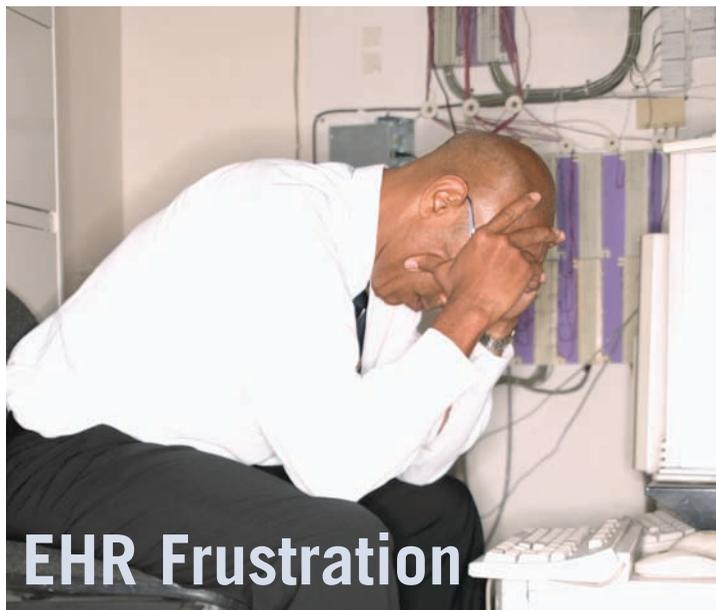




CHEST *Physician*

THE NEWSPAPER OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS



One in three profess loss of productivity

BY ALICIA AULT
IMNG Medical News

NEW ORLEANS – Frustrated with your electronic medical record system? Getting increasingly irritated? You most definitely are not alone.

A survey of thousands of physicians across multiple specialties shows that user satisfaction with electronic health records fell 12% from 2010 to 2012.

The survey was conducted by the American College of Physicians and AmericanEHR Partners, an online agent that helps physicians select and evaluate health information technology. It is supported by 16 medical so-

cieties and five health IT organizations.

“Dissatisfaction is increasing regardless of practice type or EHR system,” said Dr. Michael S. Barr, who leads ACP’s Medical Practice, Professionalism & Quality division. “These findings highlight the need for the Meaningful Use program and EHR manufacturers to focus on improving EHR features and usability to help reduce inefficient work flows, improve error rates and patient care, and for practices to recognize the importance of ongoing training at all stages of EHR adoption,” said Dr. Barr, in a

See **Survey** • page 5

Mycophenolate aids FVC in interstitial lung disease

At 1 year, mean FVC% rose by 4.9%.

BY DENISE NAPOLI
IMNG Medical News

Mycophenolate mofetil was associated with stabilization or improvement of predicted forced vital capacity in patients with connective tissue disease–associated interstitial lung disease.

Moreover, the drug was safe and well tolerated in this population over a median 2.5 years of use, wrote Dr. Aryeh Fischer and his colleagues in a study published online in the *Journal of Rheumatology*.

In the retrospective study, the drug “was well tolerated and efficacious and allowed for corticosteroid

tapering,” they added. “Prospective studies of MMF (mycophenolate mofetil) are indicated to further define the role of MMF in the treatment of CTD-ILD (connective tissue disease–associated interstitial lung disease).”

Dr. Fischer of the autoimmune and interstitial lung disease program at National Jewish Health in Denver and his colleagues looked at the medical records of all patients who received MMF and were treated by an interstitial lung disease specialist at his facility between January 2008 and January 2011.

See **Lung disease** • page 8

Macrolides tame bronchiectasis

BY SARA FREEMAN
IMNG Medical News

Low-dose macrolide antibiotics given for 12 months significantly reduced pulmonary exacerbations in non-cystic fibrosis bronchiectasis, according to findings from two random-

ized, controlled trials. However, antibiotic resistance concerns could temper the use of such an approach in clinical practice, the studies’ investigators cautioned.

In BLESS (Bronchiectasis and Low-Dose Erythromycin Study), the annualized mean rate of

pulmonary exacerbations per patient per year was 1.29 in patients treated with erythromycin, compared with 1.97 in those given placebo (*JAMA* 2013;309:1260-7).

In the BAT (Bronchiectasis and Long-Term

See **Bronchiectasis** • page 9

INSIDE

News

Glucocorticoids

All glucocorticoids linked to at least twice the risk of VTE. • 2

Azithromycin and arrhythmia

Azithromycin is associated with risk for fatal arrhythmia, FDA says. • 3

Practice Trends

EHR audits

CMS takes a close look before paying out incentives. • 5

Pulmonary Medicine Steroids and CAP

Steroids may decrease length of stay in pneumonia. • 8

News From the College

Pulmonary perspectives

Resurgency bronchiectasis. • 22

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All glucocorticoids linked to increased risk of VTE

BY MARY ANN MOON

IMNG Medical News

Use of all glucocorticoids is associated with a two- to threefold increased risk of venous thromboembolism, depending on the type of glucocorticoid, the route of administration, and other factors, according to a report in JAMA.

Systemic glucocorticoids, as compared with inhaled ones or glucocorticoids that act on the intestines, were associated with the highest risk of VTE. New use was linked to higher risk than continuing or past use, and the VTE risk increased as the dose of glucocorticoids increased, said Sigrun A. Johannesdottir of the department of clinical epidemiology, Aarhus (the Netherlands) University Hospital, and her associates.

These findings are from a population-based case-control study, which cannot prove a cause-and-effect relationship. Moreover, it is difficult to statistically account for all the confounding effects of patients' underlying disease – the reason they were taking glucocorticoids in the first place – because such disorders raise the risk of VTE directly or cause immobility that in turn can lead to VTE.

However, the timing of this adverse effect, the strength of the association across all types of glucocorticoids, and the fact that the association persisted after data were adjusted to account for multiple confounders all “increase our confidence that the results reflect a true biological effect,” investigators said. “Clinicians should be aware of this association,” they noted.

Ms. Johannesdottir and her col-

VITALS

Major finding: New use of systemic glucocorticoids was associated with the highest risk for VTE, with an estimated incidence rate ratio of 3.06, compared with nonuse.

Data source: A national population-based case-control study involving 38,765 Danish adults who developed VTE in a 7-year period and 387,650 controls.

Disclosures: This study was supported by the Clinical Epidemiological Research Foundation at Aarhus University Hospital. No relevant conflicts of interest were reported.

leagues used data from several Danish national medical registries to identify all adults who were diagnosed with VTE in Denmark in 2005-2012, all patients who filled prescriptions for glucocorticoids during the study period, and all indications for the drugs as well as all relevant comorbidities. They matched 10 control subjects for age and sex from the general population to each study subject.

A total of 38,765 VTE cases and 387,650 controls were included in this study. The median age was 67 years, and slightly more than half of those studied were women.

All glucocorticoid users were found to be at increased risk for VTE, particularly for pulmonary embolism, compared with nonusers, researchers said.

Systemic glucocorticoids, including betamethasone, methylprednisolone, prednisolone, prednisone, triamci-

nolone, and hydrocortisone, raised VTE risk to the highest degree. (No subjects filled prescriptions.)

Inhaled corticosteroids and corticosteroids that act on the intestines also raised VTE risk significantly. Among the systemic glucocorticoids, prednisolone and prednisone raised VTE risk the most.

New use of glucocorticoids was associated with the highest risk of VTE, but current use, continuing use, and former use also raised the risk significantly. Oral formulations were associated with the highest risk of VTE, but injectable formulations also raised the risk significantly, Ms. Johannesdottir and her associates reported (JAMA Intern. Med. 2013 April 1 [doi:10.1001/jamainternmed.2013.122]).

In particular, new use of systemic glucocorticoids was associated with the highest risk for VTE, with an estimated incidence rate ratio of 3.06, compared with nonuse of glucocorticoids. The risk of VTE also rose with increasing cumulative doses of all glucocorticoids. In further analyses, elevated risk for VTE persisted across all the subgroups that were examined.

The findings did not change appreciably in a sensitivity analysis that included only subjects who took glucocorticoids for at least 5 years.

“The temporality of the association (i.e., the strongest effect at initiation of therapy and the absence of an effect after discontinuation) is in line with an effect on coagulation,” Ms. Johannesdottir and her associates said.

IN THIS ISSUE

News From the College • 16

Critical Care Commentary

If done right, simulation education can be effective and fun • 18

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FDA issues warning on azithromycin arrhythmia risk

BY ELIZABETH MEHCATIE
IMNG Medical News

Use of the antibiotic azithromycin is associated with an increased risk for fatal arrhythmia, according to a warning issued by the Food and Drug Administration.

The FDA has taken the step to strengthen the existing warning on the drug's label about the risk of QT interval prolongation and torsades de pointes. In general, the people at greatest risk are those with known risk factors such as existing QT interval prolongation, low blood levels of potassium or magnesium, a slower than normal heart rate, or use of certain drugs used to treat abnormal heart rhythms or arrhythmias, according to the FDA.

Macrolides or nonmacrolides such as fluoroquinolones are among the antibiotics that physicians might consider using as alternatives to azithromycin, but there is no easy answer to which antibiotic to use in at-risk patients since these agents carry their own increased risk for QT prolongation, according to the FDA.

The FDA's statement is a result of

the agency's review of a study showing that the risk of cardiovascular deaths, and the risk of death from any cause, was increased among those treated with a 5-day course of azithromycin, compared with people

treated with amoxicillin, ciprofloxacin, levofloxacin, or no drug (N. Engl. J. Med. 2012;366:1881-90).

When compared with levofloxacin, the risk of cardiovascular death asso-

ciated with azithromycin was similar. When compared with those who took no antibiotic, the risk of cardiovascular death was increased by 2.88 and the risk of death from any cause

Continued on following page



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COMMENTARY

Dr. Jun Chiong, FCCP, comments: The FDA issued a warning that azithromycin can cause potentially fatal irregular heart rhythms and health care professionals should consider the risk of fatal heart rhythms with azithromycin when considering treatment options for patients who are already at risk for cardiovascular events.



This news has some patients and parents concerned but that doesn't mean the antibiotic is always bad or unsafe. With widespread use of antibiotics, it is also important to do controlled studies that will establish "number needed to harm" in addition to number "needed to treat."

It's very good that the public is aware of all the possible adverse side effects of the medication. However, from aspirin to azithromycin, there can be all kinds of adverse reactions.

Important Safety Information

Spiriva® HandiHaler® (tiotropium bromide inhalation powder) is contraindicated in patients with a history of hypersensitivity to tiotropium, ipratropium (atropine derivatives), or any components of SPIRIVA capsules. SPIRIVA HandiHaler is not indicated for the initial treatment of acute episodes of bronchospasm, i.e., rescue therapy.

Immediate hypersensitivity reactions, including urticaria, angioedema (swelling of lips, tongue or throat), rash, bronchospasm, anaphylaxis, or itching may occur after administration of SPIRIVA. Additionally, inhaled medicines, including SPIRIVA, may cause paradoxical bronchospasm. If any of these occurs, treatment with SPIRIVA should be stopped and other treatments considered.

Use with caution in patients with severe hypersensitivity to milk proteins.

SPIRIVA HandiHaler should be used with caution in patients with narrow-angle glaucoma or urinary retention. Prescribers should instruct patients to consult a physician immediately should any signs or symptoms of narrow-angle glaucoma, or prostatic hyperplasia or bladder-neck obstruction occur.

SPIRIVA may interact additively with concomitantly used anticholinergic medications. Avoid coadministration with other anticholinergic-containing drugs.

The most common adverse reactions in the 1-year placebo-controlled trials were dry mouth, upper respiratory tract infection, sinusitis, pharyngitis, non-specific chest pain, and urinary tract infection. In addition, the most commonly reported adverse reactions from the 4-year trial not included above were headache, constipation, depression, insomnia, and arthralgia.

Indication

SPIRIVA HandiHaler is indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema, and for reducing COPD exacerbations.

Please see accompanying Brief Summary of full Prescribing Information.

Visit SPIRIVA.com to find out how SPIRIVA can help your COPD patients breathe better

References: 1. SPIRIVA Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; 2012. 2. Data on file, Boehringer Ingelheim Pharmaceuticals, Inc.



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(tiotropium bromide inhalation powder)

Continued from previous page

was increased by 1.85 among those treated with azithromycin, both statistically significant effects.

Although this study had limitations, it was “methodologically sound and supports the validity of the overall findings,” and the excess

risk of cardiovascular death, “especially of sudden death, is consistent with arrhythmias from drug-related QT prolongation,” the FDA said.

In formulating its warning, the FDA also considered findings from a clinical QT study conducted by the manufacturer. The results of the manufacturer’s study, which have

been added to the drug label, indicated that azithromycin prolonged the QTc interval, according to the FDA statement.

The FDA statement, issued March 12, includes a list of specific groups at increased risk for torsades de pointes, including those with known prolongation of the QT interval, his-

tory of torsades de pointes, congenital long QT syndrome, bradyarrhythmias, or uncompensated heart failure, as well as those who are on drugs known to prolong the QT interval.

Also at risk are people with ongoing proarrhythmic conditions, including uncorrected hypokalemia

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

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INDICATIONS AND USAGE: SPIRIVA HandiHaler (tiotropium bromide inhalation powder) is indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. SPIRIVA HandiHaler is indicated to reduce exacerbations in COPD patients.

CONTRAINDICATIONS: SPIRIVA HandiHaler is contraindicated in patients with a hypersensitivity to tiotropium, ipratropium, or any components of SPIRIVA capsules [see WARNINGS AND PRECAUTIONS]. In clinical trials and postmarketing experience with SPIRIVA HandiHaler, immediate hypersensitivity reactions, including angioedema (including swelling of the lips, tongue, or throat), itching, or rash have been reported.

