role toward helping the COE achieve its goal.

The College views this as a unique opportunity for hospitals and other practice sites to showcase why they were selected as the “Best of the Best.” The Centers of Excellence will offer a VIP opening on Saturday or Sunday evening and will welcome other attendees and non-CHEST registrants until the Clinical Resource Center closes on Wednesday. Updates on selected COE will be listed in future articles.


Transplantation for Idiopathic Pulmonary Fibrosis. By Dr. A. Fang et al.

ICU Care Associated With Symptoms of Depression and Posttraumatic Stress Disorder Among Family Members of Patients Who Die in the ICU. By Dr. E. K. Kross et al.

Special Feature: COPD in China: The Burden and Importance of Proper Management. By Dr. X. Fang et al.

Commentary: Apologizing for Humiliations in Medical Practice. By Dr. A. Lazare and Ms. R. Sherman Levy.
Critical Care Commentary

The interventional pulmonologist plays an integral role in the management of critically ill patients with respiratory failure due to central airway obstruction, massive hemoptysis, and complications of thoracic surgery or radiation therapy. Bronchoscopy offers a minimally invasive diagnostic and therapeutic tool to palliate airway obstruction, providing symptomatic relief and potentially serving as a means to extubation.

Interventional pulmonology (IP) is a rapidly growing field that focuses on minimally invasive diagnostic and therapeutic techniques for complex airway, mediastinal, lung, and pleural diseases. The interventional pulmonologist is trained in pulmonary medicine and critical care medicine, with subsequent dedicated fellowship training in IP (Lamb et al. Chest. 2010;137(1):195). Interventional bronchoscopy requires skills to manage the complex airway with both flexible and rigid bronchoscopy, as well as mechanical ventilation.


Managing Central Airway Obstruction

A small percentage of respiratory failure is due to central airway obstruction. Airway obstruction may be due to a multitude of causes, whether benign or malignant, endoluminal or extrinsic, mechanical or functional. A high degree of morbidity is associated with such airflow obstruction (Ernst et al. Am J Respir Crit Care Med. 2004;169(12):1276). The “reserve” in airway diameter is so great that exertional symptoms may not be present until a loss of approximately 50% is experienced, roughly 7 to 10 mm at the level of the trachea. Failure to extubate a patient may reflect tracheal pathology, such as dynamic airway collapse or tracheal stenosis. Artificial airways may bypass central airway obstructions, therefore limiting the benefit of ventilator waveforms. CT scanning with both dynamic imaging (Lee et al. Chest. 2007;131(3):758) and 3-D reconstruction has greatly advanced examining the airway anatomy. CT virtual bronchoscopy affords noninvasive diagnostics of airway pathology (Boiselle et al. Respiration. 2003;70(4):383). However, bronchoscopy remains the gold standard for direct visual inspection of airway obstruction.

In the management of malignant airway obstruction, bronchoscopy is often palliative and serves as a bridge to further oncologic therapy. This can often be implemented in conjunction with external beam radiation therapy or systemic chemotherapy. In benign airway obstruction, such as tracheal stenosis or tracheobronchomalacia, bronchoscopy can palliate the airway with temporizing measures, such as balloon dilation or airway stenting.

Anesthetic choices and airway control are of key importance when approaching the patient with central airway obstruction. There must be constant communication between the bronchoscopist and the intensivist or anesthesiologist. In high-grade obstruction, rigid bronchoscopy is the instrument of choice, as you can bypass the obstruction under visualization, and it offers a secure airway with the ability to ventilate. Ventilation can be achieved with either an open circuit (jet ventilation) or a closed circuit (volume- or pressure-control). Hand-ventilation may offer a lower risk of barotrauma and the ability to identify changes, such as an acute obstruction, more readily.

If there are no immediate options for surgical resection, obstructions are best handled by rigid bronchoscopy in an operating room. Inevitably, flexible bronchoscopy is also required to navigate beyond obstructions for planning, examining distal airways, and cleaning the airways of secretions or blood.

Mechanical Debuling, Bronchoplasty, and Ablative Bronchoscopy

For patients in respiratory failure, “therapeutic,” or palliative, bronchoscopy can lead to successful extubation in select patients, decreased hospitalization, and lower health-care costs (Colt et al. Chest. 1997;111:202). If airway patency can be regained, then there is a greater chance of liberation from mechanical ventilation. Therapeutic bronchoscopy often provides a bridge to the institution of further therapies, such as radiation therapy or chemotherapy. Malignant airway obstruction can be relieved with mechanical efforts or ablative interventions. The mechanical approach focuses upon “core-out” or forces delubking, when the obstruction is endoluminal, and may or may not include ablative therapies. This acute...
The Realm of Interventional Pulmonology

Advanced Diagnostic Bronchoscopy
- Transbronchial biopsy
- Transbronchial needle aspiration (TBNA)
- Endobronchial ultrasound (EBUS), convex and radial probe
- Thoracic fluoroscopy
- Electromagnetic and virtual navigational bronchoscopy
- Autofluorescence bronchoscopy (AF)
- Narrow band imaging (NBI)
- Endoscopic optical coherence tomography
- Cytoscopy
- Alveoloscopy and fibered confocal microendoscopy

Therapeutic Bronchoscopy and Artificial Airways
- Airway stents: self-expanding metallic, silicon, and hybrid;
  placement and removal
- Balloon bronchoplasty and mechanical airway dilatation
- Laser bronchoscopy, Nd:YAG, and KTP
- Electrocautery
- Argon plasma coagulation (APC)
- Cryotherapy
- Endobronchial brachytherapy
- Photodynamic therapy
- Endoscopic abscess drainage
- Fistula and stump closure
- Foreign body removal
- Percutaneous tracheostomy
- T-tube placement
- Transtracheal oxygen
- Intradural bronchial one-way valves
- Endoscopic lung volume reduction
- Bronchial thermoplasty
- Whole lung lavage

NEWS FROM THE COLLEGE

Past ACCP President Remembered

Dr. Marvin Dunn, Master FCCP, passed away on February 16, 2011. A former Dean of the University of Kansas (KU) School of Medicine, and an internationally prominent cardiologist, Dr. Dunn served the ACCP as President in 1988-1989. An active ACCP Fellow for many years, he chaired numerous ACCP committees and served on the CHEST Editorial Board and as Governor for Kansas and chair of the Council of Governors. Dr. Dunn received one of the highest ACCP honors, that of Master Fellow, in 2002.

Dr. Dunn received his MD degree from the KU School of Medicine in 1954, and his bachelor’s degree from KU in 1950. After completing a residency in Internal Medicine at the KU Medical Center in 1959, he joined the faculty of the Department of Internal Medicine. He was a full professor by 1970, and in 1978, was named the Franklin Murphy Distinguished Professor and head of the cardiology section. Dr. Dunn rose to national and international prominence as a cardiologist who pioneered the development of coronary angioplasty. In his 46 years with the heart program, he mentored more than 90 cardiologists, some of whom now practice in leading heart programs at the KU Medical Center and around the world.
LTOT, Azithromycin in Lung Transplantation

ACCP and strengthens the development of the ACCP practice management resources.

In January 2011, a Chicago area PON subgroup, Pulmonary Administrators/Managers (PAM), met to discuss key issues facing their practices. Another Chicago area meeting is planned for April. If interested in participating in PAM, contact Marla Brichita at MBrichita@chestnet.org.

Key issues discussed were:
- Coding and reimbursement of pulmonary function testing in the office.
- Electronic medical records (EMR) implementation and use, obtaining meaningful use criteria.
- E-prescribing (eRx) CMS program requirement to e-prescribe 10 unique patients by June 2011 to avoid CMS penalties in 2012.
- Physician Quality Reporting System (PQRS) changes for 2011 to obtain CMS bonuses for improved quality of care.
- Optimal use of physician extenders (eg, nurse practitioners, physician assistants, etc) in the practice.
- High-deductible insurance collections.
- Recruitment of new physicians.

The sharing of ideas and knowledge had an immediate impact on the majority of practices that attended. One specific example is when one practice administrator shared that she had been undercoding PFT services and that the knowledge gained during the PAM meeting will enable her to appropriately increase revenues for her practice.

The PON is an example of how ACCP NetWorks can provide added value to the membership. The Practice Operations NetWork (PON) stimulates the exchange of ideas and knowledge between physicians and practice administrators/managers in order to improve patient outcomes, aid in the delivery of prompt service, optimize reimbursement, and increase practice efficiency. The PON is different from the ACCP Practice Management Committee (PMC), in that it allows for broader participation from the general membership.

