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MICHELE G. SULLIVAN/IMNG MEDICAL MEDIA

Rates of PE and DVT in children increased by about 70% from 2001 to 2007, Dr. James Callahan reported.

Expect the unexpected: More clots in kids

BY MICHELE G. SULLIVAN
IMNG Medical News

LAKE BUENA VISTA, FLA. – Venous thromboembolism is “not that uncommon in children” and seems to be on the rise, Dr. James Callahan said at a meeting sponsored by the American College of Emergency Physicians and the American Academy of Pediatrics.

In the general pediatric population, annual incidence is around 1 per 100,000. In hospitalized children, the number is much higher – up

to 57 per 100,000. Rates of pulmonary embolism and deep vein thrombosis have increased markedly over the past decade, said Dr. Callahan of the Children’s Hospital of Philadelphia.

“National hospital discharge data show that the disorders increased by about 70% from 2001 to 2007, and other studies show similar increases in other countries,” he noted.

Although no one really knows the reason behind this increase, it’s probably linked to better medical care

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Cortisol breakdown impaired during critical illness

Hydrocortisone ‘stress doses’ overly high

BY MARY ANN MOON
IMNG Medical News

The breakdown and clearance of cortisol are impaired during critical illness, which may account in part for the abnormally high blood levels of cortisol often observed in ICU patients, according to a report in the *New England Journal of Medicine*.

Hypercortisolemia often accompanies critical illness, but until now it usually has been attributed to increased cortisol production driven by stress-induced activation of the hypothalamic-pituitary-adrenal axis. However, some researchers posited that an-

other possible contributor to hypercortisolemia in this setting might be suppression of the removal of cortisol.

“We hypothesized that cortisol metabolism is reduced during critical illness, contributing to sustained hypercortisolemia with enhanced negative-feedback inhibition of corticotropin,” said Dr. Eva Boonen of the clinical division and laboratory of intensive care medicine, Catholic University of Leuven (Belgium), and her associates.

To test their hypothesis, the investigators studied 158 consecutive adults treated for critical illness in a single

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for hypertension

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Specialists get room in medical home

BY MARY ELLEN SCHNEIDER
IMNG Medical News

The National Committee for Quality Assurance has launched a new program to recognize the role of specialists in the patient-centered medical home.

The program, which launched this spring, evaluates how well specialists do in ensuring access, communication, and care coordination for their patients. The Patient-Centered Specialty Practice Recognition program is based on the concept of the medical home

“neighbor” – first developed by the American College of Physicians – and follows the same model as the NCQA’s patient-centered medical home recognition program for primary care physicians.

Most patients see multi-

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Have we come far enough in PAH patient outcomes?

CHANGEMI

Despite advances, patients' long-term outcomes remain poor

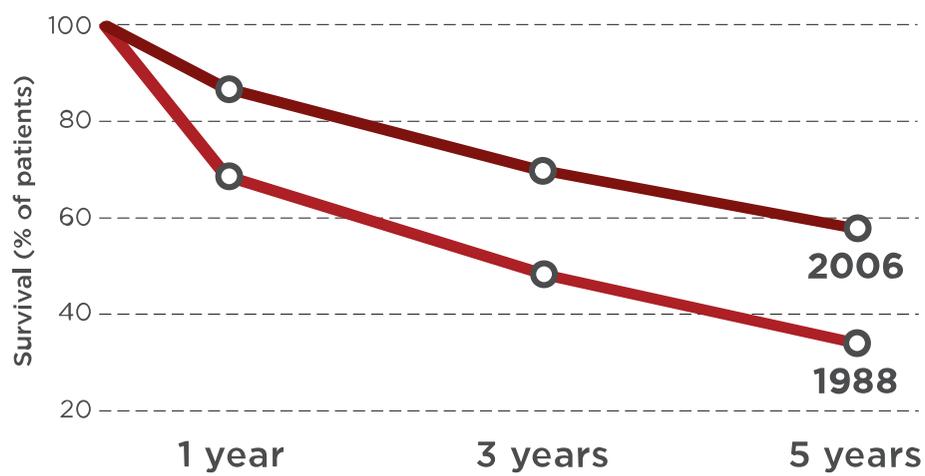
Significant progress has been made in PAH treatment over the past 2 decades, yet patient morbidity and mortality remain high.¹ There is limited information on the long-term effects of PAH-specific therapies, and many patients continue to experience death, hospitalizations, and the need for additional therapies.^{1,2}

Now is the time for a new perspective in PAH. Experts are calling for future PAH studies to deliver data on the long-term effect of therapy on clinical outcomes, such as hospitalizations and mortality.¹⁻³ Actelion is committed to investigating this evolving perspective in PAH.

References: 1. Galiè N, Manes A, Negro L, Palazzini M, Bacchi-Reggiani M, Branzi A. A meta-analysis of randomized controlled trials in pulmonary arterial hypertension. *Eur Heart J*. 2009;30:394-403. 2. Gomberg-Maitland M, Dufton C, Oudiz RJ, Benza RL. Compelling evidence of long-term outcomes in pulmonary arterial hypertension? *J Am Coll Cardiol*. 2011;57:1053-1061. 3. McLaughlin VV, Badesch DB, Delcroix M, et al. End points and clinical trial design in pulmonary arterial hypertension. *J Am Coll Cardiol*. 2009;54:S97-S107. 4. Thenappan T, Shah SJ, Rich S, Gomberg-Maitland M. A USA-based registry for pulmonary arterial hypertension: 1982-2006. *Eur Respir J*. 2007;30:1103-1110. 5. D'Alonzo GE, Barst RJ, Ayres SM, et al. Survival in patients with primary pulmonary hypertension. Results from a national prospective registry. *Ann Intern Med*. 1991;115:343-349.

PERSECT

Survival in PAH, 1988 and 2006*^{4,5}



*Survival observed over periods from 1981-1988 and 1982-2006, respectively.

Amiodarone increases cancer risk in men

BY BIANCA NOGRADY
IMNG Medical News

The antiarrhythmic drug amiodarone is associated with an increased risk of cancer, but the effect is significant only in men or at higher doses, according to a Taiwanese population-based cohort study published in *Cancer*.

"We found that there was a borderline significantly increased risk of cancer among patients who received amiodarone compared with the general population," wrote Dr Vincent Yi-Fong Su of the Taipei (Taiwan) Veterans General Hospital and his colleagues. Patients either of male sex or with more than 180 cumulative defined daily doses within the first year "had a significantly higher risk of developing cancer, and those with both

factors had an even greater SIR [standardized incidence ratio] of 1.46 ($P = .008$)."

While all patients receiving amiodarone had a slight increase in their overall risk of cancer (SIR, 1.12; 95% CI, 0.99-1.26; $P = .067$), the risk was significantly higher in men (SIR, 1.18; 95% CI, 1.02-1.36; $P = .022$) but not in women (SIR, 0.99; 95% CI, 0.79-1.23).

"One possible explanation for this difference is that there is a 37% higher clearance rate of amiodarone in females than in males because of differences in cytochrome P450 3A4 activity and the percentage of body fat," the authors reported.

The study also found a dose-dependent relationship between amiodarone and cancer risk. Among patients in the middle and top tertile of cumulative defined daily dose, the adjusted hazard

ratios were 1.70 (95% CI, 1.02-2.84; $P = .042$) and 1.98 (95% CI, 1.22-3.22; $P = .006$) respectively, after adjustment for age, sex, and comorbidities.

The researchers examined data from 6,418 patients treated with amiodarone, 43% of whom were female, using information from the Taiwan National Health Insurance Research Database.

During the median 2.6-year follow-up, 280 patients developed cancer, with no significant differences found in the type or location of cancer. Amiodarone, approved by the Food and Drug Administration in 1985, is a fat-soluble drug with a long elimination half-life, so large amounts of the drug can build up in the soft tissues after prolonged treatment, and post-marketing surveillance had suggested an increased risk of lung masses, thyroid cancer, and skin cancer.

The researchers noted an increase in the incidence of cancer in the first year after amiodarone therapy (SIR, 1.32; 95% CI, 1.05-1.64; $P = .002$), although they suggested this may be due to surveillance bias (*Cancer* April 8, 2013 [doi.wiley.com/10.1002/cncr.27881]).

"To provide an initial, thorough evaluation of the etiology of arrhythmias and to monitor the toxicity of amiodarone in follow-up studies, an increased number of medical examinations are performed in patients treated with amiodarone," the authors wrote. "Thus, the cancer incidence within the first year falsely

increases due to early detection."

While the study excluded patients with preexisting malignancies, researchers could not account for other risk factors, such as obesity, smoking and alcohol use, environmental exposure, and family history of cancer.

The authors concluded that while extensive screening for occult cancers in patients taking amiodarone was not practical, they advocated closer surveillance of cancer events in future amiodarone trials.

The study was partly supported by the Taipei Veterans General Hospital. The authors reported no relevant financial conflicts.

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CHEST PHYSICIAN Is Online

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

VIEW ON THE NEWS

Dr. Jun Chiong, FCCP, comments: Amiodarone is commonly used, especially in subjects with atrial fibrillation. This new cohort study emphasizes the fact that long-term medications must be continuously evaluated as the risk/benefit ratio may no longer be favorable. However, cohort studies should only generate hypothesis and a long-term randomized trial is necessary before label changes are instituted.



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Cortisol breakdown lags in ICU

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ICU and 64 demographically matched but not critically ill control subjects. They measured five aspects of cortisol metabolism: daily corticotropin and cortisol levels; plasma cortisol levels reflecting the clearance, metabolism, and production of cortisol during an infusion of deuterium-labeled tracers; plasma clearance of a therapeutic 100-mg IV bolus of hydrocortisone; urinary levels of cortisol metabolites; and levels of major cortisol-metabolizing enzymes in liver and adipose tissue.

Their findings demonstrated that “elevated cortisol levels in critically ill patients were only partially explained by an increase of 83% in cortisol production, as compared with controls.” In addition, impaired breakdown and clearance of cortisol contributed to hypercortisolemia, the investigators reported. They found a reduction of more than 50% in cortisol clearance after administration of the 100 mg of hydrocortisone (N. Engl. J. Med. 2013 March 19 [doi: 10.1056/NEJ-Moa1214969]).

The clinical implications of these study findings markedly change “our understanding of the stress response. Reduced inactivation of cortisol may be important not only to increase circulating levels but also to potentiate cortisol levels and activity within the vital tissues that express inactivating enzymes.

“More pragmatically, the data suggest that ‘stress doses’ of hydrocortisone, which are advocated to replace

cortisol production in critically ill patients who are presumed to have adrenal failure, are at least 3 times too high,” researchers said.

The data also suggest that “a low

cortisol response to corticotropin stimulation does not necessarily reflect adrenal failure, since cortisol production in critically ill patients is not subnormal, and the suppressed clearance maintains hypercortisolemia. Our results may therefore help to explain why studies investigating the effect of the daily adminis-

tration of 200 mg of hydrocortisone in patients with sepsis ... have had conflicting results,” they added.

This study was supported by the Belgian Fund for Scientific Research, the British Heart Foundation, the Flemish government, and the European Research Council. No relevant conflicts of interest were reported.



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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.

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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.

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



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VIEW ON THE NEWS

Dr. Steven Q. Simpson, FCCP, comments: Since the advent of low-dose steroids for septic shock nearly a decade and a half ago, it has been difficult to confirm a clear role for their administration. One has to agree that the findings of these studies may help to explain the inconsistent response to exogenous steroids of patients who are treated because they do not respond in a corticotropin stimulation test. With further work, these studies may lead to a better understanding of who should and who should not be treated with exogenous corticosteroid.



For hypertension, pair CPAP with weight loss

BY SHERRY BOSCHERT

IMNG Medical News

SAN FRANCISCO – A 24-week program combining weight-loss efforts with continuous positive airway

pressure produced greater reductions in systolic blood pressure in obese patients with obstructive sleep apnea, compared with either intervention alone, a study of 181 adults found.

In an intent-to-treat analysis, all

three groups reduced systolic pressures to a statistically similar extent, compared with baseline – decreases of approximately 8 mm Hg in the combination group and 4 mm Hg with either monotherapy. Among 136

patients who adhered to therapy by completing the trial, however, systolic blood pressure decreased by a mean of 14 mm Hg in the 62 patients randomized to the combination of weight-loss efforts and continuous positive airway pressure (CPAP), a significantly greater decrease than the reductions of approximately 7 mm Hg in 61 patients randomized to weight-loss efforts alone and 3 mm Hg in 58 patients who got CPAP alone.

A 14 mm Hg drop in systolic blood pressure is an “important reduction” with potentially significant clinical benefits in obese patients with obstructive sleep apnea, Dr.



Systolic blood pressure fell 14 mm Hg in patients receiving a combination of weight-loss efforts and CPAP.

DR. CHIRINOS

Julio A. Chirinos said at the annual meeting of the American College of Cardiology.

Previous observational studies have shown strong links in obesity, obstructive sleep apnea, and hypertension but have not been able to prove any incremental blood pressure benefit to combining treatments for obesity and sleep apnea. Dr. Chirinos and his associates conducted an ancillary analysis of data from the Cardiovascular Consequences of Obstructive Sleep Apnea trial, which focused primarily on the treatments' effects on C-reactive protein levels. The study randomized adults with at least moderate obesity and moderate to severe obstructive sleep apnea and C-reactive protein levels greater than

Continued on following page

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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

R_x 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:** gastroenteral 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 (RHDID) 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 RHDID on a mg/m² basis. In rabbits, tiotropium caused an increase in post-implantation loss at an inhalation dose of approximately 360 times the RHDID on a mg/m² basis. Such effects were not observed at inhalation doses of approximately 4 and 80 times the RHDID 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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Continued from previous page

1 mg/L to the three intervention groups. Baseline characteristics were similar among groups. Approximately 41% of patients were hypertensive at baseline.

