In New Guideline, A Road Map to Troponin Testing

Consensus on when, how to use tests.

BY ALICIA AULT
IMNG Medical News

As the sensitivity of troponin testing improves, so must clinicians refine the way they order and interpret such tests, according to a new consensus statement issued by seven professional societies.

Clinicians have used troponin as a biomarker for myocardial infarction since the early 1990s. However, while an elevated level indicates myocardial necrosis, it does not necessarily mean that a myocardial infarction has occurred. There can be other myriad reasons for an increase in troponin.

The consensus statement — written by a 14-member group of experts — reviews the most recent research on troponin testing and its clinical applications. It also addresses frequently asked questions on what an elevated troponin level means, when the test should be ordered, and prognosis with a positive test.

The statement also gives a schematic look at potential causes for a positive troponin test. The schematic is divided into ischemic and nonischemic causes, and then further broken down.

"We need to be thinking about why we are ordering the troponin test before we order it," said Dr. L. Kristin Newby, who is the cochair of the writing committee for the American College of Cardiology Foundation 2012 Expert Consensus Document on Practical Clinical Considerations in the Interpretation of Troponin Elevations.

"We hope this document provides a road map to help clinicians be more deliberate when ordering these tests and interpreting the results," said Newby.

NIPPV Benefits Severe Stable COPD

BY SHARON WORCESTER
IMNG Medical News

ATLANTA — Long-term nocturnal use of noninvasive positive pressure ventilation significantly reduced the likelihood of intensive care unit admission in patients with severe stable chronic obstructive pulmonary disease, according to findings from a systematic review of 582 patients in 13 randomized, controlled clinical trials.

After 1 year, noninvasive positive pressure ventilation (NIPPV) was associated with a significant decrease in ICU admissions (odds ratio, 0.41) compared with standard medical therapy. Patients using NIPPV for more than 3 months also had improvements in oxygenation (mean difference of 2.43 mm Hg), reduction in PCO₂ (mean difference, −2.96 mm Hg), and an improvement in 6-minute walk distance (mean difference 45.15 m). Dr. Monali Patel said at the annual meeting of the American College of Chest Physicians.

Thinking about a change? Interested in relocating? Go where the jobs are...
NIPPV

Stable COPD • page 1

A trend toward improved mortality at 1 year did not reach statistical significance, and no significant improvements in lung function were noted, according to Dr. Patil, of the University at Buffalo (N.Y.).

Dr. Patil selected the 13 trials from a review of more than 700 studies conducted between 1991 and 2011. The analysis included only randomized, controlled trials of COPD patients who had an FEV1, less than 50% of predicted and a PO2 greater than 45 mm Hg and were receiving bilevel positive airway pressure (BPAP).

The patients in the studies were aged 18-75 years, and had no COPD exacerbations within 2 weeks prior to study enrollment.

The long-term use of NIPPV in patients with severe stable COPD has been controversial, but these findings demonstrate significant benefits.

“So NIPPV can be used as adjuvant treatment for management of severe stable COPD patients,” she concluded.

Dr. Patil reported having no financial disclosures.

Guidance on Troponin Testing

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Dr. Darcy D. Marciniuk, FCCP, comments: This review of small RCTs in patients with severe stable COPD and CO2 retention demonstrated that long-term nocturnal NIPPV led to meaningful reductions in hospital admission, improved gas exchange, and greater 6-minute walk test distance. Just as NIPPV has become foundational therapy in the setting of acute exacerbation of COPD, the use of NIPPV in stable patients with severe COPD with respiratory failure may also be of significant benefit. A large RCT examining various clinical, quality of life, and economic endpoints is definitely the next step.

Dr. Newby, who is a professor of medicine in the division of cardiovascular medicine at Duke University Medical Center, Durham, N.C.

Troponin may be elevated because of heart failure, surgery, trauma, kidney disease, or pulmonary embolism, among other conditions.

The biomarker may also show up in patients who have sepsis or those who are taking certain chemotherapies, such as anthracyclines and cyclocosphamide, which are known to cause cardiac damage.

“If we are indiscriminate in how we order these tests or we aren’t paying attention to the clinical scenario before us, we may miss something important,” said Dr. Newby.

Further complicating testing, the statement warns clinicians that “all troponin assays are not created equal,” and that there is “a wide spectrum of accuracy in practice.”

The measurement of cardiac troponin is also not standardized, though there have been recommendations by the National Academy of Clinical Biochemistry on how to achieve standardization.

Most assays, however, are “able to selectively detect cardiac troponin to the exclusion of troponin from other tissues,” according to the statement.

The statement also documents that elevated troponin deserves investigation because it is associated with worse outcomes.

“If you have a pulmonary embolism or end-stage renal disease and your troponin is elevated, you prognostic – how you are expected to do – is worse,” said Dr. Newby.

According to the statement, for clinicians, the “best value of troponin testing remains in the diagnosis of MI.” But even with that use, it is important to understand the clinical context as treatment may vary considerably.

The 37-page statement was developed by the ACCF, the American Association for Clinical Chemistry, the American College of Chest Physicians, the American College of Emergency Physicians, the American College of Physicians, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions.

The statement was published online in the Journal of the American College of Cardiology (JACC 2012;60) and is available on the ACC’s website at (http://content.onlinejacc.org/article.aspx?id=1380790).

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CHEST PHYSICIAN Is Online
CHEST PHYSICIAN is available on the Web at www.chestnet.org/accp/chest-physician.
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TYGACIL provides coverage of gram-positive (including MRSA*), gram-negative, anaerobic, and atypical pathogens. TYGACIL does not cover Pseudomonas aeruginosa.

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

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

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- TYGACIL is contraindicated in patients with known hypersensitivity to tigecycline or to any of the excipients.
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- Isolated cases of significant hepatic dysfunction and hepatic failure have been reported in patients being treated with tigecycline. Some of these patients were receiving multiple concomitant medications. Patients who develop abnormal liver function tests during tigecycline therapy should be monitored for evidence of worsening hepatic function. Adverse events may occur after the drug has been discontinued.
- The safety and efficacy of TYGACIL in patients with hepatic dysfunction have not been established.
- An increase in all-cause mortality has been observed across Phase 3 and 4 clinical trials in TYGACIL-treated patients versus comparator-treated patients. In all 13 Phase 3 and 4 trials that included a comparator, death occurred in 4.0% (150/3788) of patients receiving TYGACIL and 3.0% (110/3646) of patients receiving comparator drugs. A pooled analysis of these trials, based on a random effects model by trial weight, an adjusted risk difference of all-cause mortality was 0.6% (95% CI 0.1, 1.2) between TYGACIL and comparator-treated patients. The cause of this increase has not been established. This increase in all-cause mortality should be considered when selecting among treatment options.
- TYGACIL may cause fatal harm when administered to a pregnant woman.
- The use of TYGACIL during tooth development may cause permanent discoloration of the teeth.
- TYGACIL should not be used during tooth development unless other drugs are not likely to be effective or are contraindicated.
- Acute pancreatitis, including fatal cases, has occurred in association with tigecycline treatment. Consideration should be given to the cessation of the treatment with tigecycline in cases suspected of having developed pancreatitis.
- Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including TYGACIL, and may range in severity from mild diarrhea to fatal colitis (pseudomembranous colitis).
- Monotherapy should be used with caution in patients with clinically apparent intestinal perforation.

Please see brief summary on adjacent page.
Major Finding: Good biopsy specimens (defined by a size of 0.5 x 0.4 cm) were obtained and no life-threatening complications occurred in patients who underwent transbronchial lung biopsy.

Data Source: A prospective study in 10 patients was conducted.

Disclosures: Neither Dr. Muthiah nor Dr. Elnady reported having financial conflicts.

NEWS

Pleuroscopy an Option for Unknown DPLDs

BY SHARON WORCESTER

IMAGING News

ATLANTA—Medical thoracoscopy is safe and feasible for performance lung biopsy in patients with diffuse parenchymal lung disease with unknown etiology on high-resolution computed tomography. The approach could serve as an alternative to surgical biopsy in some patients, findings from a prospective study suggest.

In 10 patients who underwent medical thoracoscopic lung biopsies as part of the study, good biopsy specimens, with an average size of 0.5 x 0.4 cm were obtained, Dr. Mohamed Elnady said at the annual meeting of the American College of Chest Physicians.

Complications with this advanced technique included persistent air leak for 5-7 days in two patients, pneumothorax after removal of the intercostal tubes in two patients, pain in six patients, and minor bleeding in one patient. The air leaks resolved spontaneously, and the pneumothoraces resolved with administration of high flow oxygen, said Dr. Elnady of Cairo (Egypt) Universities.

The mean duration of intercostal tube placement was 3.1 days, with a range of 1-7 days, no infection, respiratory failure requiring intensive care unit admission, or mortality occurred within 30 days after the procedure, he noted.

Patients in the study included four women and six men with a mean age of 42 years. The lung biopsies obtained via medical thoracoscopy were sent for histopathological examination, and patients underwent follow-up by chest x-ray for confirmation of lung expansion, as well as observation of the intercostal tube to detect complications. Among the ultimate diagnoses were metastatic adenocarcinoma, interstitial lung disease, and lymphangiioleiomyomatosis.

"Thoracoscopic lung biopsy by medical thoracoscopy is useful in the diagnosis of patients with diffuse lung infiltrates of unknown etiology when lung biopsy is needed for an accurate diagnosis," he concluded, noting that while the procedure does carry a risk of certain non-life-threatening complications, these can be minimized with good patient selection.

Moderator Dr. Muthiah P. Muthiah of the University of Tennessee Health Science Center, Memphis, said this novel approach to obtaining lung biopsy is of interest, but also "something we still have to get comfortable with."
**Directed Exchange Is Key to EHR Stage 2**

By Mitchell L. Zoler
IMNG Medical News

Philadelphia – With the federal stage 2 deadline for the meaningful use of electronic health records looming less than 2 years from now, doctors need to start thinking about interoperability, directed exchange, and health Internet service providers.

The key capability that stage 2 demands is the ability to transfer patient data in a reliably secure, confidential way between physicians, between a physician and patient, or between a physician and a health care system.

These secure, Internet-based data transfers will depend on three elements, Dr. David C. Kibbe said at the annual congress of delegates of the American Academy of Family Physicians:

- A standardized format and language for recording the data that transcend the different electronic health record (EHR) formats used by different vendors.
- A method to securely move the data between two or more EHR users, a process known as directed exchange.
- A system to verify that the person engaged in a data exchange — for example, Dr. Smith — really is Dr. Smith.

Although the software that allows these secure exchanges is still being tweaked and has generally not yet rolled out to EHR users, the systems will likely become available in the next few months, said Dr. Kibbe, a senior adviser to the American Academy of Family Physicians in Oriental, N.C.

If the systems work the way they should, physicians will not need to sweat the details. Once EHR vendors get the software finalized and providers in place, all physicians will need to do is sign up for service with the EHR vendor, Dr. Kibbe said.

A big part will be physicians becoming customers of a health Internet service provider. Those providers will be some-kind of a conventional Internet service provider, except that they’ll be geared to operate with special certification and encryption procedures to guarantee secure data transmission and validate sender and recipient identities.

EHR systems and health Internet service providers will need to use a certification process to establish and confirm the identity of each of their physician clients.

“Health Internet service providers didn’t exist 12 months ago; now many exist, and they are eager to have your business,” he said.

Physicians who plan to comply with meaningful use stage 2 and don’t hear anything from the EHR vendor by mid-2013 should ask their vendor, “When can you provide it?” said Dr. Kibbe, who also is president of Direct Trust, a nonprofit group that facilitates implementation of directed exchange.

“While some vendors are on top of this, others are clueless,” he warned.

And be prepared to pay a bit more for the ability to run secure directed exchange, he said.

On the upside, having this capability for secure transmission of EHR data should eliminate the need to send patient information by fax, a step that should save most practices time and money, Dr. Kibbe said.

Dr. Kibbe said that he had no relevant financial disclosures.

**REFERENCE:**

“VENTAVIS® (iloprost) Inhalation Solution is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise tolerance, symptoms (NYHA Class), and to delay deterioration. Studies establishing effectiveness included patients with pulmonary hypertension (WHO Functional Class III or IV) of symptoms and etiologies of idiopathic or heritable PAH (WHO Group 3) or PAH associated with connective tissue disease (WHO Group 4).”