The close collaboration between the PMC and PON increases the overall practice management efforts of the ACCP and strengthens the development of the ACCP practice management resources.

Moreover, rapidly changing technology and the availability of many types of oxygen delivery equipment make it difficult for the practicing pulmonologist to keep up with available devices. Physicians generally prescribe oxygen as a number of liters per minute but may not properly prescribe therapy that takes into account a patient’s increased oxygen demands during exercise and, perhaps, during sleep.

For example, patients generally prefer portable oxygen devices, and these devices may perform well when the patient is at rest. However, upon exertion, as both the minute ventilation and respiratory rate increase, many devices will not be adequate.

The Airways Disorders, Allied Health, and Respiratory Care NetWorks assembled a task force to review LTOT. The task force’s purpose was to evaluate the indications, prescrib- ing requirements, and available devices for providing LTOT. Their report endeavors to clarify all that the clinician should take into account when prescribing LTOT. The task force hopes to publish the full document on the ACCP Web site for easy accessibility and to also make a summary recommendation on LTOT available in an easy-to-carry format.

Dr. Rubin Cohen, FCCP
Vice-Chair, Airways Disorders

Thoracic Oncology

NetWork Updates

The Thoracic Oncology NetWork develops sessions for annual CHEST meetings, carries out projects aimed at improving the care of patients with thoracic malignancies, and provides an entry point for interested individuals to participate in ACCP activities.

A collaborative project of the ACCP and the Society of Thoracic Surgeons (STS) is approaching completion. This systematic review will summarize available evidence for the care of the high-risk, early-stage lung cancer patient. Additionally, NetWork steering committee members will be grading applications for The CHEST Foundation’s OneBreath Lung Cancer Clinical Research Award (http://onebreath.org).

The deadline for applications is May 4, 2011.

Finally, the NetWork is considering a project that would propose quality measures for lung cancer care. This is critical, as third-party payers increasingly focus on the quality of care.

The NetWork generated several sessions for CHEST 2011 in Honolulu, HI.

These include NetWork Highlights, “Becoming More Personal: What We Know, and What We Don’t Know About Individualized Therapy for Lung Cancer,” and “Radiation From Medical Imaging: How Much Cause for Concern.”

We strongly encourage all interested individuals to attend the NetWork open meeting, featuring Dr. Johan Brandes’ talk on the Emergence of Targeted Lung Cancer Therapy. The NetWork also wishes to highlight another upcoming scientific meeting of interest, The 14th World Congress on Lung Cancer, to be held July 2011, and the affiliated International Thoracic Malignancies Interest Group (ITMIG).

Dr. Douglas Arenal, FCCP
Chair, Thoracic Oncology

Transplant

Azithromycin in Lung Transplantation
Rates of chronic rejection following lung transplantation approach 45% at 5 years and reduce the 5-year survival to about 50%. The most common clinical surrogate of chronic rejection is bronchiolitis obliterans syndrome (BOS), which is defined as an irreversible loss in the FEV1, of 20% or greater.

Currently, there are no satisfactory treatments for BOS. Following the success of erythromycin in diffuse panbronchiolitis, several groups have investigated the role of azithromycin in treatment of BOS. Several retrospective and prospective studies have shown an improvement in the FEV1, which is significant both clinically and statistically. A recent report on high BAL neutrophilia, typically greater than 15%, has been predictive of a response to azithromycin.

Two recent studies by the Belgian transplant group have looked at this in greater detail. The first study published in the Journal of Heart and Lung Transplantation in December 2010 (Vos et al. J Heart Lung Transplant. 2010; 29[12]:1188) was a retrospective look at long-term azithromycin therapy for BOS in 103 patients and showed an improvement in pulmonary function and survival in patients with BOS.

The second study by the same group that was published in the European Respiratory Journal (Vos et al. Eur Respir J. 2011;37[1]:164) was a randomized, prospective, placebo-controlled trial looking at the role of azithromycin in preventing BOS and showed a much lower incidence of BOS in patients treated with the drug.

The addition of azithromycin is the first intervention that has been shown to reverse the loss of lung function in patients with BOS and is a standard therapy for BOS, but with recent data, it should be considered upfront for the prevention of BOS.

Dr. Rajat Walia, FCCP
Steering Committee Member
Discover a NEW IV Cephalosporin for

**COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA**

**CABP**

**ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS**

**ABSSSI**

**INDICATIONS**

- TEFLARO™ is indicated for the treatment of community-acquired bacterial pneumonia (CABP) caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Streptococcus pneumoniae* (including cases with concurrent bacteremia), *Staphylococcus aureus* (methicillin-susceptible isolates only), *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, and *Escherichia coli*.

- TEFLARO is also indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Escherichia coli*, *Klebsiella pneumoniae*, and *Klebsiella oxytoca*.

**IMPORTANT SAFETY INFORMATION**

**Contraindications**

- TEFLARO is contraindicated in patients with known serious hypersensitivity to ceftaroline or other members of the cephalosporin class. Anaphylaxis and anaphylactoid reactions have been reported with ceftaroline.

Please see additional Important Safety Information throughout and brief summary of Prescribing Information on last page of this advertisement. Please also see full Prescribing Information at [www.TEFLARO.com](http://www.TEFLARO.com).
INDICATIONS AND USAGE

- TEFLARO is indicated for the treatment of community-acquired bacterial pneumonia (CABP) caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Streptococcus pneumoniae* (including cases with concurrent bacteremia), *Staphylococcus aureus* (methicillin-susceptible isolates only), *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, and *Escherichia coli*.

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- To reduce the development of drug-resistant bacteria and maintain the effectiveness of TEFLARO and other antibacterial drugs, TEFLARO should be used to treat only ABSSSI or CABP that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hypersensitivity Reactions

- Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported with beta-lactam antibacterials. Before therapy with TEFLARO is instituted, careful inquiry about previous hypersensitivity reactions to other cephalosporins, penicillins, or carbapenems should be made. If this product is to be given to a penicillin- or other beta-lactam-allergic patient, caution should be exercised because cross sensitivity among beta-lactam antibacterial agents has been clearly established.

- If an allergic reaction to TEFLARO occurs, the drug should be discontinued. Serious acute hypersensitivity (anaphylactic) reactions require emergency treatment with epinephrine and other emergency measures that may include airway management, oxygen, intravenous fluids, antihistamines, corticosteroids, and vasopressors as clinically indicated.

*Clostridium difficile*-associated Diarrhea

- *Clostridium difficile*-associated diarrhea (CDAD) has been reported for nearly all systemic antibacterial agents, including TEFLARO, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, antibacterials not directed against *C. difficile* should be discontinued, if possible.
Bactericidal Activity Against a Broad Spectrum of Gram-positive and Gram-negative Pathogens, Including S. pneumoniae in CABP and MRSA in ABSSSI

Bactericidal Activity Against a Broad Spectrum of Gram-positive and Gram-negative Pathogens, Including S. pneumoniae in CABP and MRSA in ABSSSI

Proven efficacy in 2 common infections in patients admitted to the hospital

- Convenient q12h dosing in CABP and ABSSSI
  - 600 mg intravenous over 1 hour
  - Treatment duration
    - 5-7 days for CABP
    - 5-14 days for ABSSSI

IMPORTANT SAFETY INFORMATION

Direct Coombs’ Test Seroconversion

- Seroconversion from a negative to a positive direct Coombs’ test result occurred in 120/1114 (10.8%) of patients receiving TEFLARO and 49/1116 (4.4%) of patients receiving comparator drugs in the four pooled Phase 3 trials. No adverse reactions representing hemolytic anemia were reported in any treatment group. If anemia develops during or after treatment with TEFLARO, drug-induced hemolytic anemia should be considered. If drug-induced hemolytic anemia is suspected, discontinuation of TEFLARO should be considered and supportive care should be administered to the patient if clinically indicated.