WARNINGS AND PRECAUTIONS: Not for Acute Use: SPIRIVA HandiHaler is intended as a once-daily maintenance treatment for COPD and is not indicated for the initial treatment of acute episodes of bronchospasm (i.e., rescue therapy). **Immediate Hypersensitivity Reactions:** Immediate hypersensitivity reactions, including urticaria, angioedema (including swelling of the lips, tongue, or throat), rash, bronchospasm, anaphylaxis, or itching, may occur after administration of SPIRIVA HandiHaler. If such a reaction occurs, therapy with SPIRIVA HandiHaler should be stopped at once and alternative treatments should be considered. Given the similar structural formula of atropine to tiotropium, patients with a history of hypersensitivity reactions to atropine should be closely monitored for similar hypersensitivity reactions to SPIRIVA HandiHaler. In addition, SPIRIVA HandiHaler should be used with caution in patients with severe hypersensitivity to milk proteins. **Paradoxical Bronchospasm:** Inhaled medicines, including SPIRIVA HandiHaler, can produce paradoxical bronchospasm. If this occurs, treatment with SPIRIVA HandiHaler should be stopped and other treatments considered. **Worsening of Narrow-Angle Glaucoma:** SPIRIVA HandiHaler should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a physician immediately should any of these signs or symptoms develop. **Worsening of Urinary Retention:** SPIRIVA HandiHaler should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of prostatic hyperplasia or bladder-neck obstruction (e.g., difficulty passing urine, painful urination). Instruct patients to consult a physician immediately should any of these signs or symptoms develop. **Renal Impairment:** As a predominantly renally excreted drug, patients with moderate to severe renal impairment (creatinine clearance of ≤ 50 mL/min) treated with SPIRIVA HandiHaler should be monitored closely for anticholinergic side effects.

ADVERSE REACTIONS: The following adverse reactions are described, or described in greater detail, in other sections: Immediate hypersensitivity reactions [see Warnings and Precautions]; Paradoxical bronchospasm [see Warnings and Precautions]; Worsening of narrow-angle glaucoma [see Warnings and Precautions]; Worsening of urinary retention [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. **6-Month to 1-Year Trials:** The data described below reflect exposure to SPIRIVA HandiHaler in 2663 patients. SPIRIVA HandiHaler was studied in two 1-year placebo-controlled trials, two 1-year active-controlled trials, and two 6-month placebo-controlled trials in patients with COPD. In these trials, 1308 patients were treated with SPIRIVA HandiHaler at the recommended dose of 18 mcg once a day. The population had an age ranging from 39 to 87 years with 65% to 85% males, 95% Caucasian, and had COPD with a mean pre-bronchodilator forced expiratory volume in one second (FEV₁) percent predicted of 39% to 43%. Patients with narrow-angle glaucoma, or symptomatic prostatic hypertrophy or bladder outlet obstruction were excluded from these trials. An additional 6-month trial conducted in a Veteran’s Affairs setting is not included in this safety database because only serious adverse events were collected. The most commonly reported adverse drug reaction was dry mouth. Dry mouth was usually mild and often resolved during continued treatment. Other reactions reported in individual patients and consistent with possible anticholinergic effects included constipation, tachycardia, blurred vision, glaucoma (new onset or worsening), dysuria, and urinary retention. Four multicenter, 1-year, placebo-controlled and active-controlled trials evaluated SPIRIVA HandiHaler in patients with COPD. Table 1 shows all adverse reactions that occurred with a frequency of $\geq 3\%$ in the SPIRIVA HandiHaler group in the 1-year placebo-controlled trials where the rates in the SPIRIVA HandiHaler group exceeded placebo by $\geq 1\%$. The frequency of corresponding reactions in the ipratropium-controlled trials is included for comparison.

Table 1 Adverse Reactions (% Patients) in One-Year COPD Clinical Trials

| Body System (Event) | Placebo-Controlled Trials | | Ipratropium-Controlled Trials | |
|--|---------------------------|-------------------|-------------------------------|-----------------------|
| | SPIRIVA (n = 550) | Placebo (n = 371) | SPIRIVA (n = 356) | Ipratropium (n = 179) |
| Body as a Whole | | | | |
| Chest Pain (non-specific) | 7 | 5 | 5 | 2 |
| Edema, Dependent | 5 | 4 | 3 | 5 |
| Gastrointestinal System Disorders | | | | |
| Dry Mouth | 16 | 3 | 12 | 6 |
| Dyspepsia | 6 | 5 | 1 | 1 |
| Abdominal Pain | 5 | 3 | 6 | 6 |
| Constipation | 4 | 2 | 1 | 1 |
| Vomiting | 4 | 2 | 1 | 2 |
| Musculoskeletal System | | | | |
| Myalgia | 4 | 3 | 4 | 3 |
| Resistance Mechanism Disorders | | | | |
| Infection | 4 | 3 | 1 | 3 |
| Moniliasis | 4 | 2 | 3 | 2 |
| Respiratory System (Upper) | | | | |
| Upper Respiratory Tract Infection | 41 | 37 | 43 | 35 |
| Sinusitis | 11 | 9 | 3 | 2 |
| Pharyngitis | 9 | 7 | 7 | 3 |
| Rhinitis | 6 | 5 | 3 | 2 |
| Epistaxis | 4 | 2 | 1 | 1 |
| Skin and Appendage Disorders | | | | |
| Rash | 4 | 2 | 2 | 2 |
| Urinary System | | | | |
| Urinary Tract Infection | 7 | 5 | 4 | 2 |

Rx only

Arthritis, coughing, and influenza-like symptoms occurred at a rate of $\geq 3\%$ in the SPIRIVA HandiHaler treatment group, but were $< 1\%$ in excess of the placebo group. Other reactions that occurred in the SPIRIVA HandiHaler group at a frequency of 1% to 3% in the placebo-controlled trials where the rates exceeded that in the placebo group include: **Body as a Whole:** allergic reaction, leg pain; **Central and Peripheral Nervous System:** dysphonia, paresthesia; **Gastrointestinal System Disorders:** gastrointestinal disorder not otherwise specified (NOS), gastroesophageal reflux, stomatitis (including ulcerative stomatitis); **Metabolic and Nutritional Disorders:** hypercholesterolemia, hyperglycemia; **Musculoskeletal System Disorders:** skeletal pain; **Cardiac Events:** angina pectoris (including aggravated angina pectoris); **Psychiatric Disorder:** depression; **Infections:** herpes zoster; **Respiratory System Disorder (Upper):** laryngitis; **Vision Disorder:** cataract. In addition, among the adverse reactions observed in the clinical trials with an incidence of $< 1\%$ were atrial fibrillation, supraventricular tachycardia, angioedema, and urinary retention. In the 1-year trials, the incidence of dry mouth, constipation, and urinary tract infection increased with age [see Use in Specific Populations]. Two multicenter, 6-month, controlled studies evaluated SPIRIVA HandiHaler in patients with COPD. The adverse reactions and the incidence rates were similar to those seen in the 1-year controlled trials. **4-Year Trial:** The data described below reflect exposure to SPIRIVA HandiHaler in 5992 COPD patients in a 4-year placebo-controlled trial. In this trial, 2986 patients were treated with SPIRIVA HandiHaler at the recommended dose of 18 mcg once a day. The population had an age range from 40 to 88 years, was 75% male, 90% Caucasian, and had COPD with a mean pre-bronchodilator FEV₁ percent predicted of 40%. Patients with narrow-angle glaucoma, or symptomatic prostatic hypertrophy or bladder outlet obstruction were excluded from these trials. When the adverse reactions were analyzed with a frequency of $\geq 3\%$ in the SPIRIVA HandiHaler group where the rates in the SPIRIVA HandiHaler group exceeded placebo by $\geq 1\%$, adverse reactions included (SPIRIVA HandiHaler, placebo): pharyngitis (12.5%, 10.8%), sinusitis (6.5%, 5.3%), headache (5.7%, 4.5%), constipation (5.1%, 3.7%), dry mouth (5.1%, 2.7%), depression (4.4%, 3.3%), insomnia (4.4%, 3.0%), and arthralgia (4.2%, 3.1%). **Additional Adverse Reactions:** Other adverse reactions not previously listed that were reported more frequently in COPD patients treated with SPIRIVA HandiHaler than placebo include: dehydration, skin ulcer, stomatitis, gingivitis, oropharyngeal candidiasis, dry skin, skin infection, and joint swelling. **Postmarketing Experience:** Adverse reactions have been identified during worldwide post-approval use of SPIRIVA HandiHaler. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These adverse reactions are: application site irritation (glossitis, mouth ulceration, and pharyngolaryngeal pain), dizziness, dysphagia, hoarseness, intestinal obstruction including ileus paralytic, intraocular pressure increased, oral candidiasis, palpitations, pruritus, tachycardia, throat irritation, and urticaria.

DRUG INTERACTIONS: Sympathomimetics, Methylxanthines, Steroids: SPIRIVA HandiHaler has been used concomitantly with short-acting and long-acting sympathomimetic (beta-agonists) bronchodilators, methylxanthines, and oral and inhaled steroids without increases in adverse drug reactions. **Anticholinergics:** There is potential for an additive interaction with concomitantly used anticholinergic medications. Therefore, avoid coadministration of SPIRIVA HandiHaler with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects [see Warnings and Precautions and Adverse Reactions]. **Cimetidine, Ranitidine:** No clinically significant interaction occurred between tiotropium and cimetidine or ranitidine.

USE IN SPECIFIC POPULATIONS: Pregnancy: Teratogenic Effects, Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. SPIRIVA HandiHaler should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. No evidence of structural alterations was observed in rats and rabbits at inhalation tiotropium doses of up to approximately 660 and 6 times the recommended human daily inhalation dose (RHDD) on a mg/m² basis, respectively. However, in rats, tiotropium caused fetal resorption, litter loss, decreases in the number of live pups at birth and the mean pup weights, and a delay in pup sexual maturation at inhalation tiotropium doses of approximately 35 times the RHDD on a mg/m² basis. In rabbits, tiotropium caused an increase in post-implantation loss at an inhalation dose of approximately 360 times the RHDD on a mg/m² basis. Such effects were not observed at inhalation doses of approximately 4 and 80 times the RHDD on a mg/m² basis in rats and rabbits, respectively. These dose multiples may be over-estimated due to difficulties in measuring deposited doses in animal inhalation studies. **Labor and Delivery:** The safety and effectiveness of SPIRIVA HandiHaler has not been studied during labor and delivery. **Nursing Mothers:** Clinical data from nursing women exposed to tiotropium are not available. Based on lactating rodent studies, tiotropium is excreted into breast milk. It is not known whether tiotropium is excreted in human milk, but because many drugs are excreted in human milk and given these findings in rats, caution should be exercised if SPIRIVA HandiHaler is administered to a nursing woman. **Pediatric Use:** SPIRIVA HandiHaler is approved for use in the maintenance treatment of bronchospasm associated with COPD and for the reduction of COPD exacerbations. COPD does not normally occur in children. The safety and effectiveness of SPIRIVA HandiHaler in pediatric patients have not been established. **Geriatric Use:** Of the total number of patients who received SPIRIVA HandiHaler in the 1-year clinical trials, 426 were < 65 years, 375 were 65 to 74 years, and 105 were ≥ 75 years of age. Within each age subgroup, there were no differences between the proportion of patients with adverse events in the SPIRIVA HandiHaler and the comparator groups for most events. Dry mouth increased with age in the SPIRIVA HandiHaler group (differences from placebo were 9.0%, 17.1%, and 16.2% in the aforementioned age subgroups). A higher frequency of constipation and urinary tract infections with increasing age was observed in the SPIRIVA HandiHaler group in the placebo-controlled studies. The differences from placebo for constipation were 0%, 1.8%, and 7.8% for each of the age groups. The differences from placebo for urinary tract infections were -0.6%, 4.6%, and 4.5%. No overall differences in effectiveness were observed among these groups. Based on available data, no adjustment of SPIRIVA HandiHaler dosage in geriatric patients is warranted. **Renal Impairment:** Patients with moderate to severe renal impairment (creatinine clearance of ≤ 50 mL/min) treated with SPIRIVA HandiHaler should be monitored closely for anticholinergic side effects [see Warnings and Precautions]. **Hepatic Impairment:** The effects of hepatic impairment on the pharmacokinetics of tiotropium were not studied.

OVERDOSAGE: High doses of tiotropium may lead to anticholinergic signs and symptoms. However, there were no systemic anticholinergic adverse effects following a single inhaled dose of up to 282 mcg tiotropium in 6 healthy volunteers. In a study of 12 healthy volunteers, bilateral conjunctivitis and dry mouth were seen following repeated once-daily inhalation of 141 mcg of tiotropium. **Accidental Ingestion: Acute intoxication by inadvertent oral ingestion of SPIRIVA capsules is unlikely since it is not well-absorbed systemically.** A case of overdose has been reported from postmarketing experience. A female patient was reported to have inhaled 30 capsules over a 2.5 day period, and developed altered mental status, tremors, abdominal pain, and severe constipation. The patient was hospitalized, SPIRIVA HandiHaler was discontinued, and the constipation was treated with an enema. The patient recovered and was discharged on the same day. No mortality was observed at inhalation tiotropium doses up to 32.4 mg/kg in mice, 267.7 mg/kg in rats, and 0.6 mg/kg in dogs. These doses correspond to 7300, 120,000, and 850 times the recommended human daily inhalation dose on a mg/m² basis, respectively. These dose multiples may be over-estimated due to difficulties in measuring deposited doses in animal inhalation studies.

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There is no easy answer to which antibiotic to use in at-risk patients since these agents carry their own increased risk for QT prolongation, according to the FDA.

or hypomagnesemia; those with clinically significant bradycardia; and patients treated with class IA (quinidine, procainamide) or class III (dofetilide, amiodarone, sotalol) antiarrhythmic drugs. Elderly patients and those with cardiac disease “may be more susceptible to the effects of arrhythmogenic drugs on the QT interval,” the statement adds.