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January 2013 Rings In a Cold Year for Vaccines

By MICHELE YOUNG
IMMG Medical News

NEW ORLEANS – Beginning in 2013, vaccines will need to be stored in a full-sized, freezerless refrigerator, the temperature of which is constantly monitored by a digital 24-hour temperature-recording device.

The new storage guidelines, issued in early October by the Centers for Disease Control and Prevention, also require the use of a biosafe glycol-enforced temperature probe because these devices more accurately approximate the temperature of stored liquids, Dr. Herschel Lessin said at the annual meeting of the American Academy of Pediatrics.

The regulation will go into effect on Jan. 1, 2013, Dr. Lessin, a pediatrician in group practice in Phoenix, Ariz., said.

“You also won’t be able to use a dorm style refrigerator or a freezer/refrigerator/freezer combination,” he said. “In these units, the freezer is actually what chills the fridge, and when the freezer doors are opened and off, and it can change the temperature of the fridge.”

The 24-hour data recording of temperature is intended to ensure that vaccine remains within its constant recommended range of 35°-46°F. If it’s too hot, “it’s the kiss of death for your store of vaccine,” he said.

The recording unit has to be able to store at least 4,000 readings so it won’t overwrite old data or stop recording because the memory is full.

In addition to the hardware changes, human systems will need an update, Dr. Lessin, who is also a member of the American Academy of Pediatrics committee on practice and ambulatory medicine. Someone in the office needs to review the temperature log daily.

“You have to have a system that if the temperature gets close to being out of the range, you get that vaccine out of there and into an appropriate storage container.”

The system should also include a weekly review of expiration dates to facilitate stock rotation, and people who can serve as “vaccine coordinators.” These staff should be trained in proper vaccine storage and handling, and be able to perform accountability checks to make sure the protocol is followed.

After 1975 temperature-registered thermometers in different parts of the device and on the outside of vaccine bottles were taken, a regular full-sized freezerless refrigerator was found to be “fully adequate” at keeping the vaccines at the optimum temperature. Dorm-style units showed quite a lot of temperature drift, especially when they were heavily loaded. “These problems make the dormitory-style refrigerator unsuitable for vaccine storage,” Dr. Lessin said.

Dr. Lessin said he had no relevant financial disclosures.

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NEWS

DECEMBER 2012 • CHEST PHYSICIAN
Waning Herd Immunity May Spell Pertussis Outbreaks

BY SUSAN LONDON
IMNG Medical News

SAN DIEGO – The declining herd immunity to pertussis seen in the United States may be related to withdrawal of the whole cell vaccine from the market about a decade ago, a study of more than 450,000 vaccinated patients from Kaiser Permanente Medical Center has shown. Compared with their peers who had received at least one dose of whole cell vaccine, patients who had received only acellular vaccine had at least a tripling of the risk of acquiring the disease, lead author Maxwell Witt reported at the annual IDWeek conference.

The association was still present but weaker among patients who had received a total of six doses versus five. "Acellular pertussis vaccine offered significantly less protection when compared with the whole cell vaccine," commented Mr. Witt of Kaiser Permanente in San Rafael, Calif. "The risk of pertussis was mitigated, but not eliminated, by a sixth dose of pertussis vaccine, the Tdap (tetanus, diphtheria, and acellular pertussis) vaccine.

"The current generation of children is the first to have been vaccinated solely with the acellular pertussis vaccine," Mr. Witt said. "Our findings would predict a significant population of unprotected children in this group." Recent outbreaks of pertussis in the United States "had peak attack rates among those who are exactly in the same age group," he noted.

"The waning immunity associated with these outbreaks is clearly a call for development of more effective and durable pertussis vaccines," Mr. Witt said. "In the shorter term, strategies to prevent these outbreaks of pertussis could include either earlier or additional booster doses.

Dr. Susan Millard, FCCP, comments: Pertussis infection can be debilitating for people with chronic lung disease and deadly for young infants. This is an important, powerful study based on a large database. The question, though, is where do we go with this information?"
Zolpidem Linked to Higher Inpatient Fall Rates

BY TARA HAELLE
IMAGING Medical News

Administration of zolpidem in hospitalized patients is associated with a significantly higher risk of falls according to a Mayo Clinic study published in the Journal of Hospital Medicine.

After accounting for a large range of confounders, the researchers found that one additional fall could be expected for every 55 inpatients who received zolpidem. Patients receiving zolpidem were more than three times more likely to fall compared with those who were prescribed it but did not receive it.

Dr. Bhanu Prakash Kolla at the Mayo Clinic’s Center for Sleep Medicine in Rochester, Minn., and associates, analyzed the fall rate among 16,320 adult patients admitted to Mayo Clinic hospitals in 2010. All patients over age 18 who had been prescribed zolpidem but were neither pregnant nor ICU patients were included in the analysis (J. Hosp. Med. 2012 Nov 19 [doi: 10.1002/jhm.1987]).

Using the inpatients pharmacy electronic database and patient records, the authors compared the rate of falls among patients who were actually administered zolpidem to the rate among those who did not receive the medication despite being prescribed it on an “as-needed” basis.

Among the 4,962 patients who received zolpidem, their 151 falls resulted in a fall rate of 3.04%, compared to a fall rate of 0.71% in 11,358 inpatients who were prescribed but not administered the drug.

Data Source: The findings are based on a retrospective cohort study of 16,320 adult patients admitted in 2010 to Mayo Clinic hospitals who were prescribed zolpidem, excluding ICU and pregnant patients.

Disclosures: The study was funded through the Mayo Clinic’s fellowship training program; no other disclosures were reported.

Major Finding: The fall risk in 4,962 hospital inpatients who received zolpidem was 3.04% vs. 0.71% in 11,358 inpatients who were prescribed but not administered the drug.

Zolpidem use and fall risk was still significant with an OR of 6.39. There was no statistically significant association identified for the other medications accounted for in the analysis.

Methods to provide safe relief from complaints of disturbed sleep.”

The researchers controlled for confounders that may increase fall risk, including age, length of hospital stay, being on a surgical floor, zolpidem dose, visual impairment, gait abnormalities, cognitive impairment/dementia, insomnia, delirium, comorbidities (measured with the Charlson comorbidity index), and patient’s Hendrich’s fall risk score.

The analysis also controlled for medications that patients received in the 24 hours before the fall that are already associated with an increased fall risk, including antidepressants, antipsychotics, antihistamines, sedative antidepresants including trazodone and mirtazapine, benzodiazepines, and opioids.

A univariate analysis revealed that all factors significantly associated with a higher fall rate included zolpidem use (odds ratio, 4.37), being male (OR, 1.36), and having insomnia (OR, 2.37) or delirium (OR, 4.96) as well as increasing age, zolpidem dose, comorbidity scores, and fall risk scores.

When the researchers accounted for all statistically significant additional fall risk factors, the association between zolpidem use and fall risk was still significant with an OR of 6.39. There was no statistically significant association identified for the other medications accounted for in the analysis.

In advanced non–small-cell lung cancer (NSCLC)

PERSONALIZED MEDICINE STARTS WITH TESTING

Now you can do more to help improve patient outcomes through a multidisciplinary approach to biomarker testing in advanced NSCLC.

Biomarker testing is a key to individualizing treatment. The understanding and treatment of advanced NSCLC are continuing to evolve.

Recently, the predictive and prognostic value of certain biomarkers has established the need for reflex (or automatic) testing that may allow clinicians to further individualize treatment plans, which may lead to improved clinical outcomes. Communication among physicians who perform biopsies, pathologists, and oncologists is central to the effort to standardize biomarker testing in advanced NSCLC.

Biomarkers with prognostic and predictive value

Over the last decade, a growing number of biomarkers have been identified in NSCLC. In advanced NSCLC, 2 biomarkers are recognized to have both prognostic and predictive value: EGFR (ErbB1) mutations and ALK rearrangements.

- EGFR (ErbB1) may be altered or overexpressed, resulting in oncogenic signaling that promotes tumor cell growth, survival, and metastasis.

- EML4-ALK is an inversion rearrangement associated with oncogenic transformation via an increase of catalytic activity within the kinase domain.

Prevalence of key biomarkers

EGFR (ErbB1) mutations occur in an estimated 10% to 15% of NSCLC tumors. ALK rearrangements are less common—occurring in approximately 2% to 7% of NSCLC tumors. Together, EGFR (ErbB1) mutations and ALK rearrangements comprise 12% to 22% of NSCLC tumors—one in 5 patients with advanced NSCLC.

The Lung Cancer Mutation Consortium (LCMC), an initiative of the National Cancer Institute, is tracking the prevalence of biomarkers in NSCLC with a histologic subtype of adenocarcinoma. To date, 1000 patients from 14 leading cancer centers across the country (stage III/IV, performance status 0–2) have been enrolled. Results are as follows.

NSCLCs tumors (advanced)

- 15,000 to 25,000 patients
- EML4-ALK 12%-22%
- 22% of NSCLC tumors—affecting approximately 15,000 to 29,000 patients—or ~1 in 5 patients with advanced NSCLC.
FDA Eyes Pramipexole for Possible Heart Failure Risk

Elizabeth Mechcatie

Pramipexole, the dopamine agonist approved for treating Parkinson’s disease and restless legs syndrome, may be associated with an increased risk for heart failure, according to a statement issued by the Food and Drug Administration.

“Results of recent studies suggest a potential risk of heart failure that needs further review of available data,” but the FDA has not concluded that the drug increases the risk of heart failure, the FDA said in the statement.

The FDA is currently working with Boehringer Ingelheim, which markets pramipexole as Mirapex, to investigate this association and will provide an update when more information is available.

The studies include a pooled analysis of randomized clinical trials, which found more cases of heart failure (12 of 4,157 patients) among patients treated with pramipexole than among those on placebo (4 of 2,820). The difference between groups, however, was not statistically significant.

In two epidemiologic studies using European data, though, the increased risk of heart failure associated with pramipexole was statistically significant.

In one of the studies, a case control study using a database of patients aged 40-89 years treated with a anti-parkinsonian drugs, the risk of heart failure associated with any use of a dopamine agonist compared with no use was increased by almost 60% (relative risk, 1.58). The heart failure risk associated with use of pramipexole (RR, 1.86) and with another dopamine agonist, cabergoline (RR, 2.07), were each higher compared with no use of these drugs.

In the other epidemiologic study, current use of pramipexole was associated with an increased risk of heart failure, compared with levodopa. The risk was increased in the first 3 months of treatment and among patients aged 80 years and older, but was no higher among people who had been treated with pramipexole for more than 3 months.

This last finding is “hard to explain,” since heart failure is a chronic condition, and the studies had limitations, which “make it difficult to determine whether excess heart failure was related to Mirapex use or other influencing factors,” the FDA statement said. “The agency advises that health care professionals continue follow recommendations in the pramipexole label and that patients continue to take the medication as directed.

Pramipexole was approved in July 1997.

The full FDA notice is available at www.fda.gov/Drugs/DrugSafety/ucm319779.htm. Serious adverse events should be reported to the FDA at fda.gov/MedWatch or (800) 332-1088.
Pulmonary Medicine

December 2012 • Chest Physician

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Preadmission to Discharge: Best COPD Choices

BY SHARON WORCESTER
IMNG Medical News

ATLANTA – About a third of patients hospitalized for chronic obstructive pulmonary disease receive appropriate care, but a number of steps—beginning with decisions about when to admit and ending with proper discharge management—can be taken to improve outcomes, said Dr. Darcy D. Marciniuk, FCCP.

Although scientific guidance on when patients should be admitted is lacking, guidelines and consensus statements suggest that patients with an exacerbation should be admitted:

- If they experience a marked increase in dyspnea.
- If they have severe underlying COPD with little reserve, “such that there’s no room for error.”
- If they fail to respond to initial management.
- If they have comorbidities, including heart failure, arrhythmias, or renal impairment.
- If they have advanced age.
- If they experience frequent severe exacerbations.

- If they have insufficient home support.

Once a patient is admitted, controlled appropriate supplemental oxygen should be administered as directed by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines. Noninvasive ventilation should be used when indicated, Dr. Marciniuk advised.