Development of Drug-Resistant Bacteria

- Prescribing TEFLARO in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Please see additional Important Safety Information throughout and brief summary of Prescribing Information on last page of this advertisement.
TEFLARO CABP Study Designs

**Type of trial:** Two randomized, multicenter, multinational, double-blind, noninferiority trials

**Study population:** 1231 adults with a diagnosis of CABP

**Comparative agents:**
- **TEFLARO – 600 mg administered IV over 1 hour every 12 hours for 5-7 days;**
- **Ceftiraxone – 1 g ceftiraxone administered IV over 30 minutes every 24 hours for 5-7 days**

**Adjunctive therapy:**
- CABP Trial 1, two doses on Day 1 of oral clarithromycin 500 mg every 12 hours;
- CABP Trial 2, no adjunctive macrolide therapy

**TEFLARO Study Populations**

<table>
<thead>
<tr>
<th>Population</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Day 4 Population (mITT)</strong></td>
<td>A microbiological intent-to-treat population (mITT population) containing only subjects with a confirmed bacterial pathogen at baseline.</td>
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<tr>
<td><strong>Test of Cure (TOC) Populations</strong></td>
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<tr>
<td>MITT</td>
<td>Modified Intent-to-treat</td>
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<td>Modified Intent-to-treat Efficacy</td>
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<td>Clinically Evaluable</td>
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<tr>
<td>ME</td>
<td>Microbiologically Evaluable</td>
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* To evaluate the treatment effect of ceftaroline, an analysis was conducted in CABP patients for whom the treatment effect of antibacterials may be supported by historical evidence. This analysis endpoint required subjects to meet sign and symptom criteria at Day 4 of therapy: a responder had to both (a) be in stable condition according to consensus treatment guidelines, and (b) show improvement from baseline on at least one symptom of cough, dyspnea, pleuritic chest pain, or sputum production, while not worsening on any of these four symptoms.

† The protocol-specified analyses included clinical cure rates at the TOC (8 to 15 days after the end of therapy) in the coprimary MITTE and CE populations and clinical cure rates at TOC by pathogen in the ME population.

**INDICATION AND USAGE**

- **TEFLARO** is indicated for the treatment of **community-acquired bacterial pneumonia (CABP)** caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Streptococcus pneumoniae* (including cases with concurrent bacteremia), *Staphylococcus aureus* (methicillin-susceptible isolates only), *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, and *Escherichia coli*.
- To reduce the development of drug-resistant bacteria and maintain the effectiveness of **TEFLARO** and other antibacterial drugs, **TEFLARO** should be used to treat only CABP that is proven or strongly suspected to be caused by susceptible bacteria.

**IMPORTANT SAFETY INFORMATION**

**Adverse Reactions**

- In the four pooled Phase 3 clinical trials, serious adverse events occurred in 98/1300 (7.5%) of patients receiving **TEFLARO** and 100/1297 (7.7%) of patients receiving comparator drugs. Treatment discontinuation due to adverse events occurred in 35/1300 (2.7%) of patients receiving **TEFLARO** and 48/1297 (3.7%) of patients receiving comparator drugs with the most common adverse events leading to discontinuation being hypersensitivity for both treatment groups at a rate of 0.3% in the **TEFLARO** group and 0.5% in the comparator group.
- In greater than 5% of patients receiving **TEFLARO**, the most common adverse reactions occurring in >2% of patients receiving **TEFLARO** in the pooled Phase 3 clinical trials were diarrhea, nausea, and rash.
TEFLARO Demonstrated Clinical Response at Day 4 (mITT) in Community-Acquired Bacterial Pneumonia

<table>
<thead>
<tr>
<th></th>
<th>Treatment Difference</th>
<th>Clinical response, % (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FOCUS 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEFLARO</td>
<td>11.2 (95% CI: -6.6, 26.5)</td>
<td>69.6% (48/69)</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>58.3% (42/72)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment Difference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7.6 (95% CI: -6.8, 21.8)</td>
<td>69.0% (58/84)</td>
</tr>
<tr>
<td></td>
<td>61.4% (51/83)</td>
<td></td>
</tr>
<tr>
<td><strong>FOCUS 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEFLARO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CI = confidence interval.

Neither trial established that TEFLARO was statistically superior to ceftriaxone in terms of clinical response rates.

TEFLARO Demonstrated Efficacy at TOC (CE) in Community-Acquired Bacterial Pneumonia

<table>
<thead>
<tr>
<th></th>
<th>Treatment Difference</th>
<th>Clinical cure rates, % (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FOCUS 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEFLARO</td>
<td>8.4 (95% CI: 1.4, 15.4)</td>
<td>86.6% (194/224)</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>78.2% (183/234)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment Difference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5.2 (95% CI: -2.2, 12.8)</td>
<td>82.3% (191/232)</td>
</tr>
<tr>
<td></td>
<td>77.1% (165/214)</td>
<td></td>
</tr>
<tr>
<td><strong>FOCUS 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEFLARO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CI = confidence interval.

Neither trial established that TEFLARO was statistically superior to ceftriaxone in terms of clinical response rates.

Patients with known or suspected MRSA were excluded from both trials.

*FOCUS = Ceftaroline Community-Acquired Pneumonia Trial vs Ceftriaxone in Hospital Patients. FOCUS 1 = CABP Trial 1, FOCUS 2 = CABP Trial 2.
† There are insufficient historical data to establish the magnitude of drug effect for antibacterial drugs compared with placebo at a TOC time point. Therefore, comparisons of TEFLARO to ceftriaxone based on clinical response rates at TOC cannot be utilized to establish noninferiority.

IMPORTANT SAFETY INFORMATION

Drug Interactions

- No clinical drug–drug interaction studies have been conducted with TEFLARO. There is minimal potential for drug–drug interactions between TEFLARO and CYP450 substrates, inhibitors, or inducers; drugs known to undergo active renal secretion; and drugs that may alter renal blood flow.
**TEFLARO ABSSSI Study Design**

<table>
<thead>
<tr>
<th>Type of trial:</th>
<th>Two identical, randomized, multicenter, multinational, double-blind, noninferiority trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study population:</td>
<td>1396 adults with clinically documented complicated skin and skin structure infection</td>
</tr>
<tr>
<td>Comparative agents:</td>
<td>TEFLARO – 600 mg administered IV over 1 hour every 12 hours for 5-14 days; Vancomycin plus aztreonam – 1 g vancomycin administered IV over 1 hour followed by 1 g aztreonam administered IV over 1 hour every 12 hours for 5-14 days</td>
</tr>
<tr>
<td>Treatment duration:</td>
<td>Treatment duration was 5 to 14 days. A switch to oral therapy was not allowed</td>
</tr>
</tbody>
</table>

**TEFLARO Study Populations**

<table>
<thead>
<tr>
<th>Day 3 Population*</th>
<th>The analysis evaluated patients with lesion size ≥75 cm² and having one of the following infection types:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Major abscess with ≥5 cm of surrounding erythema</td>
</tr>
<tr>
<td></td>
<td>- Wound infection</td>
</tr>
<tr>
<td></td>
<td>- Deep/extensive cellulitis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test of Cure (TOC) Populations†</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>MITT Modified Intent-to-treat</td>
<td>All randomized subjects who received any amount of study drug.</td>
</tr>
<tr>
<td>CE Clinically Evaluable</td>
<td>Patients in the MITT population who demonstrated sufficient adherence to the protocol. Sufficient adherence is defined as patients who met the minimal clinical disease criteria for cSSSI and all evaluability criteria, including subjects who received at least the pre-specified minimal amount of the intended dose and duration of study drug therapy, for which sufficient information regarding the cSSSI site is available to determine the subject’s outcome, and for which there were no confounding factors that interfered with the assessment of that outcome.</td>
</tr>
<tr>
<td>ME Microbiologically Evaluable</td>
<td>This population consists of a subset of subjects from the CE population who had at least one bacterial pathogen identified from a blood culture or culture of an adequate microbiological sample obtained from the cSSSI site at baseline and who had susceptibility testing performed on at least one of the isolated baseline pathogens.</td>
</tr>
</tbody>
</table>

* To evaluate the treatment effect of ceftaroline, an analysis was conducted in 797 patients with ABSSSI (such as deep/extensive cellulitis or a wound infection (surgical or traumatic)) for whom the treatment effect of antibacterials may be supported by historical evidence. This analysis evaluated responder rates based on achieving both cessation of lesion spread and absence of fever on Trial Day 3.

† The protocol-specified analyses included clinical cure rates at the TOC (8 to 15 days after the end of therapy) in the coprimary CE and MITT populations and clinical cure rates at TOC by pathogen in the ME population.

**INDICATION AND USAGE**

- **TEFLARO** is indicated for the treatment of **acute bacterial skin and skin structure infections (ABSSSI)** caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Escherichia coli*, *Klebsiella pneumoniae*, and *Klebsiella oxytoca*.

