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Courtesy Denver Health Medical Center

Eating disorders among men are on the rise, says Dr. Jennifer L. Gaudini. High-stress and certain temperaments can increase risk. Scan the QR code to view a video interview.

Eating Disorders: Doctors' Secret Battle

BY BETSY BATES FREED
IMNG Medical News

Barely a whisper in the literature, the subject of eating disorders among American medical students and physicians often hides behind a cloak of anonymity like this posting on a virtual bulletin board:

Does anybody have any experience with dealing with an eating disorder and being in med school? I've recently been told I'm no longer able to participate in clinical work (I'm in 3rd year) because my doctor contacted the school in regards to my health. I'm not underweight and my electrolyte balance is normal. I'm just looking for anybody who has been in a similar situation or anybody who might have any advice or support – it's been a tough little while. … I've made many positive changes, stopped abusing phentermine and ephedra, stopped overexercising, but apparently it hasn't been enough.

Physicians seek treatment for eating disorders, but often only after taking desperate measures to control the disorder themselves. "Physicians are more resistant than others to recognize and come to terms with the idea that they have a serious problem and they need help," said Dr. Ovidio Bermudez, chief medical officer of the Eating Recovery Center in Denver and past president of the National Eating Disorders Association.

The environment that nourishes young doctors contains abundant seeds for triggering eating disorders, and the problem "is more rampant than people know. These are high achievers, and the pressure is on," said Dr. Vicki Berkus, medical director of the eating disorders program at Sierra Tucson Treatment Center in Arizona.

Medical school and residency training are particularly chal-

See **Eating Disorders** • *page 18*

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 of 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

See **Consensus** • *page 2*

INSIDE

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 P_{CO_2} (mean difference, –2.96 mm Hg), and an improvement in 6-minute walk distance (mean difference 45.15 m), Dr. Monali Patil said at the annual meeting of the American College of Chest Physicians.

See **Stable COPD** • *page 2*

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NIPPV

Stable COPD • *from 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 FEV_1 less than 50% of predicted and a P_{CO_2} greater than 45 mm Hg and were receiving bilevel positive airway pressure (BIPAP).

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. ■

COMMENTARY

Dr. Darcy D. Marciniuk, FCCP, comments: This review of small RCTs in patients with severe stable COPD and CO_2 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.

IN THIS ISSUE

CHEST PHYSICIAN Is Online
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Dr. W. Michael Alberts, FCCP, is Medical Editor in Chief of CHEST PHYSICIAN.

Guidance on Troponin Testing

Consensus • *from page 1*

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 cyclophosphamide, 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 assay quality 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, your prognosis – 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?articleid=1389700). ■

COMMENTARY

Dr. Jun Chiong, FCCP, comments: Algorithms employing cardiac troponin testing that can rule in or rule out an acute MI abound.

This recently published troponin guideline will help clinicians "discriminate" when and why troponin should be ordered. With our health care system reforming, it is equally important to also understand scenarios when troponin testing is not necessary.

Studies need to be done to evaluate the cost-effectiveness of testing in a low-risk population or low probability scenario.