This information has been added to the warnings and precautions section of the labels for azithromycin products – marketed as Zithromax and Zmax – which are approved for indications that include acute bacterial exacerbations of COPD, acute bacterial sinusitis, community-acquired pneumonia, pharyngitis/tonsillitis, uncomplicated skin and skin structure infections, and urethritis and cervicitis.

The FDA announcement is at www.fda.gov/downloads/Drugs/DrugSafety/UCM343347.pdf. Serious adverse events associated with azithromycin should be reported to the FDA’s MedWatch program at 800-332-1088 or www.fda.gov/medwatch/.

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Frustration, EHRs go hand in hand

Survey from page 1

statement issued along with the survey results.

The survey was released at the Healthcare Information and Management Systems Society Annual Conference and exhibition.

Dr. Alan Brookstone, a cofounder of AmericanEHR Partners, said at the meeting that satisfaction rates may be dropping in part because there had been so much adoption of technology so quickly. Also, it's not just the early adopters anymore, he said.

The largest number of respondents – almost 1,900 – was from primary care. Specialists, surgeons, hospital-based physicians, and psychiatrists were also represented.

The vast majority of respondents – 70% – were from practices with fewer than 10 physicians.

The number who said they intended to participate in meaningful use has grown over the past few years, with a full 82% saying they would apply for incentives paid by Medicare and Medicaid.

Satisfaction rates with current EHR systems were low across a spectrum of parameters. While 45% said they would recommend the product they use to a colleague, 39% said they would not. In 2010, more physicians said they'd recommend that system, while only 24% said they would urge against use.

Of those surveyed, 36% said that they had encountered unexpected events, problems, or costs after signing the initial contract for the system.

Physicians were especially frustrated with the systems' promise to decrease their workload. Thirty-four percent said they were dissatisfied with that promised ability, up from only 19% in 2010. Some respondents



'Dissatisfaction is increasing regardless of practice type or EHR system.'

DR. BARR

said that the EHR had decreased productivity and increased the amount of time needed to complete documentation. Fully a third of respondents said they had not returned to the productivity they had before they began to use the system.

About half of respondents were satisfied with functionality and ease of use, but a third were dissatisfied with those measures. That level of dissatisfaction was higher than it had been in 2010.

For instance, thirty-six percent said that it was difficult to reconcile an imported medication list with

medications listed in a patient record.

Overall, when compared with other specialties, primary care physicians were the most satisfied with their system's ability to improve patient care. Surgeons, representing about 660 respondents, were the least satisfied.

Good customer support and training for the EHR systems was rated as crucial to satisfaction. There was an 11% increase in dissatisfaction with customer support from 2010 to 2012. Thirty-three percent of respondents said they weren't happy with the customer support they received.

The number of practices using a patient portal increased by 20% from 2010 to 2012, rising to 40%. This is probably driven by the stage 2 meaningful use rules, which require physicians to be able to securely communicate with patients and for patients to be able to download and share their health information. Still, 50% of respondents did not have a portal.

Dr. Brookstone said the survey showed that vendors needed to better integrate functionality, improve training, and find ways to help physicians rebalance their workload.

If physicians' concerns aren't addressed, it will lead to a decline in willingness to use the systems, he said.

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COMMENTARY

Dr. Stuart M. Garay, FCCP, comments: The findings of this survey verify what doctors have been saying for several years.

The timeline for the government's meaningful use incentive program has forced many physicians to implement EHRs, when they and their office personnel were not ready. Hundreds of vendors have pelted physicians with empty promises. User unfriendliness, disrupted workflow, increased workload, and decreased productivity are frequent complaints heard throughout the country in doctors' offices. Documentation has become an exercise focused on checking the box on a list of "meaningful use objectives" instead of providing accurate recording of a patient's history. EHRs are not living up to their promise of paving a better way to practice medicine.

Because this survey crossed specialties and geography, it suggests that there is a systemic flaw in the current EHRs and their implementation. Other industries would not tolerate such disruption!



CMS audits EHR incentives – before paying them

BY ALICIA AULT
IMNG Medical News

NEW ORLEANS – Haven't received your meaningful use incentive? Check your mail for an audit letter.

If in January you submitted an attestation of meaningful use of your electronic health record – with an eye to reaping the federal health IT incentive – an audit letter may be on its way to you.

A contractor for the Centers for Medicare and Medicaid Services began sending audit letters this week to randomly selected Medicare-eligible professionals and hospitals, Elizabeth Holland, a director of the HIT Initiatives Group in the agency's Office of E-Health Standards and Services, said at the Healthcare Information and Management Systems Society annual conference. The audits could result in delays or ultimately, nonpayment, she said.

"We have a fiduciary responsibility to make sure that we are paying appropriately," Ms. Holland explained, adding that providers who were not selected for the audit have already received their payments.

Audit letters are being sent by Figliozi & Co. to Medicare-eligible hospitals and physicians. If recipients do not respond, "their payment will be held up until they respond and provide the documentation" to back up their attestation, Ms. Holland said. "If a certain amount of time goes by and they still don't respond, they will not be getting a payment."

These prepayment audits follow on the heels of postpayment audits that the CMS began in July

2012. Under that program, Figliozi & Co. audited Medicare-eligible professionals and states audited Medicaid-eligible professionals.

Ms. Holland said that more than 2,000 postpayment audits are underway; some are random and some are targeted. The data generated by the audits are, and will be, used to modify the agency's approach to meaningful use. For instance, one goal is to see whether providers are appropriately reporting measures, she said.

CMS also has found that professionals do not have the proper documentation to support what they are attesting to. In the next month, the CMS will issue guidance on what documentation is needed, Ms. Holland said.

She presented data showing that so far, 161,890 eligible professionals – out of 527,200 who are eligible – have attested to meaningful use. Most of those (161,677) did so successfully. About 200 were not successful.

Of the 5,011 hospitals that are eligible, 2,653 have been successful. None failed.

COMMENTARY

Dr. Stuart M. Garay, FCCP, comments: With the clock ticking away to qualify for the government's meaningful use incentive program, many physicians have recently "attested to meaningful use." Indeed, many have already "spent" this EHR incentive money – before they have actually received it. Beware! CMS has already and will continue to audit physicians who have attested to meaningful use.

Make sure your attestation does not get challenged!

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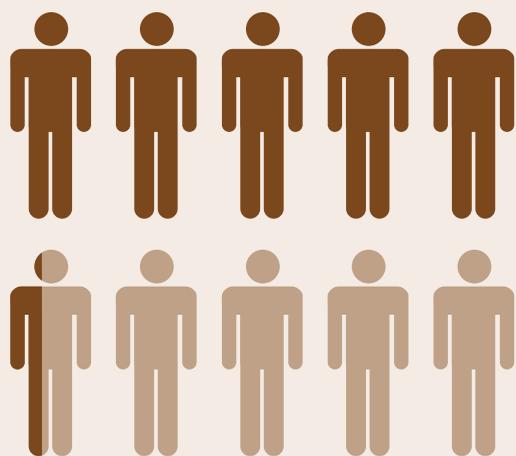
THORACIC ONCOLOGY UPDATE:

Molecular Biomarker Testing Is Essential for Non-Small Cell Lung Cancer Patients

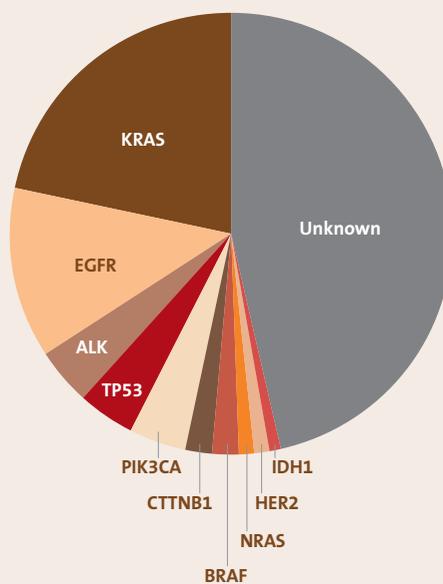
During the past decade the identification of molecular biomarkers for clinically relevant mutations or other genetic abnormalities in non-small cell lung cancer (NSCLC) has improved the understanding of lung cancer pathogenesis, and of the proliferation and survival of cancer cells.¹ This significant development is setting the stage for a paradigm shift toward the adoption of treatments directed to the particular genetic makeup of the tumor.^{1,2}

Over 50% of NSCLC Cases Are Linked to Known Molecular Biomarkers

According to recent studies, more than 50% of NSCLC cases are linked to one of at least 10 currently known biomarkers for NSCLC — and many of these patients may test positive for mutations or other genetic abnormalities that are “drivers” for their cancers and are treatable with approved biomarker-driven therapies or investigational agents in clinical trials.^{2,3}



At Least 10 Known Molecular Biomarkers in NSCLC³



Now that more than half of NSCLC cases can be linked to one or more of these biomarkers, it is possible to subdivide the histological subtypes of NSCLC — adenocarcinoma, squamous cell carcinoma, and large cell carcinoma — into clinically relevant molecular subsets.¹

These molecular subsets show the considerable heterogeneity of non-small cell tumors and suggest why patients with similar clinical stage and tumor histology can have dramatically different clinical outcomes.⁴

Indeed, biomarkers may give clinicians an indication of the patient’s prognosis (outcome independent of treatment), as well as the treatment sensitivity/resistance of the tumor to specific agents.^{4,5}

Moreover, as genomic and mutational research continues, more biomarkers will inevitably be discovered, so that the proportion of NSCLC cases with unknown drivers will continue its decline. The ultimate goal of this approach to treatment is to identify every driver mutation for non-small cell lung cancer, and design a corresponding treatment for each of these oncogenes.^{1,2,4}

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New Diagnostic Paradigm: Histology + Molecular Profile

Recently it has been proposed that lung cancer treatment be based on the histology of the tumor. But there is a growing consensus that molecular profiling — testing the tumor at biopsy for all appropriate biomarkers — should be part of the clinician's standard approach to pathologic evaluation.^{1,2} And this is supported by the National Comprehensive Cancer Network (NCCN®) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for all non-squamous non-small cell lung cancer (NSCLC) histologies, which state⁵:

“Determination of the specific molecular abnormalities of the tumor is critical for predicting sensitivity or resistance to a growing number of targeted therapies.”

— NCCN Guidelines® Version 3.2012, for Non-Small Cell Lung Cancer⁵

The NCCN® recommends EGFR and ALK testing for all advanced non-squamous NSCLC, in order to guide treatment decisions.⁵ Multiplex molecular profiling assays may make the prospective genotyping of tumors possible, to aid clinical decision making and management.¹

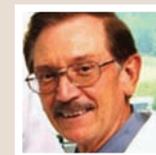
For patients whose tumors test positive for a biomarker that is treatable with approved or investigational agents, the benefits of testing are self-evident.^{1,5,6}

But in the future, molecular profiling will help an increasing proportion of patients with NSCLC because the additional information it reveals about their tumor has the potential to guide clinical management.^{2,7}

Molecular Profiling Is Key in NSCLC

The discovery of biomarkers has demonstrated the molecular complexity of NSCLC, and it highlights the need to move toward molecularly based classification and treatment of these tumors.^{1,4} But only if patients are tested is it possible for them to potentially benefit from these developments.

As additional mutations are discovered through efforts such as the National Cancer Institute's Lung Cancer Mutation Consortium (LCMC) and the Cancer Genome Atlas — and as new agents are developed to address these abnormalities — the hope for the over 215,000 people diagnosed with lung cancer each year is that these advances will lead to more treatment options.^{1,8-10} In the words of Dr. David Gandara, Director of Thoracic Oncology at UC Davis Comprehensive Cancer Center, “Our goal is to learn the ‘molecular fingerprint’ of each person's lung cancer, and to personalize their therapy based on this information. The discoveries that could make this possible are being made at a rapid pace.”



David R. Gandara, MD
Director, Thoracic Oncology
Program, UC Davis
Comprehensive Cancer Center

What is the most significant development you've seen in the treatment of lung cancer today?

DG Knowing what is driving the cancer! We have recently been using histology to treat cancer based on the appearance of the cells. But cells that look identical under the microscope can have dramatically different clinical outcomes because of what is driving them at the molecular level. And *that* is leading us to molecularly based treatment options.

Can many NSCLC patients benefit from this testing? Who should be tested?

DG When you consider both approved and investigational agents, yes, a considerable proportion of NSCLC patients can receive therapy based on molecular testing. But at present I believe that all patients with NSCLC of the adenocarcinoma subtype should be tested.

That seems like a lot of testing. Wouldn't that require a re-biopsy for many patients?

DG These tests do require adequate tumor tissue. Some patients will need to be re-biopsied — some for lack of sample tissue, but also to look for changes that have occurred over time and as a result of therapy. Other patients may not have to be re-biopsied. To do the testing that reveals the “molecular fingerprint” of each person's lung cancer, we have to get sufficient tumor tissue at biopsy.

Visit www.lungcancerprofiles.com for the patient perspective on molecular profiling.

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Steroids may cut length of hospital stay for pneumonia

BY MICHELE G. SULLIVAN

IMNG Medical News

Steroid treatment may not improve mortality in community-acquired pneumonia, but it was associated with significantly shorter hospital stays and an increase in the chance of a clean chest radiograph after treatment.

A meta-analysis of eight studies on the topic showed that steroid treatment reduced the overall length of stay by a little over 1 day. There also was an 87% reduction in the risk of an abnormal chest x-ray at 1 week and an 88% reduction in the risk of delayed shock. These last findings, however, were based on just a few of the analysis' studies, which were considered only of moderate quality, Dr. Majid Shafiq and colleagues wrote in the *Journal of Hospital Medicine*.