- To reduce the development of drug-resistant bacteria and maintain the effectiveness of TEFLARO and other antibacterial drugs, TEFLARO should be used to treat only ABSSSI that is proven or strongly suspected to be caused by susceptible bacteria.

**IMPORTANT SAFETY INFORMATION**

Use in Specific Populations

- **TEFLARO** has not been studied in pregnant women. Therefore, TEFLARO should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.

- It is not known whether ceftaroline is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TEFLARO is administered to a nursing woman.

- Safety and effectiveness in pediatric patients have not been established.

- Because elderly patients, those ≥65 years of age, are more likely to have decreased renal function and ceftaroline is excreted primarily by the kidney, care should be taken in dose selection in this age group and it may be useful to monitor renal function. Dosage adjustment for elderly patients should therefore be based on renal function.

- Dosage adjustment is required in patients with moderate (CrCl >30 to ≤50 mL/min) or severe (CrCl ≥15 to ≤30 mL/min) renal impairment and in patients with end-stage renal disease (CrCl <15 mL/min).

- The pharmacokinetics of ceftaroline in patients with hepatic impairment have not been established.
**ABSSSI**

TEFLARO Demonstrated Clinical Response at Day 3 in Acute Bacterial Skin and Skin Structure Infections

<table>
<thead>
<tr>
<th>Treatment Difference 9.4 (95% CI: 0.4, 18.2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEFLARO monotherapy 74.0% (148/200)</td>
</tr>
<tr>
<td>Vancomycin + aztreonam 64.6% (135/209)</td>
</tr>
</tbody>
</table>

Treatment Difference 5.9 (95% CI: -3.1, 14.9)

Neither trial established that TEFLARO was statistically superior to vancomycin plus aztreonam in terms of clinical response rates.

**ABSSSI**

TEFLARO Demonstrated Efficacy at TOC† (CE) in Acute Bacterial Skin and Skin Structure Infections

<table>
<thead>
<tr>
<th>Treatment Difference -2.2 (95% CI: -6.6, 2.1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEFLARO monotherapy 91.1% (288/316)</td>
</tr>
<tr>
<td>Vancomycin + aztreonam 93.3% (280/300)</td>
</tr>
</tbody>
</table>

Treatment Difference 0.1 (95% CI: -4.4, 4.5)

Neither trial established that TEFLARO was statistically superior to vancomycin plus aztreonam in terms of clinical response rates.

*CANVAS—Ceftaroline vs Vancomycin in Skin and Skin Structure Infection. CANVAS 1=ABSSSI Trial 1, CANVAS 2=ABSSSI Trial 2.

†There are insufficient historical data to establish the magnitude of drug effect for antibacterial drugs compared with placebo at a TOC time point. Therefore, comparisons of TEFLARO to vancomycin plus aztreonam based on clinical response rates at TOC cannot be utilized to establish noninferiority.


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Apnea Likely Cause of Deaths

Bariatic from page 1

Dr. Gallagher and his team measured carbon dioxide partial pressures transcutaneously (TeLfaro™) to gauge hyperventilation in 1246 patients during the first 24 hours after Roux-en-Y gastric bypass. Patients also wore blood oxygen saturation (SpO2) ear clip sensors.

Their mean body mass index was 54 kg/m², ± 10.5, and 62% were postoperative narcotics. As in the previous study, all the patients had multiple episodes of prolonged hypoxemia, with a mean of 191 episodes per patient lasting a mean of 1 minute.

In addition, 94% of them had a minimum SpO2 of 60%. Patients spent about 5% of their time (75 minutes) with SpO2 below 88%; hypoxemia lasted longer than 5 minutes in three patients. An investigator also had mild hypoxic, chronic hypoxemia, suggesting mild, chronic hypoxemia. They had a mean PCO2 of 44 mm Hg and a mean maximum of 56 mm Hg.

The maximum hypoxemia by itself was not “clinically significant,” leaving obstruc- tive sleep apnea as the most likely cause of hypoxemia following bariatric surgery, Dr. Gallagher stated.

As far as the unexplained deaths go, Dr. Gallagher and his team believe that one patients desirable, the mild narcoptic-induced hyperventilation pushes a few of them over the edge, though no one died in the study.

Because sleep apnea is the likely root cause of such deaths, Dr. Gallagher recom- mends routine postoperative moni- toring of bariatric surgery patients.

“[Apneics] need to have their CPAP on” after surgery, especially when receiving narcotics, he said.

CPAP and postoperative monitoring is necessary until sleep apnea resolves, usually after a weight loss of 75-75 kg. In his study, he noted that 14 pa- tients had machines but still desaturate. Barraging faulty gear or incorrect settings, that means the machines weren’t being used throughout the night.

He also pointed out the supplemental oxygen study didn’t prevent hypoxemia or hypoxia and seems to have no therapeutic role at this point.

In many places, sleep apnea screens, CPAP, and nighttime pulse oximetry are not the standard care following bariatric surgery, Dr. Gallagher said.

Dr. Stefan Holubar, a colorectal sur- geon and comoderator of the session, thinks that needs to change.

“There should include formal obstructive sleep apnea [screen- ing] for all patients undergoing bariatric surgery, or they should all be em- pirically treated [with CPAP] regardless of whether or not they have the diagnosis,” said Dr. Holubar, of Dartmouth-Hitch- cock Medical Center in Lebanon, N.H.

Although “it’s a small pilot study,” there are profound implications,” he added.

“The data strongly suggest that we are con- sidering a randomized study to further investigate the issue, and they plan to in- clude obese people having other kinds of operations.”

Dr. Gallagher and Dr. Haines said they have no conflicts of interest. The study received no outside funding.
Private Practice Under Pressure From EHR Mandate

BY MITCHEL L. ZOLER
Elsevier Global Medical News

LAS VEGAS – The electronic health record mandate for physicians who participate in Medicare or Medicaid may have the unintended consequence of being the cudgel that drives many remaining private practice physicians out of business, Dr. Steve G. Peters, FCCP, said at the annual meeting of the National Association for Medical Direction of Respiratory Care.

“No one will admit it, but there is de facto pressure [from the electronic health record mandate] that there won’t be private practice in the foreseeable future,” said Dr. Peters, a critical care physician and professor of medicine at the Mayo Clinic in Rochester, Minn.

“Everyone will need to report measures on hundreds of patients,” and to afford to do that they will likely have to become part of an organization, he predicted.

The challenge of meeting the electronic health record (EHR) reporting requirements will ratchet up over the next several years as the increasingly demanding stages of the Health Information Technology for Economic and Clinical Health (HITECH) Act begin to kick in.

In stage 1, which started this year, physicians using a certified EHR and participating in Medicare or Medicaid must report to the Center for Medicare and Medicaid Services (CMS) three core measures for each patient – height, weight, and blood pressure – as well as three additional measures from a list of 38 options. During the next few years, the program will expand into stages 2 and 3 with additional data reporting requirements.

“It sounds easy, but it’s not,” said Dr. Peters. The way to program an EHR to report these various measures “differs from measure to measure, and when you get into it, it’s very complicated. We’re [currently] working this through at Mayo. We have a full EHR at Mayo, but extracting out the data for reporting is proving to be difficult. We have 85% of it, but the gap, the final 15%, is hard.”

As an example, he cited the challenge of automatically reporting to the CMS what happens with patients who have a body mass index of 30 kg/m² or greater.

“You need to record and report an action plan of what you’ll do about this, and if not, why not. You need to somehow capture it in a file that can be reported out of your computer why you did not achieve the measure.”

The EHR information demands required by the HITECH law are “overwhelming,” commented Dr. Alan H. Morris, FCCP, a pulmonologist and professor of medicine at the University of Utah in Salt Lake City. “It’s a huge operation. What if a physician does not have the infrastructure of the Mayo Clinic?”

Those consequences were exemplified by an attendee at the meeting, Dr. Theodore S. Ingrassia III, FCCP, a pulmonologist in Rockford, Ill. who suffers from a plan of the Mayo Clinic? “There is de facto pressure (from the EHR mandate) that there won’t be private practice in the foreseeable future.”

DR. PETERS

“The three major hospitals in Rockford recognized the information technology and cost challenges that the new EHR requirements pose, and have offered to provide Dr. Ingrassia with the IT support he needs to meet CMS reporting demands if he gives up his private practice and joins their staff. It’s a tempting proposal, he said, but he remains very reluctant to abandon the private practice he built over the past 20 years, he said in an interview.