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CHEST PHYSICIAN

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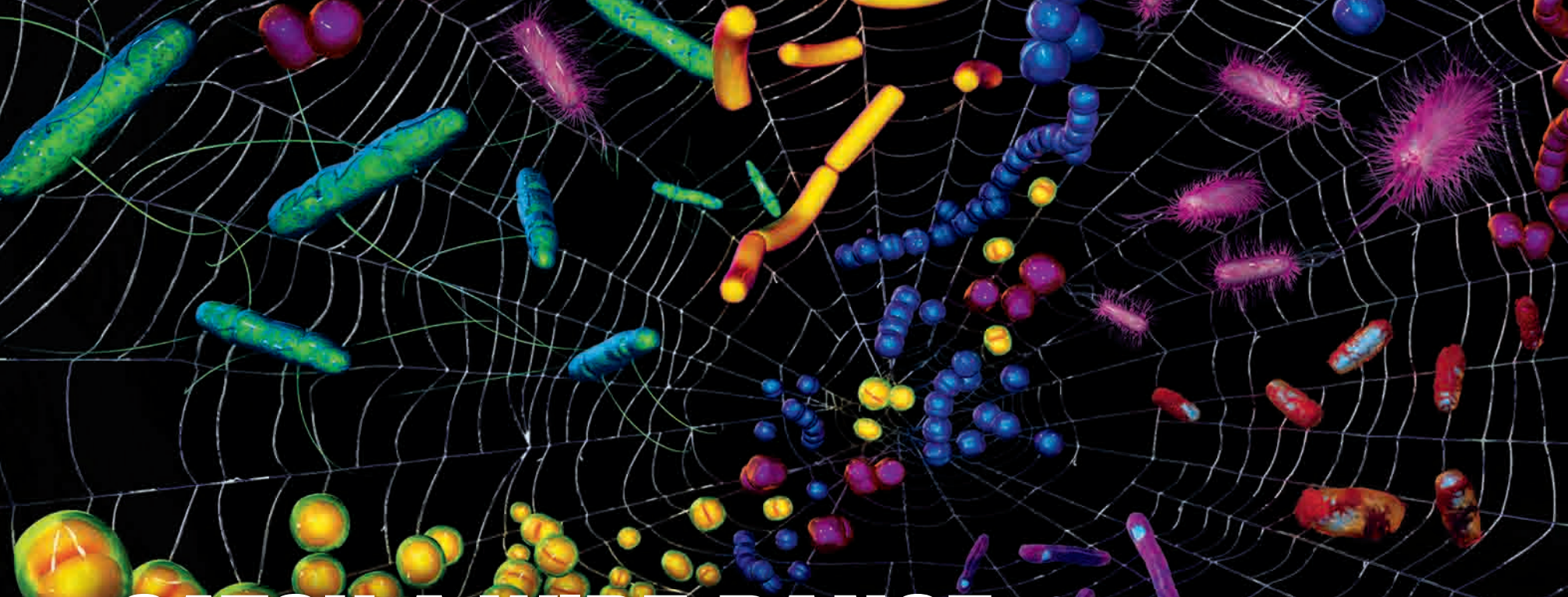

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Please see brief summary on adjacent page.

REFERENCE: 1. TYGACIL® [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc; 2011.

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Pleuroscopy an Option for Unknown DPLDs

VITALS

Major Finding: Good biopsy specimens (average size of 0.5 x 0.4 cm) were obtained and no life-threatening complications occurred in patients who underwent medical thorascopic lung biopsies.

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

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

BY SHARON WORCESTER
IMNG Medical News

ATLANTA – Medical thoracoscopy is safe and feasible for performing lung biopsy in patients with diffuse parenchymal lung disease of 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 intercostals tube 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) University Hospitals.

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 histopathologic 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 lymphangioleiomyomatosis.

"Thoracosopic lung biopsy by medical thoracoscopy is useful in the diagnosis of patient with diffuse pulmonary 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 a lung biopsy is of interest, but also "something we still have to get comfortable with." ■

COMMENTARY

Dr. Lary Robinson, FCCP, comments: Medical thoracoscopy, commonly termed pleuroscopy, has been practiced for decades in some centers by pulmonary medicine specialists primarily to evaluate and treat pleural diseases, usually performed under conscious sedation. Dr. Elmady's complication rate was significant (20% persistent air leak, 10% bleeding, 60% significant pain, etc.) for this awake procedure compared to the usual, minimal morbidity from VATS surgical thoracoscopy for lung biopsy. And the 5-mm x 4-mm diameter tissue specimen they obtained would be considered marginal at best for a definitive pathological diagnosis.

Finally, most patients requiring this procedure have significantly compromised lung function (the reason for the biopsy) so that an awake, spontaneously breathing patient can easily get into significant respiratory distress with this procedure.

Directed Exchange Is Key to EHR Stage 2

BY MITCHEL 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 something like 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 about this from the EHR vendor by mid-2013 should ask their vendor, "When can you provide it?" said Dr. Kibbe, who also is president of DirectTrust, 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. ■

COMMENTARY

Dr. Stuart M. Garay, FCCP, comments: Physicians are still struggling to qualify for meaningful use stage 1 for their electronic medical records, but the need to plan for stage 2 is already present. The bar has been raised: Physicians need to demonstrate that they can transfer data in a reliably secure, confidential way between physicians, between physicians and a health care system, and between physicians and patients. These goals are desirable and achievable, but will also raise the "cost of doing business."

January 2013 Rings In a Cold New Year for Vaccines

BY MICHELE G. SULLIVAN

IMNG 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-encased temperature probe because these devices more accurately approximate the temperature of stored liquids, Dr. Herschel Lessin said at the the annual meeting of the American Academy of Pediatrics.