Aggressive therapies should be used at the outset, and use of antibiotics or systemic corticosteroids should be considered, said Dr. Marciniuk, ACCP president, and head of the division of respirology, critical care, and sleep medicine at the University of Saskatchewan, Saskatoon, Canada.

An effort should also be made to identify the precipitating factor, as well as to recognize and optimize or prevent comorbid conditions, to prevent complications, and to address depression and anxiety, he said.

With respect to supplemental oxygen, the GOLD guidelines will help ensure there is “always enough, but never too much,” Dr. Marciniuk said.

“Now, with saturation monitors, life is good; it’s very easy to make sure patients receive appropriate therapy,” he added.

Dr. Marciniuk also highlighted noninvasive ventilation. It has revolutionized in-hospital COPD management, lowering intubation rates by 60% and substantially decreasing in-hospital mortality, he said.

“Noninvasive ventilation has been incredibly for our patients,” he said. Although it was first used in the 1980s, it is now “really the treatment of choice for acute hypercapnic respiratory failure in this setting,” he added.

Contrary to some beliefs about outcomes with COPD in the intensive care unit, mortality is actually much lower than for many other conditions. For example, mortality in COPD patients in the ICU is about half that of patients with sepsis or acute respiratory distress syndrome.

“So, even though a patient may look short of breath, and someone may think they have a poor quality of life, it is the patients who should be judging that,” he said.

“There needs to be that comfort, that back-up, of the ICU because data would suggest the outcomes are pretty good.”

There is significant evidence of benefit with the use of noninvasive ventilation, particularly with respiratory acidosis of pH less than 7.35, PaCO2 greater than 45, and significant dyspnea, which is easily detected by clinical means, he added.

Depression in COPD patients is also particularly important to address.

Studies show that patients with depression have longer hospital stays (twice as long, according to one observational study), more frequent exacerbations in the year following discharge, and higher mortality rates, he said. “Our understanding of the co-presence of depression and anxiety (in COPD patients) is growing, but our understanding of how to have an impact in this setting is also growing.”

As for discharge planning, appropriate methods and practices must be put in place, for reducing the future risk of acute exacerbations, he said.

Dr. Marciniuk reported having no financial disclosures, with the exception of research funding directed to and managed by his institution.

Left to Primary Care, COPD Guidelines Often Underutilized

BY SHARON WORCESTER
IMNG Medical News

ATLANTA – Regardless of disease severity, guideline-concordant treatment is not provided to nearly half of all patients who have stable chronic obstructive pulmonary disease and are treated in the ambulatory care setting, findings from an observational study suggest.

The study showed that guideline-concordant treatment was more likely to be provided when patients were managed by a pulmonologist and a primary care physician.

Of 450 patients, 56% received guideline-concordant care as outlined by the 2010 Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage-specific recommendations, Dr. Gulshan Sharma, FCCP, reported at the annual meeting of the ACCP.

No differences were found in treatment level with respect to age, gender, race, disease severity, or comorbidities on multivariate analysis, but patients co-managed by a primary care physician and a pulmonologist were more likely to receive an appropriate level of care, compared to patients treated by a primary care physician (odds ratio, 4.6), said Dr. Sharma of the University of Texas Medical Branch, Galveston.

Clinical practice guidelines for the treatment of patients with COPD in the ambulatory care setting are issued and updated regularly. Studies have demonstrated the value of these guidelines for improving the quality of care and for reducing exacerbations and hospitalizations.

However, the degree to which these guidelines are implemented in clinical practice has been unclear, Dr. Sharma said. The study findings suggest that they are underutilized, particularly by primary care physicians.

Study subjects were adults with a clinical diagnosis of COPD and at least one outpatient visit between January and December 2010. Mean age was 67 years, 46% were women, 20% had no comorbidities, and 75% had one or two comorbidities. About 7% had GOLD stage I disease, more than 46% had GOLD stage II disease, 33% had stage III disease, and 13% had stage IV disease.

Also, 47% were managed by a primary care physician alone, 41% were co-managed by a primary care physician and a pulmonologist, 10% did not have a primary care physician and received care mainly from a specialist, and about 2% had no regular care provider.

The findings indicate a need for increased awareness of clinical practice guidelines and the importance of adherence to the guidelines in patients with COPD, particularly among primary care physicians, said Dr. Sharma, who reported having no disclosures.
FDA Panel Gives Nod to Drug for Multidrug-resistant TB

BY ELIZABETH MECHATIE

IMAGING NEWS

SILVER SPRING, MD - Bedaquiline, an oral antitubercular drug with a novel mechanism of action, received an 18-0 vote for approval for the treatment of multidrug-resistant pulmonary tuberculosis by a Food and Drug Administration advisory panel.

At a Nov. 28 meeting, the FDA's Anti-Infective Drugs Advisory Committee concluded that phase II clinical data indicated the drug increased the time to sputum culture conversion, a surrogate marker for clinical effectiveness, when added to standard second- and third-line treatment in adults with multidrug-resistant (MDR) TB. Sputum culture conversion was defined as two consecutive negative cultures collected at least 25 days apart that were not followed by a positive test.

The panel voted 11-7 that the data provided substantial evidence that the drug was safe for this indication. There were 10 deaths among 79 patients on bedaquiline, compared with 2 deaths in 81 patients on placebo. The FDA reviewers and the drug's manufacturer could not identify any pattern or cause that could explain the imbalance in the death rate. All but one death in the bedaquiline-treated patients occurred after treatment was completed. The FDA was reviewing the drug as an accelerated approval, because bedaquiline addresses the unmet need for an effective therapy for MDR TB. In such cases, recommendation for approval can be based on surrogate clinical endpoints, with the requirement that clinical effectiveness be confirmed in a postmarketing study with hard clinical endpoints before full approval is granted. Panelists recommended that full approval require concrete evidence of increased cure rates with treatment in a confirmatory study.

Further, more data on the drug are needed in HIV-positive and black populations, and studies also are needed to address the implications of the drug's long half-life. Bedaquiline, a diarylquinoline discovered at Janssen Therapeutics, inhibits mycobacterial adenosine triphosphate (ATP) synthetase. The drug kills both replicating and nonreplicating TB bacilli, and is active against drug-sensitive and MDR TB, according to the company.

If approved, bedaquiline will be the first antituberculosis drug with a novel mechanism of action approved in the United States since rifampin was approved in 1970, and the first drug approved for TB since rifampetine was approved in 1998. In 2011, 98 cases of MDR TB were reported in the United States, but the condition is a far greater problem globally, with an estimated incidence in 2011 of 310,000 cases, according to the Centers for Disease Control and Prevention. The panel reviewed two phase II studies of almost 400 patients with MDR TB.

One study enrolled 160 nonwhite patients, most of them men from South Africa with a mean age of 35 years. All were newly diagnosed with pulmonary MDR TB, a small proportion were HIV positive. They were treated with a standard five-drug regimen that included ethionamide, pyrazinamide, ofloxacin, kanamycin, and 400 mg once daily of bedaquiline. Bedaquiline, 200 mg three times a week for 22 weeks, or placebo. After 24 weeks, patients continued background treatment for 12-18 months.

At 24 weeks, 79% of those treated with bedaquiline and background therapy achieved an effective response, compared with 58% of those on placebo, a significant difference.

The second study was an open-label trial of 233 previously treated patients with spum smear-positive pulmonary MDR TB. They received the same dosing regimen of bedaquiline combined with an individualized background regimen for MDR TB. At 24 weeks, the culture conversion rate was significantly higher in those who became negative in a mean of 57 days. The faster conversion rate likely reflected the fact that most patients were already on treatment when enrolled in the trial. The incidence of serious adverse events was higher in those on bedaquiline (6.9% vs. 1.9%). Treatment was associated with elevated transaminases in four cases, compared with zero in placebo patients. There was a modest increase in QT prolongation in patients receiving bedaquiline, but there were no cases of torsades de pointes or evidence that this caused any deaths.

The FDA's deadline for a decision on bedaquiline is the end of December. The agency usually follows the recommendations of its advisory panels. Panelists were cleared of potential conflicts.
Crizotinib Changes Advanced ALK-Positive NSCLC Tx

BY PATRICIA WENDLING
IMMG Medical News

VIENNA – Long-awaited data from the phase III PROFILE 1007 trial confirm that crizotinib provides superior progression-free survival and responses, compared with second-line chemotherapy in advanced anaplastic lymphoma kinase–positive non-small-cell lung cancer.

Median progression-free survival more than doubled from 3.0 months with single-agent chemotherapy to 7.7 months with crizotinib, according to an independent radiologic review (P value less than .0001; hazard ratio, 0.49).

Crizotinib (Xalkori) remained superior regardless of whether chemotherapy contained docetaxel (Taxotere) (7.7 vs. 2.6 months; P less than .0001) or pemetrexed (Alimta) (7.7 vs. 4.2; P = .0004), an agent previously shown to be effective against ALK-positive NSCLC.

The overall response rate was 65.3% for crizotinib and 19.9% for chemotherapy in the intent-to-treat population of 347 patients (overall response rate ratio 3.4; P less than .0001).

Crizotinib was also associated with significantly greater improvement in lung cancer symptoms and quality of life, Dr. Alice Shaw reported during a presidential symposium at the European Society for Medical Oncology Congress.

“This is a very clear and patient population who crossed over to crizotinib after progression, she noted. After adjustment for crossover, the hazard ratio suggests a survival advantage with crizotinib (HR, 0.83).

Discussant Dr. Jean-Charles Soria of Institut Gustave Roussy, Villejuif, France, agreed and said the survival times in either arm were impressive, observing that just 2 years ago survival in second-line ALK-positive NSCLC was just 9 months.

“This is really changing the natural history of the disease,” he said.

Crizotinib, an oral, first in class ALK inhibitor, was given accelerated approval in 2011 in the United States to treat advanced ALK-positive NSCLC but is not approved in Europe, where regulatory agencies have required data from the randomized trial.

“While the U.S. treats, Europe randomizes,” Dr. Soria lamented to a loud round of laughter.

He observed that worldwide use of crizotinib will require that several clinical and practical issues surrounding implementation of molecular testing in daily practice be addressed including the optimal technique, type of sample, and tissue availability. Testing for epidermal growth factor receptor, another molecular alteration that directs targeted therapy in lung cancer, “should not compete with ALK,” he said, adding that multiplexing test strategies “are key.”

Investigators at 105 sites across 21 countries in Europe, the Americas, and Asia-Pacific randomized 173 patients to crizotinib 250 mg twice daily in a 21-day cycle and 174 patients to chemotherapy containing pemetrexed 500 mg/m² or docetaxel 75 mg/m² given intravenously on day 1 of a 21-day cycle.

Treatment duration varied significantly, with patients receiving a median of 11 cycles of crizotinib vs. 4 cycles of chemotherapy. This may have influenced the higher number of all-cause deaths among crizotinib patients (23 deaths vs. 7 deaths), said Dr. Shaw, a thoracic oncologist at Massachusetts General Hospital Cancer Center in Boston.

Crizotinib patients were more likely than chemotherapy patients to experience the now well-known side effect of visual disturbances (any grade 60% vs. 9%), as well as diarrhea, nausea, elevated transaminases (16% grade 3/4), edema, upper respiratory infection, dysgeusia, and dizziness. In contrast, fatigue, alopecia, dyspnea, and rash were more common in those receiving chemotherapy.

Despite the fact that patients on crizotinib experienced more nausea and vomiting, antiemetic use was significantly higher in the chemotherapy arm (67% vs. 20%), observed Dr. Shaw, who said the majority of adverse events were grades 1/2, generally manageable and tolerable. This was reflected in patient-reported lung cancer symptoms and quality of life. Based on the EORTC Quality of Life Questionnaire (QLQ-C-30) and QLQ-LC 13, crizotinib patients had greater improvement from baseline in cough, dyspnea, fatigue, alopecia, insomnia, and pain as well as global quality of life (both P less than .0001).

“This is a compound with very mild toxicity,” commented Dr. Soria. He said clinicians need to be aware of crizotinib’s distinct side-effect profile, including other rare events such as renal cysts, pneumonitis, asymptomatic bradycardia, and low cell gonadotropin, “although we don’t really know if it impacts sexual life.”