For the time being, his strategy rests on deferring the EHR with the hope that the financial penalties scheduled to start in 2015 for noncompliance may get delayed or that some other option emerges. Dr. Peters, Dr. Morris, Dr. Ingrassia, and Dr. Doherty had no disclosures relevant to this topic.
By Mary Ann Moon

Omalizumab Cuts Asthma Symptoms, Hospitalizations

Adding omalizumab to guideline-based asthma treatment decreased symptoms, exacerbations, hospitalizations, and the need for glucocorticoids in children, adolescents, and young adults living in the inner city, according to a recent report.

The monoclonal anti-IgE antibody was particularly effective in patients who were allergic to cockroach and dust allergens. Moreover, “a striking additional post hoc finding was the marked reduction in seasonal exacerbations seen with omalizumab,” said Dr. William W. Busse of the University of Wisconsin, Madison, and his associates.

“Our purpose in designing this study was to examine whether specifically targeting the allergic component in persistent asthma would offer a benefit beyond that provided by conventional treatment for asthma control, regardless of disease severity,” they noted.

The investigators compared subcutaneous injections of omalizumab vs. placebo injections in a multicenter clinical trial involving 419 children, adolescents, and young adults (aged 6-20 years) who had persistent allergic asthma. After 1 month on guideline-based treatment, the study participants were randomly assigned to additionally receive active (208 subjects) or placebo (211 subjects) injections every 2 weeks or 4 weeks, for a total of 60 weeks.

At baseline, the average number of days during the preceding 2 weeks in which participants had asthma symptoms was 4.9, and 25% of patients had been hospitalized at least once during the preceding year for an asthma-related event.

The average age of the study subjects was 11 years. In all, 38% were male; 60% were black, and 37% were Hispanic.

The primary outcome (defined as the number of symptomatic days during the preceding 2 weeks) was decreased to 0.48 days with omalizumab, compared with 1.48 days with placebo, a significant 25% reduction. Exacerbations occurred in 40% of the placebo group, compared with 30% of the omalizumab group, which was also a significant difference. And the rate of asthma-related hospitalizations also was significantly lower with omalizumab (1.5%) than with placebo (6.5%).

Patients who took omalizumab were able to significantly reduce their use of inhaled glucocorticoids, with an overall budesonide-equivalent dose of 663 mcg/day, compared with 771 mcg/day with placebo.

These benefits “were similar in patients of all ages and at all levels of asthma severity,” and were first observed within 4 weeks of beginning the injections, Dr. Busse and his colleagues said (N. Engl. J. Med. 2011;364:1009-13).

“No differences of concern regarding safety were noted between the two groups,” they added.

The greatest treatment effect was seen in participants who were sensitized to cockroach allergens and were known to be exposed to it, based on environmental sampling from their bedrooms. These subjects had a 71% reduction in asthma exacerbations. Subjects who were allergic to dust mites also showed greater reductions in days with symptoms and the use of glucocorticoids, compared with those not sensitized to dust mites.

“Even though we found omalizumab effective at all levels of asthma severity, we do not advocate its use outside of current recommendations given its cost and remaining questions regarding long-term safety in children. We do, however, believe that this study provides a strong proof of concept that the allergic component of asthma is crucial in this population,” the investigators said.

In a post hoc analysis, the researchers found that omalizumab also markedly reduced seasonal exacerbations of asthma. “Viral respiratory infections are a major cause of exacerbations, especially in the fall, with the start of school, but they were identified in less than 60% of the samples available for analysis, suggesting that other factors, such as allergen exposure, pollution, stress, or bacteria, also contribute to the risk of exacerbation. These findings imply that targeting the drug to patients who are sensitized to cockroach and dust mite allergens, as well as focusing its use on preventing seasonal peaks in asthma exacerbations, would yield the optimal effectiveness and cost benefit, they added.

This study was supported by the National Institute of Allergy and Infectious Diseases, the National Center for Research Resources, and Novartis Pharmaceuticals. Dey Pharma provided EpiPens and S.C. Johnson provided household pest control products. Dr. Busse and his associates reported ties to numerous drug and device manufacturers.

Dr. Burt Lesnicky, FCCP, comments: Omalizumab is not yet approved by the U.S. FDA for children under 12 years of age. In this study population, there were no adverse effects in children aged 6-12 years.
Relieving Needless Suffering

The care starts at diagnosis, continues through the trajectory of the illness, and is directed at the underlying illness and at the psychological, social, and spiritual needs of the child and family. More than 15,000 children and teens die in the United States each year from life-limiting diseases – and less than a quarter of them have cancer, according to data cited by Dr. Friedrichsdorf. Neurромorphic or neurodegenerative disorders cause a significant proportion of those deaths, followed by congenital or genetic disorders, cardiovascular disorders, and metabolic disorders.

“The vast majority of these children do not have access to pediatric palliative care in this country,” Dr. Friedrichsdorf said in an interview. Data show that these children are suffering needlessly from pain, breathlessness, nausea, and vomiting. Praised by the awards committee for “innovative symptom management, communication, and family-centered care,” Dr. Friedrichsdorf said he and his team take “an extremely aggressive approach” to managing pain and distressing symptoms in children with life-threatening or life-limiting conditions.

He believes strong pain medications are underused in children (and one of the “myths” he debunkes is that increasing doses of opioids and/or benzodiazepines causes respiratory depression and quickens death), but also that pharmacology alone is insufficient. His department employs both pharmacology and complementary therapies such as biofeedback, massage, hypnosis, acupuncture, and acupressure. Physicians and other staff are trained in such modalities. “It’s not one or the other. It’s using the whole breadth [of therapies] at the same moment,” said Dr. Friedrichsdorf, who is trained in hypnotherapy.

“We want to promise each family, if your child is suffering from distressing symptoms like nausea, pain, or dyspnea, we can usually make the symptoms go away,” he said. “Our goal is for children to live as long as possible, as well as possible.”

In addition to physicians and nurses, the pain and palliative care team at Children’s includes social workers, psychologists, a physical therapist, a child-life specialist, massage therapists, and advanced practice nurses.

Each of these professionals can see patients as part of the Children’s-based pain and palliative care “rounding team” in the department’s pain and palliative care clinic, or for patients in the Minneapolis/St. Paul area, in the home through the department’s home-based component.

The team can be called upon by anyone – a doctor, a patient, or a relative or friend – for a consultation, and its members meet regularly to discuss patients.

“My philosophy is that I may not tell me, for instance, that I need to change [a patient’s] pain medications because she sees side effects,” Dr. Friedrichsdorf said.

A pilot study of pediatric palliative care teams at children’s hospitals to be published soon, found that professionals in the teams had a “clear idea of what the other professionals offered to the patient and family,” said Nancy Berlinger, Ph.D., deputy director and research scholar at the Hastings Center, which conducted the study with researchers at Rush University, Chicago.

A chaplain knows, for instance, how the physician and nurse are addressing the patient’s medical needs, and the physician is aware that the chaplain is supporting the parents and, in some cases, the child, she said in an interview.

“Having shared goals of care and strong communication is also important so that everything doesn’t have to be explained every time a shift changes or a patient is transferred to a different setting,” she said.

“Most of these pediatric palliative care teams are fairly newly established,” she noted. “There was some pediatric palliative care before then, but not necessarily with a strong team approach.”

Dr. Nageswaran, who led the establishment of the first pediatric palliative care program at her hospital in 2008, said she was struck by the amount of coordination needed to provide good palliative care and by the flexibility needed to design a good program.

She and her colleagues started the program as a consultant service for children who were hospitalized with complications. “As palliative care might be the service used a half-time nurse coordi- nator, a one-quarter full-time equivalent (FTE) clinician post to be shared by a handful of physicians for rotating on-call duty, and a 1% FTE post for a physician coordinator.

“Very soon, we realized that the biggest need was to facilitate collaboration between multiple providers and to ensure sufficient continuity of care as these children transition back and forth from the hospital to home,” Dr. Nageswaran said in an interview. “We weren’t achieving this with the traditional consult model and the home care services in the hospital and leave recommendations for the primary medical team.”

In a subsequent restructuring, physi- cian time was consolidated into a one-third–time FTE coordinator post, which Dr. Nageswaran fills herself, and funding was obtained from the federal Maternal and Child Health Bureau to add another half-time nurse coordinator who could focus on making home visits and coor- dinating home-based care in one county.