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

"You also won't be able to use a dorm-style refrigerator or a refrigerator/freezer combination," he said. "In these units, the freezer is actually what chills the fridge, and when the freezer cycles on and off, it can change the temperature of the refrigerator."

The 24-hour data recording of temperature is intended to ensure that vaccine remains within its constant recommended range of 35°-46° F. "If the data logger hits outside that range, 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, said 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

'If the data logger hits outside that [temperature] range, it's the kiss of death for your store of vaccine.'

DR. LESSIN

can serve as "vaccine coordinators." These staffers should be trained in proper vaccine storage and handling, and be able to perform accountability checks to make sure the protocol is followed.

In writing the new recommendation, the CDC relied on a 2010 study on refrigerator types and how they can affect vaccines. The study tested two types of refrigerators – household and dormstyle.

After 19 thermometer-recorded temperatures in different parts of the devices 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. ■

Pages 6a—6b

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.

In the shorter term, strategies to prevent outbreaks could include either earlier or additional booster doses.

MR. WITT

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 underprotected 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, and targeted vaccination programs to address insufficient immunity in outbreak situations."

The field of pertussis vaccination has undergone transition, with the introduction of the acellular vaccine in 1991 and retirement of the whole cell vaccine in 2001. "In 2010, we saw the largest epidemic of *Bordatella pertussis* in California in more than 50 years, and that epidemic subsequently spread across the United States," he said at IDWeek, the combined annual meetings of the Infectious Diseases Society of America, the Society for Healthcare Epidemiology of America, the HIV Medicine Association, and the Pediatric Infectious Diseases Society.

In a previous study, the investigators noted waning pertussis immunity among preadolescents (with a peak attack rate among 8- to 12-year-olds) but also robust immunity among adolescents (with a sharply lower attack rate among 13-year-olds) (Clin. Infect. Dis. 2010;54:1730-35), suggesting a possible role for the vaccine transition.

VITALS

Major Finding: Compared with their peers who had received at least one dose of whole cell vaccine, patients who had received only acellular vaccine had a 3.55- to 8.57-fold higher risk of pertussis.

Data Source: A cross-sectional study of 465,059 vaccinated patients aged 8-20 years from a single health care system

Disclosures: Mr. Witt disclosed no relevant financial conflicts.

In the new study, the investigators used electronic health records to identify vaccines administered and cases of laboratory-confirmed pertussis among Kaiser Permanente members aged 8-20 years in Northern California.

This age range was chosen to include patients who were old enough to have received whole cell vaccine and young enough to have received acellular vaccine, explained Mr. Witt. The search identified 465,059 patients, among whom there were 1,424 cases of pertussis.

A total of 253,005 patients had received all of their vaccine doses at Kaiser Permanente. Analyses restricted to this group showed that among patients who had received five total doses of vaccine, the pertussis attack rate was 786/100,000 for those who had received only acellular vaccine, compared with 92/100,000 for those who had received at least one dose of whole cell vaccine. The difference corresponded to an 8.57-fold higher risk for the former group (*P* less than .0001).

Similarly, among patients who had received six total doses of vaccine, the attack rate was 378 vs. 106/100,000 for those who received only acellular vaccine compared with those who had received at least one dose of whole cell vaccine. Here, the difference amounted to a smaller but still significant 3.55-fold higher risk.

The study findings were essentially the same when analyses were based on all patients, including those who had received at least some doses of vaccine outside of Kaiser Permanente, with respective 6.76- and 2.46-fold higher risks for patients given only acellular vaccine, depending on the total number of doses. ■

COMMENTARY

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 now go with this information?

PCR Best for Detecting MRSA in Patients on Antibiotics

BY DOUG BRUNK
IMNG Medical News

SAN DIEGO – Polymerase chain reaction testing recovered methicillin-resistant *Staphylococcus aureus* significantly more frequently than did nasal swab culture in hospitalized patients receiving antibiotics concurrently, a study has shown.

All of the patients studied had a history of MRSA colonization.

"Because close to 50% of hospitalized patients receive antibiotics, it's important to know whether or not your MRSA screening test is going to be accurate in detecting persistent colonization," Dr. Erica S. Shenoy said in an interview during a poster session at IDWeek, the combined annual meetings of the Infectious Diseases Society of America, the Society for Healthcare Epidemiology of America, the HIV Medicine Association, and the Pediatric Infectious Diseases Society.