The topic of hypogonadism was raised in a separate session on second-generation ALK inhibitors at the meeting and in a recent report of rapid-onset hypogonadism secondary to crizotinib use in 19 men with metastatic NSCLC (Cancer 2012 [doi:10.1002/cncr.27450]).

Dr. Shaw said in an interview that the study was small and “requires a lot more validation.” Although testosterone levels were not checked in PROFILE 1007, it is being done for the next generation of ALK inhibitors, she added.

Dr. Soria said resistance to crizotinib will become a problem with increasing worldwide use, and that strategies to counter this may include the second-generation ALK inhibitors, increased crizotinib dosing, and crizotinib plus ablative therapy given the poor penetration of crizotinib in the brain.

Brain metastases were present in 33% of patients in both arms. Three-fourths of patients were never smokers, roughly 95% had adenocarcinoma, and their median age was about 50 years.
FDA Panel Backs Avian Flu Vaccine

Adult H5N1 formulation moves a step closer to U.S. pandemic stockpile; pediatric studies continue.

BY ELIZABETH MECHCATIE

SILVER SPRING, MD. – A Food and Drug Administration advisory panel gave its unanimous support to an H5N1 influenza vaccine designated for a national stockpile, where it would be reserved for use during an avian influenza pandemic or outbreak.

The FDA’s Vaccines and Related Biological Products Advisory Committee voted 14-0 that the influenza A (H5N1) Virus Monovalent Vaccine should be approved based on the safety and immune responses to the vaccine in clinical studies.

GlaxoSmithKline contracted with the U.S. government to develop the vaccine, which contains an antigen-sparing adjuvant that boosts the immune response.

If licensed, it will be deposited in the U.S. Strategic National Stockpile and owned by the U.S. government, which would control the distribution and use of the vaccine in the case of a pandemic. GSK has no plans to market the vaccine.

The advisory committee agreed Nov. 14 that immunogenicity and safety data on the “Q-Pan H5N1” vaccine support licensure for use in adults at increased risk of exposure or during a pandemic.

The proposed indication is for the “active immunization for the prevention of disease in persons 18 years of age and older at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine.”

The vaccine is administered in two doses about 21 days apart. Mortality from the infection is highest among children and young adults. GSK is conducting studies in children aged 17 months and older, with plans to expand the approval.

The influenza A (H5N1) virus is highly pathogenic, contagious, and deadly among birds, particularly domestic poultry, but it is relatively rare in humans.

However, there are sporadic outbreaks in humans: since November 2003, there have been 608 confirmed cases in 15 countries – mostly in Asia – with a high (59%) mortality rate, according to the Centers for Disease Control and Prevention.

The vaccine was studied in two pivotal studies of 5,241 patients, including 3,574 who received the Q-Pan H5N1. In a phase III study comparing the vaccine with a saline placebo, seroconversion rates 42 days after the second dose were 90% among those aged 18-64 years and 74% of those over age 64 years. This exceeded FDA criteria for immunogenicity for a vaccine. Injection site reactions were the most common adverse reactions.

The vaccine is being considered for an accelerated approval, with the immune responses to the vaccine being considered a surrogate for clinical effectiveness.

Moreover, the vaccine is manufactured using the same process as GSK’s seasonal influenza vaccine, FluLaval.

Full approval is dependent on post-approval studies confirming clinical benefit.

The Q-Pan H5N1 vaccine has been licensed in 30 countries, including in Europe and Australia, and is under review in Canada.

The FDA usually follows the recommendations of its advisory panels, which are not binding.

Panelists have been cleared of potential conflicts of interest related to the topic of the meeting, although a panelist may be given a waiver.

No waivers for conflict of interest were granted at this meeting.

Important Safety Information

Spiriva® HandiHaler® (tiotropium bromide inhalation powder) is contraindicated in patients with a history of hypersensitivity to tiotropium, atropinium (atropine derivatives), or any components of SPIRIVA capsules.

SPIRIVA HandiHaler is not indicated for the initial treatment of acute episodes of bronchospasm, i.e., rescue therapy.

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

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

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

SPIRIVA may interact additively with concomitantly used anticholinergic-containing drugs.

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Please see accompanying Brief Summary of full Prescribing Information.

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Acute Dyspnea: Try Physiologic Approach

BY SHEMY BOSCHERT
IMNG Medical News

DENVER—If you presume that a patient coming to the emergency department with acute dyspnea primarily has a pulmonary cause, you’ll almost always be right. Those few other cases, though, take a bit of detective work. In Denver, approximately 9% of cases in which dyspnea is not easily referable to the lungs, the culprit may be a cardiac problem (usually in a very young child) or, rarely, other problems — hemoglobinopathies, diseases that cause metabolic acidosis, or neurologic disorders, Dr. Jeffrey Sankoff said at a meeting of the American College of Emergency Physicians.

Take a physiologic approach that can guide you through the diagnostic process, he suggested. “A physician who is well trained in critical care, everything boils down to physiology,” said Dr. Sankoff of the University of Colorado, Denver, and director of quality and patient safety at Denver Health Medical Center.

Take of thing that diseases of cause hypoxemia (V/Q mismatch) as the most common cause of hypoxemia, and occur in which blood flows in the lungs but areas are not getting oxygen. Diffusion abnormalities, in which oxygen gets into alveoli but oxygen transit to the bloodstream is impaired, also cause hypoxemia. These occur in primary pulmonary disease.

Acute respiratory disease processes create four causes of hypoxemia: a shunt, low mixed venous oxygen saturation (MVO2), decreased fraction of inspired oxygen (FiO2), and alveolar hypventilation. A V/Q mismatch is at the most extreme of a shunt, in which blood bypasses the lungs altogether, he said. Disease processes that cause blood to go directly from the right to the left side of circulation result in hypoxemia. A shunt is almost always intracardiac, rarely intrapulmonary.

In children, shunts are seen at characteristic times for the development of cyanotic congenital heart disease, most commonly patent ductus arteriosus in an infant. Look for a shunt by its hallmark — oxygen saturation will not improve when

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Early End-of-Life Discussions Cut Aggressive Care

BY SHERRY BOSCHERT
IMAGING Medical News

Patients with stage IV lung cancer who had end-of-life discussions with caregivers before the last 30 days of life were less likely to receive aggressive care in their final days and more likely to get hospice care and to enter hospice earlier, a study of 1,231 patients found.

Nearly half received aggressive care in their last 30 days (47%), including chemotherapy in the last 14 days (16%), ICU care in the last 30 days (6%), and/or acute hospital-based care in the last 30 days of life (40%), Dr. Jennifer W. Mack and her associates reported.

Guidelines advise starting end-of-life care planning for patients with incurable cancer early in the course of the disease while patients are relatively stable, not when they are acutely deteriorating.

Many physicians in the study postponed the discussion until the final month of life, and many patients didn’t remember or didn’t recognize the end-of-life discussions. Discussions that were documented in charts were not associated with less aggressive care or greater hospice use, if patients or their surrogates said no end-of-life discussions took place.

In the study, 88% of patients who had end-of-life discussions reported that they’d had an end-of-life discussion until the final month of life, and many patients didn’t remember or didn’t recognize the end-of-life discussions. Discussions that were documented in charts were not associated with less aggressive care or greater hospice use, if patients or their surrogates said no end-of-life discussions took place.

The study was published in the Journal of Clinical Oncology (DOI: 10.1200/JCO.2012.43.6055).

Chemotherapy in the last 2 weeks of life was 59% less likely, acute care in the last 30 days was 57% less likely, and ICU care in the last 30 days was 23% less likely when patients or their surrogates reported having end-of-life discussions.

Major Finding: Chemotherapy in the last 2 weeks of life was 59% less likely, acute care in the last 30 days was 57% less likely, and ICU care in the last 30 days was 23% less likely when patients or their surrogates reported having end-of-life discussions.

Data Source: This was a longitudinal study of 1,231 patients with stage IV lung or colorectal cancer at HMOs or Veterans Affairs sites in five states.

Disclosures: Dr. Mack and her associates reported having no financial disclosures.

VITALS

When Patients or Surrogates Had End-of-Life Discussions ...

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<th>Chemotherapy in the last 2 weeks was</th>
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<td>59% less likely</td>
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53% of discussions occurred in the patient setting.

Note: Based on a study of 1,231 patients. Source: J. Clin. Oncol. 2012 (DOI: 10.1200/JCO.2012.43.6055)

Continued from previous page

Sionally a hereditary hemoglobinopathy such as thalassemia or sickle cell disease. To diagnose these, have a high index of suspicion. You’ll see no patient improvement on oxygen therapy, and some diseases create a characteristic appearance of the blood.

Alveolar hypoventilation may be the most insidious cause of hypoxemia, and dyspnea and may be a flag for impending respiratory compromise if there is peripheral weakness. The most common acquired condition is Guillain-Barré syndrome, amyotrophic lateral sclerosis, and Colorado tick paralysis. Make the diagnosis in context with other findings, he said. Expect an abnormal motor exam. Check the negative inspiratory force; if it isn’t at least 20 cm H2O it’s abnormal and the patient likely will need respiratory support.

Hypercapnia

Diseases that cause hypercapnia can cause dyspnea. Three things cause carbon dioxide levels in the blood to rise: increased metabolic rate (more likely in the ICU than in the emergency department), decreased minute ventilation, and increased pulmonary dead space. All can be diagnosed by checking arterial blood gases.

Metabolic Acidosis

Acidosis, usually due to high levels of lactate, stimulates respiratory drive to try to balance pH. Sepsis is the most important cause of acidosis. When sepsis is developing, dyspnea frequently is a subtle sign. Have a high index of suspicion for sepsis, and be wary of a normal oxygen saturation level in a patient with dyspnea, he said. Other causes of metabolic acidosis that lead to dyspnea include diabetic or alcoholic ketoacidosis.

Putting this physiologic approach to dyspnea into context, consider three scenarios, Dr. Sankoff suggested. A patient with dyspnea who responds to oxygen therapy and has an abnormal chest x-ray has a primary pulmonary problem. A patient who responds to oxygen but has a normal chest x-ray may have sepsis, another cause of acidosis, or alveolar hypoventilation; their response to oxygen may be transient. They will respond to oxygen but continue to be tachypneic. The third scenario – normal x-ray, but the patient does not respond to oxygen therapy – raises a broad differential diagnosis including sepsis, other causes of acidosis, hypercapnia, cardiac causes, and hemo-globinopathies. Narrow the differential by recalling the history and physical findings and getting arterial blood and gas tests.

Dr. Sankoff reported having no relevant financial disclosures.

It’s a compassionate instinct,” she said. “Being in the room with a family when I deliver this kind of news, that emotional impact is right in front of me. I believe there are bigger consequences” from not discussing end-of-life care, such as perpetuating false hopes and asking people to make decisions about what’s ahead without a clear picture of the situation, she added.

The conversation should take place more than once because patient preferences may change over time and patients need time to process the information and their thoughts about it, Dr. Mack said.

Further work is needed on why some documented end-of-life discussions were not reported by patients/surrogates.

“Every physician can relate to this – that sometimes when conversations but they’re not heard or understood by pa-

Note that palliative chemotherapy or radiation will cure their disease.

Some previous studies suggest that patients dying of cancer increasingly are receiving aggressive care at the end of life and that this trend may be modifiable.

Other studies have reported an association between having end-of-life discussions and reduced intensity in care. The current study was longitudinal and is one of the first to look at the effects of the timing of these discussions.

Most patients who realize that they are dying do not want aggressive care. Also, studies report that less aggressive end-of-life care is easier on family members and less expensive.

Dr. Mack and her associates reported having no financial disclosures.
IMPLEMENTING HEALTH REFORM
Cutting Red Tape

While critics charge that the Affordable Care Act makes health care more complex, at least one provision has the opposite aim: Section 1104 of the ACA directs the Health and Human Services department to standardize many elements of electronic interactions between doctors and health plans.

In July 2011, HHS issued the first in a series of regulations aimed at administrative simplification, adopting operating rules to make it easier for physicians to determine a patient's eligibility for coverage and to obtain the status of a submitted claim. The HHS also has issued rules for electronic funds transfers and remittance advances between health plans and physicians, and established a standard for a national unique health plan identifier. Regulations to outline standards and operating rules for electronic claims attachments are planned.