In the per-protocol analysis of patients who adhered to therapy, the decreases in systolic blood pressure, compared with baseline, were statistically significant in the combination and weight-loss groups but not the CPAP group, reported Dr. Chirinos of the University of Pennsylvania, Philadelphia.

Body weight and body mass index decreased significantly in the weight-loss and combination groups, compared with baseline, but did not change significantly in the CPAP group. Patients in the weight-loss and combination groups dropped approximately 7 kg in the intent-to-treat analysis and 10-11 kg in the per-protocol analysis. BMI decreased by a mean of two to three points in the intent-to-treat analysis and by approximately four points among those who adhered to therapy. No specific details were provided about the weight-loss efforts.

Mean arterial pressure decreased significantly in all three groups, compared with baseline, in both intent-

to-treat and per-protocol analyses, but fell significantly more in the combination group, compared with monotherapy, in the per-protocol analysis. Among patients adherent to treatment, mean arterial pressure decreased by more than 10 mm Hg in the combination group, compared with approximately 4 mm Hg—de-

Only combination therapy significantly reduced brachial pulse pressure, compared with baseline (by approximately 3 mm Hg), in the intent-to-treat analysis.

clines with either monotherapy.

Only combination therapy significantly reduced brachial pulse pressure, compared with baseline (by approximately 3 mm Hg), in the intent-to-treat analysis. In the per-protocol analysis, brachial pulse pressure dropped significantly, compared with baseline, in the combination group (a 6 mm Hg decrease) and the weight-loss group (a 4 mm Hg—decrease) but not in the CPAP group.

Brachial pulse pressure decreased significantly with combination therapy in the intent-to-treat analysis but

not with either treatment alone. Mean brachial pulse pressure in the per-protocol analysis decreased significantly with combination therapy (a 6-mm Hg reduction) or weight-loss therapy (a 4-mm Hg decrease), but increased in the CPAP group.

Carotid-radial pulse pressure amplification measurements did not change significantly from baseline in any group.

The findings are limited by the study's strict criteria for patient inclusion, its lack of arterial blood pressure monitoring, the use of noninvasive estimates of central pressure measurements, and its short duration. The study used carotid tonometry to measure central pulse pressure.

The study excluded patients with blood pressures greater than 160/95 mm Hg, those with predominantly central sleep apnea, patients using supplemental oxygen, and anyone in a high-risk occupation or with a record of dangerous driving. Also among the excluded were patients with confounders of systemic inflammation, sustained arrhythmia, unstable cardiopulmonary disease, severe restless leg syndrome or chronic pain causing frequent night awakenings, pregnancy, severe depression, or serious medical or psychological condi-

tions that might compromise their safety in the study, and prior CPAP within 8 weeks of the study.

The American Heart Association funded Dr. Chirinos's analysis. Dr. Chirinos reported having no financial disclosures. Some of his associates reported financial relationships with multiple pharmaceutical companies.

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VIEW ON THE NEWS

Dr. Vera DePalo, FCCP, comments:

There can be many contributing factors to hypertension: genetics, lifestyle, diet, medications, and other comorbidities. The potential multifactorial etiology of a patient's hypertension may allow practitioners to plan a multipronged strategy for treatment and control. Addressing all the variables that are in the control of the physician and the patient may offer the greatest improvement.



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Only 11% of health plan payments are value based

BY ALICIA AULT

IMNG Medical News

WASHINGTON – Only about 11% of health plan payments to physicians and hospitals are tied to performance or efficiency – meaning that almost 90% of payments are still fee for service, according to a report released by Catalyst for Payment Reform.

The San Francisco-based nonprofit is a collaborative of employers and health plans that advocates the overhaul of the nation's health care payment infrastructure by encouraging more value-based payment.

Using data provided by commercial health plans, the group determined that 11% of hospital payments, 6% of outpatient specialist payments, and 6% of primary care physician payments are “value oriented.”

Of those payment arrangements, 57% involve provider risk such as bundled payment, capitation, and shared-risk payment. The remaining 43% provide incentives, such as shared savings or pay for performance.

The main goal of Catalyst for Payment Reform (CPR) is to raise the volume of value-based commercial payments to health care providers to 20% by 2020. Coalition members said that they saw reason for both pessimism and optimism in the report's findings.

“Obviously, these results are pretty disappointing,” said Dr. Robert Galvin, chief executive officer of Equity Healthcare, which buys health care cov-

erage for private equity companies. Even so, the report itself represents “the triumph of transparency,” he said at the press briefing. “It is just simply good to know.”

Susan Delbanco, executive director of CPR, noted that in 2010, 1%-3% of provider payments were tied to performance. Given the latest information, “it looks to me like we are on a fast track and that we may get there before 2020,” she said.

The group's research also found that about 2% of health plan enrollees are enrolled in an accountable care organization or a patient-centered medical home.

Most health plan payments (about 75%) are still made to specialists, while 25% go to primary care physicians, according to the analysis. Non-fee-for-service payments are still not entirely rewarding or providing incentives to improve the quality of care. Only 35% of those value-based payments have quality of care as a factor.

Dr. Richard Gilfillan, director of the Center for Medicare and Medicaid Innovation at the Centers for Medicare and Medicaid Services, said that the agency was “thrilled” with the report, noting that it showed that private payers were helping encourage a transformation in payment.

“We're not discouraged – we think that change is happening, it's underway,” Dr. Gilfillan said at the press briefing.

The growing number of physicians participating in new payment models reflects a cultural shift, said Dr. Mark Smith, president and chief executive officer of the California HealthCare Foundation. “I

VIEW ON THE NEWS

Dr. Burt Lesnick, FCCP, comments: Pay for quality is a trend in commercial insurance payments. It is not yet clear what will be the tipping point at which practices change how they deliver services. Of course, the big question is how Medicare might be restructured.

think we have turned the corner on providers recognizing the feasibility, the desirability, and in fact, the inevitability of the kinds of payment reforms that you've heard about.”

The California HealthCare Foundation and the Commonwealth Fund provided the funding for the National Scorecard on Payment Reform, and a sister effort, the National Compendium on Payment Reform.

The scorecard tabulated data that 57 health plans provided to the National Business Coalition on Health. Participation is voluntary, and not all 57 plans answered all questions posed. The plans represent 104 million people in the commercial group market, or about two-thirds of the total commercially insured population in the United States.

Respondents were primarily large health plans, which means the results may not necessarily reflect the entire group market.

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Medical home makes room (and rules) for specialists

NCQA from page 1

ple physicians, so a program to help specialists see how they are doing on care coordination is essential, Margaret E. O'Kane, NCQA president, said during a press conference.

NCQA estimates that the typical primary care physician coordinates with 229 physicians across 117 different practices. And the average Medicare beneficiary sees seven physicians and fills more than 20 prescriptions each year.

“The opportunity for gaps to emerge among all those complex relationships – or for things to happen that really are in conflict with each other – obviously is great,” Ms. O'Kane said.

Specialists who take on a key management role for patients are prime candidates, according to NCQA.

“Pulmonologists who treat chronic conditions like asthma and COPD would be a good fit for this type of recognition program,” a committee spokesperson said.

Under the program, specialists will be required to meet several standards for care coordination and

information sharing:

- ▶ **Track and coordinate referrals.** Specialists will be required to create referral arrangements and care plans with primary care practices. They will also need to monitor the communication to make sure information is being received and that it meets the needs of all the providers.
- ▶ **Provide access and communication.** Specialists need to provide 24/7 access, either through in-person visits or electronically.
- ▶ **Identify and coordinate care for patient populations.** Specialists must track their patients over time and across clinical encounters.
- ▶ **Plan and manage care.** This standard includes previsit planning, creation of care plans, and medication management and reconciliation.
- ▶ **Track and coordinate care.** This involves tracking laboratory and radiology tests, hospitalizations, and emergency department visits.
- ▶ **Measure and improve performance.** This standard measures clinical quality, utilization, care coordination, and patient experience.

The program requires specialists to complete an online survey and submit documentation on their ability to meet the standards.

The NCQA offers three levels of recognition. Level 1 is awarded to practices that meet the minimum score of 25 points out of 100 and all of the “must pass” standards. Practices who score higher can qualify for higher levels of recognition. The recognition status lasts for 3 years.

Dr. John Cox, a Dallas oncologist and member of the NCQA advisory council that developed the standards, said his practice interacts with more than 500 referring physicians each year and too often does not have necessary information from other providers when they sit down to work out care plans with their patients.

“We do a terrible job of really coordinating our efforts,” he said.

Dr. Cox said he and other specialists are eager for the kind of tool the NCQA is offering.

“I think a lot of specialists are

VIEW ON THE NEWS

Dr. Burt Lesnick, FCCP, comments: The medical neighbor model appears to be a good concept. It will be interesting to see what hurdles will be necessary for accreditation and if payers will reimburse providers who make the effort to document this level of service.



somewhat thirsty for having an external yardstick by which we can measure and aspire to get our practices up to speed,” he said.

NCQA officials foresee that specialists who achieve this recognition potentially could see a financial benefit. Ms. O'Kane said payers might use the NCQA recognition as the basis for offering care coordination payments to specialists as part of pay-for-performance programs.

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Clots are a growing culprit in children

VTE from page 1

for children with chronic illness. “As we keep children with more and more complex diseases alive longer and longer, we’re going to keep seeing this trend,” he said.

VTEs can be harder to recognize in children than in adults. The symptoms can be subtle and non-specific. When signs and symptoms do occur, Dr. Callahan said, “we

CT angiography is probably the most reliable diagnostic tool. ‘The scan is quick, which is good, but the child has to be immobilized and you need at least a 22G intravenous cannula and may need a 20G.’

may not have PEs and DVTs high on the list of possibilities for children, so we can miss them. Sometimes it takes a while to figure it out. In autopsy studies, up to 4% of children showed signs of a pulmonary embolism or DVT. Only half of them had any symptoms at all, and a DVT was suspected in only about 15%.”

Risk peaks at two times during a child’s life: in babies younger than 1 year and in older teens. In infants, the incidence is often linked to prematurity and the need for an indwelling catheter. The second peak

is in teens around 15-18 years old who don’t have any underlying illness. These cases account for about 50% of childhood DVTs. In older children, the pathophysiology is similar to what’s seen in adults – they have some circulatory stasis, get a clot, and it breaks off.

A minority of children who develop a DVT or PE have some chronic predisposing illness – often a thrombophilia, but renal disease, systemic lupus erythematosus, and even some medications also can be underlying culprits. The indwelling line remains the single biggest risk factor for children of all ages.

What to look for

Pleuritic chest pain, the most common symptom, is present in up to 84% of cases. The incidence of dyspnea, at 58%, is much lower than in adult patients. About half of children with a VTE will cough, and about a third show hemoptysis. Children are likely to be hypoxemic and tachypneic, run a fever, and have abnormal breath sounds and increased second heart sound.

Hypoxemia can be a very telltale sign. “If I see that in a child in the absence of pneumonia, I start to get worried. If I see an adolescent who presents with unexplained pleuritic chest pain, dyspnea, hypoxemia, and one risk or more of the risk factors, I go looking for it,” Dr. Callahan said.

The Wells criteria – a classic risk-stratification system for adults – just don’t work in children. “Even if you change the numbers to make it age specific, it’s not really helpful,” he said.

Sinus tachycardia is the most reliable cardiac sign for pulmonary embolism in a child, but the ECG is completely normal in up to 25%. D-dimer levels are helpful in adults but have never been validated in children. A ventilation/perfusion scan is useful in otherwise healthy children, but “many of these kids have underlying disease, and that can make it inaccurate,” he pointed out.

CT angiography is probably the most reliable diagnostic tool. “The scan is quick, which is good, but the child has to be immobilized and you need at least a 22G intravenous cannula and may need a 20G,” Dr. Callahan said.

Treatment options

The treatment approach for children is also different than it is for adults, Dr. Callahan said.

“There are no good studies on thrombolysis for children, but in certain cases – such as a massive PE with hemodynamic instability – it can be considered.”

There are strict contraindications, however, including major surgery needed within 7-10 days; active bleeding; surgery on the central nervous system; ischemia, trauma, or

VIEW ON THE NEWS

Dr. Susan Millard, FCCP,

comments: This is another great example that kids are NOT little adults. More research in the area is needed, but this is a great study that provides important information.



hemorrhage within the past 30 days; recent seizures; a low platelet count and fibrinogen level; and uncontrolled hypertension.

Tissue plasminogen activator has not been well studied in pediatric populations and isn’t indicated for use in children, but it is often used off label. Low-molecular-weight heparin has become the treatment of choice for most. Its longer half-life and more predictable response make it a good choice for children, who will also need less frequent monitoring.

“Neither low-molecular-weight nor unfractionated heparin should ever be used in children with heparin-induced thrombocytopenia,” Dr. Callahan said. “In this setting, one of the newer anticoagulants, such as direct thrombin or selective Xa inhibitors, should be used.”

About 10% of children with a clot will die, but mortality is highly associated with underlying disease. Children who do survive have a risk of recurrence and an increased risk of death with each recurrence.

Dr. Callahan reported having no financial conflicts of interest.

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Genetics factor into adolescent, adult smoking habits

BY HEATHER LINDSEY
IMNG Medical News

Genetic risk may contribute to the rapid progression of daily and heavy smoking during adolescence and subsequent problems with nicotine dependence and smoking cessation in adulthood, according to a recent study.