Dr. Shenoy of Massachusetts General Hospital's division of infectious diseases and infection control unit, Boston, and her associates compared the effect of concurrent administration of antibiotics with activity against MRSA on detection from nasal surveillance swabs.

The study population included 259 patients who were admitted to Massachusetts General Hospital between Dec. 6, 2010, and Sept. 16, 2011, with a history of MRSA colonization, but no culture more recent than 90 days. Patients underwent simultaneous screening for nasal carriage of MRSA using both nasal swab culture and commercial PCR testing.

VITALS

Major Finding: Without antibiotics, the concordance rate between nasal swab culture and PCR testing was 94%. With antibiotics, the rate between paired samples was 91%, with a greater tendency for positive results with PCR vs. culture.

Data Source: Researchers studied 259 with a history of MRSA colonization who underwent simultaneous screening for nasal MRSA with both culture and commercial PCR testing.

Disclosures: The study was supported by a Massachusetts General Hospital Clinical Innovation Award, a NIAID Training grant, the Harvard Catalyst, and Harvard University. Cepheid provided reagents and a loaner GeneXpert for the randomized trial free of charge. The researchers reported having no financial conflicts.

Samples obtained within 2 days after administration of select antibiotics were considered to be obtained in the presence of "concurrent antibiotics."

The list of select antibiotics included trimethoprim/sulfamethoxazole, mupirocin, ciprofloxacin, clindamycin, daptomycin, doxycycline, levofloxacin, linezolid, nitrofurantoin, quinupristin/dalfopristin, rifampin, tetracycline, tigecycline, and intravenous vancomycin.

Dr. Shenoy reported that 132 of the 259 paired samples were obtained in the presence of antibiotics while the remaining 127 were not.

In the absence of antibiotics, the concordance rate between culture and PCR was 94%, with neither test being significantly more likely to yield a positive result. However, in the presence of antibiotics, the concordance rate between paired samples was 91%, with a significantly greater tendency for PCR to yield positive results compared with culture, suggesting to the researchers better performance of PCR testing in the setting of antibiotic exposure.

"In populations exposed to antibiotics with activity against MRSA, culture assays may miss true positives," Dr. Shenoy said.

She emphasized that while PCR is more expensive than nasal swab culture on a per-test basis, the "cost of the capital equipment investment and the personnel time to actually do the swabbing is potentially dwarfed by the downstream impact on the patient and the hospital overall." ■

COMMENTARY

Dr. Marcos I. Restrepo, FCCP, comments: Infection control strategies are directed to the prevention of transmission of multidrug resistant pathogens such as methicillin resistant *Staphylococcus aureus*. Therefore, appropriate pathogen identification is critical in order to prevent transmission. This report suggests that PCR performs better than nasal culture swabs for patients receiving anti-MRSA antimicrobial therapies. In addition, it suggests that despite the cost, newer methodologies are needed to identify patients colonized with MRSA and at risk of transmission.

Zolpidem Linked to Higher Inpatient Fall Rates

BY TARA HAELLE
IMNG Medical News

Administration of zolpidem in hospital 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.

VITALS

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.

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.

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 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.1985]).

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% (81 falls) in the 11,358 patients who were prescribed but not administered zolpidem during their hospital stay.

Incidentally, patients not prescribed zolpidem (n = 25,627) had a fall rate of 1.42%, just slightly lower than the overall fall rate of 1.47% among all patients prescribed zolpidem, whether they received it or not. But when all patients who did not receive zolpidem were combined independent of whether they were prescribed it, their 1.24% fall rate was a significant 1.8% higher than that of patients receiving the drug.

The authors recommended that, given the current absence of evidence for other safer hypnotic alternatives for inpatients, "nonpharmacological measures to improve the sleep of hospitalized patients should be investigated as preferred 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 antidepressants 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. ■

FDA Eyes Pramipexole for Possible Heart Failure Risk

BY ELIZABETH MECHCATIE
IMNG Medical News

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 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 ONE STUDY, PRAMIPEXOLE WAS ASSOCIATED WITH AN INCREASED RISK OF HEART FAILURE, COMPARED WITH LEVODOPA.

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 "difficult 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 following 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. ■

Preadmission to Discharge: Best COPD Choices

Noninvasive ventilation has revolutionized in-hospital COPD management.