Robert M. Tennant, senior policy adviser at the MGMA-ACMPE, formerly known as the Medical Group Management Association, offered his thoughts on whether these regulations will reduce practices' administrative burden.

CHEST PHYSICIAN: Section 1104 of the ACA contains many provisions that physician groups have been advocating for years. Does the law offer a good chance for relieving the paperwork burden on physician practices?

Mr. Tennant: Yes, it does. It has a number of provisions that we long called for. After the passage of HIPAA, we found that the implementation of the electronic transaction standards required under the law did not achieve the level of simplification that we had hoped for.

So back in 2005, an industry group came together to create what are called operating rules. One of the first transactions they tackled was eligibility. The operating rules were set up so that if a health plan agreed to participate, it would have to provide information to practices on patient financials, copays, and deductibles, and they would have to get back to the practice within 20 seconds. But since the operating rules were voluntary, not all the health plans adopted them and not all the vendors saw the value in supporting them.

The ACA has made those operating rules mandatory. That is a huge change. To have the kind of real-world capabilities that the operating rules bring, such as identifying immediately the patient financial responsibility, will be extremely beneficial.

CHEST: Will practices see efficiency as a result?

Mr. Tennant: There's no question. Just that one simple operating rule for eligibility means that, in 20 seconds, you can get an answer from the health plan. That alone is going to really improve patient intake and speed up the claim adjudication process.

CHEST: When will these changes begin to affect physicians?

Mr. Tennant: Jan. 1, 2013. Health plans must be compliant with operating rules for eligibility verification and checking the status of previously submitted claims on that date. But the linchpin here is the vendor. There's a lot going on in health care. There's meaningful use EHR (electronic health records) and e-prescribing incentive programs, not to mention the huge challenge that adoption of ICD-10 will bring, and all of these require practices to upgrade or replace vendor software.

With all of these mandates and opportunities, this is probably a good opportunity for the practice to take a step back and look at what they have currently in the way of technology. What transactions are you conducting in-house? What are you outsourcing? What are the costs for that? What are your manual processes? Take stock of how you are managing the claims revenue cycle. Then ask yourself, is this a good time for the practice to move ahead with a more automated approach?

CHEST: Many of the Section 1104 requirements apply to health plans. Will the plans do most of the work or do physicians need to make changes, too?

Mr. Tennant: Health plans and clearinghouses have to be able to accept and generate these transactions and support the new operating rules. And providers must use the standards if they conduct those transactions. But the government is not requiring practices to accept an EFT [electronic funds transfer] payment, for example. On the other hand, there is no prohibition against a health plan, such as what Medicare does now, saying that they will only issue EFTs. That's a business decision that the health plan may make. It's something that practices should be asking their health plans about.

CHEST: Do physicians need to buy new systems to take advantage of the operating rule requirements?

Mr. Tennant: In the past, providers may have asked themselves, 'Do I want to spend a lot of money and buy a practice management system that has all the bells and whistles only to find out that not all the health plans are supporting these automated transactions?' The answer to that question was probably no.

But, with the ACA, it solves that problem to a certain extent. Now health plans are required by law to offer, in a more standardized format, all of these electronic transactions and operating rules. It's not voluntary anymore. That should be a signal to the vendor community that they now can start to build these supporting software products, with practices now able to take better advantage of these standards and operating rules. But if the practice doesn't have the capability in the office to handle these transactions electronically, then they're not going to see an advantage from the regulations.

The challenge is going to be to determine if your current vendor, or the vendor that you're exploring, has the capability of accepting an EFT transaction, for example.

Mr. Tennant works on federal legislative and regulatory health information technology issues at the MGMA-ACMPE. He is also a member of the Board of Directors of the Workgroup for Electronic Data Interchange.

Dr. Stuart M. Garay, FCCP, comments: The Affordable Care Act section 1104 may help lessen some administrative burden by simplifying the ability to identify patient eligibility for coverage, obtain the status of a claim, and facilitate transfer of electronic funds. A key element is to ensure your practice management software has the capability to ‘play the game’ – specifically with respect to electronic funds transfer.
ONLY inhaled prostacyclin analogue approved as an add-on to oral PAH monotherapy

- 52% of patients improved 6MWD by greater than 20 m³
- Improvement in 6MWD at peak (20 m) and trough (14 m) exposure

Dosing regimen fits into patients’ schedules

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

INDICATION

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

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

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

IMPORTANT SAFETY INFORMATION

Tyvaso is intended for oral inhalation only. Tyvaso is approved for use only with the Tyvaso Inhalation System.

The safety and efficacy of Tyvaso have not been established in patients with significant underlying lung disease (such as asthma or chronic obstructive pulmonary disease) and in patients under 18 years of age. Patients with acute pulmonary infections should be carefully monitored to detect any worsening of lung disease and loss of drug effect.

Tyvaso may increase the risk of bleeding, particularly in patients receiving anticoagulants.

In patients with low systemic arterial pressure, Tyvaso may cause symptomatic hypotension. The concomitant use of Tyvaso with diuretics, antihypertensives, or other vasodilators may increase the risk of symptomatic hypotension.

Hepatic or renal insufficiency may increase exposure to Tyvaso and decrease tolerability. Tyvaso dosage adjustments may be necessary if inhibitors of CYP2C8 such as gemfibrozil or inducers such as rifampin are added or withdrawn.

Adverse events

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

STUDY DESIGN: TRUMPH I was a 12-week, randomized, double-blind, placebo-controlled, multicenter study of patients (N=235) with PAH who were receiving a stable dose of bosentan or sildenafil for 3 months before study initiation. Patients were administered either placebo or Tyvaso in 4 daily treatment sessions with a target dose of 9 breaths (0.4 mg) per session over the course of the 12-week study. Primary endpoint was change in 6MWD at 12 weeks. Secondary endpoints included time to clinical worsening, Borg dyspnea score, NYHA functional class, trough 6MWD at week 12 (obtained at least 4 hours after study drug administration), peak 6MWD at 6 weeks, quality of life as measured by the MLWHF questionnaire, and PAH signs and symptoms.

Many adverse events were transient, but some were dose related during the study. The most common adverse events seen with Tyvaso in ≥4% of patients and more than 3% greater than placebo in the placebo-controlled clinical study were cough (54% vs 29%), headache (41% vs 23%), throat irritation/pharyngolaryngeal pain (25% vs 14%), nausea (19% vs 11%), flushing (15% vs <1%), and syncope (6% vs <1%).

Tyvaso should be used in pregnancy only if clearly needed. Caution should be exercised when Tyvaso is administered to nursing women.

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


PRACTICE TRENDS

Physicians’ Secret Struggles

Eating Disorders • from page 1

by them. But those hard-driving traits and the uniquely stressful professional demands inherent in medical training and beyond may unmask disordered eating or sharply accelerate patterns that began in adolescence.

“Whoohoo,” said Dr. Gaudiani. “It’s a bonfire. Symptom complexity issues are the issue and adds fuel to the disorder. “Doctors can be an unusually unsympathetic group when it comes to colleagues’ illnesses of any kind,” she noted. Underpaid, overworked residents are virtual poster children for compassion fatigue, notoriously tough on “colleagues not able to pull their weight.”

So most physicians hide the disorder, said Dr. Gaudiani, past president of the International Association of Eating Disorders Professionals. In lecturing to medical school classes about the risk for eating disorders, she said, “It’s not unusual to see people tearing up, and two or three people will come up afterward to find out where they can get help. It takes so much energy to keep the secret. Some plaintively, but anonymously, appeal for advice on such websites as Student Doctor Network. I have binge eating disorder and was in medical school for a year and a half. I’ve been in recovery for a while, but sometimes I have setbacks and become a whole different person... I just want to know if there’s the experience of dealing with an eating disorder (the depression, lack of concentration, and nervousness that are symptoms), and the stress, lack of sleep, and amount of work that involves medical school.

Responses to that posting ranged from notes of encouragement to ad-

Dr. Vera De Palo, FCCP, comments: The demands and stress of the profession of medicine and those of the process of obtaining necessary training are significant. Individual responses to those demands and stresses vary from subtle to overt, and can have life-altering consequences. As physicians, we have learned to focus on the patients. It is often our own health and medical or psychiatric problems that we overlook, so we don’t readily realize when we have become the patient. We must focus our keen observation skills inwardly to guide our search for appropriate treatment of our own problems and look to our families, physician colleagues and friends to help us to recognize those issues.
struggling with eating disorders, said Dr. Berkus. "The message that 'you don't belong,' can be a universal message that they've carried for a long time."

Further, some don’t see eating disorders as an issue. On the website, some medical students questioned the judgment of program coordinators who insisted the poster get help before continuing her studies.

Said one: Exactly what danger is this person in risk of? Passing out while rounding? Erosive esophagitis? Neither of these truly present a risk to the patient. "Danger to others" implies explicit threats, or impaired behavior, e.g., substance abuse. Certainly she is placing her own body at risk, but what about those who overeat and place themselves at risk?

"Denial is part and parcel of the eating disorder mentality, but in doctors, it runs a little deeper. Medical training reinforces that mind-set of 'I have it under control to the nth degree.' On the other hand, medical professionals, like other eating disorders patients, 'absolutely can recover.' said Dr. Bermudez.

Eating disorders are treatable illnesses, much like depression. The propensity remains with an individual—(he or she maintains) the vulnerability factors, but those can go back to being under check."

Anecdotally, he's seen it happen, as have the other experts interviewed for this story. But data chronicling the prevalence, severity and prognosis of eating disorders in the medical profession are scarce.


However, the study preceded publication of the DSM-IV, and subsequent studies have found that anorexia nervosa, in particular, is diagnosed more often under DSM-IV criteria.

Research at Northwestern University in Downers Grove, Ill., has found a prevalence of significant eating disorders and behaviors of 13% in 700 male and female graduate health care professionals, including medical students. A rate similar to that seen in the general population, according to Midwestern behavioral medicine professor Ann Sauer, Ph.D.

Until more is published, the issue of eating disorders in physicians will continue to be characterized by glimpses of the toll taken on affected individuals.

An acute, intensive medical stabilization unit for patients with severe eating disorders is expanding, based on high demand, according to Dr. Jennifer L. Gaudium, assistant medical director for the ACUTE Center for Eating Disorders at Denver Health.

Beginning in the fall of 2008, a five-patient inpatient unit opened at Denver Health to serve eating disorders patients who delayed getting treatment until their conditions had become destabilized to the point that, "to their astonishment, they were too sick to be served," even at dedicated inpatient eating disorders units within psychiatric facilities, she said.

The Acute Comprehensive Urgent Treatment of Eating Disorders (ACUTE) Center accepts only patients whose weight has fallen below 70% of ideal body weight.

The first 200 or so patients served by the center ranged in age from 17 to 65 years (mean, 27 years), and averaged a body mass index of 12.5 upon admission. The average length of stay was 2 weeks.

A report on outcomes published this year in the International Journal of Eating Disorders found that in the unit, 44% of patients had hypoglycemia, 76%, abnormal liver function, and 83%, abnormal bone density, and 45% developed refeeding hypophosphatemia. While on the unit, 92% had hyperthermia (Int. J. Eat. Disord. 2012;45:85-92).

Once patients are stabilized at the ACUTE unit, they are transferred to inpatient residential eating disorders programs, and often fare well, she added in an interview. Dr. Ovidio Bermudez, chief medical officer of the Eating Recovery Center in Denver, said the need for the unit (which collaborates with his center for psychiatric care) demonstrates the need for better education and training in eating disorders among medical professionals.

"Early recognition and timely intervention is the utmost importance," he said.

Physicians need to be alert for subtle symptoms in patients who may try to hide symptoms of the disease. "It's a clear area where we've got to chisel away at the disorder," said Dr. Bermudez. "Loved ones quite often express the concern that they consulted with a physician who falsely reassured them about the seriousness of a patient's condition. In defense of physicians, this is not a population that wants to be discovered."

On the other hand, certain medical conditions such as electrolyte imbalances or cardiac abnormalities, particularly in adolescents or young adults, should "make the light go off, so they say, 'Ahah!' " he said.

A number of resources exist to educate physicians about promptly diagnosing eating disorders, including a video CME course offered by the American Medical Association and a 18-page downloadable pamphlet for professionals designed by the Academy for Eating Disorders.