"The data are not strong enough to recommend routine use of steroids among all adults hospitalized with" community-acquired pneumonia, wrote Dr. Shafiq and his coauthors at the Mayo Clinic in Rochester, Minn. "However, considering that there



was no increase in mortality or hospital length of stay with steroid use, it is reasonable to continue steroids if warranted for treatment of underlying comorbid conditions," they noted (*J. Hosp. Med.* 2013;8:68-75).

The analysis included a total of 1,119 patients; four randomized controlled trials were among the studies. In seven studies, the mean patient age ranged from 60 to 80 years. In one study, patients in the experimental arm were a mean of 32 years and those in the control arm were a mean of 41 years. Only one study used a chest x-ray score.

The mean length of stay in the intensive care unit was 13 days for patients taking steroids and 12 for the control patients.

The mean hospital length of stay was 10 days for those taking steroids, 14 days for those who did not.

Steroid use did not significantly impact the length of ICU stay or mortality. Four studies showed significantly lower clinical cure rates more late failures in patients taking steroids. Two showed no between-group differences in the occurrence of superinfections. Three studies reported that the drugs did not

'It is reasonable to continue steroids if warranted' for underlying comorbidities.

DR. SHAFIQ

COMMENTARY

Dr. Vera DePalo, FCCP, comments: The authors present interesting data. Taken in total, there seems to be significantly shorter hospital stay and significant reductions in the risk of an abnormal film at 1 week and in the risk of delayed shock, without other significant negative findings. However, the results of some of the individual studies were more mixed. Further study is needed to best understand a potential role for steroids in pneumonia.



affect glycemic levels, while four found more frequent hyperglycemia in the steroid group.

The authors noted that "it is not inconceivable that steroid use led to a quicker decline in cytokine levels resulting in an earlier resolution of fever and hence earlier discharge without a faster cure per se."

The researchers reported no financial conflicts.

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Mycophenolate a boost in CTD-ILD

Lung disease from page 1

VITALS

Major finding: At 156 weeks after initiation of mycophenolate mofetil, patients with connective tissue disease-associated interstitial lung disease had a mean forced vital capacity improvement of 7.3%.

Data source: A retrospective study of 125 patients at a single center.

Disclosures: Dr. Fischer reported having no industry disclosures relevant to the current study. He and several coinvestigators also are involved with the Scleroderma Lung Study II, which is investigating mycophenolate mofetil vs. oral cyclophosphamide in scleroderma interstitial lung disease and has no industry sponsorship. The present study was partially funded by a grant from the National Institutes of Health.

In total, 125 of these patients had CTD-ILD, plus 6 months of follow-up data (*J. Rheumatol.* 2013 March 1 [doi:10.3899/jrheum.121043]).

Patients' mean age was 60.4 years; 42% were female and 83% were white.

A total of 44 of these patients had systemic sclerosis, 32 had polymyositis/dermatomyositis, 19 had lung-dominant connective tissue disease, 18 had rheumatoid arthritis, 5 had Sjögren disease, 4

had systemic lupus erythematosus, and 3 had mixed connective tissue disease.

Most subjects took 3,000 mg/day (65%) of MMF, with none exceeding that dosage and only four subjects taking less than 2,000 mg/day.

Overall, the authors reported that, over a median duration of MMF use of 897 days (2.5 years), only 13 subjects discontinued the drug, citing gastrointestinal intolerance, ILD progression, hepatic transaminase elevation, recurrent infections, and cytopenias.

Even among those who discontinued the drug, however, the median duration of use was still more than 2 years, at 763 days.

Dr. Fischer and his associates then looked at changes in pulmonary physiology. Over the 156 weeks prior to MMF initiation, a mixed-effects model of the entire cohort showed no significant changes in either estimated percentage of predicted forced vital capacity for sex, ethnicity, age, and height (FVC%) or the estimated percentage of predicted diffusing capacity for sex, ethnicity, age, and height (DLCO%).

At 52 weeks, however, there was a mean increase in FVC% of 4.9% ($P = .01$) and of DLCO% of 6.3% ($P = .02$), they reported. At 104 weeks af-

ter initiation of MMF, the change in FVC% had increased to 6.1% ($P = .0008$), and at 156 weeks, it had improved 7.3% from baseline ($P = .004$).

Similarly, by 104 weeks, the



Even among those who discontinued the drug, median duration of use was still more than 2 years.

DR. FISCHER

DLCO% had increased by 7.1% ($P = .01$); at 156 weeks, there was a mean 7.8% change from baseline ($P = .05$).

Patients taking MMF were able to taper prednisone doses once they initiated the drug.

Indeed, according to the researchers, model estimates for mean daily prednisone doses for the entire cohort at 52 and 26 weeks before MMF initiation were 14 and 7 mg, respectively. At MMF initiation, the mean dose was 20 mg/day.

In contrast, "estimated prednisone dose at 26 and 52 weeks after MMF initiation was 12 and 5 mg, respectively (P less than .0001 for each, compared to 20 mg at MMF initiation)," they calculated.

The researchers conceded several limitations to their study, including its retrospective design.

"From our data, one cannot know whether treatment with other immunosuppressive agents would yield similar results or even whether MMF definitively caused the observed changes in FVC% and DLCO%," they wrote.

COMMENTARY

Dr. Darcy D. Marciniuk, FCCP, comments: As noted by the authors, there are limitations in this retrospective review of CTD-ILD patients receiving mycophenolate. However, in a disease with no current beneficial directed therapies, and after a mean follow-up of 2.5 years, significant improvements in



FVC and mean dose of prednisone were accompanied by a trend to an improved diffusing capacity. While it is premature to change current practices, this retrospective analysis certainly whets our appetite for the outcomes from ongoing and planned randomized controlled trials.

Low-dose antibiotic cut flare-ups

Bronchiectasis from page 1

Azithromycin Treatment) study, the median number of exacerbations after 1 year was 0 in azithromycin-treated patients, compared with 2 in patients given placebo (JAMA 2013;309:1251-9).

Both studies' findings are consistent with those of the EMBRACE trial published last year, which showed a 500 mg-dose of azithromycin given for 6 months reduced the incidence of pulmonary exacerbations, compared with placebo, in patients who had at least one exacerbation in the past year (Lancet 2012;380:660-77).

"The BLESS and BAT trials provide robust evidence for a beneficial effect of long-term macrolide maintenance therapy in patients with bronchiectasis," observed Dr. J. Stuart Elborn and Michael Tunney, Ph.D., in an editorial accompanying the articles (JAMA 2013;309:1295-6).

"Given the paucity of evidence for treatments in bronchiectasis, the results of these studies and the recently published EMBRACE trial are welcome, because they provide a good evidence base for an effective therapy for bronchiectasis," added the commentators, both of Queen's University Belfast, Northern Ireland

Bronchiectasis is characterized by widening of the airways – specifically, the small and medium-size bronchi – mucosal thickening, and bronchial inflammation. Sufferers are usually dogged by a chronic cough and sputum production, impaired lung function, and infection-related exacerbations.

BLESS was a single-center trial conducted in Australia involving 117 outpatients with a history of two or more infective exacerbations in the past year. Patients were treated with twice-daily erythromycin (400 mg) or placebo. The mean ages of antibiotic- and placebo-treated patients were 61.1 years and 63.5 years, respectively.

Treatment with erythromycin resulted in a 43% relative reduction in the mean annualized exacerbation rate. Exacerbations also were significantly decreased in a pre-specified subgroup of patients with *Pseudomonas aeruginosa* airway infection.

Furthermore, "erythromycin reduced 24-hour sputum production and attenuated lung function," wrote Dr. David Serisier and his colleagues at Mater Adult Hospital in South Brisbane, Australia.

The BAT study was conducted in 14 Dutch hospitals and involved 83 outpatients with a history of three

or more lower respiratory tract infections in the past year. Patients were randomized to a daily dose of 250 mg azithromycin or placebo. The mean ages of antibiotic- and placebo-treated patients were 59.9 years and 64.6 years, respectively.

The risk of patients experiencing at least one exacerbation during the trial was significantly lower if they had been treated with the antibiotic rather than being given placebo (46.5% vs. 80%, hazard ratio = 0.29).

"The number of patients needed to treat with azithromycin to maintain clinical stability was 3.0," Dr. Josje Altenburg, Medical Centre Alkmaar, the Netherlands, and associates reported. Azithromycin therapy also was associated with improved lung function, compared with placebo.

One concern with long-term treatment using these antibiotics is the possible development of macrolide resistance. Dr. Altenburg and colleagues reported a macrolide resistance rate of 88% with azithromycin, vs. 26% with placebo. In BLESS, Dr. Serisier and his coauthors observed an increased proportion of macrolide-resistant oropharyngeal streptococci, with a median increase of 27.7%, compared with 0.04% with placebo.

"The bacterial resistance caused by macrolide therapy mandates a cautious application of this therapy in clinical practice," Dr. Serisier and

associates acknowledged. They added that the potential for resistance must "curb enthusiasm" for widespread erythromycin use.

"The benefits of long-term macrolide treatment for individual patients with bronchiectasis need to be balanced with increasing concerns regarding the development of resistance to both macrolides and other antibiotics among airway microbiota," Dr. Elborn and Dr. Tunney similarly observed in their accompanying editorial.

COMMENTARY

Dr. W. Michael Alberts, FCCP,

comments: Non-cystic fibrosis bronchiectasis is not an uncommon clinical challenge. The oft-accompanying chronic productive cough along with periodic purulent exacerbations have the potential to negatively impact quality of life. Three trials (BLESS, BAT, and EMBRACE) have now shown that long-term macrolide therapy is effective in reducing purulent exacerbations but (there's always a "but") such therapy has the potential to result in resistant bacteria. The risk/benefit equation must be frequently reassessed.



FDA gives up on graphic cigarette labels

The Food and Drug Administration, facing opposition from the tobacco industry and court decisions that didn't go its way, has dropped its proposals for graphic photos on cigarette warning labels.

The agency said it will develop labels that satisfy the courts' requirements not to infringe on tobacco companies' First Amendment right to free speech. The 2009 Tobacco Control Act requires the FDA to implement new warning labels.

The graphic labels, unveiled in 2011 and intended for placement on all cigarette packages, included photos of a man's corpse, disease-riddled lungs, and rotting teeth.

A group of tobacco manufacturers sued the agency to overturn the requirement to use the labels, and two courts – most recently the U.S. Court of Appeals for the D.C. Circuit – sided with the manufacturers. The Justice Department elected not to appeal the case to the U.S. Supreme Court.

The American Cancer Society Cancer Action Network, the ACS' advocacy arm, urged the FDA to work quickly. "The current warning labels have not been changed in 25 years and are widely considered to be ineffective," group president Chris Hansen said in a statement.

–Jane Anderson

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Deadly CRE infections on the rise, CDC says

BY DOUG BRUNK

IMNG Medical News

Between 2001 and 2011, the percentage of carbapenem-resistant Enterobacteriaceae infections reported by acute care hospitals in the United States increased nearly fourfold, from 1.2% to 4.2%. More recent data from the first 6 months of 2012 suggest that the percentage of such infections is now slightly higher, at 4.6%.

The findings, which appear in a Vital Signs report released by the Centers for Disease Control and Prevention, are significant because CRE can kill up to 50% of patients who get bloodstream infections from them.

For one component of the report, CDC researchers analyzed data from the National Healthcare Safety Network (NHSN) and its predecessor, the National Nosocomial Infections Surveillance system (NNIS), for the number of Enterobacteriaceae isolates; the percentage reported to be tested against carbapenems; and the percentage reported as carbapenem resistant in 2001 and in 2011. For another component, the researchers evaluated NHSN data for the number and percentage of facilities reporting CRE from a catheter-associated urinary tract infection or central line-associated bloodstream infection between January and June of 2012.

Of the CRE cases reported during the first half of 2012, about 18% occurred in long-term acute care hospitals and about 4% occurred in short-stay hospitals.

The risk of CRE infection is highest

among patients who are receiving complex or long-term medical care, including those in short-stay hospitals or long-term acute care hospitals, or nursing homes. It's commonly spread by people with unclean hands but "medical devices such as ventilators or catheters [also] increase the risk of life-threatening infection because they al-



COURTESY CDC

Killer bug: *Klebsiella pneumoniae*

low new bacteria to get deeply into a patient's body," CDC Director Tom Frieden said.

According to the report, health care facilities in Northeastern states report the most cases of CRE, with 42 states reporting having had at least one patient test positive for the infection. In addition, one type of CRE, a resistant form of *Klebsiella pneumoniae*, demonstrated a nearly sevenfold increase between 2001 and 2011, jumping from 1.6% to 10.4%.

"In some of those places, these bacteria are now a routine challenge for patients and clinicians," Dr. Frieden said. He listed six practical ways that health care providers can prevent CRE in their facilities:

- ▶ Know if your particular patient has CRE and request immediate alerts

from your lab every time it identifies any patient with the infection.

- ▶ When receiving or transporting patients, make sure to ask or find out if the patient you're receiving has CRE.

- ▶ Protect your patients from CRE by following contact and other precautions whenever you're treating patients with CRE "so you don't inadvertently spread their organism to someone else."

- ▶ Whenever possible, have specific rooms, equipment, and staff to care for CRE patients. "This reduces the chance that CRE will spread from one patient to others," he said.

- ▶ Remove temporary medical devices such as catheters as soon as possible.

- ▶ Prescribe antibiotics carefully. "Unfortunately, half of the antibiotics prescribed in this country are either unnecessary or inappropriate," Dr. Frieden said.

These and other recommendations for hospitals, long-term acute care facilities, nursing homes, and health departments can be found in a CRE prevention toolkit released by the CDC in 2012.