The flexibility to coordinate care outside the hospital is critical, Dr. Nageswaran said. One of the 253 children cared for by the palliative care program was a child with a rare genetic disorder characterized by skeletal abnormalities, urologic abnormalities, and severe neu- rologic impairment and seizures.

“My family wanted end-of-life care to be delivered at home, but they didn’t want to forgo medical care,” Dr. Nageswaran recalled. “We went step-by-step, aligning the family’s wishes with the care the child received. We worked with the primary care doctor, the sub- specialists, the home health agency, and the parents to provide medical treat- ment, pain and symptom management, palliative care at home.”

Both she and Dr. Friedrichsdorf em- phasized the value of open inquiry with parents, children, and families.

“Each family is unique in how they perceive illness and how they make dec- isions about treatment and end-of-life care,” said Dr. Nageswaran. “When we meet families, we meet them without a set agenda, and we make sure we don’t impose our structure.

Similarly, Dr. Friedrichsdorf said, “When I enter a room, the first thing I say is, ‘How can I help you?’ We start with that open question.” At that point, he said, sur- veys or other structured tools can be used to help determine needs and care plans.

One of the thorns in the field of pe- diatric palliative care is the unavailability of hospice services for many children, who often have chronic uncertainty about childhood life-threatening conditions and the desire for continued treatment. Currently, most families have to forgo home- health services in order to receive hospice services.

Some states have taken action; policy reform passed in California in 2006, for instance, makes it easier for parents to utilize the Medi-Cal hospice benefit for children. A section of the federal Patient Protection and Affordable Care Act, moreover, is expected to change the Medicaid system to allow children with life-limiting conditions to receive both hospice care and curative treatment.

Another problem is poor provider re- imbursement. “Physician services are re- imbursed, but not enough to account for the amount of time involved,” said Dr. Nageswaran. “And the services of nurs- es and social workers, who are key to pedi- atric palliative care programs, are not reimbursed.”

She jump-started her program with a grant from the Duke Endowment, a pri- vate foundation, but now relies primar- ily on financial support from the hospital.

Dr. Friedrichsdorf estimates that his hos- pital is reimbursed for only about half of its costs, and says that it relies heavily on philanthropy to make up the difference.

Philanthropy recently benefited the pediatric palliative care program at Akron (Ohio) Children’s Hospital. With $1.2 million in donations from the Haslinger Family Foundation and other leadership gifts, the hospital has created an endowed chair for its services, which began in 2002.

One goal in the meantime, said Dr. Berlinger, is to “influence the culture of health care so that pediatric palliative care is recognized as ethically mandatory.”

The $15,000 awards Dr. Nageswaran and Dr. Friedrichsdorf received were given by the Hastings Cen- ter, a bioethics research institute based in Garrison, N.Y., in partnership with the Cumniff-Dixon Foundation, a foun- dation that focuses on the doctor-patient relationship near the end of life.

New Subspecialty Is Evolving

In terms of education, pediatric pain medicine was added to both subspecialties – pediatric pain medicine and pediatric palliative care – and recognized as a new subspecialty. The American Board of Medical Specialties (ABMS) approved the creation of HPM as a subspecialty of 10 participating boards in 2006. Prior to 2006, board certification in hospice and palliative medicine was ad- ministered by the American Board of Hospice and Palliative Medicine but not recognized by the ABMS. Other pediatricians have taken complementary and attended educational re- treatments through organizations such as the Initiative for Pediatric Palliative Care, Dr. Berlinger said.

Ideally, she and Dr. Friedrichsdorf say both educational tracks – fellow-ships and educational opportunities for mid-career physicians – will grow. Starting in 2013, residents who want to sit for the HPM board exam will have to have completed an Accreditation Council for Graduate Medical Education-accredited fellowship – a change that should spur the development of more fel- lowship programs. Children’s Hospital and Clinics of Minnesota, Dr. Friedrichsdorf’s hospital, houses one of a handful of fellowship programs in pediatric palliative care. It has applied for ACGME approval.

Dr. Friedrichsdorf is the principal investigator of a National Institutes of Health/National Institute of Aging study on the creation and implementa- tion of a pediatric palliative care curriculum that is slated to be of- fered to physicians who are in the midst of their careers and are not seeking subspecialty training.

“Many professionals working in children’s hospitals are likely to care for a dying child, and need to be comfortable and knowledgeable,” said Dr. Friedrichsdorf, who completed a fellowship in pediatric pain and palliative care at the Children’s Hospital at Westmead, Australia, after finishing his pediatric residency in Germany.
LAS VEGAS - The results from the National Lung Screening Trial constitute a "game changer" for lung cancer screening, Dr. James R. Jett, FCCP, said at the annual meeting of the National Association for Medical Direction of Respiratory Care.

The study results, reported in a press release by the National Cancer Institute last November, "changed the landscape" for screening by showing that lung imaging by low-dose helical CT done annually for 3 years in people with a smoking history of at least 30 pack-years cut their lung cancer mortality during follow-up by 20%, compared with those who had three annual chest x-rays. "This is the biggest advance in lung cancer in my career, an absolutely stunning result," said Dr. Jett, a pulmonologist and lung cancer specialist at National Jewish Health in Denver.

The researchers who ran the National Lung Screening Trial will likely publish their full results this spring, after which annual screening of people who match the profile of those in the study should become the standard of care, Dr. Jett predicted.

The screening trial enrolled 53,454 current or former cigarette smokers aged 55-74 years, who had each accumulated at least 30 pack-years of smoking history but had quit within the previous 15 years. The more than 75,000 total screening events by CT and more than 73,000 total screens by chest x-ray yielded 24% positive CT images and 7% positive x-rays. During roughly 144,000 person-years of follow-up in each arm, the mortality due to lung cancer reached 246 deaths per 100,000 person-years in the CT group and 308 deaths per 100,000 person-years in the x-ray group, a 20% absolute mortality reduction with CT screening, statistically significant, and which led the trial's Data and Safety Monitoring Board to stop the study and release the results.

The people screened by CT also had a 7% reduction in all-cause mortality, compared with those screened by x-ray, also a statistically significant difference.

As about 160,000 Americans die from lung cancer annually, a 20% cut in mortality from low-dose helical CT screening could potentially save about 32,000 lives a year in the United States alone. "That's almost like eliminating all 40,000 breast cancer deaths each year," Dr. Jett said.

The results did not directly address the question of how long annual screening should continue. In the trial, screening stopped after three annual examinations because of limited financial resources, although despite the study cost about $200 million higher than expected, Dr. Jett said his review of the results identified no suggestion that in routine practice screening should stop after 3 years. "There was no drop in the number of cancers" during each sequential year of screening, "I don't see anything that tells me you can stop [screening] after 3 years," he said.

"The biggest question is, can we afford it" to do annual CT screening on the scale needed to include all people who fit the profile included in the trial.

A second issue is the annual CT imaging, but Dr. Jett presented a brief analysis suggesting that it is safe. A low-dose CT scan involves a radiation exposure of about 0.65 mSv, less than 10% of the dose of a conventional chest CT, Dr. Jett said. With that level of exposure, annual low-dose CT imaging of currently smoking patients who had a history of 3 excess of 5 excess lung cancer deaths for every 10,000 people screened, compared with a background lung cancer mortality of 100 for every 10,000 people with no screening. Because screening could prevent 20% of these 100 deaths, it would avert 20 more deaths that it might cause. For smokers, the risk benefit ratio runs even higher because currently smoking men undergoing annual CT screening would have about 2 extra lung cancer deaths per 10,000 people due to the radiation exposure, compared with 101 with no screening. Because screening could prevent about 20% of these 100 deaths, it would avert 20 more deaths that it might cause.

"No data are available on the effects of increasing radiation exposure, compared with continued to smoke," the researchers said.

"Even with the positive NLST results, however, a blanket recommendation for annual CT screening is not currently prudent. The NLST study involved a specific population and therefore may not be applicable to all. Fortunately, help is on the way. A multisociety task force has been formed and is poised to review the full study results when available. The plan is to then rapidly formulate and publish guidelines for lung cancer screening. Additionally, the third edition of the ACCP's Evidence-based Guidelines on the Diagnosis and Management of Lung Cancer is being prepared. The new "Screening for Lung Cancer" chapter will be helpful to front-line clinicians. So encourage your patients to stop smoking and look for guidelines in the near future."

"Data Suggest Preop Smoking Cessation Not Harmful"

PATIENTS who quit smoking shortly before undergoing surgery are not at increased risk of postoperative complications, compared with those who continue to smoke, according to a report published online in the Archives of Internal Medicine.