Additionally, awareness comes through "ruminating about these patients for awhile" so that the patterns and behaviors intrinsic to the disorder become obvious, said Dr. Bermudez.

If physicians, medical students, and residents begin to recognize eating disorders in patients, they may also begin to see its signs and symptoms among themselves and their peers, he added.

Dr. Linda M. Worley teaches a course for distressed physicians without current substance abuse problems at Vanderbilt University in Nashville, Tenn. Many take the course as a condition of their continued employment. After screenings and interviews to assess their mental health needs, the participants engage in an initial 3-day session at Vanderbilt and have three subsequent 1-day sessions over the ensuing 6 months.

"It's a transformative learning experience. This is an opportunity to critically reflect on their life events, and that helps them to change their beliefs and their behaviors," Dr. Worley said. The techniques employed include intellectual dialectics, peer group exercises, emotional awareness training, and helping participants identify triggers of their inappropriate behaviors.

The growing recognition of the impact of physician burnout also has prompted the growth of wellness programs for physicians in training, noted Dr. Mai-Lan Rogoff, associate dean of student affairs at the University of Massachusetts in Worcester.

In addition to providing counseling and therapy services, the wellness program at the University of Massachusetts focuses on providing medical students with an increased sense of institutional support and peer support through group and team activities and exercises.

Burnout is a combination of emotional exhaustion (feelings of being emotionally overloaded and exhaused by your work), depersonalization (feelings of being a cog in a machine, having an unfeeling response toward those who receive your services), and having a low sense of personal accomplishment.

Burnout is associated with a variety of negative outcomes, Dr. Rogoff noted, including loss of empathy, substance abuse, and suicidal ideation.

"On a personal level, you've got perfectionism, low resilience, negative focus, and all those issues, one of the risk factors for burnout is unclear or impossible requirements or excessive workloads," she added.

Medical students also acutely feel a lack of time and a lack of control over their own circumstances, and that they face major consequences from mistakes and often have to deal with angry, upset, or ungrateful patients.

Although there are no objective data showing that such wellness programs work, "there's absolutely no question that students like these programs," she said.

Dr. Myers, Dr. Worley, and Dr. Rogoff all reported having no relevant conflicts of interest.
A t the culmination of my year of presidency, I look back and reflect on the diverse and important projects with long-term ramifications that were achieved. I realize very quickly that this impressive list, mirroring the successes of the College, reflects the stewardship, dedication, and vision and focus of the leadership, membership, and staff of the College. The executive and governing bodies of the College, the committees, and NetWorks should rightfully feel proud of their expansive accomplishments. All have strategically steered the College in a direction that will fulfill the changing needs of its membership, keeping the society relevant for and engaged with its multi-disciplinary colleagues. They have made the College even more effective as an organization that delivers the best, clinically relevant chest education globally.

Our accomplishments this past year reflect the vision, dedication, selfless hard work, and exceptional talent of ACCP members and staff. Many of these accomplishments represent work that was conceived in the preceding years and came to fruition this year, while others were initiated this year and will continue in the ensuing years.

Annual CHEST Meeting

This is the showcase of the College that brings together a large number of people from all over the world. A bit of a historical perspective...The first annual meeting of the Federation of American Sanatoria, a precursor of the American Sanatoria, a medical meeting of the Federation of American Sanatoria, was held in 1935. There were 39 registrants who paid $5 membership dues to participate. The meeting was revered and excellent for its time. This year, the College was honored to host more than 5,000 attendees from over 60 countries, bringing an exceptional program of advanced clinical education. The annual meeting provided opportunities to share ideas with colleagues, mentor future leaders, identify research opportunities, and position attendees to navigate the changing health-care landscape. All new daily opening sessions featured internationally renowned speakers presenting on leadership, diversity, and innovations in health care.

Other opportunities included:

- A radiology self-study journal and new Radiology Cases iPad app with radiographic and pathology images
- 3-hour learning opportunities in the ACCP Simulation Center
- Incentives Sporometer, a fun but serious game
- A NetWorks Open House

The scientific program committee, under the guidance of Dr. Doreen Adz rico-Harris, promoted simulation-based education and problem-based self-directed learning.

Leadership Development

"He who influences the thoughts of his time, influences all the times that follow." -Thomas Kempis

As a College, we should strive to be agents of change, inspiring and mentoring others and leading our organization in a strategic direction. An energized task force, under the direction of Dr. Lisa Moores, defined leadership skills and implemented them.

Projects included:

- A standardized standing committee orientation procedure
- Leadership development session at the annual meeting
- Leadership training for existing ACCP leaders
- Leadership course for junior faculty at CHEST 2012
- Leadership development webpage

Let me elaborate on the webpage. I urge you to read the compilation of leadership stories. They exemplify the qualities that make ACCP mentors so inspirational and inspiring.

Expanded Global Outreach

The ACCP has been called "a college without walls." Almost 20% of members, 30% of CHEST attendees, 40% of the CHEST abstracts, and 50% of CHEST journal articles originate from outside North America.

This year, the ACCP hosted several new international education courses, including the first joint ACCP-Israel Society of Pulmonology course, courses at the International Medical Center, Jerusalem, and in Riyadh, Saudi Arabia, and we held the first annual India CHEST Challenge Game. We also strengthened our collaboration with the Chinese Thoracic Society. Another exciting development is CHEST World Congress that is scheduled to be held in Madrid in 2014.

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While the goal of this document was to provide recommendations that are well-supported by evidence in the literature, the panel also provided some suggestions that were felt to be important but lacked adequate evidence in published literature. These recommendations were based on good clinical practice and generally could not be tested in a prospective, randomized clinical trial. For example, there was no evidence that CBCs should be monitored while patients were receiving cytotoxic chemotherapy, but bone marrow toxicity was well described, and a potentially catastrophic side effect of such therapy.

Therefore, a section that provides recommendations for the clinician is available for each drug. The authors of this guideline state that this section could be the first source for pulmonologists and other caregivers to conveniently search for basic information concerning a specific agent. Clinicians can look elsewhere in the document for more specific information that they may require.

Another feature of the guideline is that it provides information for patients regarding each drug. This information will be provided in the CHEST Foundation’s patient website for easy access by patients who wish information on potential side effects, recommendations for the safe use of the medications; and recommendations for monitoring. This information page can be printed, and caregivers can provide it to patients to enhance their awareness of potential problems and specific symptoms and signs they should watch for when taking these immunosuppressive drugs.

Direct additional questions to Joseph Orenelas, MS, PA-C, ACCP Clinical Standards Specialist, at jorenelas@chestnet.org.
ACCP Breaks Ground on New Headquarters Building

By Barbara Storms Granner

Editorial Specialist, The CHEST Foundation

As a cold breeze whipped across the prairie, ACCP staff members, leadership, and partners were warmed by a glimpse of the future of chest medicine during groundbreaking ceremonies for ACCP’s new headquarters in Glenview, Illinois.

“The ACCP is poised to dramatically advance lung and heart health around the world through the delivery of preeminent medical education for our physicians of today and tomorrow,” said Paul A. Markowski, CAE, ACCP Executive Vice President and CEO. “Today’s groundbreaking is the first step in expanding our role as a leader in chest medicine.”

The new building will include a state-of-the-art training center, enabling the College to expand its role as a global education resource and network for its 18,500 members. “Our headquarters campus will become a center for cutting-edge education, a catalyst for new ideas, and an active partner in disseminating and implementing new clinical practices,” said Dr. Darcy Marciniuk, FCCP, ACCP President.

Plans for the innovation and training center include an auditorium to support group meetings and didactic learning, eight breakout rooms for smaller training sessions, six simulation training rooms, wet and dry labs, and a new technological infrastructure to facilitate virtual learning.

The new building is designed to be Silver LEED-certified, reflecting the College’s commitment to environmental sustainability and to promoting healthier lungs through cleaner air. LEED (Leadership in Energy and Environmental Design) is an internationally recognized program that provides builders with a framework for implementing green design, construction, operations, and maintenance. LEED-certified buildings are designed to lower operating costs and increase asset value; conserve energy and water; be healthier and safer for occupants; reduce harmful greenhouse gas emissions; and qualify for tax rebates and zoning allowances.

Go to chestnet.org to view an animated tour of the building and watch real-time construction progress through a Web cam. For information on donating to the “Beyond Our Walls: Advancing the Future of Chest Medicine” building campaign, contact Marilyn Lederer, CHEST Foundation Executive Director, at mlederer@chestnet.org.

Continued from previous page

Society of Pulmonology and Thoracic Surgery.

New ACCP Headquarters Building

The ACCP purchased property for a new ACCP HQ building, completed a building design, secured financing, and will begin a three-phased Capital Campaign. The target completion date, October 2013, is just in time for CHEST 2013 in Chicago!

New Educational Offerings

The repertoire of educational offerings has truly diversified. Highlights include:

▶ three new evidence-based guidelines, including venous thromboembolism and NSCLC collaborative projects;
▶ a 6-year reaccreditation from ACCME with Commendation;
▶ over 6,000 CME claims made, exceeding the previous year’s target by over 2,000; and
▶ 30 participants completing the ACCP Certificate of Completion Course in Critical Care Ultrasound.

New Technology Platforms

The ACCP is overhauling its IT infrastructure to better serve its members. A significant milestone this year was the launch of ACCP’s e-community, which has enabled closed discussions, information exchange, resource sharing, and professional networking among ACCP members. All NetWorkS of the College are now live in the e-community, and the Diversity Group and other groups are being added.

Several innovative platforms have recently been launched, including a new CHEST Publications site, a financial management system, and a learning management system.

A new chestnet.org site is scheduled to launch in 2013, and several new ACCP apps have been developed.

Health-care Reform

After hearing the issues of our members, the ACCP published a series of seven articles in CHEST Physician to address member concerns ranging from legislative and regulatory changes to surviving private practice and the top 10 things a practitioner should do to prepare. Moving forward, our involved standing committees will monitor and proactively provide our members with relevant and focused information that will equip them to accept the inevitable, conform to the unavoidable, and, thus, be better prepared to deliver evidence-based, quality-driven health care.

Pulmonary Diseases Worldwide

The ACCP was part of a global effort to brand pulmonary diseases, working with FIRS to increase public awareness of lung diseases across five continents. World Spirometry Day was shining proof of this successful endeavor. We stand 150,000 members strong in the area of critical care through the Critical Care Societies Collaborative. As a public-education campaign, the OneBreath® website was redesigned, incorporating Facebook and Twitter.

We restructured to improve our governance and aligned strategic goals of the staff with the six ACCP strategic goals for better internal support. We began an initiative, commencing in New York, I am proud to report, of holding regional Board of Regents meetings in conjunction with outreach events, to percolate to the grassroots level. We exceeded all budget targets. Our membership grew to 18,522. We are strong indeed.

A word about my Presidency—Thank you for vesting confidence in me and allowing me to serve as the 7th president of ACCP. It was an incredible experience, which I will cherish throughout my life. It has bestowed upon me a unique perspective—one that has broadened my horizon, deepened my respect for global cultures and innovations, and refined my leadership skills. It was the best of times, it was the most demanding of times. It was a year that I would not trade for anything.

I know the College is in great hands. Drs. Darcy Marciniuk, Michael Baumann, and Curtis Sessler will each take the College to greater heights with their resplendent leadership skills and exceptional vision. I can hardly wait to see where the College will be in the next 5 years.

PULMONARY • CRITICAL CARE • SLEEP

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Recognized around the world as the authority in clinical chest medicine, CHEST 2013 will feature a learning program in pulmonary, critical care, and sleep medicine. The rich curriculum will include a robust range of topics relevant to chest medicine, so you will easily find sessions to match your clinical interests and needs.

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Critical Care Commentary

“Each man is master of his own death, and all that we can do when the time comes is to help him die without fear of pain.”

Gabriel Garcia Marquez – Love in the Time of Cholera

Pain recognition and control remain two of the most elusive aspects of treatment in critically ill patients. Pain is a part of virtually every patient’s critical care experience. It may be a consequence of surgery or procedures, conditions for which the patient is being acutely assessed and treated, chronic medical conditions, invasive devices, and/or routine nursing care. The fundamental conditions for which patients are being treated in the ICU or the treatments rendered to correct them can significantly reduce a patient’s ability to communicate his or her pain. Further, there is considerable variability among providers in how effectively they perceive and treat such pain. The combination of these challenging factors results in a tendency for pain to be underrecognized and consistently undertreated in critical care settings (Broekmans et al. Int J Nurs Stud. 2004;41(2):183; Leong et al. J Canec Educ. 2010; 25(2):224).