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 spotlighted 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 incredible 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.

'Now, with saturation monitors, life is good.'

DR. MARCINIUK

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, PCO_2 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 copresence of depression and anxiety (in COPD patients) is growing, but our understanding that it appears 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 comanaged 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 comanaged 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 comanaged 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. ■

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FDA Panel Gives Nod to Drug for Multidrug-Resistant TB

BY ELIZABETH MECHCATIE
IMNG Medical News

SILVER SPRING, MD. – Bedaquiline, an oral antimycobacterial 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 background 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 confirmed positive culture.

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 drugmaker 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 is 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 end points, with the requirement that clinical effectiveness be confirmed in a postmarketing study with hard clinical end points 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 diarylquinolone 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's approval in 1970, and the first drug approved for TB since rifapentine 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 pulmonary 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 for 2 weeks, followed by 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 had a culture conversion, compared with 58% of those on placebo, a significant difference.

The second study was an open-label trial of 233 previously treated patients with sputum 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 80%, and sputum cultures 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, although 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 PATRICE WENDLING
IMNG Medical News

VIENNA – Long-awaited data from the phase III PROFILE 1007 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 19.5% 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.

VITALS

Major Finding: Median progression-free survival was 3.0 months with chemotherapy and 7.7 months with crizotinib (*P* less than .0001; hazard ratio, 0.49).

Data Source: Results came from a phase III study involving 318 patients with advanced ALK-positive non–small cell lung cancer.

Disclosures: Dr. Shaw reports advisory ties with crizotinib-maker Pfizer and other industry firms. Dr. Soria has reported receiving honoraria from Pfizer.

"Taken together, these results establish crizotinib as the standard of care for patients with advanced, previously treated ALK-positive non–small cell lung cancer," she said.

ALK rearrangements are present in about 5% of lung cancers, typically in younger, never smokers.

Overall survival in the study was 22.8 months for chemotherapy and 20.3 months for crizotinib (*P* = .5394; HR, 1.02). The interim survival analysis was immature with just 40% of expected deaths reported and likely confounded by the high number (87%) of chemotherapy patients 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 financial 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."

Crizotinib changed the natural history of the disease, Dr. Jean-Charles Soria said.

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/m^2 or docetaxel 75 mg/m^2 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 (25 deaths vs. 7 deaths), said Dr. Shaw, a thoracic oncologist at Massachusetts General Hospital Cancer Center in Boston.

Crizotinib patients were more likely than were 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.

PHOTOS PATRICE WENDLING/IMNG MEDICAL MEDIA

Data now support crizotinib as the standard of care, said Dr. Alice Shaw.

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 testosterone, "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 35% 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
IMNG Medical News

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 VACCINE IS BEING CONSIDERED FOR ACCELERATED APPROVAL BY THE FOOD AND DRUG ADMINISTRATION.

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. ■

Acute Dyspnea: Try Physiologic Approach

BY SHERRY BOSCHERT
IMNG Medical News

DENVER – If you presume that a patient who comes 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 the approximately 5% 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 the annual meeting of the American College of Emergency Physicians.

Take a physiologic approach that can guide you through the differential diagnosis, he suggested. "As somebody who 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.

To begin, think of diseases that cause hypoxemia, hypercapnia, or metabolic acidosis, which lead to dyspnea.

Hypoxemia

The most common cause of hypoxemia is ventilation-perfusion (V-Q) mismatch, 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.

Extrapulmonary disease processes create four causes of hypoxemia: a shunt, low mixed venous oxygen saturation ($M\bar{v}O_2$), decreased fraction of inspired oxygen (FiO_2), and alveolar hypoventilation.

A V-Q mismatch at its most extreme is 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 you give the patient oxygen. "This is the test for any young child under the age of 6 weeks who comes to the emergency department hypoxemic," Dr. Sankoff said.

IT TAKES A BIT OF DETECTIVE WORK TO FIND THE CAUSE IN THE FEW CASES OF DYSPNEA THAT ARE NOT EASILY REFERABLE TO THE LUNGS.

Adults with shunts will have a murmur as well as dyspnea. "Adults don't develop shunts de novo. This is going to be happening as part of some acute process," he said. The chest x-rays in adults with shunts often are normal.