"Until now, some evidence of harm emerges, firm advice to stop smoking and an offer of smoking cessation treatment to those who need it can be provided to all surgical patients at any time," said Katie Myers of Queen Mary, University of London and her associates.

Publication of a study in 1989 with 39 subjects suggested that "stopping smoking leads to a decrease in coughing and an increase in sputum production." Although that article did not actually show a significant effect of smoking cessation on postoperative complications, it has continued to influence routine practice; in fact, some treatment guidelines recommend against smoking cessation in the 2 months prior to surgery "to minimize the increase in pulmonary complications in recovering patients."

Ms. Myers and her colleagues reviewed the literature for all studies that allowed comparisons of postoperative complications in patients who stopped smoking 8 weeks or less before undergoing surgery (recent quitters) and patients who continued to smoke. They then performed a meta-analysis of the nine studies that did so, rating as "high quality" the three studies that had randomized patients to biochemical testing to validate subjects' self-report of their smoking status.

These studies involved 889 subjects, including 448 recent quitters and 441 continuing smokers.

Only one of the nine studies showed a significant effect of smoking cessation, and that was in favor of recent quitters. When the results were pooled, there was "no beneficial or detrimental effect of quitting within 8 weeks before surgery compared with continued smoking," the researchers said.

The results were the same in an analysis of the three high-quality studies, and likewise when the analysis was restricted to only pulmonary postoperative complications.

"In conclusion, there is currently no suggestion, from any single study or from combinations of studies, that quitting smoking shortly before surgery increases postoperative complications," the investigators said (Arch. Intern. Med. 2011 [doI:10.1001/archinternmed.2011.97]).

The reluctance to allow or encourage smoking cessation shortly before surgery is based on unconfirmed assumptions. Only one study in the literature has directly examined mucociliary clearance in surgical patients shortly after smoking cessation, and that study found no significant difference between surgical patients who had recently quit and those who continued to smoke, Ms. Myers and her associates noted.

"No data are available on the effects of only a few days' abstinence from smoking. Early abstinence generates more intense withdrawal discomfort, but there is no clear rationale to translate into postoperative complications," they added.

However, they acknowledged that their study is limited by its observational nature and by the small number of studies available for review that have evaluated this issue. "Our findings are necessarily tentative and may be modified when more data become available," the researchers said.

"Dr. Richard Fischel, FCCP, comments: The News was eagerly anticipated and extremely well received. In November 2010, the Data and Safety Monitoring Board of the National Lung Screening Trial stopped the study and released the results. It appears that annual screening low-dose CT scans can save about 32,000 lives when compared with annual chest x-rays in a defined patient population over a defined period of time. This mortality benefit was the missing piece of information. Since screening for lung cancer is not without risk (cost, false positives, anxiety, and radiation exposure), it was difficult to recommend screening without knowing if a mortality benefit could be anticipated. Even with the positive NLST results, however, a blanket recommendation for annual CT screening is not currently prudent. The NLST study involved a specific population and therefore may not be applicable to all. Fortunately, help is on the way. A multisociety task force has been formed and is poised to review the full study results when available. The plan is to then rapidly formulate and publish guidelines for lung cancer screening. Additionally, the third edition of the ACCP's Evidence-based Guidelines on the Diagnosis and Management of Lung Cancer is being prepared. The new "Screening for Lung Cancer" chapter will be helpful to front-line clinicians. So encourage your patients to stop smoking and look for guidelines in the near future."

"CT Trial Said to Change Lung Ca Screening Landscape"

BY MITCHELL L. ZOLER
Elsevier Global Medical News

APRIL 2011 • CHEST PHYSICIAN

BY MARY ANN MOON
Elsevier Global Medical News

PULMONARY MEDICINE

Dr. W. Michael Alberts, FCCP, comments: The news was eagerly anticipated and extremely well received. In November 2010, the Data and Safety Monitoring Board of the National Lung Screening Trial stopped the study and released the results. It appears that annual screening low-dose CT scans can save about 32,000 lives when compared with annual chest x-rays in a defined patient population over a defined period of time. This mortality benefit was the missing piece of information. Since screening for lung cancer is not without risk (cost, false positives, anxiety, and radiation exposure), it was difficult to recommend screening without knowing if a mortality benefit could be anticipated. Even with the positive NLST results, however, a blanket recommendation for annual CT screening is not currently prudent. The NLST study involved a specific population and therefore may not be applicable to all. Fortunately, help is on the way. A multisociety task force has been formed and is poised to review the full study results when available. The plan is to then rapidly formulate and publish guidelines for lung cancer screening. Additionally, the third edition of the ACCP's Evidence-based Guidelines on the Diagnosis and Management of Lung Cancer is being prepared. The new "Screening for Lung Cancer" chapter will be helpful to front-line clinicians. So encourage your patients to stop smoking and look for guidelines in the near future.
There is much debate over certain aspects of the prevention and treatment of venous thromboembolism. However, most physicians agree that pulmonary embolism (PE) is a serious and potentially fatal condition, with approximately 300,000 patient deaths nationwide each year. Most of these deaths occur in hospitalized patients, and PE is considered to be the leading cause of preventable in-hospital mortality in the United States.

More than 12 million patients admitted to hospitals across the country are known to be at high risk of pulmonary embolism and need prophylaxis (Am. J. Hematol. 2007;82:777-82).

The most recommended therapy, based on the ACCP guidelines, is the use of heparin or low-molecular-weight heparin as prophylactic anticoagulation (Chest 2008;133:454S-545S). An alternative for patients who cannot be anticoagulated, inferior vena cava (IVC) filters are an effective alternative for preventing pulmonary embolism.

The incidence of PE in patients who have vena cava filters in multiple clinical trials is about 1.3%, which is similar to the incidence reported in the PREPIC (Prevention of Recurrent Pulmonary Embolism by Vena Cava Interruption) study, a trial that randomized patients to anticoagulation plus a vena cava filter or to anticoagulation alone. In this study, the rates of PE during the first 12 days in patients with filters was 1.1%, and lower than in patients receiving anticoagulation alone (N. Engl. J. Med. 1998;338:409-16).

The research on IVC filters has not kept pace with the increasing clinical application of these devices. Why is there no randomized, clinical trial studying the use of filters?

In my opinion, it is because trials are extremely complicated to do in this population of patients. These are patients who have a high risk of venous thromboembolism, who already have a VTE or pulmonary embolism, and who can’t safely receive anticoagulation for many reasons, such as multiple trauma with bleeding, multiple operations, or intracerebral hemorrhage.

These patients are at high risk for developing a PE and something must be done for them. If we can’t give anticoagulation, we can protect them with the use of IVC filters.

Only about 250,000 of the 12 million at-risk patients are receiving vena cava filters, and complications, even if considered severe, occur in fewer than 3% of the patients who receive filters as prophylaxis. The complications from vena cava filters are related to the period of time for which we use these devices, with few reported complications during the first 30 days. In some cases, the filters are used for a short period of time and are removed when the patient can go on anticoagulation therapy, or when he or she no longer has significant risk of VTE.

In my opinion, the IVC filters are effective for preventing a pulmonary embolism and are safe for most of these high-risk patients.

In conclusion, the significant alarm about filter use is mostly related to the long-term complications and the lack of randomized studies evaluating their effectiveness. Although these devices are complicated, that is not to say that they are not useful in a select group of patients, most of whom are in critical care or have contraindications to anticoagulation therapy.

If we monitor these patients closely, follow them with prophylactic anticoagulation, and improve the rates of IVC filter retrieval, we can balance the risk-benefit profile of these devices, and they will continue to be considered a good alternative for high-risk patients.

Don’t Miss These Sessions

**IVC Filters Still Have a Role for Some Patients**

LUIS ANGEL, M.D.

Dr. Angel is the director of the lung transplantation program in the department of medicine and CT surgery at the University of Texas Health Science Center in San Antonio, and works with a company developing products for critically ill patients, including a vena cava filter.
SIR, ACCP Vena Cava Filter Guidelines Diverge

BY MITCHEL L. ZOLER
Eliezer Global Medical News

MIAMI BEACH – Two major U.S. medical societies have released guidelines on who patients need an inferior vena cava filter.