The research may have implications for the development of initiatives that deter smoking in adolescents, reported Daniel W. Belsky, Ph.D., of the University of North Carolina at Chapel Hill and Duke University Medical Center, Durham, N.C., and his associates in *JAMA Psychiatry*. The 38-year longitudinal study included 1,037 men and women from the Dunedin Multidisciplinary Health and Development Study of New Zealand. Researchers assessed participants with a multilocus genetic risk score (GRS), originating from three meta-analyses of genome-wide association studies (GWAS) that used the number of cigarettes smoked daily as their phenotype. Dr. Belsky and his team focused their investigation on the single-nucleotide polymorphisms in 15q25.1 and 19q13.2 (*JAMA Psychiatry* 2013

March 27 [doi:10.1001/jamapsychiatry.2013.736]).

Genotyping was possible in 880 Dunedin subjects. In addition to evaluating family history in these individuals, researchers gathered smoking information at eight assessments from age 11 years to age 38 years.

The GRS was not associated with whether or when subjects started smoking. "In fact, daily smokers who did not progress to heavy use were at lower genetic risk than individuals who never smoked," researchers wrote.

Among 627 ever-smokers in the cohort, those with a higher genetic risk were more likely to rapidly progress to heavy smoking, meaning 20 or more cigarettes daily (hazard ratio, 1.35; 95% confidence interval, 1.14-1.58).

Adolescents with high genetic risk had a greater chance of becoming daily smokers by age 15 (relative risk, 1.24; 95% CI, 1.06-1.45) and progressing to heavy smoking by age 18 (RR, 1.43; 95% CI, 1.10-1.86).

Over the course of the study, subjects with a high genetic risk accumulated more pack-years of smoking. As adults, 27% of ever-smokers became nicotine dependent

and those at higher genetic risk had a greater chance of doing so (HR, 1.27; 95% CI, 1.09-1.47). Additionally, of 277 cohort members who smoked daily during their 30s, those with a higher genetic risk were more likely to use smoking to cope with stress.

Further analyses found that smoking cessation was also difficult in adults at high genetic risk. For example, in the cohort of 277 daily smokers, 53% quit smoking a month or longer across 72 months' follow-up; however, relapse occurred in 62%. Quitters with a higher genetic risk had a greater chance of relapsing (HR, 1.22; 95% CI, 1.02-1.45). Only 20% of daily smokers abstained from smoking for a year or more.

Associations detected between the GRS and smoking phenotypes were small, noted the study authors. "Children who our study would classify at high genetic risk are not guaranteed to become addicted if they try smoking, and, even more importantly, children we would classify at low genetic risk are not immune to addiction."

Finally, researchers found that the GRS score did not correlate with

family history. "The GRS contained different information about risk for developmental and mature phenotypes of smoking behavior, compared with family history," investigators reported.

The authors said that their research "adds a genetic dimension to longstanding arguments" in favor of early cigarette prevention of cigarette consumption, including surtaxes and age restrictions on tobacco purchases.

VIEW ON THE NEWS

Dr. Vera DePalo, FCCP, comments: Genetics dictate so much of our body's responses, whether it is the response to an infectious organism, how efficiently our enzymes will metabolize a toxin or which diseases are likely to affect us later in life. The understanding that there is a genetic risk for the progression to daily and heavy smoking is important.

It is clear that continued efforts to prevent smoking in children and adolescents are so important for controlling the burden of smoking-related lung disease later in life.

Tailored online feedback is asthma tool

BY SHERRY BOSCHERT
IMNG Medical News

SAN FRANCISCO – A website designed to give people with asthma tailored feedback about whether they need to see a doctor and what questions to ask when they do may have helped improve asthma control in a randomized, controlled trial.

The study randomized patients to get access to one of two modules in a "patient activation website." The asthma module provided tailored feedback about patients' asthma control, helped them decide whether they needed to visit a medical provider sooner than already scheduled, and suggested questions for patients to ask their providers. The control group got access to a module that suggested questions they should ask their primary care providers about preventive services such as cancer screening.

Among 325 adults who completed 12 months of follow-up (157 in the intervention group and 168 in the control group), measures of asthma control improved significantly in both groups, with most measures improv-

ing significantly more in the intervention group vs. the control group.

Mean scores on the Asthma Control Test (ACT) increased from 17.7 at baseline to 19.9 at 12 months in the intervention group and from 17.9 to 19.1 in the control group, both of which were significant improvements. The greater improvement in the intervention group was statistically significant compared with the control group, Jennifer M. Poger and her associates reported in a poster presentation at the annual meeting of the Society of Behavioral Medicine.

The proportion of patients with controlled asthma (defined as an ACT score of 20 or greater) increased from 50% at baseline to 73% at 12 months in the intervention group, and from 53% to 67% in the control group, both of which were statistically significant improvements. The difference between groups, however, did not reach statistical significance, reported Ms. Poger, a researcher at Pennsylvania State University, Hershey, Pa.

The mean number of inhaled asthma medications being used increased by 0.4 in the intervention group be-

tween baseline and the 12-month follow-up, compared with 0.2 more medications in the control group, a statistically significant difference.

The results suggest that websites that provide tailored feedback to patients with chronic conditions such as asthma may help them control their diseases, Ms. Poger said.

The investigators' financial disclosures were not available.

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VIEW ON THE NEWS

Dr. Vera DePalo, FCCP, comments: Care providers strive for engagement by the patient in managing their own health care. This model promises improved control and engagement. As the population of health care consumers becomes more comfortable with online activities, a greater segment of patients may become more active managers of their health, resulting in a healthier population overall.

Providers order fewer tests when fees are listed

BY JANE ANDERSON
IMNG Medical News

Providers order slightly fewer laboratory tests when given test fee information at the time of ordering, and adopting this tactic on a widespread basis might help reduce the number of inappropriately ordered diagnostic tests, a study from Johns Hopkins University, Baltimore, found.

The researchers compared ordering behavior among all providers in Johns Hopkins' computerized system during both a baseline period and an intervention period, when fees were shown for some tests. Orders fell 9.1% for the tests that had fee data shown, and the number of tests per patient-day decreased, too. Meanwhile, orders for tests that did not have fee data shown increased. Overall, the hospital saved \$400,000 in lab charges during the 6-month intervention period when test fee data were displayed, the study said.

NHANES follow-up captures asthma/allergy mortality

BY SHARON WORCESTER
IMNG Medical News

SAN ANTONIO – A diagnosis of asthma, allergic disease, or obstructive or restrictive lung disease among participants in the first National Health and Nutrition Examination Survey conferred a significantly in-

VITALS

Major finding: The long-term risk of death was significantly increased among NHANES I subjects with asthma who were aged 40-75 at baseline (hazard ratio, 1.22), but not among those aged 25-39 years at baseline (HR, 1.20).

Data source: Epidemiologic follow-up study (NHEFS) of the longitudinal NHANES I study.

Disclosures: Dr. Savage reported having no conflicts of interest.

creased long-term risk of all-cause mortality for adults who were aged 40-75 years at baseline but not for those who were aged 25-39 years at baseline, according to findings from the study.

A diagnosis of asthma in the younger group conferred an in-

creased long-term risk of death due to respiratory causes – as did a diagnosis of asthma in the older group, Dr. Jessica R. Savage reported in a poster at the annual meeting of the American Academy of Allergy, Asthma, and Immunology.

“This association was not likely explained by underlying bronchitis or an increased risk of death due to respiratory infection but was likely due to asthma itself,” said Dr. Savage of Brigham and Women’s Hospital, Boston.

“I think the main conclusions are reassuring – no increase in mortality if you are young and have allergies. Some studies show an association between allergy and stroke/heart disease. We were worried that with the rising increase in allergy, there would be also an increase in these other diseases. But we did not see that, fortunately.

“We saw an association with asthma and respiratory death even in the young. Of course, one always needs to remember to be vigilant with asthmatics, but overall for young people the news is good,” she said during an interview.

Data were obtained from the Na-

tional Health and Nutrition Examination Survey (NHANES I), which was conducted from 1971 to 1975 and included 31,937 adults.

Of these participants, 14,407 were included in the NHANES I Epidemiologic Follow-Up Study (NHEFS) and were assessed for doctor-diagnosed asthma, allergic rhinitis, food allergy, and urticaria.

Asthma and allergic diseases, which typically manifest in childhood, have increased in the United States over the last 3 decades.

A subcohort of 6,913 subjects received a more detailed health interview and examination, including prebronchodilator spirometry and percent predicted forced expiratory volume and forced vital capacity. Vital status and cause of death were obtained in 2006.

After adjustment for age, gender, income, education, race, and smoking history, a sensitivity analysis for the association between asthma and mortality demonstrated a significantly increased long-term risk of death in those who were aged 40-75 years at baseline (hazard ratio, 1.22), but not for those aged 25-39 years at baseline (HR, 1.20).

The hazard ratios for all-cause mortality in these groups, after exclusion of subjects with bronchitis, were not statistically significant (1.16 and 1.52, respectively).

Hazard ratios for the association between asthma and respiratory mortality were significant for the older and younger groups, respectively. The hazard ratios for these groups remained statistically significant at 8.56 and 1.82, respectively, after ex-

clusion of subjects with bronchitis.

This study also demonstrated that older subjects with obstructive lung disease were at significantly increased risk of both all-cause and respiratory mortality and that older subjects with restrictive lung disease were at significantly increased risk of both all-cause and cardiovascular mortality.

Conversely, older adults with urticaria had a reduced risk of cardiovascular mortality.

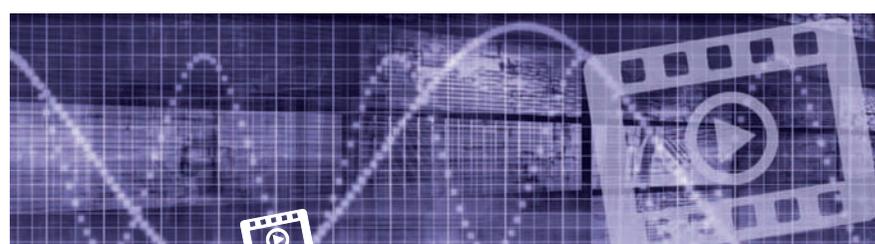
Cancer-related mortality was slightly, but not significantly, increased in the younger subjects diagnosed with urticaria, and in the older subjects diagnosed with asthma or moderate-to-severe lung obstruction.

“Asthma and allergic diseases, which typically manifest in childhood, have increased in the United States over the last 3 decades. Asthma and allergy may increase mortality by directly reducing lung function or may be markers of immune dysregulation that could lead to systemic inflammation,” Dr. Savage noted.

Although prior studies have demonstrated associations between allergic sensitization and stroke, hives and cancer, asthma and mortality, and obstructive lung disease and cardiovascular events, the effects of asthma and allergic disease on long-term mortality have been unclear, Dr. Savage added.

“The findings (of this follow-up study) provide some insight regarding the effects of asthma and allergic disease on long-term mortality,” Dr. Savage said.

The NHEFS is a joint project of the National Center for Health Statistics and the National Institute on Aging in collaboration with other agencies of the U.S. Public Health Service.



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Assisted-suicide program delicately meets needs

BY MARY ANN MOON
IMNG Medical News

The Death with Dignity program, a pioneering program that includes medically assisted suicide for competent, terminally ill adults treated at a comprehensive cancer center in Seattle, has been well accepted by patients, families, and clinicians, according to a report published online in the *New England Journal of Medicine*.

The report details the experience in 2009-2011 with the Death with Dignity program at the Seattle Cancer Care Alliance, which serves all of the Pacific Northwest. The program, "designed to adhere to legal regulations, maintain safety, and ensure the quality of patient care," allows patients with a life expectancy of 6 months or less because of a diagnosed medical condition (usually cancer) to request and self-administer lethal medication prescribed by a physician.

This experience may help to inform efforts to introduce similar programs in other states. At present, Hawaii, Pennsylvania, and Vermont are all considering pertinent legislation, said Dr. Elizabeth Trice Loggers of the Fred Hutchinson Cancer Research Center, Seattle, and her associates.

The program's policy – written by the Seattle Cancer Care Alliance's medical director and approved by a majority of the medical executive committee members, as with any clinical policy – requires that patients request information about medically

assisted suicide from their physicians, or that these clinicians raise the topic, to be considered for referral. Participation is entirely voluntary for medical staff and faculty members.

Every patient who is a potential

participant is first assigned an advocate, a licensed social worker employed by the Alliance, who assists patients, family members, pharmacists, and physicians throughout a multistep process of participating.

This advocate also tracks compliance with required documentation for the state Department of Health.

The advocate, as well as the attending physician, ensures that all

Continued on following page

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VIEW ON THE NEWS

Dr. Paul A. Selecky, FCCP, comments: Physician-assisted suicide (PAS) is legal in only a small number of patients, although this may increase in time. This article describes a well-organized and seemingly thorough process to assist patients who might consider such a death. Although 97% of patients identified loss of autonomy as the reason for requesting, only 21% chose PAS. Their assurance of preserving autonomy may have satisfied the remaining patients.



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What's in a name? Is 'palliative care' too loaded?

Labeling service as 'supportive care' is more favorable and easier to understand, patient survey suggests.

BY PATRICE WENDLING
IMNG Medical News

NEW ORLEANS – That which we call a rose by any other name would smell as sweet. Perhaps not, if the true topic is palliative care.

A telephone survey of 169 patients with advanced cancer found that those randomized to hear the term

“supportive care” instead of “palliative care” rated their understanding, overall impressions, and future perceived need for those services significantly higher.

In contrast, there was no significant difference in outcomes when patients heard either a “patient-centered” or “traditional” description of palliative/supportive care services,

Rachael Maciasz said at the annual meeting of the American Association of Hospice and Palliative Medicine.

“It may be that ‘palliative care’ is so loaded ... because of family members’ or friends’ experiences with this in the past that [they think] their family member is going to die,” she said. “Perhaps what comes after that, no matter how you describe it, you can’t change that impression.”