Reliable and reproducible pain assessment tools are essential factors in recognizing and treating pain in the critically ill. To date, the most reliable tool in assessing pain has been the patient’s own commentary about the location, nature, and degree of his or her pain.

In critical care settings, however, where sedation, mechanical ventilation, and hemodynamic instability are common, patients are, more often than not, unable to indicate their level of pain or whether it exists at all. The most frequently used tools for assessing pain in nonverbal critical patients are the Critical Care Pain Observation Tool (CPOT) and the Behavioral Pain Scale (BPS). Both rely on nonverbal cues, such as grimacing, elevated heart rate, and ventilator dysynchrony, to determine the presence and severity of pain (Puntillo et al. Chest. 2009;135(4):1069).

Such tools are fundamentally inadequate, however. They are unable to distinguish pain from confounding factors, such as anxiety, delirium, sleep deprivation, and inadequate sedation. Further, provider variability in interpretation of these nebulous factors makes their recognition sporadic and inconsistent. Finally, neither CPOT nor BPS has been validated in assessing responsiveness to analgesic treatment.

What, then, is the future of pain recognition and treatment among the critically ill? Several areas of potential investigation bear mention. Among these is the exploration of how providers’ personal characteristics may bias their interpretation and treatment of pain in such patients. Very little information on how such factors may impact recognition and prompt treatment of critically ill patients’ pain has been assessed or established. However, there are clues that such factors may be important. The question remains – what effect do factors such as culture and ethnicity among providers have on perceptions and treatment of pain?

Limited literature in this area suggests that culture and ethnicity may have an impact on pain recognition and treatment. These factors have been studied, to some extent, among patient populations, but they have not been investigated to any great extent among providers.

For example, languages in East Asia and parts of the Middle East typically have very few words or expressions that indicate or distinguish different types of pain. In contrast, English and various dialects of Indian languages contain literally dozens of words and expressions devoted to variations in the meaning of the word (Bagchi. Acta Neurol. 1987,38:S182). Both patients and providers alike are susceptible to trends that are consistent with his or her language and further, within their culture. Preliminary studies at our own institution suggest that health-care providers’ culture and ethnicity may be important predictors of trends in pain recognition and treatment. In fact, when multiple providers’ personal comments are assessed, it becomes apparent that cultural acceptance of pain is related to patient population demographics and the cultural bias that providers have on pain recognition and treatment.

Cultural Bias as a Barrier to Recognition of Pain

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Until recently, we have been stalled in the fight against lung cancer. Early detection and screening programs have largely failed, with 75% of patients still identified in late, incurable stages. A dismal 5% 5-year survival is the result (Goldstraw et al. J Thorac Oncol. 2007;2(8):766). When potentially curative resection is offered, lack of technical development and procedure standardization in thoracic surgery has meant that the majority of patients are offered surgical techniques dating back to the 1950s. The selection limitations, pain, complications, prolonged recovery, delay in adjuvant therapy, and potential for chronic discomfort associated with these procedures are well documented. Chemotherapeutic regimens have made some impact on outcomes, but survival differences between treated and untreated patients are still less than 10%, again largely due to late stage identification. And in spite of numerous studies examining the phenomenon of smoking addiction and its relation to lung cancer, a minority of adult smokers can adopt and sustain a smoke-free lifestyle. This perfect storm of variables results in an annual tally of over 150,000 deaths, health-care expenditures of incalculable billions, and untold misery for millions of patients and family members (Smith et al. J Clin Oncol. 2009;27(17):2758).

On the periphery of this cataclysm, however, two separate forces are steadily gaining momentum. Separately, they hold the promise of meaningful change in this frustrating picture; together, they offer a potential inversion of the field. Robotics and annual low-dose CT screening; one diagnostic, one therapeutic; both technically sophisticated, user-dependent, controversial, and incredibly effective when properly executed.

The results of the National Lung Cancer Screening Trial were published in August 2011 (N Engl J Med. 2011;365(5):395). It showed a 27% reduction in mortality for smokers who underwent annual low-dose CT (LDCT) scanning of the chest as compared with an annual chest radiograph. Twenty percent of this reduction was attributable to early detection of lung cancer, and 7% to identification of “other” pathologic conditions (often smoking-related). Such a dramatic impact on a disease falls short of penicillin certainly, but it is the best news the field has seen in decades.

But this is lung cancer, a largely “self-inflicted” disease, caused by that “dirty,” stigmatized, and now, relegated to the out-of-doors habit of smoking. Really! As if the link between lifestyle choices and hypertension, obesity, diabetes, coronary artery disease, etc is a mystery. Fortunately, the myopic view of tobacco addiction as solely a matter of choice has been tempered by studies evaluating the calculated chemical construction of cigarettes, ensuring physiologic attachment, and by those documenting the complexity of the dependence. And so, it is okay to offer smokers, addiction and all, the same hope of early detection and cure that persons at risk for breast cancer or coronary artery disease enjoy.

So let’s get on it! Carefully constructed, multidisciplinary bodies overseeing and evaluating annually offered LDCT scans offer more promise for shifting the survival curve of lung cancer than any chemotherapeutic regimen – 20%! Build consensus among the stakeholders, identify the at-risk populations, inform them of the programs, and screen them. Ultimately, there is a role in such a program. Patients live, doctors work, hospitals pay the bills and, suddenly, only 100,000 people die each year of lung cancer; then 75,000, and then . . . It is a tough process to build such a program. There are departmental and territorial politics, financial concerns, and logistical issues that all must be handled with finesse. In the end, however, you find yourself face-to-face with a father of three, two in college, to whom you can offer a potential cure.

A potential cure? In 2012, this means surgical resection. Unfortunately, those of us in the thoracic surgical world have not made a tremendous amount of progress in this arena over the last several decades. Granted, we introduced video-assisted thoracic surgery (VATS) in the 1990s, but this terminology currently has no consistent reality. Without question, there are talented surgeons who effectively remove lung cancer using a true “port only” approach, and they have made an impact (McKenna et al. Ann Thorac Surg. 2006;81(2):421). But there are others, many others, for whom visualization issues, instrument limitations, and a lack of standardization have led to simply placing a camera into the chest as an adjunct to the standard or slightly smaller incision. Even counting these “hybrid” approaches, however, our own literature documents an application of this “minimalist” platform and its benefits to a minority of lobectomy patients (Boffa et al. J Thorac Cardiovasc Surg. 2008;136(2):247).

Enter Da Vinci: not the 15th century genius, but the robot, a four-armed, solder-turned-surgeon, which has, over the last decade, been used to redefine therapy in urology and gynecology. And now, its three-dimensional vision has been turned to lung cancer. The weaknesses of VATS have been addressed. This technology combines video-gaming speed with 10X, 3-D vision. It drops the surgeon into the chest, allowing precise dissection with multiple instrument options, all through four or five three-quarter-inch incisions. A fantasy? Not for the few thousand people who have undergone a robotic lobectomy for lung cancer over the last several years, a number growing more rapidly every month. At one instant, too expensive? The adoption curve suggests otherwise, and patients who hurt less, go home sooner, and are able to more quickly resume “life” rarely quibble about costs. And several single-surgeon studies demonstrate such outcomes: superior when compared with open techniques and at least equivalent to VATS procedures (Cerfolio J Thorac Cardiovasc Surg. 2011;142(7):740). But those published VATS outcomes are in the hands of high-volume experts. What the robot offers are such outcomes achievable by the “everyman” surgeon, the practitioner in whose hands 70% of patients place their trust for lung cancer resection (Louie et al. Ann Thorac Surg. 2012;93(5):1396).

In our own experience, robotics was successfully utilized in over 90% of all patients undergoing lobectomy in the last 3 years. Our length of stay dropped by 3 days, with over 80% of patients home before even half of those who suffered through our previous procedural endeavor had been released. Now, 10% rather than 90% of our patients spend time in the ICU! Complication rates are roughly one-half of previous, transfusion rates are one-twentieth, and we are fortunate enough to have had no 30-day or in out of hospital mortality. And we are “everyman”: a community-based, mixed cardiac, thoracic, and vascular practice, providing services to about 300,000 people in rural Kentucky. Go ahead, say it: “If they can do it . . .”

Currently, these two forces are moving along parallel courses at a remarkably similar pace. About 200 robotic thoracic surgical programs exist nationwide, a number roughly equivalent to the number of lung cancer screening programs also in place. Nine months ago, that number was 100 each. The point is simple. Little hope has existed in this field for decades and now, two independent juggernauts are on the move.

Good science exists around lung cancer screening: a well-designed, prospective, randomized trial. Strong evidence and developing science surround robotics in the lung cancer arena, and robust outcomes studies are in place. These forces must be seriously considered and integrated into practices where appropriate. Information to facilitate this evaluation is readily available: www.lungcanceralliance.org, www.myroboticlungsurgery.com, and www.davincisurgery.com are good places to start.

It is a rare opportunity to encounter one technology that offers so much in a field. Here are two – don’t miss them.

Dr. R. Douglas Adams, FCCP
Chairman
Lung Cancer Screening Program
Division of Cardiac and Thoracic Surgery
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  BROVANA (arformoterol tartrate) should not be used with other medications containing long-acting beta₂-agonists.

- 12-hour bronchodilation, few daily troughs¹
  While some tolerance to the bronchodilator effect was observed after 6 weeks of dosing (at the end of the dosing interval), it was not accompanied by other clinical manifestations of tolerance.¹ ²

- Requires low peak inspiratory flow rate
  As with other inhaled beta₂-agonists, BROVANA can produce paradoxical bronchospasm that may be life-threatening.

- Minimal coordination or dexterity required

- Covered under Medicare Part B*¹

- To learn more, please visit us at www.brovana.com/CP

*No guarantee of coverage.

INDICATION

BROVANA is indicated for the long term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. BROVANA is for use by nebulization only.

IMPORTANT SAFETY INFORMATION

WARNING: ASTHMA-RELATED DEATH

Long-acting beta₂-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta₂-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including arformoterol, the active ingredient in BROVANA (see WARNINGS). The safety and efficacy of BROVANA in patients with asthma have not been established. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication (see CONTRAINDICATIONS).

Please see the Brief Summary of Prescribing Information on the following pages for additional Important Safety Information.

Please visit www.brovana.com for full Prescribing Information.


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Twice-Daily
Brovana
(arformoterol tartrate) Inhalation Solution

Get them back into daily living
BROVANA® (arformoterol tartrate) Inhalation Solution 15 mcg*/2 mL *potency expressed as arformoterol FOR ORAL use of a long-term asthma control medication (see CONTRAINDICATIONS).

CHEST_

Fatalities have been reported in association with excessive use of inhaled Immediate hypersensitivity reactions may occur after administration of BROVANA BROVANA, the physician should also provide the patient with an inhaled, short-acting beta-(see CONTRAINDICATIONS).

BROVANA (arformoterol tartrate) Inhalation Solution is contraindicated in patients with a history of hypersensitivity to arformoterol, raemic formotrol or to any other components of this product. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication. (see WARNINGS).

b. Uncontrolled depression or psychosis
   - Moderate to severe depression
   - Persistent psychotic symptoms
   - History of suicide or suicidal ideation

Indications and Usage:

1. COPD:
   - Maintenance treatment to control chronic obstructive pulmonary disease
   - Improvement in bronchodilator responsiveness

2. Asthma:
   - Long-term control of asthma
   - Symptomatic management of acute exacerbations of asthma

3. Patients should be informed that treatment with beta-agonists may lead to adverse events which include palpitations, chest pain, rapid heart rate, tremor, or nervousness.

4. Patients should be instructed to use BROVANA by nebulizer only and not to inject or swallow this inhalation solution.

5. Patients should protect BROVANA ready-to-use vials from light and excessive heat. The protective foil pouches should be opened only when the nebulizer cup is in position and the nebulizer is operating. The nebulizer should not be removed from the patients when refilling.

6. The drug compatibility (physical and chemical), efficacy and safety of BROVANA when mixed with other drugs in a nebulizer have not been established.