The current, published guidelines of the American College of Chest Physicians (ACCP) and the Society of Interventional Radiology (SIR) lack agreement on the indications for placement of inferior vena cava filters during routine practice. And the implications of the contradictory guidelines are growing because use of inferior vena cava filters has risen significantly in recent years, Dr. Amanjot S. Baadh and his associates said in a poster they presented at ISET 2011, an international symposium on endovascular therapy.

Their analysis of 187 of these filters placed by interventional radiologists working at Lenox Hill Hospital in New York during January 2008–April 2010 showed that the hospital staff ordered 106 filters (57%) for indications not approved by the ACCP guidelines (Chest 2008;131:1083-1095) and 39 filters (21%) not in compliance with the SIR guidelines (J Vasc Interv Radiol. 2006;17:449-459), reported Dr. Baadh, a physician at Lenox Hill, and his associates in the hospital’s department of medicine. The review showed that 36% of the placed filters met SIR criteria for appropriate placement but failed to fall within an indication sanctioned by the ACCP.

The findings highlight a wide disparity in national guidelines, and they suggest a need for standardization of current guidelines espoused by professional societies, the researchers said in their poster.

Most of the filter placements that met the SIR guidelines but fell outside of the indications approved by the ACCP were done in patients judged to have failed risks, patients who had failed anticoagulation management or were noncompliant with anticoagulation medications, and patients with limited cardiopulmonary reserve.

Dr. Baadh and his associates reviewed 443 inferior vena cava filters placed at their hospital during the study period. They excluded 230 of these cases because the filters had not been placed by a member of the interventional radiology staff. They excluded another 26 cases because of incomplete patient records. The patients who received the 187 filters included in the analysis had an average age of 75 years, and 56% were women.

The analysis also showed a statistically significant link between which hospital service initiated the order for filter placement and compliance with the indication guidelines. About three-quarters of the patients who received filters included in the analysis were in a ward served by the internal medicine department or one of its subspecialties, and these patients received 87% of the 187 filters included in the analysis. The filters ordered by physicians from medicine or a medicine subspecialty met the SIR guideline criteria in 84% of cases and the ACCP criteria in 46% of cases. In contrast, the smaller number of patients who received filters ordered by physicians not from medicine or a subspecialty met the SIR criteria in 46% of cases and met the ACCP criteria in 25% of cases.

Dr. Baadh said that he had no disclosures.

Survey Sheds Light on Vena Cava Filter Practices

BY DOUG BRUNK
Eliezer Global Medical News

SAN DIEGO – In the hands of experienced vascular surgeons, the use of retrievable inferior vena cava filters was less common than with other specialists, except in trauma or bariatric cases, and superior vena cava filter placement was very rare.

Vena cava filter (VCF) “use has skyrocketed over the past 20 years with percutaneous insertion, low-profile retrievable devices, relative and prothrombotic indications, and other interventionists now placing filters,” Dr. Mark Friedell said at the annual meeting of the American Venous Forum.

However, in August 2010 the Food and Drug Administration said it had received 921 reports of adverse events with inferior vena cava (IVC) filters since 2005, and recommended that patients be referred for removal of retrievable filters when feasible and clinically indicated.

Dr. Friedell, director of surgical education for Orlando Health, and his associate, Dr. Peter Nelson, assistant professor of vascular surgery at the University of Florida, Gainesville, sent a 17-question survey about VCF practices to all 276 members of the Southern Association for Vascular Surgery, an organization composed exclusively of board-certified vascular surgeons. Of the 276 members, 126 responded, for a response rate of 46%.

When asked about the IVC, respondents cited the Greenfield filter as their preferred permanent device (31%), followed by a variety of retrievable devices. Half of the respondents said that they rarely placed retrievable filters, 26% said that they placed them selectively, and 24% said that they usually placed them. They cited the Bard as their preferred retrievable filter (45%).

Despite the fact that 52% and 46% of respondents placed VCFs in trauma and bariatric patients, respectively, filters were placed for prophylactic indications less than 50% of the time by 63% of respondents.

Continued on following page
Remove IVC Filters Promptly to Avoid Complications

BY M. ALEXANDER OTTO
Elsiever Global Medical News

HUNTINGTON BEACH, CALIF. — Reversible inferior vena cava filters should be removed once the acute risk of pulmonary embolism or deep vein thrombosis has passed, instead of being left in patients indefinitely, according to Dr. J. Curtis, a vascular surgeon at Washington University, St. Louis.

Despite the dearth of data about long-term risks, there are reports of filters thrombosing, migrating, fragmenting, and embolizing, with severe complications. Use of the filters has grown in recent years, and currently in U.S. patients, only about half of them are removed when no longer needed, he said (J Hosp Med. 2009;4:414-8).

‘That’s notminor, to have a piece of your filter in your heart.’

DR. CURCI

just based on the fact that we don’t have good long-term data, the answer is yes,” he said, noting that filter removal is “fast, easy, and billable,” with potentially an 85% or better retrieval rate.

About 60 embolizations to the heart have been reported over the past 15 years. Such reports ‘need to be scaring the retrieval rate.

He said, noting that filters should not be used as permanent filters. As with other antibacterial drugs, tigecycline can be absorbed with slight reductions in fetal weights and an increased incidence of minor skeletal anomalies (delays in ossification) at exposures of 5 times and 1 times the human daily dose based on AUC in rats and rabbits, respectively.

In patients with severe hepatic impairment (Child Pugh C), the initial dose of tigecycline should be 100 mg followed by 75 mg every 12 hours. Patients with moderate hepatic impairment (Child Pugh B) should be treated with caution and monitored for treatment response [see Dosage and Administration].

Warning and Precautions

In patients with severe hepatic impairment (Child Pugh C), the initial dose of tigecycline should be 100 mg followed by 75 mg every 12 hours. Patients with moderate hepatic impairment (Child Pugh B) should be treated with caution and monitored for treatment response [see Dosage and Administration].

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The following adverse reactions were reported infrequently (<2%) in patients receiving TYGACIL: chest pain, dyspnea, and syncope. The following adverse reactions have been reported in <1% of patients receiving TYGACIL: myocardial infarction (MI), pericarditis, cholecystitis, and phlebitis.

In bone (all Bard filters), and 9 cases of uterine perforation (all Bard filters), and 9 cases of uterine perforation (all Bard filters), and 9 cases of uterine perforation (all Bard filters).

In cIAI studies (n=1642), 6 patients treated with TYGACIL (100 mg initially, then 50 mg every 12 hours) or a comparator. In addition, 2 patients treated with imipenem/cilastatin presented with intestinal perforations and developed sepsis/infections (cIAI) secondary to clinically apparent intestinal perforation. In cIAI studies (n=1642), 6 patients treated with TYGACIL (100 mg initially, then 50 mg every 12 hours) or a comparator. In addition, 2 patients treated with imipenem/cilastatin presented with intestinal perforations and developed sepsis/
TYGACIL is in the 2009 IDSA/SIS guidelines for cIAI and the 2009 SIS guidelines for cSSSI.¹²

*TYGACIL does not cover Pseudomonas aeruginosa.

**TYGACIL is indicated for the treatment of adults with:**

- **Complicated skin and skin structure infections** caused by Escherichia coli, Enterococcus faecalis (vancomycin-susceptible isolates), Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus agalactiae, Streptococcus anginosus gr. (includes S. anginosus, S. intermedius, and S. constellatus), Streptococcus pyogenes, Enterobacter cloacae, Klebsiella pneumoniae, and Bacteroides fragilis

- **Complicated intra-abdominal infections** caused by Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Enterococcus faecalis (vancomycin-susceptible isolates), Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus anginosus gr. (includes S. anginosus, S. intermedius, and S. constellatus), Bacteroides fragilis, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Clostridium perfringens, and Peptostreptococcus micros

- **Community-acquired bacterial pneumonia** caused by Streptococcus pneumoniae (penicillin-susceptible isolates), including cases with concurrent bacteremia, Haemophilus influenzae (beta-lactamase negative isolates), and Legionella pneumophila

**Important Safety Information**

- **TYGACIL is contraindicated in patients with known hypersensitivity to tigecycline.
- Anaphylaxis/anaphylactoid reactions have been reported with nearly all antibacterial agents, including TYGACIL, and may range in severity from mild diarheaa to fatal colitis.
- The safety and efficacy of TYGACIL in patients with hospital-acquired pneumonia have not been established.
- The safety and efficacy of TYGACIL in patients below age 18 and lactating women have not been established.
- Concurrent use of antibacterial drugs with oral contraceptives may render oral contraceptives less effective.

**Please see brief summary of Prescribing Information on adjacent page.**