Patients with stage IV solid tumors or refractory/recurrent hematologic malignancies were recruited from 20 oncologists at two comprehensive cancer centers in Pittsburgh, and randomized to one of four survey groups: “palliative care/patient-centered,” “palliative care/traditional,” “supportive care/patient-centered,” and “supportive care/traditional.”

Outcomes were measured using 10-point Likert scales, with zero meaning “do not understand at all,” or impression “not favorable at all” or “strongly disagree with” a need for services.

The majority (63%) of patients were female, 95% were white, 88% were Catholic/Christian, 4% Jewish, and 7% other religion or agnostic. The most common cancer diagnoses were breast (32%), lung (18%), and gastrointestinal (13%). Their average age was 62, and roughly 11% had prior exposure to palliative care services.

The supportive care groups had significantly higher mean ratings than did the palliative care groups for overall understanding of what the service had to offer (7.7 vs. 6.8) and for overall favorable impressions (8.4 vs. 7.3), said Ms. Maciasz, a fourth-year medical student and a Doris Duke Clinical Research Fellow at the University of Pittsburgh.

Patients rated their current need for supportive and palliative care services equally, but were more likely to perceive a future need for supportive

services for themselves or family (8.6 vs. 7.7).

The qualitative results paralleled the quantitative results.

“I had the impression that fewer patients went in with an impression of palliative care and that if you could explain it in ways that made perfect sense and described how awesome it is, that it wouldn’t matter if it was [called] palliative or supportive,” Ms. Maciasz said.

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PATRICE WENDLING/IMNG MEDICAL MEDIA

No matter how you describe it, when people hear “palliative care,” they think their family member is going to die, said researcher Rachael Maciasz.

VIEW ON THE NEWS

Dr. Paul A. Selecky, FCCP, comments: Use of the term “palliative care” has been an ongoing problem of misunderstanding for years, not only for patients, but for their physicians as well. Too many associate palliative care directly with the act of dying, which is only one aspect of the spectrum of what is included in the application of palliative care.

The focus is to treat the patient’s suffering of whatever cause (physical, emotional, spiritual, psychosocial), often well in advance of the dying process. Either term (supportive or palliative) needs to be well-defined and publicized.

Continued from previous page

potential participants are aware of alternatives to medically assisted suicide, such as palliative care and hospice care. The patient’s terminal status is verified, and if the attending physician doesn’t wish to participate, a prescribing physician and a consulting physician are chosen from a group of willing providers.

Psychosocial and psychological assessments are required to ensure the patient’s competence to make the choice of assisted suicide and to identify any depression, which would make the patient ineligible to participate. The patient’s preferences for interventions and health-care directives are documented. Grief support, legacy support, and bereavement support are offered through periodic calls and visits.

The patient and his or her family meet with the prescribing clinician and the consulting clinician to review the diagnosis, prognosis, treatment alternatives, and end-of-life issues. After a mandatory waiting period of 15 days, a written prescription is then sent to the pharmacy, and the pharmacist schedules another appointment with the patient and family to discuss preparation of the drug(s), potential side effects, and the concomitant use of prescription antiemetics.

Patients are then free to fill the prescription or

not and to take the drug(s) or not, as they wish.

To date, 114 patients have inquired about the Death with Dignity program, and 44 (38%) either did not pursue the matter further or were deemed ineligible to participate.

Thirty patients (26%) have made a first oral request to initiate the process but either decided not to participate or died before completing the

Patients and families are grateful for the prescription, ‘regardless of whether it is ever filled or ingested, typically referencing an important sense of control in an uncertain situation.’

process. Forty patients (35% of those who made an initial inquiry) received prescriptions for lethal medication, and all 40 have died. Twenty-four chose to die by ingesting the medication (secobarbital).

Thus, only 21% of the participants actually used assisted suicide. Death with Dignity participants accounted for 2.4% of all annual deaths among patients at the Seattle Cancer Center Alliance.

The reasons patients gave most often for participating in the assisted-suicide program were loss of autonomy (97%), inability to engage in enjoyable

activities (89%), and loss of dignity (75%).

“We have not received any complaints from family members or caregivers regarding our process or the manner of death. Anecdotally, families describe the death as peaceful (even when death has taken longer than the average of approximately 35 minutes),” Dr. Loggers and her associates wrote (N. Engl. J. Med. 2013;368:1417-24 [doi:10.1056/NEJMsa1213398]).

“Both patients and families frequently express gratitude after the patient receives the prescription, regardless of whether it is ever filled or ingested, typically referencing an important sense of control in an uncertain situation,” they noted.

Opponents of medically assisted suicide have argued that legislation would disproportionately affect vulnerable populations, such as racial or ethnic minorities, low-income groups, or cognitively impaired patients. The Death with Dignity experience refutes this argument, as most participants were white, male, and well educated, the investigators said.

There have been no unexpected complications among patients who chose assisted suicide, but one patient remained alive for a day after taking the medication. This protracted dying process caused distress to both the family members and the clinicians involved. Similar cases have been reported previously, they added.



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Please see brief summary of PROLASTIN-C full Prescribing Information on adjacent page.

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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HIGHLIGHTS OF PRESCRIBING INFORMATION

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SLEEP STRATEGIES: Is a cry in the dark best for childhood insomnia?

No area of pediatric sleep medicine stirs more controversy in the mainstream media than the treatment of behavioral insomnia of childhood (BIC), defined in the International Classification of Sleep Disorders (American Academy of Sleep Medicine [AASM], 2005) as difficulty falling and/or staying asleep that is behavioral in etiology and not explained by a medical or psychiatric cause.

The diagnosis, which is usually made via a caretaker report, is divided into three subtypes: limit-setting type (ie, bedtime problems), sleep-onset association type (night-wakers), and a combined type. Including all three subtypes, disease prevalence is estimated at 20% to 30% in infants, toddlers, and preschoolers (Morganthaler et al. *Sleep*. 2006;29[10]:1277). Though the disease has been associated with diurnal behavioral problems, it also has significant adverse effects on the parents, including sleep deprivation, maternal depression, and increased parental stress (Wake et al. *Pediatrics*. 2006;117[3]:836). Unfortunately, an astounding 84% of children with sleep disturbances continue to have them at 3-year follow-up, with persistent sleep fragmentation noted in as many as 18% of school-age children (Kataria et al. *J Pediatr*. 1987;110[4]:642; Sadeh et al. *Dev Psychol*. 2000;36[3]:291).

Treatment options

One likely contributor to the endurance of BIC into later childhood is the uncertainty about the optimal method of treatment. According to the AASM's behavioral practice parameters for bedtime problems and night-waking in infants and children, the standard of care is to use the behavioral strategy of unmodified extinction, more commonly known as the "cry-it-out" method. This technique involves putting the child to bed at a designated time and not responding to the child's protests/cries until it is time to wake up in the morning, unless there are significant safety or illness concerns.

Another practice standard is to use unmodified extinction, allowing a parent to remain in the room without reacting to the child ("extinction with parental presence"); a gentler method called "graduated extinction" or "modified extinction" allows the parent to briefly check on the child at predetermined times but with progressively longer intervals until sleep is achieved. The idea behind each of these methods is to allow the child to develop self-soothing skills so that he or she is able to fall asleep independent of

parental intervention. By not providing the positive reinforcement of parental attention, the undesired behavior (crying or screaming) is extinguished.

Although a number of studies support the efficacy of these behavioral interventions in significantly reducing bedtime resistance and night-wakings (Mindel et al. *Sleep*. 2006;29[10]:1263), controversy understandably exists about the morality of allowing a child to cry for extended periods of time without consolation. Proponents of attachment parenting dub unmodified extinction as cruel and unusual punishment. The debate lies in whether withholding a parent's response to a child's cries at night results in long-term dam-



Of children with sleep disturbances, 84% continue to have them at 3-year follow-up.

age to the child or the parent-child relationship.

A well-written theoretical review of this practice has questioned the use of extinction techniques to help infants sleep independently (Blunden et al. *Sleep Med Rev*. 2011;15[5]:327), arguing that nocturnal crying has culturally been deemed undesirable, even pathological. The authors make arguments for the social and biological utility of infant crying and cite studies proposing that prolonged crying could result in increased cortisol, stress, withdrawal behaviors, attachment disorders, and potential neuronal changes. Because extinction methods are likely to involve prolonged periods of crying and thereby increase biological stress, they postulate that these methods are not completely benign, though the referenced studies of adverse outcomes of prolonged crying were not specifically related to the use of extinction therapy for BIC.

Until recently, no long-term studies had addressed the longitudinal effects of "crying-it-out," though short-term studies had shown no adverse effects. A recent publication evaluated the effects of an infant behavioral sleep program at 5-year follow-up on the child, the parent-child relationship, and maternal outcomes (Price et al. *Pediatrics*.

2012;130[4]:643). This study was an extension of the previously published Infant Sleep Study, a randomized controlled trial evaluating the shorter-term effects of a behavioral sleep intervention on infants who were identified by mothers as having sleep problems at 8 months of age (Hiscock et al. *Arch Dis Child*. 2007;92[11]:952).

Two techniques were used in this study: "controlled comforting" (graduated extinction) and "camping out." This latter technique, also known as adult fading, is similar to "extinction with parental presence," with the parent gradually distancing himself or herself from the child. Price and colleagues followed up on those children at 6 years of age, analyzing differences in intervention vs control groups based upon parental reports and standardized questionnaires of emotional and behavioral problems, perception of sleep as a problem, clinical sleep problems, psychosocial health-related quality of life, and stress, as measured by morning cortisol levels. Additionally, researchers assessed the child-parent relationship; parenting styles; and evaluated maternal depression, anxiety, and stress. Results showed no statistically significant difference between the intervention and control groups in any of the measured outcomes, supporting the theory that behavioral sleep interventions have no long-term adverse effects on children.

Prevention strategies

Regardless of whether or not extinction methods are benign or harmful to an infant, there are parents who simply prefer noncrying methods for getting their child to sleep. In addition to extinction, the AASM practice parameters also propose parent education/prevention as a standard recommendation. This intervention focuses on preventing sleep problems by teaching parents to establish good sleep routines within their child's first 6 months of life.

Strategies typically include developing consistent sleep schedules and providing an appropriate level of parental interaction during sleep initiation and nighttime awakenings. Putting the infant to bed in a "drowsy but awake" state can foster development of self-soothing and sleep initiation skills. Outside of these standard recommendations, two guideline recommendations are "delayed bedtime with

removal from bed/positive bedtime routines" and "scheduled awakenings."

The first refers to the technique of temporarily delaying the child's bedtime in order to increase the likelihood of the child falling asleep in the bed by increasing sleep pressure. Optionally, the child may be removed from the bed if he or she is unable to achieve sleep within a predetermined time period. Implementation of scheduled awakenings requires that parents be familiar with their child's night waking patterns; based upon this schedule, the child is preemptively woken up 15 to 30 minutes prior to the expected spontaneous awakening and consoled in a typical manner. Gradually, these scheduled awakenings are faded out, with the intention of increasing consolidated sleep. There was insufficient evidence for the task force committee to support any one technique or combination of techniques over another.

Beyond BIC

Despite the emotional wear that extinction therapy for BIC can have on a parent, the lack of direct data suggesting harm makes it reasonable to include as a recommendation to frustrated caregivers. It is critical to be aware that underlying medical issues, which may be contributing to nighttime awakenings (eg, gastroesophageal reflux, pain due to acute illness such as hand-foot-and-mouth disease, and upper respiratory infection) must be ruled out before a behavioral sleep problem is diagnosed and treated in this fashion.

Most importantly, both providers and parents should be aware that extinction methods are not the only behavioral methods available to manage BIC. Further studies to demonstrate the efficacy of these other methods in larger populations or to develop additional methods need to be conducted, hopefully leading to an expansion of the practitioner's toolbox for treating BIC. When a family presents for management of an infant with behavioral insomnia, the provider should practice the art of tailoring a treatment plan that considers parent and child temperaments, schedules, and social and cultural perspectives to optimize success while minimizing parental stress.

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FROM THE PRESIDENT: What's on Darcy's desk?

DR. DARCY D. MARCINIUK,
FCCP

I am now past the midpoint of my term as ACCP President and wanted to share with you some of the “work” that has been on my desk. This doesn't represent all that is happening at the College (... there are other stacks and stacks of those files on my desk), but these activities have lately been active in the middle of my desk.

Before I speak to these issues, I did want to share with you my “Post Midterm Presidency Mood” – it is very upbeat! This is a great organization to work with and for, and the dedication and commitment I feel in working with our skilled staff and volunteer leadership makes it even better. I [we] still have got a lot of work to do before CHEST 2013, but this has been a wonderful opportunity and personally most fulfilling. But enough about me!

So what is on Darcy's desk?

Strategic planning

An effective organization must have goals – boring but important, ambitious and exciting, and every kind of goal in between. These goals must be regularly established and agreed upon, and the progress of the organization periodically assessed and judged against these same goals. This is an exercise many organizations speak about (and perhaps hold the occasional strategic planning session), but few undertake with genuine passion, and even fewer critically judge their performance and activities.

The ACCP is presently critically assessing its performance and activities. The ACCP is viewed as the premier organization delivering the very best



DR. DARCY D.
MARCINIUK, FCCP

possible clinical education for our members and our professions, and it is essential for us to regularly review/revise/update our strategic goals and direction. Traditionally we've compiled 1-year goals/strategies/tactics, but we are now looking farther into the future with longer-term goals and direction. The process started in earnest this January and most recently involved the participation of more than 200 individuals this spring. You could sense the excitement and enthusiasm for what we are doing, and the desire to do even more, and better. Currently, the Board of Regents and College staff are carefully reviewing and refining the information garnered to date and will continue to work on this important task this spring and summer, and into the fall.

We are not in a rush—this is far too important a process to rush—but we will be sharing much more with you as the outcomes of this important and intensive process become available.