Authors of the report acknowledged at least three limitations of the data. First, they wrote, "antimicrobial susceptibility data reported to NNIS and NHSN were generated at individual institutions rather than [at] a central laboratory, and testing methodologies vary between facilities. Second, susceptibility interpretation is based on the recommended break points used when tested. Although carbapenem break points for Enterobacteriaceae were lowered in 2010 and might have influenced the increase in

the percentage of isolates that were carbapenem-resistant, most laboratories would not have incorporated those changes by 2011.

Finally, in some instances, complete susceptibility test results, particularly for carbapenems, were not reported to NNIS or NHSN, leading to a subset of isolates that were not included in these analyses."

The researchers reported having no relevant financial disclosures.

COMMENTARY

Dr. Steven Q. Simpson, FCCP, comments: More and more we are faced with serious infections caused by multidrug-resistant

bacteria and even pan-resistant organisms. Clearly, such infections impact the ICU when



they fail to respond to standard antibiotic treatment.

As intensivists, we need to help fix the problem by careful adherence to hand hygiene, aseptic techniques, and antibiotic stewardship, including cessation of antibiotic therapy when it is not clear that we are treating an actual infection – but only if we hope to have antibiotics to treat our own sepsis someday.

Eritoran fails to improve mortality in severe sepsis

BY MARY ANN MOON

IMNG Medical News

Eritoran, a highly active and specific lipopolysaccharide inhibitor, failed to improve 1-month or 1-year mortality in an international phase III clinical trial of nearly 2,000 patients with severe sepsis, according to a report published in JAMA.

Eritoran had appeared very promising in preclinical, phase I, and phase II trials, blocking cytokine responses, terminating lipopolysaccharide-associated inflammatory events, and ultimately reducing patient mortality. "Despite these promising early results, no evidence of significant benefit was observed with eritoran in this large phase III trial," said Dr. Steven M. Opal of the division of infectious diseases at Memorial Hospital of Rhode Island, Pawtucket, and his associates. "Eritoran joins a long list of other experimental sepsis treatments that do not improve outcomes in clinical trials in

these critically ill patients."

Eritoran is a synthetic analog of lipid A and a potent, specific antagonist against lipopolysaccharide activity, which drives the inflammatory response. In this 5-year double-blind study conducted at 197 ICUs throughout North America, Europe, South America, Africa, Asia, and Australia, 1,984 patients with severe sepsis or septic shock were randomly assigned to receive intravenous eritoran (1,322 subjects) or matching placebo (662 subjects) and followed at 1 month, 3 months, 6 months, and 1 year.

The pathogens that most commonly caused sepsis in this study were *Escherichia coli* (22%), *Staphylococcus aureus* (12%), and *Streptococcus pneumoniae* (11%). The lung was the site of infection in approximately half of the patients in each group.

Bloodstream infection incidence was similar between the groups, affecting 38% of the eritoran group and 40% of the placebo group. Both groups received comparable supportive care, ap-

propriate antimicrobial therapy, and timely infection control.

The primary outcome measure was 28-day mortality in these patients who were at high risk of dying. This rate was not significantly different between the group that received active drug (28%) and the group that received placebo (27%). Similarly, all-cause mortality at 1 year was comparable between the two groups, at 44% and 43%, respectively, the investigators said (JAMA 2013;309:1154-62).

In subgroup analyses, eritoran showed no beneficial effect on patient mortality. Rates were similar regardless of baseline APACHE score, baseline SOFA score, presence or absence of septic shock, site of the primary infection, or whether the infection was gram negative or gram positive.

"Our results ... call into question the role of an endotoxin-blocking agent in halting the inflammatory progression and organ dysfunction once sepsis is already underway," the researchers said.



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References: **1.** Data on file, Grifols. **2.** Campos MA, Alazemi S, Zhang G, Wanner A, Sandhaus RA. Effects of a disease management program in individuals with alpha-1 antitrypsin deficiency. *COPD*. 2009;6:31-40.

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New care guidelines stress certification, diversity

Biggest changes made to social, cultural, spiritual domains as number of board subspecialties grows.

BY PATRICE WENDLING
IMNG Medical News

NEW ORLEANS – New palliative care guidelines encourage discipline-specific certification for each of the major disciplines in a palliative care program, even for chaplaincy.

The guidelines are critical in raising the bar to guide the training of professionals and the development of programs, said Dr. Diane Meier, coleader of the National Consensus Project for Quality Palliative Care (NCP), which released the guidelines during the annual meeting of the American Academy of Hospice and Palliative Medicine.

Since the guidelines' last revision in 2009, the Accreditation Council for Graduate Medical Education recog-



Dr. Diane Meier is coleader of the National Consensus Project for Quality Palliative Care.

nized hospice and palliative medicine as a subspecialty of 11 different parent boards. That paved the way for the development of hospice and palliative medicine fellowships, now an eligibility requirement for the board certification exams.

This year, the Centers for Medicare and Medicaid Services also began implementing an annual quality reporting program for hospice organizations that includes a financial incentive for hospice provider participation. Data from roughly 600 hospi-

tals are also filed with the Center to Advance Palliative Care (CAPC), which releases a report card on access to palliative care in U.S. hospitals.

“Right now it’s too early in the field to use it for public reporting or payment, but it’s not too early to use it to be able to say, ‘Look, here are the standards, and here’s how we compare in terms of staffing ratios to peer hospitals in our part of the country, and we aren’t even close,’” Dr. Meier, CAPC director and professor of geriatrics and palliative medicine at Mount Sinai Hospital in New York, said in an interview.

In 2011, 46% of the roughly 2.5 million deaths in the United States were under the care of one of the nation’s more than 5,000 hospices, with data suggesting that costs during the last year of life are cut by an average of \$2,309 per hospice user.

The new, third edition of the Clinical Practice Guidelines for Quality Palliative Care, endorsed by some 50 organizations, emphasizes the need to deliver palliative care from the time of diagnosis, through an interdisciplinary team. Earlier editions of the guidelines were used as the basis for the National Quality Forum Framework and Preferred Practices for Quality Palliative Care, as well as the Joint Commission’s 2011 palliative care advanced certification.

Although hospice and palliative care at a 300-bed tertiary hospital will look substantially different than at a 40-bed community hospital, it must include all eight domains of care. It is not a physician and a half-time nurse doing pain consults, insists NCP coleader Betty Ferrell, Ph.D., R.N.

She observed that the social, cultural, and spiritual domains have undergone the biggest changes in the latest edition.

The social domain emphasizes the need to collaborate with patients

and families to identify and capitalize on their strengths, and to use a social worker with patient population-specific skills in assessment and interventions.

The cultural domain contains new content stressing the need for cultural and linguistic competence, including plain language, literacy, and delivering written materials in languages other than English. Translators also should be used for patients and families who do not speak or understand English, or for those who feel more comfortable communicating in another language.

“We really need to do a lot of this [work] because, if you look at our literature, you could say it’s kind of uni-perspective,” Dr. Ferrell, a professor and research scientist at the City

‘It’s not too early to use it to be able to say, “Look, here are the standards, and here’s how we compare in terms of staffing ratios to peer hospitals ...”’

of Hope Medical Center in Los Angeles, acknowledged.

The spiritual domain was revised to include a definition of spirituality stressing assessment, access, and staff collaboration in attending to the spiritual, religious, and existential concerns throughout the illness trajectory.

“Chaplains may see a small minority of patients in the hospital; thus it’s important for all health care providers to address spiritual needs,” she said.

The ethical and legal domain was reorganized into three sections to highlight the need for ongoing discussions about goals of care as well as greater communication and documentation of advance-care planning documents. The section also describes team competencies in the identification and resolution of ethical issues, and acknowledges the frequency and complexity of legal and regulatory issues in palliative care.

During a discussion of the guidelines, audience members said they’ve



Previously, the guidelines were “kind of uni-perspective,” said project coleader Dr. Betty Ferrell.

often been kept from doing the next step in care because of fear of legal reprisal. Only a dozen or so of the roughly 200 members in the audience, however, raised their hands when asked whether legal counsel had ever attended a palliative care meeting at their hospital.

“We’ve had ethics committees involved in palliative care; but we actually need more access to our legal counsel so we can feel safer and that we’re making consistent judgments,” Dr. Ferrell said at the meeting, also sponsored by the Hospice and Palliative Nurses Association.

Finally, the domain previously called “Care of the imminently dying” was renamed “Care of the patient at the end of life.” It highlights the need to meticulously assess and manage pain and other symptoms, to guide families about what to expect in the dying process, and to begin bereavement support before the actual death.

“Families need support, given that they have often never witnessed a death until faced with losing someone they love,” she said. “The reality of death is very different from images on film and television.”

The guidelines were sponsored by the American Academy of Hospice and Palliative Medicine, the Center to Advance Palliative Care, the Hospice and Palliative Nurses Association, the National Hospice and Palliative Care Organization, the National Association of Social Workers, and the National Palliative Care Research Center.

Dr. Meier and Dr. Ferrell reported no relevant conflicts of interest.

WHAT MATTERS: CPAP vs. appliances for sleep apnea

BY JON O. EBBERT, M.D.

Most likely I am not alone with the feeling that we spend a lot of resources diagnosing sleep apnea, meticulously titrating continuous positive airway pressure devices, and patiently listening to some of our patients as they list the reasons for not using it.

Many times, the patients have been back to the sleep specialists, who try in earnest to make it work because we all know the litany of potential adverse downstream effects if apnea is left untreated.

We all also know that frightening our patients (“untreated sleep apnea can increase the risk for sudden cardiac death and heart failure. . .”) into CPAP compliance is ineffective. So, for the lucky patients whose insurance coverage facilitates the fitting of oral appliances, such as the mandibular advancement device (MAD), we can try these.

Although the reduction in overall apneic episodes is less with MAD than with CPAP devices, the adherence to the MAD may be higher.

So how do CPAP and oral appliances fare head-to-head?

Australian investigators conducted a randomized controlled clinical trial evaluating the health outcomes of patients using the MAD or CPAP for obstructive sleep apnea (Am. J. Respir. Crit. Care Med. Feb. 14, 2013 [doi:10.1164/rccm.201212-2223OC]).



DR. EBBERT

In this study, 126 patients with moderate to severe obstructive sleep apnea were randomly assigned to use of MAD or CPAP for 1 month. Patients were excluded if they had central sleep apnea, need for immediate treatment, a coexisting sleep disorder, regular use of sedatives or narcotics, or pre-existing lung or psychiatric disease.

The primary outcome was a difference in 24-hour mean arterial blood pressure. Secondary outcomes included cardiovascular events and arterial stiffness. Neurobehavioral function and quality of life also were measured.

CPAP was significantly more effective than MAD for reducing the apnea-hypopnea index (AHI), but compliance was significantly greater with MAD (6.5 hours per night vs. 5.2 hours per night). No differences in the 24-hour mean arterial pressure were observed, though neither treatment improved blood pressure. Sleepiness, driving simulator performance, and disease-specific quality of life improved with both treatments by similar amounts. MAD was superior to CPAP on several quality-of-life domains.

This study is extremely informative for our practices in which we cannot consistently provide either motivational enhancement or interventions to improve adherence with CPAP. For CPAP-nonadherent patients for whom an appliance seems like an appropriate next step, this should be pursued. In the case of sleep apnea, we should not let perfect be the enemy of good.

This column, What Matters, regularly appears in Internal Medicine News, a publication of Frontline Medical Communications.

Dr. Ebbert is professor of medicine and primary care clinician at the Mayo Clinic in Rochester, Minn. He reports having no conflicts of interest. The opinions expressed are those of the author. Reply via e-mail at imnews@frontlinemedcom.com.

COMMENTARY

Dr. Paul A. Selecky, FCCP, comments: This study will be very helpful to the practicing sleep physician and pulmonologist who often has felt that a mandibular advancement device was less effective than CPAP, but these data on compliance shed a new light. It seems worth a try if a patient is not adherent to use of CPAP. The problem is that medical insurance generally does not cover a MAD – another obstacle.



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Deep suctioning ups stay in bronchiolitic infants

BY MICHELE G. SULLIVAN

IMNG Medical News

Deep suctioning and long lapses between suction treatments were associated with significantly increased lengths of stay in babies hospitalized with bronchiolitis.

Patients who never had deep suctioning stayed a little more than a day, but the length of stay was more than 2 days in patients for whom deep suctioning accounted for 60% or more of their treatments, Dr. Grant M. Mussman and his colleagues reported in *JAMA Pediatrics* (2013 [doi:10.1001/jamapediatrics.2013.36]).

Similarly, patients who experienced several lapses of 4 hours between treatments were hospitalized significantly longer than were those with no treatment lapses (mean of 2.3 days vs. 1.7 days).

Compared with a noninvasive nasal-type suction device, deep suctioning may aggravate the bronchial swelling and mucus sloughing that already causes breathing problems in these tiny patients, wrote Dr. Mussman of Cincinnati Children's Hospital Medical Center. "[It] may be that deep suctioning causes edema and irritation of the upper airway. Alternatively, noninvasive suctioning could be more effective in mobilizing nasal secretions through the larger caliber catheter."

Regular treatments with no lapses probably keep the airways open more consistently, they noted. "It is also possible that regular suctioning results in agitation of the patient, with resultant increased minute volume and secretion mobilization, resulting in shorter length of stay."

The study cohort consisted of 740 patients who were studied for device type (deep or noninvasive), 695 of which were studied for treatment timing. The patients were a mean of 6 months old, and all had been hospitalized for bronchiolitis.

Deep suction was defined as the insertion of a nasopharyngeal catheter, and noninvasive as the use of nasal-type aspirators, excluding bulb syringe. The exposure was the percentage of treatments that used deep suctioning (0%-35%; more than 35%-60%; and more than 60%).