The second cause of hypoxemia – low $M\bar{v}O_2$ – occurs mainly when blood flows too slowly through the capillary bed, allowing excess oxygen extraction, and blood returns to the heart in a deoxygenated state. Focus on right ventricular impairment to identify the etiology. Left ventricular impairment will show up on x-ray as pulmonary edema. A right-sided infarction or cor pulmonale from pulmonary embolism will impair right ventricular function. Cardiac tamponade from infectious, inflammatory, or neoplastic processes also can cause low $M\bar{v}O_2$ and dyspnea, though nobody really understands why, he added.

The third cause of hypoxemia – decreased FiO_2 – usually is a problem relegated to people at high altitudes or industrial workers in enclosed spaces, where hypoxemia (low partial pressure of oxygen in blood) causes hypoxia (low oxygen levels in tissues). Dr. Sankoff uses this category to remind himself to look for diseases that are not associated with lower FiO_2 and hypoxemia but still are associated with hypoxia – primarily hemoglobinopathies.

"If a patient has 100% oxygen saturation yet is hypoxic, they have a problem with hemoglobin," Dr. Sankoff said. It may be a severe or acute garden-variety anemia causing the dyspnea, or occa-

Continued on following page

Early End-of-Life Discussions Cut Aggressive Care

BY SHERRY BOSCHERT
IMNG Medical News

VITALS

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.

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 had end-of-life discussions. Among the 794 patients with end-of-life discussions documented in medical records, 39% took place in the last 30 days of life and 63% happened in the inpatient setting. Fifty-eight percent of patients entered hospice care, reported Dr. Mack, a pediatric oncologist at the Dana-Farber Cancer Institute and Harvard Medical School, Boston, who studies patient-related communications issues.

The study was published 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 surrogates reported having end-of-life discussions.

Patients whose first end-of-life discussion happened while they were hospitalized were more than twice as likely to get any kind of aggressive care at the end of life and three times more likely to get acute care or ICU care in the last 30 days and to have hospice care start within the last week before death.

Having a medical oncologist present at the first end-of-life discussion increased the odds of having chemotherapy in the last 2 weeks of life by 48%, decreased the odds of ICU care in the last 30 days by 56%, increased the likelihood of hospice care by 43%, and doubled the chance of hospice care starting in the last 7 days of life. All of these odds ratios were significant after controlling for other factors.

Data came from a larger cohort of 2,155 patients with stage IV lung or colorectal cancer receiving care in HMOs or Veterans Affairs medical centers in five states. All were followed for 15 months after diagnosis in the Cancer Care Outcomes Research and Surveillance Consortium.

An earlier analysis by the same investigators showed that 87% of the 1,470 patients who died and 41% of the 685 still alive by the end of follow-up had end-of-life care discussions. Oncologists documented end-of-life discussions with 27% of their patients, suggesting that most discussions were with non-oncologists. (Ann. Intern. Med. 2012;156:204-10).

The current study analyzed data for 1,231 of the patients who died but who lived at least 1 month after diagnosis, in order to assess whether the timing of discussions influenced end-of-life care.

Patients were significantly less likely to say they'd had an end-of-life discussion if they were unmarried, black or non-white Hispanic, or not in an HMO.

When discussions don't begin until the last 30 days of life, the end-of-life period usually is already underway, the investigators noted. Physicians should consider moving end-of-life care discussions closer to diagnosis, they suggested, while patients are relatively well and have time to plan for what's ahead.

"It's something that any physician can do," but some previous studies report that physicians are reluctant to start end-of-life discussions early because these are emotionally difficult conversations, they worry about taking away hope, and they are concerned about the psychological impact on patients – though there is no clear evidence that it does have psychological consequences for patients, Dr. Mack said.

"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 we have conversations but they're not heard or understood by patients," she said. "It reminds me that I need to ask patients what they're taking away from these conversations and use that to guide me going forward."