Leadership development

We have also been further augmenting our efforts in leadership develop-

ment. As you may know, we held a bigger and more intensive Leadership Summit this past March for current ACCP leadership at the annual Spring Leadership Meeting, which included various keynote and breakout sessions targeted at different levels of experience within the organization. But that was just a few days in the year, and we know that the needs for leadership in health care exist every day of the year.

We are currently targeting more intensive activities to those members who have previously attended our past leadership development courses, in order to build on the substantive skills and understanding they have garnered to date. In addition, we are presently soliciting current/past ACCP senior leaders to serve as mentors and will be rolling out a more formal mentorship program this summer.

Work is also underway on a leadership development certificate program, which would give successful participants an ACCP Certificate of Completion for specific leadership development courses/curricula. And finally, we are markedly augmenting this important initiative and theme at CHEST 2013 in Chicago, with “Brown Bag” lunch sessions, which will address various leadership topics in a very welcoming atmosphere. Who can say no to a free lunch? Of course, our very successful Leadership Development Course will once again be held at CHEST 2013, targeting participation from those within 5 years of finishing their fellowship—

the call for nominations for the course will be sent out in the next few weeks.

Organization leadership

But leadership goes well beyond just individuals, and it is important for the ACCP to also enable and practice inspiring organization leadership. Our patients and their families, our members and colleagues in various clinical professions, and health-care systems are looking for that exact type of leadership—trusted, responsible, and innovative. With that in mind, the ACCP has had the honor of serving as Chair of the Forum of International Respiratory Societies (FIRS) this year. Born in 2001, FIRS is composed of the leading international respiratory societies in the world (American College of Chest Physicians [ACCP], American Thoracic Society [ATS], Asian Pacific Society of Respirology [APSR], Asociación Latinoamericana de Tórax [ALAT], European Respiratory Society [ERS], International Union Against Tuberculosis and Lung Disease [IUATLD], and the Pan African Thoracic Society [PATS]; with observer participation by the Global Initiative for Asthma [GINA] and the Global Initiative for Chronic Obstructive Pulmonary Disease [GOLD]).

FIRS represents over 70,000 professionals worldwide, who devote their working lives to various aspects of respiratory health or disease.

Recently, FIRS has been developing

Continued on following page

‘Beyond Our Walls’: New ACCP headquarters taking shape

Construction of the ACCP's headquarters is in full swing for the new Glenview, Illinois, ACCP campus. With the foundation laid out and framing starting to go up, the inspired plans for the ACCP offices and Innovation and Simulation Center are becoming concrete (and steel).

“It's very exciting to see the plans literally taking shape,” says ACCP President Dr. Darcy Marciniuk, FCCP. “What is being built is much more than just a building. It's a campus, which will allow us to bring cutting-edge education and innovative technologies together with the great minds of the ACCP, all for the betterment of patient care.”



Watch us grow! Visit us online at beyondourwalls.chestnet.org.

ACCP members and campaign supporters can witness the evolution of the campus themselves with a virtual visit to the “Beyond Our Walls: Advancing the Future of Chest Medicine” website (beyondourwalls.chestnet.org). There, visitors can watch a live video feed of real-time construction taking place at the building site and view aerial and ground photographs that uniquely capture initial phases of development.

Visitors to the “Beyond our Walls” site can also take a three-dimensional animated tour of the campus, hear donor testimonials, and make a financial commitment in support of the building project.

There are many ways to express support of the campaign in a lasting, memorable way. A number of prime naming opportunities are still available for those ACCP members interested in a legacy gift that exemplifies their commitment to advancing chest medicine and the health of their patients. Whether a donation is a combined group gift for the naming of an interior innovation space or a personal commitment showcased on an exterior sidewalk paver, financial support at any level is vital.

“We recognize that ACCP members are very generous and support many philanthropic efforts,” says Dr. Marciniuk. “Your personal pledge to this effort means improved care and a healthier outlook for patients and their families in the future.”

Visit the website for information on the benefits of giving, or contact Marilyn Lederer at (847) 498-8370 or mlederer@chestnet.org for more details on individual or group giving.

Continued from previous page

a document which outlines the enormous worldwide burden of respiratory illness. The intent is to better inform, to raise awareness, and to assist those who advocate for protecting and improving respiratory health. The document also highlights the many and varied threats to lung health and the stark realities of respiratory diseases throughout the world. Importantly, it outlines practical steps to make a positive difference in the respiratory health of the world. We believe it will be a useful and frequently used tool in the fight against respiratory diseases and illness throughout the world. Final editing is currently underway on this document, which we expect to be published later this spring. We'll be sure to let you know when it becomes available.

Royal Health-care Commission

The Commission recently completed its charge and submitted its report to the Board of Regents in March. I want to again personally thank those involved, and notably Commission Chair Dr. Scott Manaker, for their time and efforts.

The report covered a lot of ground but had a focus on College actions around health-care reform. It provided a comprehensive environmental scan of various activities and issues and developed a broad sense of priority issues affecting our members and our professions. The commission report importantly raises the practical issue of whether we can do things better to address the needs in this area. There may be an opportunity for innovative solutions and structures to meet both current and future needs—I think we can do better. We are giving considerable thought right now as to how best to provide the leadership our support and direction for our members and professions on this important subject.

CHEST World Congress 2014

Finally, the CHEST World Congress 2014, to be held in Madrid, Spain, on March 21-24, is certainly creating some excitement. This event will be a unique and innovative educational opportunity very different from other meetings and builds upon the proven expertise in clinical education of both the ACCP and SEPAR (Sociedad Española de Neumología y Cirugía Torácica - our colleagues from Spain).

The Scientific Program Committee, led by Co-Chairs Drs. Richard Irwin and Dr. Joan Soriano, and consisting of leading experts from around the world, is working hard to put together

the very best clinical educational offering. The committee is developing a scientific programme that uses innovative educational methods to cover the full spectrum of clinical pulmonary, critical care, and sleep medicine. You can learn more about CHEST World Congress 2014 at chestnet.org.

You should know that this might be a 'meeting' for the entire family—it will be springtime and a great time of year to visit Madrid, Spain. Your family (... especially if you promise to bring them along) might actually want you to register for this meeting! Now is the time to mark your calendars, and plan to join colleagues from

around the world at the CHEST World Congress 2014.

So that is what the center of my desk looks like right now. As always, feel free to let me know what you think, or provide feedback on any activities of the College. Now I'm going to starting working on some of those other stacks....

VENTAVIS® (iloprost) Inhalation Solution is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (65%) or PAH associated with connective tissue disease (23%).

VENTAVIS DELIVERED A SPECTRUM OF PAH EFFICACY AT WEEK 12¹⁻³



Significant clinical improvement through a combined endpoint (p=0.0033)¹

- VENTAVIS 19% (n=68); placebo 4% (n=78)

Significant functional class improvement (p=0.03)^{1,3}

- VENTAVIS 25% (n=68); placebo 8% (n=78)
- At week 12: VENTAVIS 19% (FC II), 43% (FC III), 38% (FC IV); placebo 4% (FC II), 46% (FC III), 50% (FC IV)³

Significant 6MWD improvement (p<0.01)¹

- VENTAVIS 43% (n=68); placebo 26% (n=78)

Significant hemodynamic improvement (p<0.001)^{1,2}

- 32% decrease in pulmonary vascular resistance (PVR):
– VENTAVIS –23% (n=70); placebo 9% (n=77); treatment effect† –335 dyn·sec/cm⁵
- 20% increase in cardiac output (CO)[†]:
– VENTAVIS 15% (n=89); placebo –5% (n=80); treatment effect† +0.7 L/min
- 9% decrease in mean pulmonary arterial pressure (mPAP)[†]:
– VENTAVIS –9% (n=90); placebo 0% (n=82); treatment effect† –4.5 mmHg

VENTAVIS 20 mcg/mL: Higher concentration provides appropriate patients shorter treatment times[‡]

BASELINE VALUES^{1,3}

Parameter	VENTAVIS	Placebo
PVR (dyn·sec/cm ⁵)	1029±390	1041±493
mPAP (mmHg)	53±12	54±14
CO (L/min)	3.8±1.1	3.8±0.9
SVO ₂ (%)	60±8	60±8
FC III	59%	59%
FC IV	41%	41%
6MWD (m)	332	315

AIR PIVOTAL TRIAL Randomized, double-blind, multicenter, placebo-controlled trial to evaluate the efficacy and safety of VENTAVIS monotherapy compared with placebo in the treatment of PAH (WHO Group 1) NYHA Class III or IV (n=146). Clinical improvement is a combined endpoint defined as ≥10% increase in 6MWD, improvement in NYHA functional class, and absence of clinical deterioration or death.^{1,2}

*AIR PIVOTAL TRIAL: Hemodynamics assessed at week 12 before inhalation in both groups (at least 2 hours after previous dose, trough) and after inhalation in the VENTAVIS group (approximately 15 minutes after dose, peak). Study included patients with chronic thromboembolic disease (CTEPH) and all etiologies of PAH.¹

†Placebo corrected.

‡The 20 mcg/mL concentration is intended for patients who are maintained at the 5 mcg dose and who have repeatedly experienced extended treatment times which could result in incomplete dosing. VENTAVIS 10 mcg/mL ampules are still available. VENTAVIS should be taken 6 to 9 times daily during waking hours, at least 2 hours apart.¹

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Risk of Syncope

- Hypotension leading to syncope has been observed; VENTAVIS should therefore not be initiated in patients with systolic blood pressure less than 85 mmHg.

Pulmonary Venous Hypertension

- Stop VENTAVIS immediately if signs of pulmonary edema occur; this may be a sign of pulmonary venous hypertension.

Bronchospasm

- VENTAVIS inhalation may cause bronchospasm and patients with a history of hyperreactive airway disease may be more sensitive.

ADVERSE REACTIONS

Serious Adverse Events

- Serious adverse events reported at a rate of less than 3% included congestive heart failure, chest pain, supraventricular tachycardia, dyspnea, peripheral edema, and kidney failure. Vital signs should be monitored while initiating VENTAVIS.

Adverse Events

- Adverse events reported in a Phase 3 clinical trial occurring with a ≥3% difference between VENTAVIS patients and placebo patients were vasodilation (flushing) (27% vs 9%), increased cough (39% vs 26%), headache (30% vs 20%), trismus (12% vs 3%), insomnia (8% vs 2%), nausea (13% vs 8%), hypotension (11% vs 6%), vomiting (7% vs 2%), alkaline phosphatase increased (6% vs 1%), flu syndrome (14% vs 10%), back pain (7% vs 3%), tongue pain (4% vs 0%), palpitations (7% vs 4%), syncope (8% vs 5%), GGT increased (6% vs 3%), muscle cramps (6% vs 3%), hemoptysis (5% vs 2%), and pneumonia (4% vs 1%).

DRUG INTERACTIONS

Antihypertensives and Vasodilators

- VENTAVIS has the potential to increase the hypotensive effect of vasodilators and antihypertensive agents.

Anticoagulants and Platelet Inhibitors

- VENTAVIS also has the potential to increase risk of bleeding, particularly in patients maintained on anticoagulants or platelet inhibitors.

Please see brief summary of full prescribing information on adjacent page.



**A spectrum of
inhaled PAH efficacy**

www.ventavis.com

1-866-ACTELION (1-866-228-3546)

REFERENCES: 1. VENTAVIS (iloprost) Inhalation Solution full prescribing information. Actelion Pharmaceuticals US, Inc. August 2012. 2. Olschewski H, Simonneau G, Galie N, et al. Inhaled iloprost for severe pulmonary hypertension. *N Engl J Med*. 2002;347:322-329. 3. Data on file, Actelion Pharmaceuticals.



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Drug-resistant CRE: A new foe in our hospitals

BY GLENN S. TILLOTSON,
PHD, FCCP

A recent health advisory issued by the CDC has highlighted the emergence of another clinically

challenging, multidrug resistant pathogen—CRE.

This collection of species has a mortality rate of over 40% and is steadily spreading across the United States with the highest number of

cases being reported from northeastern states. Moreover, the incidence of these organisms has increased four-fold in the past decade, while CRE *Klebsiella pneumoniae* has shown a sevenfold rise in the same period. The

first half of 2012 saw almost 200 hospitals report at least one patient with CRE (CDC. *MMWR Morb Mortal Wkly Rep.* 2013;62[9]:165).

There are few clinical options to treat CRE infections, typically drugs include colistin, aminoglycosides, tigecycline, and fosfomycin, but none of these drugs is ideal, and each has either toxicity or administration issues.

Combination therapies or prolonged infusions of carbapenems are unproven; but in these situations, it may be the only option. Interestingly, there are several β -lactamase inhibitors (BLIs) in clinical development; some of which may provide some respite from CREs, including RPX7009 (Rempex Pharmaceuticals), avibactam (Forest Laboratories), and MK-7655 (Merck Laboratories). All are in phase 3 clinical trials for infections, such as hospital-acquired pneumonia and complicated urinary tract, bloodstream, and intra-abdominal infections. These BLIs are being paired with both approved and developmental antibiotics, such as ceftazidime, ceftolozane, imipenem, and biapenem. Most are being developed under the FDA's new qualified infectious disease program (QIDP) program, which should enhance the regulatory approval process and encourage further pharmaceutical investment.

The emergence of CRE is a serious threat to not only hospitals but to the community, where there is an increasing number of patients with predisposing factors, such as advanced age, broad spectrum antibiotics use, comorbidities, and medical interventions. To reduce the impact of these strains, the CDC urges active case detection and strict contact precautions for infected patients or those with evidence of colonization appropriate antibiotic use in all settings, and clear communication about infections when patients transfer.

Learn more at: cdc.gov/hai/organisms/cre/cre-toolkit.