The adjusted mean length of stay for infants who had no deep suctioning was 1.75 days. The stay was 1.91 days for those with up to 35% deep suctioning, 1.96 days for more than 35%-60% deep suctioning, and 2.35 days for more than 60% deep suctioning.

For the suction treatment timing

group, a suctioning lapse was defined as two sequential suctioning events separated by more than 4 hours during the first 24 hours of admission. The investigators said that the 4-hour increment is the most common re-

assessment timing.

Infants with no treatment lapses had a mean adjusted hospital stay of 1.62 days. In contrast, the mean length of stay was 1.72 days for infants with one treatment lapse, 2.09 days for those

with two lapses, and 2.64 days for those with three or four lapses.

Dr. Mussman reported having no relevant financial disclosures.

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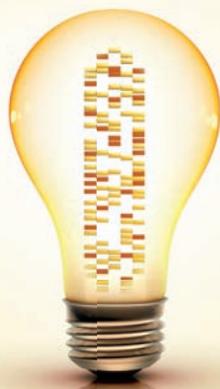
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FROM THE EVP/CEO: Ecofriendly ACCP headquarters is on horizon

BY PAUL A. MARKOWSKI, CAE

As we go to press with this column, construction crews are very busy in Glenview, Illinois, creating the ACCP's new headquarters – a center for innovative, interactive education that will provide unprecedented opportunities for advancement in chest medicine.

As you can see in the attached photo, the foundation and footprint are in place, and the headquarters is beginning to take shape. The building, which will have two wings anchored by a lobby, will house the Innovation and Simulation Center in one wing and staff offices in the other.

We anticipate that the center will be completed by October, just in time for our annual meeting. If you will be attending CHEST 2013, I hope you will join a tour of the building and see why we are so excited about our plans.

As thrilled as we are with what the

new building will provide, we are committed to reducing our carbon footprint with the goal of obtaining a Leadership in Energy and Design (LEED) rating of Silver. The US Green Building Council developed the LEED green building certification system to verify that a structure has been designed and built to minimize environmental impact. Within each of the LEED credit categories, projects earn points in the categories of sustainability, water efficiency, energy and atmosphere, materials and resources, and indoor environment quality. In

keeping with the ACCP's commitment to healthy air and lungs, we have focused specifically on the air quality and general air environment in the new headquarters. A healthy building will benefit our staff and member community.

We look forward to your comments about the new headquarters. After all, it's going to be used by our member community, as well as our staff, and your input is invaluable.



PAUL A. MARKOWSKI, CAE



The ACCP's new headquarters, located in Glenview, Illinois, is beginning to take shape. The building is designed to minimize its impact on the environment.

There are several ways to follow our progress as the headquarters takes shape: updates on Twitter (@PMarkowskiACCP) and detailed information posted regularly on the ACCP Facebook page (accpchest). In addition, you'll be able to follow the

construction via webcam on the website for the Beyond Our Walls campaign (beyondourwalls.chestnet.org).

Please join us as we make our vision of innovative learning and cutting-edge medical education a reality.

CHEST 2013: Inspire Chicago

Travel+Leisure readers voted Chicago the nation's "Best Skyline." It's easy to see why. There are iconic architectural wonders everywhere you look, including The Bean, a larger-than-life modern art sculpture in

chest medicine. Don't miss:

- ▶ Five postgraduate courses.
- ▶ More than 300 general sessions.
- ▶ An expanded simulation program.
- ▶ Opening sessions with keynote speakers to kick off the day.

- ▶ Original investigation presentations.

- ▶ New diagnostic and treatment solutions in the Clinical Resource Center.

CHEST 2013 takes place October 26-31. Begin planning your trip to Chicago now with the Choose Chicago Mobile App, available at ChooseChicago.com/

Millennium Park. Pair the best skyline with the best clinical learning experience, and you've got CHEST 2013 in Chicago.

Recognized as the global authority in clinical chest medicine, CHEST 2013 will feature a learning program in pulmonary, critical care, and sleep medicine. Relevant updates on patient care and practice management strategies will offer insight, perspective, and inspiration you can seamlessly incorporate into your practice to stay at the forefront of clinical

mobile-app. Download to access contact information and maps for restaurants, theaters, museums, and more. Find things to do near your location, from shopping to sightseeing tours. Learn about events happening all around the city, and get the latest Chicago weather. Also from this Web page, you can request The Chicago Official Visitors Guide, subscribe to e-newsletters, or connect with visitor information centers.

Learn more about CHEST 2013 at chestmeeting.chestnet.org.

ACCP Simulation Program for Advanced Clinical Education

Upcoming Summer Courses

BRONCHOSCOPY

Essentials of Bronchoscopy
August 1-2, Wheeling, IL

Endobronchial Ultrasound (EBUS)
August 3-4, Wheeling, IL

MECHANICAL VENTILATION

Essentials of Mechanical Ventilation for Providers
July 25, Northbrook, IL

Mechanical Ventilation: Advanced Critical Care Management
July 26-28, Northbrook, IL

AIRWAY MANAGEMENT

Fundamentals of Airway Management: Skills, Planning, and Teamwork
July 19, Northbrook, IL

Difficult Airway Management: A Critical Care Approach
July 20-22, Northbrook, IL

CRITICAL CARE

Achieving Optimal Outcomes in the ICU: Knowledge, Skills, and Behaviors
August 16-18, Northbrook, IL

Learn More and Register
chestnet.org/simulation



Simulation Education. Real Results.



CHEST app redesigned

The fully redesigned *CHEST* app for iPhone®, iPad®, and iPod touch® is now available. Existing users will be prompted to update through their device, and new users can find it in the App Store™ or iTunes™ by searching for *CHEST*.

This latest update to the July 2012 release that brought the full searchable archive and playable podcasts to the app in conjunction with the *CHEST* Publications site launch is part of the ACCP's ongoing commitment to bring you the most up-to-date information when and where you need it.

The app's new dynamic home page features:

- ▶ Highlighted articles from the most recent issue.
- ▶ New articles posted just after acceptance.
- ▶ Access to the monthly podcast, which can be played directly from the device.

Other new features include:

- ▶ An expanded menu providing central navigation to 11 different areas of the app, such as the full *CHEST* archive and Guidelines.

- ▶ Access to *CHEST* Collections: content curated by topic area (ie, Asthma, Critical Care, Procedures) and special series (ie, Medical Ethics, Topics in Practice Management).



The updated *CHEST* app for iPhone®, iPad®, and iPod touch® offers podcasts, articles, and searchable archives.

- ▶ Updates from ACCP's Twitter feed.
- ▶ Log-in credentials, favorite articles, and viewing history will be carried over when the app is updated.
- ▶ Download or update the *CHEST* app today for free to get the latest information in chest medicine on demand and on the go.

Distinguished Scholar creates online CME tool

Sandra Adams, MD, MS, FCCP, believes in making education accessible, affordable, practical, and engaging. With a grant from The *CHEST* Foundation, she is creating an interactive, online continuing medical educational tool to teach health-care professionals evidence-based best practices for identifying and treating COPD.

Dr. Adams is the 2010 recipient of the GlaxoSmithKline Distinguished Scholar in Respiratory Health grant. This \$150,000 grant is awarded every 3 years by The *CHEST* Foundation, the philanthropic arm of the American College of Chest Physicians (ACCP). Applications are now being accepted for the 2013 grant.

Her online curriculum fills a critical knowledge gap, notes

Dr. Adams, Associate Professor in the Division of Pulmonary Disease and Critical Care at the University of Texas Health Science Center, and staff physician at the South Texas Veterans

Health Care System in San Antonio.

"Too often, COPD is not diagnosed or managed until it is very advanced," she says.

It also is designed to fit into a health-care professional's busy schedule, available in short, convenient modules that

can easily fit into a short lunch break. "One of the biggest challenges in medicine is managing the explosion of new information and data occurring on a daily basis," she says.

Called WipeCOPD (for Web-Based Interactive Professional Education in COPD), the pro-

Continued on page 19



DR. ADAMS

ACCP e-community celebrates a year of growth and success

The ACCP launched the e-Community to allow members to communicate, collaborate, and learn virtually throughout the year, not just during live meetings like *CHEST*.

As we approach the 1-year milestone of the e-Community's launch, it's hard not to notice the rapid growth and evolution occurring in this online platform. Some highlights:

- ▶ In the first 2 months of 2013, e-Community log-ins increased by 24%, with 1,300 new log-ins.
- ▶ 70% of ACCP NetWork members have logged in to the e-Community.
- ▶ Active participation (creating discussion posts, posting resources, etc) increased by 113% between July 2012 and February 2013.

With an increase in log-ins and participation, content has become more diverse and far-reaching. Hassan Bencheqroun, MD, FCCP, member of the Chest Infections NetWork Steering Committee and Vice-Chair of the Pulmonary Physiology, Function, and Rehabilitation NetWork, said the e-Community discussions are valuable

for international knowledge sharing. "Someone across the world can ask a clinical question and get many interesting, knowledgeable responses in a short timeframe. The e-Community is a great venue for sharing ideas, practices, and new uses to old therapies not commonly practiced in the United States from international colleagues and vice versa," Dr. Bencheqroun said. "It's also beneficial to discuss challenges regarding rising resistances to anti-microbials across borders."

The e-Community has hosted discussions on unique clinical cases, hot-button topics, journal article reviews, and much more. In celebration of its successful beginning, the e-Community teamed up with ACCP's official journal, *CHEST*, to host a contest in early April. NetWork members shared *CHEST* articles and were awarded special, virtual e-Community birthday badges.

Learn more about NetWorks and the e-Community on chestnet.org, and e-mail communityadmin@chestnet.org with questions.

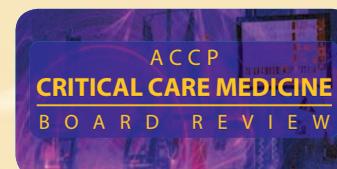
ACCP Board Review.

The Proven Leader in Comprehensive Review Programs

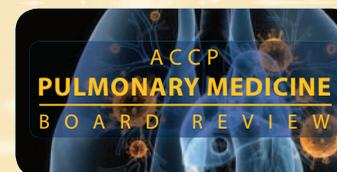
Rely on the ACCP, the leader in board review curriculums, for comprehensive review programs of proven success. World-renowned clinicians present exam-focused content to offer relevant board preparation courses that make the best use of your study time. Save these dates.



ACCP Sleep Medicine Board Review 2013
August 23 - 26
San Antonio, Texas
Exam Date: October 16



ACCP Critical Care Medicine Board Review 2013
August 23 - 26
San Antonio, Texas
Exam Date: October 9



ACCP Pulmonary Medicine Board Review 2013
August 28 - September 1
San Antonio, Texas
Exam Date: October 8



Register Early and Save
chestnet.org/boardreview

CRITICAL CARE COMMENTARY: A call for more simulation education

“Educational simulations are, in many respects, analogous to the play of the young of any species.”

McGuire et al. “Simulation: Its Essential Nature and Characteristics,” Chicago, 1999

Critical care is serious business. Our specialty prides itself on caring for the sickest of the sick, yet what it takes to be a competent critical care physician is ever changing.

Due to the promulgation of PICC lines (Pittirati et al. *Crit Care*. 2012;16:R21); goal-directed therapy of sepsis, which has prompted emergency medicine physicians to place the CVP line (Otero et al. *Chest*. 2006;130[5]:1579); and the National Heart, Lung, and Blood Institute (NHLBI) trial that suggested Swan-Ganz catheters may be superfluous (Wheeler et al. *N Engl J Med*. 2006;354[21]:2213), we are putting in far fewer central lines and pulmonary artery catheters (PAC). Someone should tell the ABIM, judging from all the PAC questions on my recent recertification exam – just ask a fellowship program director how difficult it is to get an adequate experience in central-line placement for their fellows before they graduate. On the other hand, there was a myriad of other procedures not taught to me in my fellowship. Being a boomer, my list may be longer than most, but bedside ultrasound, ultrasound-guided line placement, videoscopic airway placement, supraglottic airway placement, airway pressure release ventilation (or bilevel ventilation), Aquapheresis, and continuous end-tidal capnography are all procedures that I learned after becoming board-certified in critical care medicine.

The changing landscape of critical care is not just limited to procedures. Work-hour restrictions in academic institutions and postboomers demanding more shift work in general, has led to more frequent changes of responsibility for our patients and the idea of the handoff as a skill unto itself. The concept of team-focused critical care is relatively new (and certainly not universally practiced) as is the application of crew (or crisis) resource management adapted from the airline industry. The e-ICU has led some critical care physicians away from the bedside to the front of a computer screen, while bringing noncritical care practitioners (hospitalists and midlevels) closer to critical care patients under supervision. Both

have to learn a different way to practice. Advance directives, do not resuscitate orders, terminal sedation, and palliative care are all concepts that have evolved into the practice of critical care differently across the country over the past several decades.

So how can one keep up with these changes and practice state-of-the-art critical care? Simulation is part of the answer, and it can be serious fun! Imagine yourself sitting in a lecture with the instructor showing slides of

‘Our challenge in medical simulation education is to prove that it is worth the cost, especially as we enter a period of austerity in medical care.’

PAC waveforms and imagining a new cure for insomnia. Now imagine yourself caring for a simulated patient who is in shock with a holosystolic murmur. You place a PAC, and the occlusion waveform reveals a V-wave. Just like experiential learning at the bedside, this lesson is likely to stay with you for a lot longer than sporadic slides from a lecture. Whether fellowship program directors should spend valuable training time learning PACs is a question that needs to be asked, however.