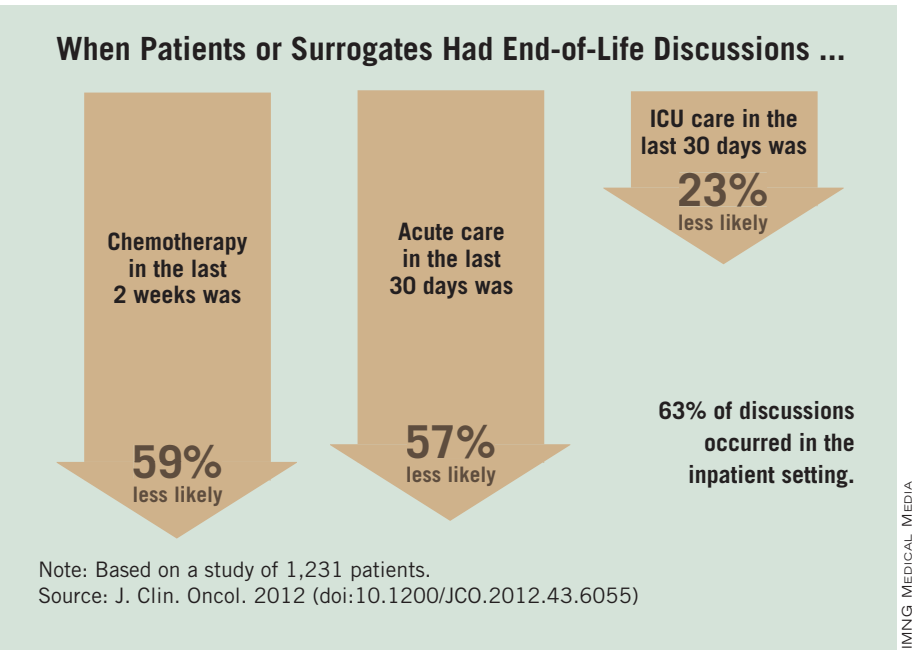
That finding echoes two recent large, population-based studies that found many patients with terminal cancer mistakenly think that palliative chemotherapy or radiation will cure their disease.

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. ■



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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 causes of peripheral neuromuscular weakness are 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 H_2O, 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 hemoglobinopathies. Narrow the differential by recalling the history and physical findings and getting arterial blood gas tests.

Dr. Sankoff reported having no relevant 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 advance 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 operating rule for eligibility will improve patient intake and speed up the claim adjudication process.

MR. TENNANT

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.

CP: 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.

CP: 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?

CP: 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.

CP: 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.

MEANINGFUL USE EHR, E-PRESCRIBING, AND ICD-10 ADOPTION WILL 'REQUIRE PRACTICES TO UPGRADE OR REPLACE VENDOR SOFTWARE.'

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.*

COMMENTARY

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.

For PAH (WHO Group 1) patients on oral monotherapy

TYVASO: the ONLY inhaled prostacyclin analogue approved for 4x-daily dosing[1]

Short treatment sessions: just 2 to 3 minutes each[2]

ONLY inhaled prostacyclin analogue approved as an add-on to oral PAH monotherapy[1]

- 52% of patients improved 6MWD by greater than 20 m[3]
- Improvement in 6MWD at peak (20 m) and trough (14 m) exposure[3]

Dosing regimen fits into patients' schedules

- Short treatment sessions: just 2 to 3 minutes, 4x daily[2]
- Set up once daily[1,2]
  - —One plastic ampule per day—no need to replace ampule for each treatment session[1]
  - —About 5 minutes a day for device preparation—once in the morning, and the device is ready to go all day[2]
- Treatment timing can be adjusted for planned activities[1]

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[1]

STUDY DESIGN: TRIUMPH I was a 12-week, randomized, double-blind, placebo-controlled, multicenter study of patients (N=235) with PAH who were receiving a stable dose of bosentan or sildenafil for 3 months before study initiation. Patients were administered either placebo or Tyvaso in 4 daily treatment sessions with a target dose of 9 breaths (54 mcg) per session over the course of the 12-week study. Primary endpoint was change in 6MWD at 12 weeks. Secondary endpoints included time to clinical worsening, Borg dyspnea score, NYHA functional class, trough 6MWD at week 12 (obtained at least 4 hours after study drug administration), peak 6MWD at 6 weeks, quality of life as measured by the MLWHF questionnaire, and PAH signs and symptoms.[3]

INDICATION

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

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

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

IMPORTANT SAFETY INFORMATION

- Tyvaso is intended for oral inhalation only. Tyvaso is approved for use only with the Tyvaso Inhalation System
- The safety and efficacy of Tyvaso have not been established in patients with significant underlying lung disease (such as asthma or chronic obstructive pulmonary disease) and in patients under 18 years of age. Patients with acute pulmonary infections should be carefully monitored to detect any worsening of lung disease and loss of drug effect
- Tyvaso may increase the risk of bleeding, particularly in patients receiving anticoagulants
- In patients with low systemic arterial pressure, Tyvaso may cause symptomatic hypotension. The concomitant use of Tyvaso with diuretics, antihypertensives, or other vasodilators may increase the risk of symptomatic hypotension
- Hepatic or renal insufficiency may increase exposure to Tyvaso and decrease tolerability. Tyvaso dosage adjustments may be necessary if inhibitors of CYP2C8 such as gemfibrozil or inducers such as rifampin are added or withdrawn
- The most common adverse events seen with Tyvaso in ≥4% of PAH patients and more than 3% greater than placebo in the placebo-controlled clinical study were cough (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.