PCCSU CME credit available until June 30

Several new PCCSU entries, Vol 25—Lessons 25 to 33, have been posted on chestnet.org. Topics include TB and Pregnancy, Childhood OSA, ECMO, and Intubation in the ICU. Claim CME credit up until **June 30, 2013**, for all lessons in Volume 25.

Effective July 1, 2013, PCCSU Volume 25 is available for review purposes only.



BRIEF SUMMARY

The following is a brief summary of the Full Prescribing Information for Ventavis® (iloprost) Inhalation Solution. Please review the Full Prescribing Information prior to prescribing Ventavis®.

INDICATIONS AND USAGE

Ventavis® is a synthetic analog of prostacyclin indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (65%) or PAH associated with connective tissue disease (23%).

DOSAGE AND ADMINISTRATION

Recommended Dosing

Ventavis is intended to be inhaled using either of two pulmonary drug delivery devices: the I-neb® AAD® System or the Prodose® AAD® System. The first inhaled dose should be 2.5 mcg (as delivered at the mouthpiece). If this dose is well tolerated, dosing should be increased to 5.0 mcg and maintained at that dose; otherwise maintain the dose at 2.5 mcg. Ventavis should be taken 6 to 9 times per day (no more than once every 2 hours) during waking hours, according to individual need and tolerability. The maximum daily dose evaluated in clinical studies was 45 mcg (5 mcg 9 times per day).

Direct mixing of Ventavis with other medications in the I-neb® AAD® System or the Prodose® AAD® System has not been evaluated; do not mix with other medications. To avoid potential interruptions in drug delivery due to equipment malfunctions, the patient should have easy access to a back-up I-neb® AAD® System or Prodose® AAD® System.

Ventavis is supplied in 1 mL ampules in two concentrations: 10 mcg/mL and 20 mcg/mL.

	Delivered dose from ampule of:	
	10 mcg/mL	20 mcg/mL
Nebulizer	10 mcg/mL	20 mcg/mL
I-neb® AAD®	2.5 or 5 mcg from one ampule	5 mcg from one ampule
Prodose® AAD®	2.5 or 5 mcg from two ampules	N/A

The 20 mcg/mL concentration is intended for patients who are maintained at the 5 mcg dose and who have repeatedly experienced extended treatment times which could result in incomplete dosing. Transitioning patients to the 20 mcg/mL concentration using the I-neb® AAD® System will decrease treatment times to help maintain patient compliance.

For each inhalation session, the entire contents of each opened ampule of Ventavis should be transferred into either the I-neb® AAD® System or the Prodose® AAD® System medication chamber immediately before use (see **PATIENT COUNSELING INFORMATION**). After each inhalation session, any solution remaining in the medication chamber should be discarded. Use of the remaining solution will result in unpredictable dosing. Patients should follow the manufacturer's instructions for cleaning the I-neb® AAD® System or the Prodose® AAD® System components after each dose administration.

Monitoring

Vital signs should be monitored while initiating Ventavis. (see **WARNINGS AND PRECAUTIONS**).

Use in Patients with Pre-existing Hepatic Impairment

Because iloprost elimination is reduced in patients with impaired liver function (see **SPECIAL POPULATIONS**), consider increasing the dosing interval (e.g., 3-4 hours between doses depending on the patient's response at the end of the dose interval) in patients with Child-Pugh Class B or C hepatic impairment.

Use in Patients with Pre-existing Renal Impairment

Dose adjustment is not required in patients who are not on dialysis. The effect of dialysis on iloprost is unknown (see **SPECIAL POPULATIONS**).

DOSAGE FORMS AND STRENGTHS

1 mL ampules in two concentrations: 10 mcg/mL and 20 mcg/mL.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Ventavis solution should not be allowed to come into contact with the skin or eyes; oral ingestion of Ventavis solution should be avoided.

Risk of Syncope

Monitor vital signs while initiating Ventavis. Do not initiate Ventavis in patients with systolic blood pressure below 85 mmHg. Syncope can also occur in association with pulmonary arterial hypertension, particularly in association with physical exertion. The occurrence of exertional syncope may reflect a therapeutic gap or insufficient efficacy, and the need to adjust dose or change therapy should be considered.

Pulmonary Venous Hypertension

Should signs of pulmonary edema occur when inhaled Ventavis is administered in patients with pulmonary hypertension, stop treatment immediately, as this may be a sign of pulmonary venous hypertension.

Bronchospasm

Ventavis inhalation can induce bronchospasm. Bronchospasm may be more severe or frequent in patients with a history of hyperreactive airways. Ventavis has not been evaluated in patients with chronic obstructive pulmonary disease (COPD), severe asthma, or with acute pulmonary infections.

ADVERSE REACTIONS

Clinical Studies 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.

Pre-marketing safety data on Ventavis (iloprost) were obtained from 215 patients with pulmonary arterial hypertension receiving iloprost in two 12-week clinical trials and two long-term extensions. Patients received inhaled Ventavis for periods of from 1 day to more than 3 years. The median number of weeks of exposure was 15. Forty patients completed 12 months of open-label treatment with iloprost.

Table 1 shows adverse events reported by at least 4 Ventavis patients and reported at least 3% more frequently for Ventavis patients than placebo patients in the 12-week placebo-controlled study.

Table 1: Adverse Events in Phase 3 Clinical Trial

Adverse Event	Ventavis n=101	Placebo n=102	Placebo subtracted %
Vasodilation (flushing)	27	9	18
Cough increased	39	26	13
Headache	30	20	10
Trismus	12	3	9
Insomnia	8	2	6
Nausea	13	8	5
Hypotension	11	6	5
Vomiting	7	2	5
Alk phos increased	6	1	5
Flu syndrome	14	10	4
Back pain	7	3	4
Tongue pain	4	0	4
Palpitations	7	4	3
Syncope	8	5	3
GGT increased	6	3	3
Muscle cramps	6	3	3
Hemoptysis	5	2	3
Pneumonia	4	1	3

Pre-marketing serious adverse events reported with the use of inhaled Ventavis and not shown in Table 1 include congestive heart failure, chest pain, supraventricular tachycardia, dyspnea, peripheral edema, and kidney failure.

In a small clinical trial (the STEP trial), safety trends in patients receiving concomitant bosentan and Ventavis were consistent with those observed in the larger experience of the Phase 3 study in patients receiving only Ventavis or bosentan.

Adverse events with higher doses

In a study in healthy subjects (n=160), inhaled doses of iloprost solution were given every 2 hours, beginning with 5 mcg and increasing up to 20 mcg for a total of 6 dose inhalations (total cumulative dose of 70 mcg) or up to the highest dose tolerated in a subgroup of 40 subjects. There were 13 subjects (32%) who failed to reach the highest scheduled dose (20 mcg). Five were unable to increase the dose because of (mild to moderate) transient chest pain/discomfort/tightness, usually accompanied by headache, nausea, and dizziness. The remaining 8 subjects discontinued for other reasons.

Postmarketing Experience

The following adverse reactions have been identified during the postapproval use of Ventavis. 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.

Cases of bronchospasm and wheezing have been reported, particularly in patients with a history of hyperreactive airways (see **WARNINGS AND PRECAUTIONS**). Bleeding events most commonly reported as epistaxis and hemoptysis were observed on Ventavis treatment (see **DRUG INTERACTIONS**). Cases of thrombocytopenia, dizziness, diarrhea, mouth and tongue irritation, dysgeusia, hypersensitivity, and rash have also been reported with the use of Ventavis.

OVERDOSAGE

In clinical trials of Ventavis, no case of overdose was reported. Signs and symptoms to be anticipated are extensions of the dose-limiting pharmacological effects, including hypotension, headache, flushing, nausea, vomiting, and diarrhea. A specific antidote is not known. Interruption of the inhalation session, monitoring, and symptomatic measures are recommended.

DRUG INTERACTIONS

During clinical trials, iloprost was used concurrently with anticoagulants, diuretics, cardiac glycosides, calcium channel blockers, analgesics, antipyretics, nonsteroidal anti-inflammatory drugs, corticosteroids, and other medications. Intravenous infusion of iloprost had no effect on the pharmacokinetics of digoxin. Acetylsalicylic acid did not alter the clearance (pharmacokinetics) of iloprost.

Cytochrome P450

Although clinical studies have not been conducted with Ventavis (inhaled iloprost), *in vitro* studies of iloprost indicate that no relevant inhibition of cytochrome P450 drug metabolism would be expected.

Antihypertensives and Vasodilators

In studies in normal subjects, there was no pharmacodynamic interaction between intravenous iloprost and either nifedipine, diltiazem, or captopril. However, Ventavis has the potential to increase the hypotensive effect of vasodilators and antihypertensive agents.

Anticoagulants and Platelet Inhibitors

Since Ventavis inhibits platelet function, there is a potential for increased risk of bleeding, particularly in patients maintained on anticoagulants or platelet inhibitors.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C. Ventavis (iloprost) has been shown to be teratogenic in rats as described below. There are no adequate and well controlled studies in pregnant women. Ventavis should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In developmental toxicity studies in pregnant Han-Wistar rats, continuous intravenous administration of iloprost at a dosage of 0.01 mg/kg daily (serum levels not available) led to shortened digits of the thoracic extremity in fetuses and pups. In comparable studies in pregnant Sprague-Dawley rats which received iloprost clathrate (13% iloprost by weight) orally at dosages of up to 50 mg/kg/day (C_{max} of 90 ng/mL), in pregnant rabbits at intravenous dosages of up to 0.5 mg/kg/day (C_{max} of 86 ng/mL), and in pregnant monkeys at dosages of up to 0.04 mg/kg/day (serum levels of 1 ng/mL), no such digital anomalies or other gross-structural abnormalities were observed in the fetuses/pups. However, in gravid Sprague-Dawley rats, iloprost clathrate (13% iloprost) significantly increased the number of non-viable fetuses at a maternally toxic oral dosage of 250 mg/kg/day and in Han-Wistar rats was found to be embryolethal in 15 of 44 litters at an intravenous dosage of 1 mg/kg/day.

Nursing Mothers

It is not known whether Ventavis is excreted in human milk. In studies with Han-Wistar rats, higher mortality was observed in pups of lactating dams receiving iloprost intravenously at 1 mg/kg daily. In Sprague-Dawley rats, higher mortality was also observed in nursing pups at a maternally toxic oral dose of 250 mg/kg/day of iloprost clathrate (13% iloprost by weight). In rats a passage of low levels of iloprost or metabolites in the milk was observed (less than 1% of iloprost dose given intravenously). No disturbance of post-natal development and reproductive performance was seen in animals exposed during lactation. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Ventavis, a decision to discontinue nursing should be made, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and efficacy in pediatric patients have not been established.

Geriatric Use

Clinical studies of Ventavis did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.

Hepatic Impairment

Ventavis has not been evaluated in subjects with impaired hepatic function. However, in an intravenous iloprost study in patients with liver cirrhosis, the mean clearance in Child-Pugh Class B subjects (n=5) was approximately 10 mL/min/kg (half that of healthy subjects). Following oral administration, the mean AUC_{0-2h} in Child-Pugh Class B subjects (n=3) was 1725 pg*^h/mL compared to 117 pg*^h/mL in normal subjects (n=4) receiving the same oral iloprost dose. In Child-Pugh Class A subjects (n=5), the mean AUC_{0-2h} was 639 pg*^h/mL. Although exposure increased with hepatic impairment, there was no effect on half-life.

Renal Impairment

Ventavis has not been evaluated in subjects with impaired renal function. However, in a study with intravenous infusion of iloprost in patients with end-stage renal failure requiring intermittent dialysis treatment (n=7), the mean AUC_{0-4h} was 230 pg*^h/mL compared to 54 pg*^h/mL in patients with renal failure (n=8) not requiring intermittent dialysis and 48 pg*^h/mL in normals. The half-life was similar in both groups. The effect of dialysis on iloprost exposure has not been evaluated.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Iloprost was not mutagenic in bacterial and mammalian cells in the presence or absence of extrinsic metabolic activation. Iloprost did not cause chromosomal aberrations *in vitro* in human lymphocytes and was not clastogenic *in vivo* in NMRI/SPF mice. There was no evidence of a tumorigenic effect of iloprost clathrate (13% iloprost by weight) in Sprague-Dawley rats dosed orally for up to 8 months at doses of up to 125 mg/kg/day (C_{max} of 45 ng/mL serum), followed by 16 months at 100 mg/kg/day, or in CrI:CD-1[®](CR)BR albino mice dosed orally for up to 24 months at doses of up to 125 mg/kg/day (C_{max} of 156 ng/mL serum). The recommended clinical dosage regimen for iloprost (5 mcg) affords a serum C_{max} of 0.16 ng/mL. Fertility of males or females was not impaired in Han-Wistar rats at intravenous doses up to 1 mg/kg/day.

PATIENT COUNSELING INFORMATION

Patients receiving Ventavis should be advised to use the drug only as prescribed with either of two pulmonary drug delivery devices: the I-neb® AAD® System or the Prodose® AAD® System, following the manufacturer's instructions (see **DOSAGE AND ADMINISTRATION**). Patients should be trained in proper administration techniques including dosing frequency, ampule dispensing, I-neb® AAD® System or the Prodose® AAD® System operation, and equipment cleaning.

Advise patients that they may have a fall in blood pressure with Ventavis, so they may become dizzy or even faint. They should stand up slowly when they get out of a chair or bed. If fainting gets worse, patients should consult their physicians about dose adjustment.

Advise patients that Ventavis should be inhaled at intervals of not less than 2 hours and that the acute benefits of Ventavis may not last 2 hours. Thus patients may want to adjust times of administration to cover planned activities.