7. Patients should be advised to contact their physician if they become pregnant or if they are nursing.

Drug Interactions:

If additional long-acting beta-agonists are to be administered by any route, they should be used with caution because the pharmacological effects of LABAs on the cardiovascular system may be potentiated by these drugs. Drugs that are known to potentiate the intravenous use of BROVANA are listed in the section entitled “Concomitant Use of Beta-agonists and/or Non-potassium-Sparing Diuretics.”

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term studies were conducted in mice using oral administration and rats using inhalation administration to evaluate the carcinogenic potential of arformoterol.

In a 24-month carcinogenesis study in CD-1 mice, arformoterol caused a dose-related increase in the incidence of uterine and/or periuterine steroidal polyps and stromal cell sarcoma in female mice at oral doses of 1 mg/kg and above (AUC exposure approximately 100 times adult exposure at the maximum recommended daily inhalation dose). There were no tumor findings with arformoterol in rats at oral doses of 40 mg/kg (AUC exposure approximately 35 times adult exposure at the maximum recommended daily inhalation dose).

Adverse Reactions:

Emergency Hyperreactivity Reactions:

No adequate and well-controlled studies in pregnant women. BROVANA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Labor and Delivery:

There are no studies that have investigated the effects of BROVANA on preterm labor or labor at term. Because beta-agonists may potentially interfere with uterine contractility, BROVANA should be used during labor and delivery only if the potential benefit justifies the potential risk.

Nursing Mothers:

Arformoterol was not mutagenic or clastogenic in the following tests: mutagenicity tests in bacteria, chromosome aberration analyses in mammalian cells, and micronucleus test in mice. Arformoterol had no effects on fertility and reproductive performance in rats at oral doses up to 100 mg/kg (approximately 7000 times the maximum recommended daily inhalation dose in adults on a mg/m2 basis).

Pregnancy: Teratogenic Effects

Pregnancy Category C

Arformoterol has been shown to be teratogenic in rats based upon findings of emphysema (alveolar hyperplasia), a malformation, and oral doses of 1 mg/kg and above (AUC exposure approximately 370 times adult exposure at the maximum recommended daily inhalation dose). Increased pup loss was observed in female rats at an inhalation dose of 200 mcg/kg (AUC exposure approximately 150 times adult exposure at the maximum recommended daily inhalation dose). There were no tumor findings with arformoterol in mice at oral doses of 40 mg/kg (AUC exposure approximately 1200 times adult exposure at the maximum recommended daily inhalation dose).

The safety and efficacy of BROVANA have been established in pediatric patients with asthma and chronic obstructive pulmonary disease. Use in pediatric patients should be made with caution because the long-term safety and efficacy in this age group have not been established.

In patients receiving BROVANA, patients who have been taking inhaled, short-acting beta-agonists on a regular basis (e.g., for 4 hours a day) should be instructed to discontinue the regular use of these drugs and use them only for symptomatic rescue.

[More text follows in a similar pattern.]
Practice Management: Notes on Selecting an EMR

BY DR. MARC BENTON, FCCP
Member of the EHR Subcommittee of the Practice Management Committee

Editor’s Note: Dr. Benton’s list below is in response to an ACCP member’s question to the ACCP about choosing an EMR. This is just one example of the many resources available to our members and the willingness of our leadership to provide expertise to assist our members and advance the mission of the College.

There are so many moving parts to the process of selecting an EMR. This is the approach we’ve taken in our practice to managing the basic steps:

1. Identify one physician to work with the Practice Coordinator (PC), and make sure that the physician communicates well with the other docs so things don’t happen in a vacuum – these two people become your EMR Team.

2. The Team should get some familiarity with commonly deployed EMRs, in terms of look and feel, functionality, features, and cost. The best way to do this would be to go to a symposium or an EMR “road show,” where you can see a number of different products all at once and side-by-side. Some hospitals and/or medical systems sponsor these events to educate the physicians in the community. Visit other medical practices that have them, especially in your area. Have the PC network with other PCs to share experiences. Some hospital IT divisions have people who can directly help you with this. Larger conferences, like HIMSS and CHEST, offer this, but it might be difficult because of the size and noise to get a feel for what you’re seeing.

3. Register with one or more of the online EMR review registries, like KLAS (www.klasresearch.com/EMR_Software), and select information relevant to your practice size and specialty. This can usually be done free of charge, at least for the basic material. It will not answer all of your questions, but it will help you get a feel for the differences between the products, and the pros and cons of the systems that you look at.

4. Find out what your local medical system is promoting and/or supporting – going with a local “preferred provider” will often get you benefits in terms of pricing, interfaces, and interoperability with other providers and the hospital system. On the other hand, don’t lock into the locally preferred provider if it is the wrong choice for you.

5. Once you understand the workflow of the systems out there, try to match them to your practice workflow to get a better understanding of how you might be able to integrate the systems into your current operations. Understand that you will need to modify certain aspects of your current workflow to accommodate any EMR, so be prepared.

6. Go see the system(s) you’re interested in being actively deployed in practices in your area, preferably a practice as similar to yours as possible.

7. Try to hone the process down to a few systems that appear to be best for you (two to four, ideally), and then have each vendor do a demo for all the docs and other key employees. Structure the demo so that they show you how to make the system do what you will need it to do, not just what they want to show you. Nearly all of the system vendors can demonstrate how well their system can manage a standard asthmatic patient right out of the box, but anything else might be much more difficult. Arrange to have a provider pose as a sample patient, and make the demos similarly structured, so you can compare apples-to-apples while making decisions.

8. Before you sign a contract, find a lawyer who specializes in reviewing EMR contracts, preferably one who has dealt with the specific company you’re looking to purchase, as you’ll get better quality and less expensive advice in most circumstances.

9. Make sure you have an IT team that is fully capable of assisting in the implementation and support of whatever you purchase.

10. Ensure that the product is certified to meet “Meaningful Use” criteria if deployed in an appropriate manner.

11. Be patient, hope for the best, expect the worst.

12. All of these issues hold true when you’re assessing the EMR and the practice management (PM) components of the system – ideally, you want matched products from the same vendor, but don’t assume that because the EMR is good that the PM components will also be good, or vice versa.

This is all generic advice. For some people and/or groups, hiring an EMR consultant to shepherd you through this process may be best – see what Continued on following page

Table 1: Number of Patients Experiencing Adverse Events from Two 12-Week, Double-Bound, Placebo Controlled Clinical Trials

<table>
<thead>
<tr>
<th></th>
<th>BROVΩA (1) mg</th>
<th>Placebo (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (100)</td>
<td>n (100)</td>
<td>n (100)</td>
</tr>
<tr>
<td>Total Patients</td>
<td>208 (100)</td>
<td>206 (100)</td>
</tr>
<tr>
<td>Pain</td>
<td>23 (8)</td>
<td>18 (5)</td>
</tr>
<tr>
<td>Chest Pain</td>
<td>16 (6)</td>
<td>13 (4)</td>
</tr>
<tr>
<td>Back Pain</td>
<td>19 (8)</td>
<td>6 (2)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>16 (6)</td>
<td>13 (4)</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>12 (4)</td>
<td>6 (2)</td>
</tr>
<tr>
<td>Leg Cramps</td>
<td>11 (4)</td>
<td>7 (2)</td>
</tr>
<tr>
<td>Urticaria</td>
<td>11 (4)</td>
<td>5 (2)</td>
</tr>
<tr>
<td>Fetal Syndrome</td>
<td>10 (3)</td>
<td>4 (1)</td>
</tr>
<tr>
<td>Persistent Erythema</td>
<td>8 (3)</td>
<td>7 (2)</td>
</tr>
<tr>
<td>Lung Distress</td>
<td>6 (2)</td>
<td>4 (1)</td>
</tr>
</tbody>
</table>

Noteworthy terms coded to “Long Disorder” were predominantly palmar or plantar congestion.

Adverse events occurring in patients treated with BROVΩA 15 mg twice daily with a frequency of greater than 2%, but greater than placebo were as follows:

- **Body as a Whole**: abcesses, allergic reaction, digitalis intoxication, fever, hermia, jejunal site pain, neck rigidity, nephritis, pelvic pain, peritoneal hemorrhage
- **Cardiovascular**: anemia, aortic valve, atrial flutter, AV block, congestive heart failure, heart block, myocardial infarct, QT interval prolonged, supraventricular tachycardia, inverted T-wave
- **Dietary**: constipation, diarrhea, melena, oral moniliasis, peridontal abscess, rectal hemorrhage
- **Metabolic and Nutritional Disorders**: dehydration, edema, glucose tolerance decreased, growth, hyperglycemia, hypoglycemia, hypokalemia, hypercalcemia
- **Musculoskeletal**: arthritis, arthrosis, bone disorder, rheumatoid arthritis, tendinous contracture
- **Neoplasms**: aseptic, cerebellum, cerebral infarct, circumscribed paraneoplasia, hypoglycemia, paralytic, somatoleukemia, tremor
- **Respiratory**: carcinoma of the lung, respiratory disorder, voice alteration
- **Skin and Appendages**: dry skin, herpes simplex, herpes zoster, skin discoloration, skin hypertrophy

**Special senses**: abnormal vision, glaucoma

**Urogenital**: carcinoma of the bladder, carcinoma of the prostate, cystitis, frequency, hematuria, kidney calculi, nocturia, PSA increase, prostate hypertrophy

Other adverse reactions which may occur with selective beta-adrenergic agonists such as BROVΩA include: angina, hypertension or hypotension, tachycardia, arrhythmias, arrhythmia, headache, tremor, dry mouth, palpitation, muscle cramps, nausea, dizziness, fatigue, malaise, hypokalemia, hyperglycemia, metabolic acidosis and insomnia.

**Drug Abuse and Dependence**

There were no reported cases of abuse or evidence of drug dependence with the use of BROVΩA in the clinical trials.

**OVERDOSAGE**

The expected signs and symptoms associated with overdosage of BROVΩA (albuterol/sulfate) Inhalation Solution are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the signs and symptoms listed under ADVERSE REACTIONS, e.g., angina, hypertension or hypotension, tachycardia, with rates up to 200 bpm, arrhythmias, myocardial ischemia, angina, chest pain, palpitations, tremor, dry mouth, palpitation, muscle cramps, nausea, dizziness, fatigue, malaise, hypokalemia, hyperglycemia, metabolic acidosis and insomnia.

With all inhaled sympathomimetic medications, cardiac arrest and even death may be associated with an overdose of BROVΩA.

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

Clinical signs in dogs included flushing of the body surface and facial area, reddening of the ears and gums, tremor, and increased heart rate. A death was reported in dogs after a single oral dose of 5 mg/kg (approximately 4500 times the maximum recommended daily inhalation dose in adults of a mg/m² basis). Death occurred for a rat that received albuterol at a single inhalation dose of 1600 mg/kg (approximately 410 times the maximum recommended daily inhalation dose in adults on a mg/m² basis).
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Contact: WellStar Provider Services, Phone: 770-792-7539, Fax: 770-792-1738, Email: providerpositions@wellstar.org

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Please send CV to: Fred Martinez, Practice Administrator, Suburban Pulmonary & Sleep Assoc, LTD, 700 E. Ogden Avenue, Suite 202, Westmont, IL 60559, Phone: 630-789-9785 x 350, Fax: 630-789-9788, Email: fmartinez@spassamed.com

NEWS FROM THE COLLEGE

In Remembrance

Harold Clifton Urschel Jr., MD, ACCP Past President of the ACCP died on November 12, 2012. He was attending the American Heart Association meeting in Los Angeles at the time of his death, where he was present on his latest research interest – the use of stem cells for the treatment of heart failure.

Dr. Urschel attended Harvard University Medical School and trained in surgery at Massachusetts General Hospital, Boston. He was most recently with Baylor University Medical Center in Houston. Dr. Urschel served the ACCP as a member of several committees, as a Regent-at-Large, and as President in 1978-1979. He served in leadership capacities with many other societies. He was past president of the Society of Thoracic Surgeons, the Southern Thoracic Surgical Association, and the Texas Surgical Association, and had been a Governor of the American College of Surgeons, Chairman of the American Board of Thoracic Surgery, and Chairman of the Residency Review Committee for Thoracic Surgery.

The ACCP extends condolences to the Urschel family.

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