Simulation has become a part of medical school education, mostly in a formative way. Examples include the use of standardized patients to teach the physical exam, specialty task trainers to teach the cardiac exam, high-fidelity patient simulator mannequins to teach emergency evaluation, as well as team skills and video game-like screen-based simulators to teach clinical reasoning. Simulators are also being used in a summative fashion with objective standardized clinical evaluations such as the United States Medical Licensing Examination (USMLE) clinical skills exam, which uses multiple simulated patient scenarios for testing. Simulation training is certainly used in residency training, and a recent report showed that 4 hours of simulator training prior to doing an ICU rotation led to better performance on a post-rotation checklist (Schroedl et al. *J Crit Care*. 2012;27[2]:219). The majority of medicine-based critical care fellowship programs have some type of simulation in their curriculum (Joffe et al. *Respir Care*. 2012;57[7]:1084). Simulation is used to teach all mem-

bers of the critical care team to include nurses (Brown et al. *Austr Crit Care*. 2012;25[3]:178) and respiratory therapists (Tuttle et al. *Respir Care*. 2007;52[3]:263).

Every national medical society in the United States that serves critical care physicians offers CME using simulation education. When simulation education is done well, it can be a magnificent thing. Simulation done well incorporates: (a) preparation to make the scenario true to life, as high fidelity as possible, and to fit the students learning needs; (b) learner engagement with respect for the simulated patient and suspense of disbelief; (c) the scenario pushing the learners to their limits of knowledge, allowing them to make a mistake, which can become a “benign learning scar”; (d) a debrief occurring with a facilitator who recognizes that the best teacher for the student is the student him or herself; and (e) the students being left with an experience that helps them reflect on lessons learned and how this will apply to their practice.

Buying a simulator and holding a meeting is not enough. Simulation education costs more money than traditional CME due to the need for a smaller student-to-faculty ratio, the preparation time, the time that students must be away from their practice, the venue with supporting props, and the cost of the actual simulators. Our challenge in medical simulation education is to prove that it is worth the cost, especially as we enter a period of austerity in medical care.

For physicians, maintenance of certification (MOC) is the norm for those who want to maintain board certification in critical care medicine

through the ABIM, since the certificate has been time-limited since its inception. The American Board of Medical Specialties (ABMS) is working toward all physicians participating in MOC at least every other year rather than waiting until the “multiple guess exam” every 10 years. Although there are some naysayers, most physicians agree that maintaining board certification through a process that improves physician knowledge leading to improved patient care is a good thing (like the ABMS website). Clearly, our patients want this and want us to be certified, and our patients would rather we make novice mistakes on a simulator rather than on them. Simulation lends itself extremely well to formative feedback (designed to improve the learner) but is evolving and should be able to be used for summative evaluation (designed to assess the learner’s ability). The latter clearly requires more effort and preparation since there can be high stakes and the simulator will never be just like the real human patient.

As an educator who uses medical simulation at every level (medical student, resident, fellow, and staff), I truly believe that we owe it to our patients to further develop simulation to keep us the best critical care physicians we can be. And guess what, we can have serious fun doing it!

*Dr. Bernard J. Roth, FCCP
Professor of Medicine,
Uniformed Services
University of the Health Sciences
Clinical Professor of Medicine,
Pulmonary Division
University of Washington
Tacoma, WA*

EDITOR’S COMMENTS

I would like to thank Dr. Roth for his provocative and thoughtful commentary. It is amazing that in a fairly brief time, we have gone from “see one, do one, teach one” as the primary teaching and learning paradigm in medicine to a sophisticated, interactive simulation environment. Though not perfect, lessons imparted and experiences gained seem to serve all learners well, as their new skills are honed in a realistic but safe environment. The cost of this is high in resource,



time, and even producing faculty capable of teaching in this style.

Another question yet unanswered is how often, the interval involved, and does this training need to be repeated, if ever? It is too late and unacceptable to go back, but the journey forward requires thoughtful consideration and balance to maximize education.

*Dr. Peter Spiro, FCCP
Section Editor,
Critical Care Commentary*

Continued from page 17

gram is chiefly intended for primary care clinicians (physicians, physician assistants, and nurse practitioners) but is also appropriate for respiratory therapists, nurses, and pharmacists. Topics include the diagnosis, assessment, management, and differential diagnosis of COPD and acute exacerbations.

Dr. Adams and a multidisciplinary team of colleagues developed the content under the guidance of ACCP educational specialists; the ACCP is also providing the CME credit.

The program is divided into six parts. CME credit will be available for all modules within the next few months, and will be claimable online.

"A to Z of COPD" presents COPD basics in 15-min segments, including interactive questions and immediate feedback. The Facilitated Clinical Learning section includes several patient-clinician scenarios (starring fellow ACCP members), with commentary by Dr. Adams. Two modules on inhalers include demonstrations on a variety of devices and guidance to help teach patients the proper use of their inhalers. The Virtual Clinic Patients section, which was previewed at CHEST 2012 in Atlanta, gives students an opportunity to practice differential diagnosis skills.

There are also eight modules of self-directed learning covering 15 themes.

Dr. Adams has set up a nonprofit organization called the WipeDiseases Foundation to provide support for future Web-based educational offerings. In addition to the grant from

The CHEST Foundation, she recently received a grant from the University of Texas System to develop a WipeAsthma curriculum. Her plans include developing similar programs on DVT and pulmonary hypertension, offering the programs free to medical schools, and marketing them to clinicians around the world.

For more information, visit WipeCOPD.com.

About the GlaxoSmithKline Distinguished Scholar in Respiratory Health Grant

The 2013 grant will be presented to a Fellow of the ACCP to support a clinical educational project that is designed to improve patient care. The grant is intended for the investigation of an issue that is not easily supported through traditional funding and that does one or more of the following:

- ▶ Promotes alternatives for the treatment of respiratory disease
- ▶ Educates patients about options for the diagnosis and treatment of respiratory disease
- ▶ Educates and disseminates new knowledge about the diagnosis and treatment of respiratory disease
- ▶ Addresses family, legislative, and regulatory issues
- ▶ Defines new mechanisms leading to innovations and improvements in the treatment of respiratory disease

The grant is for \$150,000 over 3 years. Applications are due May 1.

Find details and apply online at onebreath.org, or call Lee Ann Fulton, Program Manager, at (847) 498-8332.

This Month in CHEST: Editor's Picks

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

Sex, Race, and the Development of Acute Lung Injury. By Dr. L. B. Lemos-Filho et al.

Evidence of Vascular Endothelial Dysfunction in Young Patients With Cystic Fibrosis. By Dr. S. Poore et al.

Everolimus Plus Octreotide Long-Acting Repeatable in Patients With Advanced Lung Neuroendocrine Tumors: Analysis of the Phase 3, Randomized, Placebo-Controlled RADIANT-2 Study.

By Dr. N. Fazio et al.

ULTRASOUND CORNER

"Online Only" A 47-Year-Old Man With Dyspnea and Hypotension. By Dr. P. K. Sarkar et al.

Note:

Watch for the **ACCP Lung Cancer Guidelines** in May's issue of *CHEST*. Executive Summary, Methodology chapter, and Introduction in print issue, all other material will be available online.



An update on critical care ultrasonography at the ACCP

BY DR. PAUL H. MAYO,
FCCP

The ACCP continues to lead the ultrasonography revolution in North America. Over 2,000 critical care clinicians have taken the ACCP Ultrasonography: Essentials in Critical Care course, hundreds more have taken the Focused Thoracic and Pleural Ultrasonography and Critical Care Echocardiography courses, and the Critical Care Ultrasonography Certificate of Completion Program remains well-subscribed. At the annual meetings, ultrasonography is popular in the simulation training area, plus ultrasonography has been featured prominently in general sessions, PG courses, and the fellows' course. The ultrasound working group has submitted applications for new courses at the new Innovation and Simulation Center in Glenview, Illinois, in 2014. These include courses designed for fellowship program directors, hospitalists, advanced practice clinicians, and a course on transesophageal echocardiography. In tandem, *CHEST* has published a series of high-quality articles on critical care ultrasonography and

has initiated the Ultrasound Corner, a monthly feature presenting an instructive case.

The ACCP ultrasound working group is pleased to announce a new course, Advanced Critical Care Echocardiography. This 3-day course will be held in New York City from May 31 through June 2 and is the first such course in North America. The skilled ACCP faculty will be joined by two preeminent French echocardiographers, Drs. Antoine Vieillard-Baron and Michel Slama, to give learners an exceptional educational experience.

There are several reasons why the development of ultrasonography at the ACCP has been so successful. In 2007, the College funded a consensus meeting with the Société de Réanimation de Langue Française that resulted in the Statement on Competence in Critical Care Ultrasonography. This was followed by College support of an international consensus meeting on training standards in which the competence statement was established as the foundation document for training. This has been very helpful in designing course content. Simultaneously, the College provided unstinting ad-

ministrative and financial support for course and faculty development.

Another major factor has been the expert guidance provided by the education staff at the College. Their emphasis on well-defined learning objectives, identification of learner needs, standardization of cognitive content, faculty training, and formal testing of training effect has resulted in iterative quality improvement in course design. The ultrasound working group thanks the College for guidance of the ultrasound program and for the early requirement that every course include testing for learning effect. With this approach, failure points are identified, and corrective action is

taken to improve teaching function at each subsequent course. This continuous commitment to improving the education process has resulted in favorable faculty ratios for hands-on training; organized training sessions for the faculty; standardization of teaching methods and curriculum; assigned training supervisors; and the development of a cohesive, effective, and motivated faculty group.

The ultrasound working group looks forward to continued activity and growth at the new Innovation and Simulation Center and to presenting the first North American course on Advanced Critical Care Echocardiography this spring in New York City.

New PCCSU lessons now available

PCCSU
PULMONARY, CRITICAL CARE, SLEEP UPDATE

Vol 25, Lesson 28

ICU-Acquired Weakness, Sedation, and Immobility
By Drs. Rita N. Bakhru and William D. Schweickert

Vol 25, Lesson 29

Cardiovascular Effects of Air Pollution
By Dr. Alessandra D'Alessandro

www.chestnet.org/Publications/CME-Publications/PCCSU

NETWORKS: A survey, a course, unique liaisons, and more

Sleep Medicine

Survey results

Last year, the Sleep Medicine Network sent out a survey to its members to explore their relative comfort in managing different types of patients who may be seen in practice and the degree to which they encouraged referral of such patients to their practices. Though one could certainly debate the validity of the measurement tool, there were two main goals in collecting these data: we were hoping to debunk the commonly propagated myth that pulmonary sleep specialists “only like to manage apnea” and that we are also planning on developing sessions at the CHEST meeting to focus on those areas in which our members were least comfortable.

One hundred and fifty NetWork members responded to the survey. Unsurprisingly, 93% reported that they were extremely comfortable managing obstructive sleep apnea; but we were surprised to see that the next most “comfortable” area was restless legs syndrome, followed by central sleep apnea, and circadian rhythm disorders. Narcolepsy, parasomnias, insomnia, and management of the psychiatric patient with sleep

problems rounded out the list. Based upon these data, the steering committee is planning a broader slate of sleep-related educational opportunities at CHEST 2013, with focus on some of the areas identified by our membership as areas in which they were less comfortable.

The steering committee has also started an online journal club, available through the College’s e-Community. Each month, one of our members will post a brief commentary on a recent sleep medicine publication. The conversation has been robust, and we hope you will join in!

Dr. David Schulman, FCCP, Chair

Occupational and Environmental Health

Course coming in June

From respiratory health hazards in the home and workplace to outdoor air pollution and global warming, the **Occupational and Environmental Lung Disease Conference**

2013 will cover everything you need to know about respiratory exposures and their effects on human

health. Hear the most important new knowledge in the field and the clinical updates essential for patient care. This targeted intensive educational immersion in occupational and environmental lung diseases is a “can’t miss” course for pulmonary clinicians and others. This multiday conference will

bring together an expert faculty of educators and investigators. The last time this course was held was in 1999 – so don’t miss this one! Go to the College’s website, chestnet.org, to find all the information you need about this course in Toronto, Canada, on June 21-23.

Dr. Ware Kuschner, FCCP

Palliative and End-of-Life Care

How to make ethics consultations in hospitals more helpful and accessible

The practice of hospital clinical ethics is maturing. From the earliest days of hospital ethics committees to today (Rothman. *Strangers at the Bedside*, 2003), the practice of hospital clinical ethics consultation (CEC) has become ubiquitous (Fox et al. *Am J Bioethics*. 2007;7[2]:13; Hurst et al. *Health Care Annals*. 2007;15[4]:321; Nagao et al. *BMC Med Ethics*. 2008;29[9]:2). Currently, most hospitals have ethics committees that perform consultations.

Physicians do not call ethics consultations for many reasons: They take too much time, might make the situation worse, or will be unqualified (DuVal et al. *J Gen Intern Med*. 2004; 19:251). These published data are inconsistent with the authors’ experience, as we consult on over 300 cases annually, but are consistent with what physicians elsewhere report. At the 2013 North American Burn Society meeting, burn surgeons said they did not typically call consultations because they did not find them helpful; and when they did, the services were not available in a timely fashion.

The problem, we think, is a result of how the whole field of clinical ethics has evolved. The “facilitative” model has dominated (ASBH Core Competencies, Vol. 2). One might muse that if there haven’t been qualified clinical ethicists, then simply facilitating the

relevant parties in coming to their own recommendations was prudent. But today we know what a qualified clinical ethicist looks like (Acres et al. *J Clin Ethics*. 2012;23[2]:156) and what processes are needed to hire one (Mokwunye et al. *HEC Forum*. 2010;22[1]:51). Hospitals need to stop relying completely on ethics committee members, the vast majority of whom are untrained volunteers.

Instead, hospitals need to start building clinical ethics programs. Just hiring one qualified clinical ethicist would allow for training for the ethics committee (Edelstein et al. *HEC Forum*. 2009;21[4]:34; Mokwunye et al. *HEC Forum*. 2012;23[2]:147), hospital-wide ethics education, and the establishment of upstream clinical ethics practices (DeRenzo et al. *Cambridge Quarterly of Healthcare Ethics*. 2006;15[2]:207). Once a hospital makes these changes, physicians will find they have better access to a helpful, full-service clinical ethics program that provides timely consultative services.