Manufactured by:



5000 Shoreline Court, Ste. 200, South San Francisco, CA 94080
Revised August 2012 ACT20120809
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BLOG: The world of medicine is flat and shrinking

BY DR. MARK J. ROSEN, FCCP

Director, ACCP Global Education and Strategic Development

Columbus gets the credit, but in 240 BC, Eratosthenes of Cyrene discovered that the earth was round. In 1990, the Hubbell telescope proved that the universe is expanding. However, in the 21st century, we know that the world is flat and the universe shrinking with a globalized economy, ease of travel, and technology. All aspects of modern life are changed, including medical science, practice, and education.

The term “global health” usually refers research and activity to improving health worldwide, integrating the perspectives of medical science, sociology, economics, and politics. It focuses on eliminating social and economic disparities that lead to problems in the undeveloped world, such as high rates of child and maternal mortality, along with so-called “diseases of poverty,” like malnutrition, malaria, cholera, and epidemic TB.

The affluent world has a different set of health problems, with global approaches to medical science and practice replacing old models of local expertise guiding patient care in local settings.

► Evidence-based medicine (EBM). Formal methodology is used to review and assess research in populations and to guide clinical deci-

sion-making for individual patients. Systematic review and grading of all available research is carried out, regardless of where the research is conducted.

► Clinical practice guidelines. These recommendations arise from the synthesis of the highest-quality evidence to inform practice. Where medical problems are similar in populations in different countries, it follows that medical practice should be similar, influenced by local resources and culture. Clinicians are obligated to keep up with guidelines related to their practice, regardless of where they practice.

► Globalized training. Physicians cross borders to train, including “international medical graduates” who come to the United States and who often return home.

► Academic and clinical outreach. Leading institutions, like Harvard University and Cleveland Clinic, collaborate in global educational and health system development.

► Medical tourism. Affluent patients from poor countries have always travelled to the United States and Europe for medical expertise and advanced technology. Patient travel to less-developed areas to receive expert care by Western-trained physicians in modern facilities at lower costs is increasingly popular.



DR. MARK J. ROSEN,
FCCP

► Telemedicine. Patient monitoring and clinical expertise are available everywhere but still limited by high costs.

Technology is transforming medical education, with ongoing overhaul of content and delivery, framed by today’s approach to adult learning principles. In local and global contexts, paper

Global approaches to medical science and practice are replacing old models of local expertise guiding patient care in local settings.

textbooks and journals are being rendered obsolete because they are expensive to produce and distribute, usually outdated before they are published, not immediately accessible in daily patient care, and have no interactive features. With the disappearance of paper, the physical library is replaced with a virtual one that we carry in our pockets, that offers decision support, and allows interaction with peers. Likewise, the physical classroom is being replaced with online learning accessible any time and anywhere, and simulation technology is replacing the “see one, do one, teach one” approach to all aspects of practice.

Reprinted from Mark Rosen’s blog on April 14, 2013, at chestnet.org.

CHEST 2013: Inspire Chicago

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CHEST 2013 takes place October 26-31. Recognized as the global authority in clinical chest medicine, it will feature a learning program in pulmonary, critical care, and sleep medicine. Watch for developing details at chestmeeting.chestnet.org.

Readiness assessments

BY RHONDA BUCKHOLTZ,
CPC, CPMA, CPC-I, CGSC,
COBGC, CPEDC, CENTC

AAPC Vice President of the International
Statistical Classification of Diseases and
Related Health Problems (ICD-10) Education
and Training

A crucial step in preparing for ICD-10 is clinical documentation improvement. Providers need help in getting their chart documentation ready to support the new level of specificity in ICD-10. If you randomly pull charts and assess the diagnosis documentation, you may get multiple diagnoses that cover multiple guideline issues in ICD-10. Struggling to cover too many things at once would make it difficult and frustrating to discuss with a provider. So where do you start?

First, run a report in your computer system and sort it by diagnosis code. Next, start with your top 10 codes, and run another report listing patients who had those diagnoses appended to them. Pull 10 to 20 charts with your top-used diagnosis code. Review the ICD-10-CM guidelines (if there are any) for the chapter in which the diagnosis is located. Then, review the notes for diagnosis ONLY. Look at the history and the as-

essment, and code it under ICD-10-CM. Put together a report based on the diagnosis: how many notes could be coded under ICD-10-CM? How many notes need more specific information to code? How many notes had to be coded to an unspecified code?

Take these findings to each provider and review them to show the specificity in ICD-10-CM and what is needed in the documentation to support the diagnosis. Go through all of the notes and answer all questions. Depending on how well the provider did on the assessment, you may either perform another assessment on the same diagnosis or move on to the next diagnosis on your “Top 10” list. The facility/office should have a target percentage for the assessments that all providers should meet. Reports should be kept on each assessment to show progression of the providers.

Once the assessments begin, they should continue until the implementation date of October 1, 2014. How often they occur depends on the number of providers you have, the number of different specialties, the type of specialties, and how the providers perform. When the code set begins official use, it will become part of the regular audit process.

Survey: How pulmonologists use biomarker testing

The American College of Chest Physicians (ACCP) recently partnered with Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) on a survey exploring how pulmonologists from the ACCP incorporate biomarker testing into the care of patients with lung cancer; a similar survey was also conducted by Boehringer Ingelheim among pathologists. The survey results point to an increased role of these physicians in biomarker testing, as well as greater multidisciplinary collaboration. They also reveal an opportunity to improve how soon these tests are requested and to identify challenges with testing, including collecting a sufficient amount and quality of lung tissue.

Biomarker testing is critical in the diagnosis of lung cancer, as it helps physicians determine a patient's specific type of cancer and inform a personalized treatment approach.

The results from the two surveys reflect responses and experiences of 100 ACCP pulmonologists and 250 pathologists practicing in the United States. The surveys were conducted online by Harris Interactive in November and December 2012.

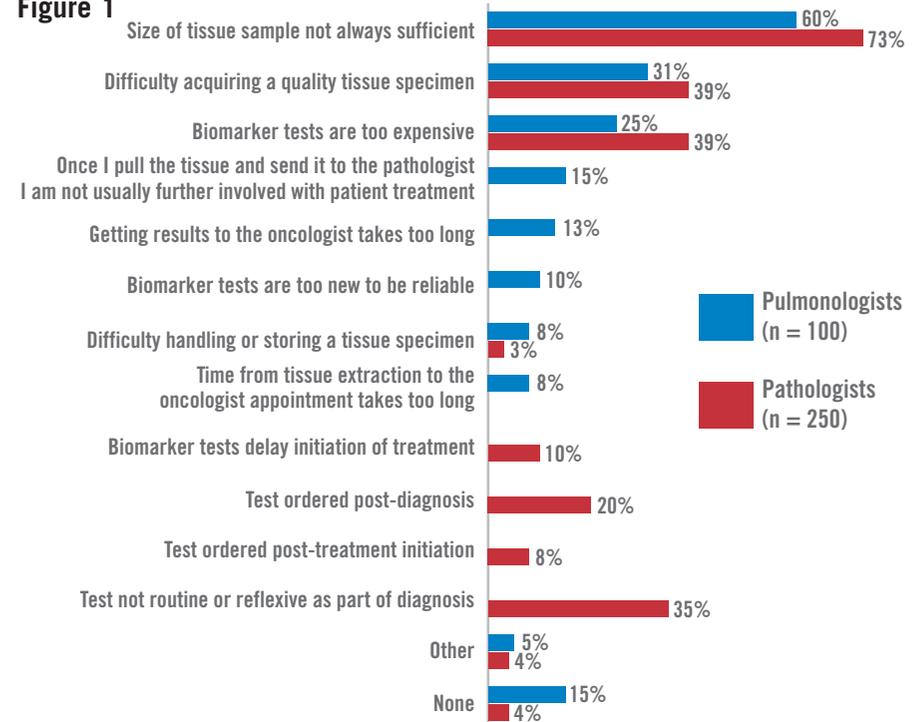
Facing similar challenges

The two surveys revealed the potential need for consistent guidelines on the size and quality of tissue needed to perform biomarker testing. Both pulmonologists and pathologists said the biggest challenges with biomarker testing include not always acquiring a tissue sample that is sufficient in size (60% and 73%, respectively) or quality (31% and 39%, respectively). About half of pulmonologists surveyed (41%) do not believe they have enough information about the size of tissue needed (Fig 1).

Differing opinions

Survey responses highlighted a difference in opinions around the most appropriate tissue acquisition methods: 51% of pulmonologists believed endoscopy biopsy to be the method yielding the most appropriate balance between quantity and quality of tissue and risk to the patient; just 15% of pathologists agreed. In contrast, one-third of pulmonologists (33%) believed fine needle aspiration to be the best method, with only 10% of pathologists agreeing. Interestingly, 63% of pathologists and 44% of pulmonologists believe core

Figure 1



Source: Boehringer Ingelheim

IMNG Medical Media

Biggest challenges regarding biomarker testing. Results taken from two surveys conducted online by Harris Interactive in late 2012, including 100 ACCP pulmonologists and 250 pathologists, respectively.

biopsy to be the most appropriate method.

These findings suggest a need for

greater guidance around the proper techniques to obtain tissue samples

Continued on following page

New Guidelines Now Available

Diagnosis and Management of Lung Cancer, 3rd Edition

New and updated lung cancer guidelines are now available, published in May 2013 as a supplement to *CHEST*. The 3rd edition includes innovative procedural and methodological advancements that have changed previous recommendations, including:

- The most recent staging system and methods for staging.
- Recommendations for tobacco dependence treatment in lung cancer patients.
- A more critical approach to guideline development, employing the latest standards of evidence-based medicine.
- Focus on advancements in symptom management and palliative and end-of-life care.
- Focus on outcomes deemed patient-important.

The print version of the guidelines includes the executive summary, introduction, and methodology for the development.

The online version features the complete guidelines, including articles on individual topics, evidence profile tables, and more.

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- Determine when to refer a patient for special evaluation and testing.



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Continued from previous page

of adequate size and quality at first biopsy. This is not only important for an accurate and rapid diagnosis, which can help inform treatment decisions, but also important for patients who would otherwise be subjected to additional risk by undergoing more than one invasive procedure to gather enough tissue samples for testing.

Opportunity for greater adoption of 'reflex' testing exists

Through reflex – or automatic – testing in advanced non-small cell lung cancer (NSCLC), tissue samples are tested for biomarkers immediately after diagnosis, with the goal of allowing oncologists to review the results before the patient's first visit. The re-

sults from surveyed pulmonologists and pathologists suggest that they have started to embrace reflex testing, but there is potential to increase its use.

Specifically, nearly half (43%) of pulmonologists and one-third (33%) of pathologists implement reflex testing in their practice or local health-care community for patients with NSCLC (Fig 2).

Greater collaboration with the multidisciplinary team

In what should be good news for patients, the survey also showed that pulmonologists and pathologists are increasingly utilizing a multidisciplinary approach to care. In fact, pulmonologists and pathologists report having increased discussions with a multidisciplinary team over the past 5

years (65% and 57%, respectively), and most pulmonologists and pathologists report consulting with oncologists (85% and 92%, respectively) (Fig 3).

"The medical community is moving in a positive direction, but an opportunity exists for greater collaboration in incorporating biomarker testing into a patient's care early on, with the goal of initiating an appropriate lung cancer treatment plan as soon as possible," said Kevin Lokay, vice president and business unit head, Oncology, Boehringer Ingelheim Pharmaceuticals, Inc. "It is encouraging to see how a multidisciplinary approach to testing is becoming more common in the diagnosis and care of cancer patients."

The surveys complement Boehringer Ingelheim's Let's Test ini-

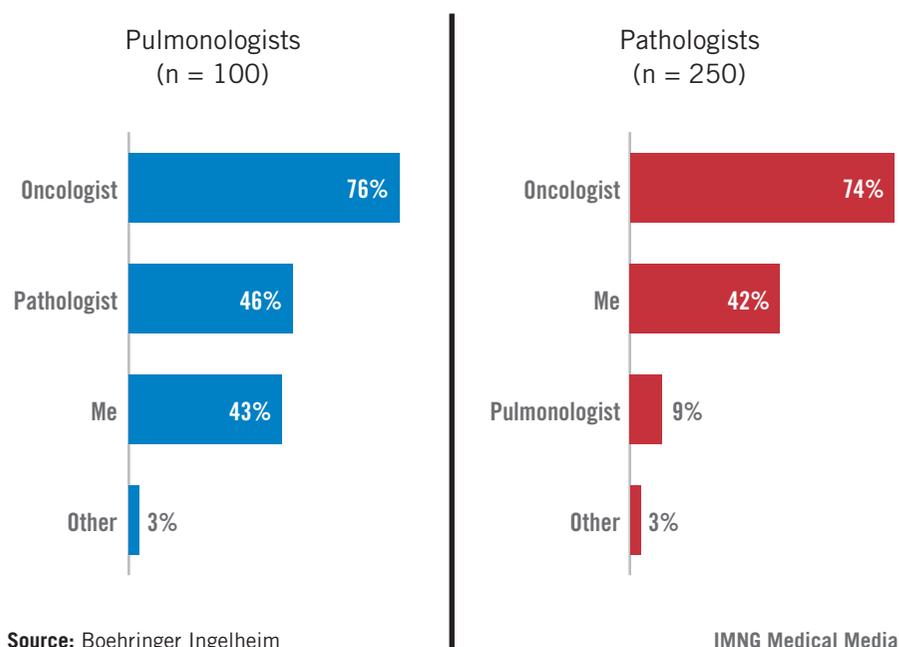
tiative, which aims to educate health-care professionals about the important role they play in the diagnosis and treatment of NSCLC, and the critical role of biomarker testing.

If you would like to learn more about what ACCP is doing in the area of caring for patients with lung cancer, the new ACCP Lung Cancer Guidelines, 3rd edition, has been published as a supplement to *CHEST* in May 2013.

For more information, visit journal.publications.chestnet.org/.

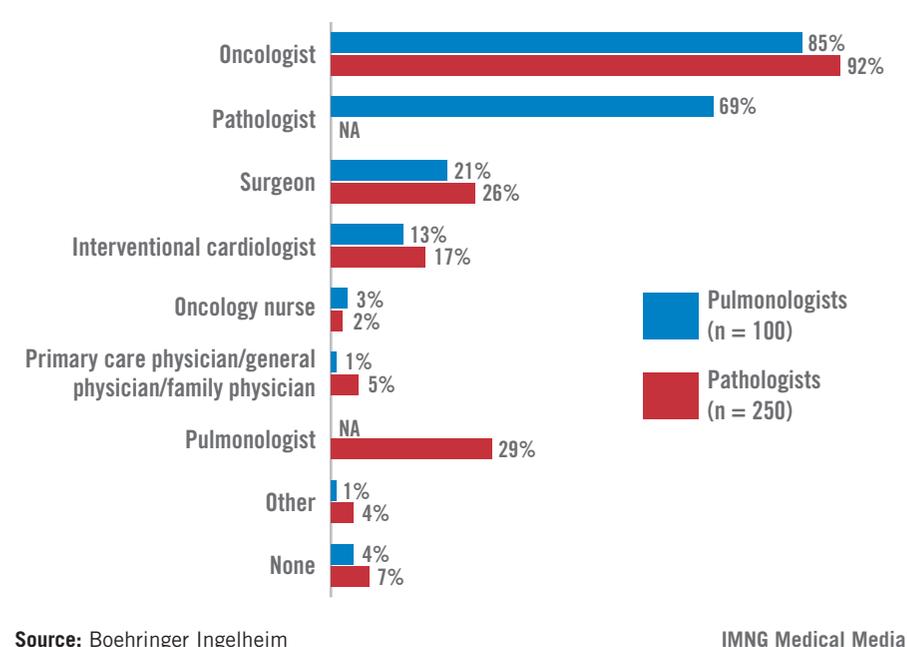
Disclaimer: The data obtained from these surveys are self-reported and subjective; the ACCP was not directly involved in the writing of the survey questions, but rather participated by facilitating the collection of anonymous responses from its members.

Figure 2



Physicians who order biomarker tests for lung cancer patients. Results taken from two surveys conducted online by Harris Interactive in late 2012, including 100 ACCP pulmonologists and 250 pathologists, respectively.

Figure 3



Consulting with various health-care professionals about biomarker testing. Results taken from two surveys conducted online by Harris Interactive in late 2012, including 100 ACCP pulmonologists and 250 pathologists, respectively.

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In today's health-care environment, our industry sales teams do not get a second chance to establish their credibility and knowledge. From the outset, they must be prepared and confident to truly engage with clinicians.

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ACCP PREP uses leading hospitals as the learning environment, so teams can experience the pressures and choices that clinicians face on a daily basis. Conducted at one site or multiple sites, after participants complete PREP, they're better equipped to perform their daily duties and affect patient outcomes. They're able to communicate more effectively with health-care teams and are more confident to begin the conversation. Most important, upon meeting all requirements, participants become certified by ACCP in a specific disease state for 3 years.

PREP's value to ACCP's mission

As a resource for evidence-based clinical practice guidelines and a world leader in forward-looking medical education, the ACCP is known for its ability to translate the latest data into clinical practice. Most recently, ACCP members helped develop and deliver a VTE PREP program. The ACCP would like to extend thank s to the following:

Curriculum faculty

Curriculum advisor: Lisa K. Moores MD, FCCP, Assistant Dean for Clinical Sciences, Professor of Medicine, The Uniformed Services University of the Health Sciences

Subject matter experts:

Jacob Collen, MD; Michael Gould, MD, FCCP; Christopher King, MD; David J. Rosenberg, MD; Aaron Tolley, MD.

On-site faculty:

Venkata Bandi, MD, FCCP; James Bartholomew, MD; Clayton T. Cowl, MD, MS, FCCP; Suhail Raouf, MD, FCCP.

ACCP PREP programs help promote the education of our industry partners and help financially support the mission of the College. For more information or to become involved, contact Noreen Matthews at nmatthews@chestnet.org.

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3rd Edition of the ACCP Lung Cancer Guidelines published

BY SANDRA ZELMAN LEWIS, PHD;
REBECCA DIEKEMPER, MPH; AND
VICKI TEDESCHI

The Diagnosis and Management of Lung Cancer, 3rd ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines, was published as a supplement to the May issue of *CHEST*.

The print supplement includes the Executive Summary, which features all the recommendations, the Introduction, and Methodology chapters. The online version provides the complete supplement, with all full-text articles, supplemental tables, podcasts, and more. The guidelines can be viewed on any smartphone using the mobile-enhanced site or on the *CHEST* journal app for iOS devices.

The ACCP lung cancer guidelines, first published in 2003, have become one of the most comprehensive and respected guidelines in the lung cancer community. The 2nd edition had more than 300,000 accesses from the journal's website and, even 5 years later, more than 163,000 views were chronicled in this past year alone through the National Guideline Clearinghouse.

Readers will note many advances in the updated guidelines. This 3rd edition of the guidelines (LC III) heralds a significant advance in the science of evidence-based medicine. Innovative procedural and methodological advances¹ have resulted in many changes in the recommendations, both clinically

and in terms of the strength of the recommendations. Some of the strong recommendations in the 2nd edition have been downgraded to moderate or weaker levels mainly because the newer more rigorous assessments of the quality of the evidence have led to lower confidence in the estimates of effect.

The ACCP Guidelines Oversight Committee conducted meticulous reviews of nominees' conflicts of interest. The final manuscripts underwent a thorough and precise review process, resulting in recommendations that readers can trust.

Specific changes to these guidelines include: The screening recommendations in LC III are very specific and more inclusive of other modalities. These follow a 2012 multisociety guideline² on screening in which the ACCP was a leading partner.

An article on tobacco cessation for lung cancer patients breaks new ground in this publication. Patients with lung cancer who smoke should be treated by their physicians using pharmacotherapeutic and behavioral approaches to help end their dependence on tobacco.

The newest staging system is demonstrated, and methods for staging lung cancer in patients are explored in detail. As with past editions, the treatment articles are divided by stage of illness, small cell lung cancer, and special treatment issues. But the comprehensive and systematic evidence reviews have yielded the newest evidence on treatments for these patient populations.

This edition includes a comprehensive review

with recommendations for managing the symptoms experienced by patients with lung cancer even before they approach the end of life.

Complementary and integrative oncology treatments are explored and held to the same evidence-based standards. A number of randomized controlled trials, meta-analyses, and systematic reviews were revealed, and many recommendations address the benefits of integration of approaches from pulmonary rehabilitation to acupuncture and massage and more.

Clinical resources, including slide sets for presentations to lay and professional audiences, and educational programs will be made available over the next several months and during CHEST 2013 in Chicago in October. Please watch for announcements in your inbox and on www.chestnet.org.

The ACCP is working hard to produce the very best evidence-based clinical guidelines in chest medicine. You can access the LC III guidelines at journal.publications.chestnet.org.

For more information, please contact Sandra Zelman Lewis, PhD, slewis@chestnet.org.

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AMERICAN COLLEGE OF CHEST PHYSICIANS

2013 Education Calendar

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Occupational and Environmental Lung Disease Conference 2013
June 20-23
Toronto, ON, Canada

ACCP/STS Advanced Diagnostic and Therapeutic Bronchoscopy
July 12
Northbrook, IL

ACCP Sleep Medicine Board Review 2013
August 23-26
San Antonio, TX

ACCP Critical Care Medicine Board Review 2013
August 23-26
San Antonio, TX

ACCP Pulmonary Medicine Board Review 2013
August 28-September 1
San Antonio, TX

Mechanical Ventilation 2013
August 27
San Antonio, TX

ABIM Critical Care Medicine and Pulmonary Disease SEP Modules 2013
August 27
San Antonio, TX

CHEST 2013
October 26-31
Chicago, IL

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BRONCHOSCOPY

Essentials of Bronchoscopy
August 1-2
Wheeling, IL

Endobronchial Ultrasound
August 3-4
Wheeling, IL

CRITICAL CARE

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

ULTRASONOGRAPHY

Focused Thoracic and Vascular Ultrasound
September 19-20
Wheeling, IL

Critical Care

Echocardiography
September 21-22
Wheeling, IL

Advanced Critical Care Echocardiography
May 31-June 2
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July 25
Northbrook, IL

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

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NETWORKS: Lung cancer, new procedure codes

Thoracic Oncology

CHEST sessions, e-Community, and projects

CHEST 2013 will provide a spectrum of educational forums and topics related to thoracic oncology. The general sessions and highlights will address areas relevant to the practicing clinician, trainee, and thoracic oncology specialist. The ACCP Lung Cancer Guidelines, 3rd ed (LCIII), will be highlighted throughout the meeting. There are plans to share some sessions via video teleconferencing with the World Conference on Lung Cancer taking place in Sydney, Australia, at the same time. Other sessions focusing on lung cancer screening, lung nodule evaluation, staging, chest imaging, and appropriate tissue acquisition have been planned. In addition, there is a lung cancer track the final morning of the meeting where one-half day will be spent focused on our specialty. Our NetWork Featured Lecture is a great opportunity to meet others with shared interests and find ways to be engaged in the NetWork's activities.

The College has provided us with a venue to improve communication

within and between the NetWorks and their membership. The ACCP e-Community provides relevant resources for those interested and a forum for discussions about new or controversial topics in thoracic oncology. Look forward to enhanced links to helpful material and a series of focused topic discussions. We encourage you to visit and contribute to this site.

Our NetWork and our membership are involved in projects of various scope and at different stages of development. Many NetWork members have dedicated a great deal of time to the production of the LCIII guidelines. A project aiming to develop Quality Indicators for the Evaluation and Staging of Lung Cancer is nearing completion, and a project aiming to provide guidance on the ideal means of tissue acquisition and processing is being discussed.

Overall, it is an exciting time, with many developments in thoracic oncology leading to opportunities for education and research. Our NetWork welcomes your ideas and participation in these efforts.

*Dr. Peter Mazzone, FCCP
NetWork Chair*



32405 for percutaneous biopsy of the lung or mediastinum (32420 has been deleted).

For small-bore percutaneous pleural catheters (without cuff), there are two new codes with similar distinction as thoracentesis; without (32556) and with (32557) imaging guidance. These are used when a catheter is placed into the pleural space, without dissection. Traditional open large-bore tube thoracostomy is still coded as 32551; however, references to hemothorax and empyema have been removed.

Radiology codes (75989, 76942, 77002, 77012, 77021) are not to be used with 32554 or 32556, and imaging is bundled into both 32555 and 32557.

Placement (32550) and removal (32552) of indwelling tunneled pleural catheters, pleurodesis (32560), and intrapleural fibrinolysis (32561, 32562) codes remain unchanged.

*Dr. Mohit Chawla, FCCP,
Steering Committee Member;
Dr. Kevin L. Kovitz, FCCP; and
Ms. Kim French, MHSA, CAPP*

In memoriam:

Robert G. Loudon, MBChB, FCCP, died January 1, 2013. He was the Pulmonary and Critical Care Division Chief from 1971 to 1992 at the University of Cincinnati Medical Center.

During his 21 years as Division Chief, he helped expand the division with the introduction of flexible bronchoscopy, critical care, and sleep medicine. Dr. Loudon moved from studies of cough as a method to transmit tuberculosis to studies of lung and cough sounds. With Raymond Murphy, MD, FCCP, he founded the International Lung Sounds Association. This multinational group helped codify lung sound terminology.

As a Fellow of the ACCP, Dr. Loudon participated in the International Affairs Committee; as Chair of the Credentials Committee; and as a Regent at Large.

He is survived by his wife, Dorothy, and three daughters, Elizabeth, Sarah, and Kate.

Interventional Chest/Diagnostic Procedures

New codes for percutaneous pleural procedures

Pleural procedures have long been part of the routine practice of pulmonary and critical care providers. The widespread use of imaging guidance, primarily ultrasound, is now prevalent. In addition, the use of various pleural catheters has extended beyond interventional radiology. Traditional tube thoracostomy has been largely replaced by pigtail or indwelling tunneled pleural catheters.

Pleural interventions can be done in an ambulatory setting, at the bedside, or in a procedure/operative setting. Ultrasound and/or fluoroscopy is used to guide the procedure to minimize risk and to access small or loculated collections.

For thoracentesis, there is no longer a distinction between needle-only (diagnostic, 32421 deleted) and catheter-based drainage (therapeutic, 32422 deleted). These are now equivalent and coded without (32554) or with (32555) imaging guidance. Code 76942 is no longer reported for imaging guidance during thoracentesis. Report

This Month in CHEST: Editor's Picks

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



EDITORIAL

The American College of Chest Physicians Lung Cancer Guidelines (3rd Edition): Is the Pulmonologist Moving From Special Teams to Quarterback? *By Dr. N. J. Pastis.*

COMMENTARY

US Food and Drug Administration-Mandated Trials of Long-Acting β -Agonists Safety in Asthma: Will We Know the Answer? *By Drs. S. Suissa and A. Ariel.*

ORIGINAL RESEARCH

Efficacy of Single-Dose Antibiotic Against Early-Onset Pneumonia in Comatose Patients Who Are Ventilated. *By Dr. J. Valles et al.*

Incidence of Severe Asthmatic Reactions After Challenge Exposure to Occupational Agents. *By Dr. O. Vandenplas et al.*

Obstructive Sleep Apnea in Patients With Typical Atrial Flutter: Prevalence and Impact on Arrhythmia Control Outcome. *By Dr. V. Bazan et al.*

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