Dr. Nneka O. Mokwunye
Steering Committee Member
Dr. Evan G. DeRenzo

Respiratory Care

Unique liaisons

Did you know this NetWork has unique liaisons from the ACCP community? Here is a brief description of these organizations with their liaisons from the ACCP:

AARC-BOMA: American Association for Respiratory Care – Board of Medical Advisors (aarc.org)

The AARC is an association for respiratory care professionals and allied health specialists interested in cardiopulmonary care. The AARC is committed to enhancing professionalism of respiratory care practitioners, improving performance, and helping to broaden the practitioners’ scope of knowledge. The AARC publishes *AARC Times* and *Respiratory Care*.

AARC-BOMA liaisons: Dr. Robert Aranson, FCCP; Dr. Kent L. Christopher, RRT, FCCP; Dr. Woody V. Kageler, FCCP; and Dr. Harold Manning, FCCP.

CoARC: Commission on Accreditation for Respiratory Care (coarc.com)

CoARC’s mission is to promote high quality respiratory care education through accreditation services. The CoARC accredits first professional respiratory care degree programs at the Associate,

Continued on following page



Occupational and Environmental Lung Disease Conference 2013

June 21 - 23
Toronto, Ontario, Canada

Hear New Findings and Clinical Updates for Patient Care

Don't miss this educational immersion in occupational and environmental lung disease.

Learning Objectives:

- Describe the clinical features of classic and emerging occupational and environmental lung diseases.
- Identify diagnostic techniques to support or confirm diagnosis.
- Explain treatment principles and delineate management strategies.
- Determine when to refer a patient for special evaluation and testing.

AMERICAN COLLEGE OF
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chestnet.org/O-E

Continued from previous page

Baccalaureate, and Master Degree level in the United States and internationally and also accredits professional respiratory care degree programs in polysomnography.

CoARC liaisons: Dr. David L. Bowton, FCCP; Dr. Joseph P. Coyle, FCCP; and Dr. Kevin M. O'Neil, FCCP.

NAMDRC: The National Association for Medical Direction of Respiratory Care (namdrc.org)

NAMDRC is a national organization of physicians whose mission is to educate its members and address regulatory, legislative, and payment issues that relate to the delivery of health care to patients with respiratory disorders. NAMDRRC represents physicians in respiratory care departments, critical/ICUs, sleep labs, pulmonary rehabilitation, and managing blood gas labs. NAMDRRC publishes *Washington Watchline* and *Current Controversies*.

NAMDRC has a representative to the ACCP Respiratory Care Network: Dr. Paul A. Selecky, FCCP.

NBRC: The National Board for Respiratory Care (nbrc.org)

The NBRC is a voluntary health certifying board that evaluates the professional competence of respiratory therapists. The NBRC strives

for excellence in providing credentialing examinations and associated services to the respiratory community. The NBRC's CRT examination is currently the basis for state licensure for RTs in 49 states. Through its Continuing Competency Program, the NBRC demonstrates compliance with the accreditation standards of the National Commission for Certifying Agencies.

NBRC Liaisons: Dr. Robert A. Balk, FCCP; Dr. Brian W. Carlin, FCCP (also the current NBRC Vice President); Dr. David A. Kaminsky, FCCP; Dr. Carl Kaplan, FCCP; and Dr. Robert A. May, FCCP.

Dr. Herbert Patrick, FCCP, Chair
Dr. Kevin M. O'Neil, FCCP, Vice-Chair

Home Care

Home sleep testing

The field of sleep medicine is evolving in multiple ways. One critical change involves the growing, and increasingly mandated, adoption of home sleep testing (HST) for the diagnosis of obstructive sleep apnea (OSA). In a comprehensive review in 2003 by the ATS, AASM, and ACCP, HST was considered acceptable when attended, but its widespread use discouraged. A decision by Medicare to approve HST as an acceptable diagnostic modality paved

the way for a more widespread adoption of HST. Recent data emerged that seemed to suggest that HST has acceptable degree of specificity and sensitivity in diagnosing OSA, but it was also clear that such results were seen only in a carefully selected and circumscribed population of patients without significant comorbidity and with high pretest probability of OSA. The broader applicability of such results is hence unclear. Advantages to HST are convenience, better patient acceptance, low barrier to deployment, and lower cost. Disadvantages include data loss, a large percentage of indeterminate study results, misdiagnosis – both false-positive and false-negative, and finally, inability to determine effects on sleep architecture, as well as diagnose comorbid sleep conditions. Important concerns regarding HST have been raised that include the lack of large outcome studies and lack of external validity.

A clinical guidelines paper by the AASM portable monitoring task force highlights the limitations and contraindications of HST. The key elements include selecting patients with high pretest probability and excluding patients with moderate to severe pulmonary disease, neuromuscular disease, and congestive heart failure, or when other sleep disorders are either

suspected or comorbid.

Issues to consider as one incorporates an HST strategy include selecting the appropriate equipment and outlining an appropriate triage and distribution plan that includes an appropriate chain of custody. A recent paper from the AASM, published in the *Journal of Clinical Sleep Medicine*, categorizes the different systems on the basis of a SCOPER system, to enable a ready comparison of the features across different systems. Factors that need to be considered would include costs, not only of the equipment itself, but more importantly of the disposables, as well as data management and software integration with your existing platform.

Dr. Shyam Subramanian, FCCP
Vice-Chair

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PULMONARY PERSPECTIVES: Bronchiectasis—a resurgence

Bronchiectasis, once characterized as an orphan disease, is experiencing resurgence in North America and around the world. Pulmonary physicians are encountering increasing numbers of patients who need evaluation and treatment for their bronchiectasis and the resultant infectious and noninfectious complications of the permanently damaged airways.

Bronchiectasis is defined as permanent dilatation of bronchi and

An association between bronchiectasis and moderate to severe COPD is being increasingly recognized.

bronchioles with associated airway wall damage; it is thought to be a consequence of the vicious cycle of infection and inflammation.

Bronchiectasis is found in patients across the span of age (pediatric to geriatric) and in both genders and all ethnic groups. Women are more frequently affected than men in North America, and older adults have a higher prevalence than chil-

dren and the young and middle-aged.

Patients with bronchiectasis present to their physicians with chronic cough, usually productive of significant mucus. CT scan of the chest with high resolution cuts (HRCT) is the gold standard for diagnosing bronchiectasis; some patients will be referred to pulmonologists because a CT scan, done for a different clinical indication, demonstrates bronchiectatic findings (Figure).

Recognizing bronchiectasis

Patients with bronchiectasis usually have a chronic productive cough; other symptoms are wheezing, exertional dyspnea, and hemoptysis. Some patients with bronchiectasis have a nagging dry cough. Patients are often initially diagnosed as having recurrent bronchitis or pneumonia; imaging studies are needed to confirm the presence of bronchiectasis. Although bronchiectasis may be suspected based on plain chest radiographic imaging, HRCT scan is the diagnostic imaging study that confirms the presence of bronchiectasis. High resolution thin cut slices through the chest are needed to de-



Dr. Anne E. O'Donnell, FCCP

tect more subtle findings in bronchiectasis and to help characterize the severity and extent of the disease. Traditionally, bronchiectasis is characterized as cylindrical, varicose, or cystic based on the CT findings of airway involvement and associated destruction of surrounding lung tissue.

Bacterial infection of bronchiectatic airways is common, and bacterial cultures of expectorated sputum should be obtained in all patients who are diagnosed with bronchiectasis. If expectorated sputum is not available, induced sputum collection or bronchoscopy with bronchoalveolar lavage may be necessary to obtain adequate material for culture.

About one-third of patients with bronchiectasis is infected with *Pseudomonas aeruginosa*; *Haemophilus influenzae*

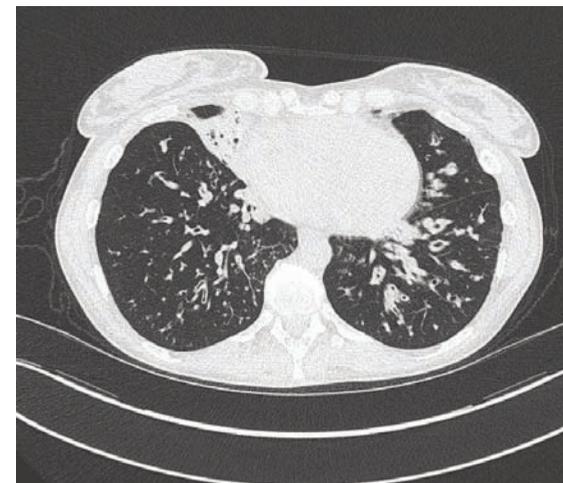
and other gram-negative bacteria are also exceedingly common. Some patients with bronchiectasis are infected with gram-positive organisms, including *Streptococcus pneumoniae* and *Staphylococcus aureus*. In North America, nontuberculous mycobacterial (NTM) organisms are frequently cultured from the respiratory secretions of patients with bronchiectasis. *Mycobacterium avium* complex (MAC) is the most commonly encountered NTM organism; rapid growing organisms like *Mycobacterium abscessus* are also seen but in fewer patients.

The pathophysiology of infection in bronchiectasis is not entirely clear. Whether the infection precipi-

tates bronchiectasis, particularly in the case of NTM infection, or whether NTM infection is a consequence of bronchiectasis has not yet been conclusively determined (Griffith and Aksmit. *Clin Chest Med.* 2012;33[2]:283). There are some radiographic correlations between infecting organisms and severity of bronchiectasis; *P aeruginosa* is associated with more severe disease and cystic bronchiectasis. MAC infection is often associated with nodular bronchiectasis, particularly in the right middle lobe and lingula, significant mucus plugging of the airways, and “tree in bud” small airway mucus impaction.

Causes

Many congenital and acquired systemic and pulmonary diseases can cause bronchiectasis, but over 50% of cases are thought to be idiopathic. Another 25% to 30% of patients with bronchiectasis had a prior chest infection (recent or remote) that resulted in the damaged airways. Genetic causes of bronchiectasis



High resolution CT image shows right middle lobe and bilateral lower lobe bronchiectasis with extensive mucus plugging.

include cystic fibrosis, primary ciliary dyskinesia, congenital disorders of humoral immunity, inherited connective tissue disorders, and alpha₁-antitrypsin (AAT) deficiency. Acquired immunodeficiency syndromes, swallowing dysfunction/aspiration or gastroesophageal reflux, rheumatologic disorders, and inflammatory bowel disease also cause bronchiectasis. Allergic bronchopulmonary aspergillosis is associated with central “finger in glove” bronchiectasis. Determining an etiology for the bronchiectasis can be important for prognosis and treatment decisions. Of note, an association between bronchiectasis and moder-

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Continued from previous page

ate to severe COPD is being increasingly recognized; bronchiectasis has been associated with an increased risk of all-cause mortality in this patient group (Martinez-Garcia et al. [*Am J Respir Crit Care Med*. Published online ahead of print Feb 7, 2013.]

Treatment

There are no current US Food and Drug Administration-approved treatments for bronchiectasis or for bronchiectasis-associated infections. However, there are a number of phase 2 and 3 clinical trials underway that will hopefully address this gap in therapy. In the meantime, there are several therapeutic modalities that can be individualized to the patient in order to potentially mitigate symptoms, improve quality of life, and reduce infectious exacerbations. These treatments include airway clearance, exercise/pulmonary rehabilitation, chronic antiinflammatory therapy and chronic antibiotic therapy, and surgical resection.

Many patients can be treated con-

servatively; if daily symptoms are minimal to mild, then airway clearance and exercise may be effective. If patients are having frequent troublesome symptoms of cough and mucus production, then therapy can be scaled up to include mechanical and pharmacologic airway clear-

Chronic maintenance antibiotic therapy may be indicated for patients who experience exacerbation (and require systemic antibiotic therapy) more than two or three times per year.

ance measures, chronic antiinflammatory therapy with inhaled steroids, and oral macrolides. Chronic maintenance antibiotic therapy (inhaled or oral) may be indicated for patients who experience exacerbation (and require systemic antibiotic therapy) more than two or three times per year. All antibiotic therapy, whether maintenance or

for exacerbations, should be targeted at the organisms known to be present on culture.

Care must be taken to evaluate the patient for nontuberculous mycobacterial infection. Not all patients infected with NTM organisms require treatment, but if antibiotic treatment is indicated, it must be done with careful attention to efficacy and side effects. Surgery is a consideration for localized bronchiectasis to control otherwise untreatable bleeding or to debulk the worst areas of infection.

Other supportive treatments for patients with bronchiectasis include appropriate immunizations and nutritional support, if needed. If there is an identified primary treatable cause of bronchiectasis, such as immunoglobulin deficiency, AAT deficiency, or allergic bronchopulmonary aspergillosis, then treatment aimed at those disorders may help to control the bronchiectasis.

Conclusion

Bronchiectasis has experienced a resurgence in North America, and

pulmonologists must be prepared to diagnose and treat patients and to keep our primary care colleagues up to date about bronchiectasis. Helpful recent reference/guideline publications include a comprehensive review (*Clin Chest Med*. 2012;33[2]:x1-404) and British Thoracic Society Guidelines (*Thorax*. 2010;65[suppl 1]:1-58).

The Bronchiectasis Research Registry (csc.unc.edu/bron), sponsored by the COPD Foundation, is currently enrolling patients in a multicenter database in order to better understand the demographics and natural history of this heterogeneous condition. Clinical trials for new therapies are currently underway (clinicaltrials.gov), and pulmonary specialists are encouraged to refer their patients for enrollment in studies aimed at understanding this "old" but new disease.

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