6MWD=6-minute walk distance. MLWHF=Minnesota Living With Heart Failure. NYHA=New York Heart Association. WHO=World Health Organization.

References: 1. Tyvaso [package insert]. Research Triangle Park, NC: United Therapeutics Corporation; 2011. **2.** Tyvaso [patient package insert]. Research Triangle Park, NC: United Therapeutics Corporation; 2011. **3.** McLaughlin VV, Benza RL, Rubin LJ, et al. Addition of inhaled treprostinil to oral therapy for pulmonary arterial hypertension: a randomized controlled clinical trial. *J Am Coll Cardiol*. 2010;55(18):1915-1922.

www.tyvaso.com **www.livingpah.com** **1-877-UNITHER**

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United Therapeutics CORPORATION

TYVASO® (treprostinil) INHALATION SOLUTION

PROSTACYCLIN MADE PRACTICAL

Physicians' Secret Struggles

Eating Disorders • *from page 1*

lenging, because of competition, stress, and wildly erratic schedules for eating, sleeping, and self-care, agreed Dr. Jennifer L. Gaudiani, assistant medical director the ACUTE Center for Eating Disorders at Denver Health.

"Temperamental traits such as perfectionism, rigidity, and anxiety can be very useful in the pursuit of a medical career," Dr. Gaudiani said in an interview. "A lot of us share them and have done very well 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.

"Whoosh," said Dr. Gaudiani. "It's a bonfire."

Secrecy complicates 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. Berkus, 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 been 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 neurosis that are involved) and the stress, lack of sleep, and amount of work that involves medical school.

Responses to that posting ranged from notes of encouragement to admonishments about whether a person with an eating disorder can competently serve patients or keep up with the pace of training or practice.

'DENIAL IS PART AND PARCEL OF THE EATING DISORDER MENTALITY, BUT IN DOCTORS, IT RUNS A LITTLE DEEPER.'

Wrote one: *Despite how good a narrative it may seem to you to be bouncing back and striving forward, medicine is an extremely high pressure lifestyle that can wreak havoc on anyone, and stress/sleep/competition are primary triggers for a range of mental illnesses. It does no one any good, not society, not to yourself, to have some med student break down, or a resident wash out, or yet another doctor commit suicide.*

The fear of discovery or being rejected by and drummed out of the profession, casts a dark shadow over those

Continued on following page

COMMENTARY

Dr. Vera De Palo, FCCP, comments: The demands and stresses of the profession of medicine and those of the process of completing the necessary training are significant. Individual responses to those demands and stresses range 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.

Continued from previous page

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.

The most recent study on the prevalence of eating disorders among U.S. medical students was published in December 1985 (J. Nerv. Ment. Dis. 1985;173:734-7). The article reported a 15% lifetime prevalence of an eating disorder among 121 female medical students aged 19-36 years.

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 Midwestern 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 characterized by glimpses of the toll taken on affected individuals. ■

ACUTE Addresses Severe Eating Disorders

A unique, intensive medical stabilization unit for patients with severe eating disorders is expanding, based on high demand, according to Dr. Jennifer L. Gaudiani, 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 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 hypothermia (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 of 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 obvious," 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, 'Aha!' " 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 "rubbing elbows with 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.

Programs Grow to Meet Physicians' Mental Health Needs

BY NEIL OSTERWEIL
IMNG Medical News

NEW YORK – The stigma of mental illness keeps most physicians with burnout or depression from seeking mental health services.

At-risk physicians hesitate to seek care because they don't want to impose on others, they have a tendency toward self-reliance, or they are too wrapped up in their work to pay attention to their own needs. They also worry that breaches in confidentiality could harm their careers, said Dr. Michael Myers, of the department of psychiatry and behavioral sciences at the State University of New York in Brooklyn.

Within the helping professions, among patients and within health care institutions, there is an unspoken denial that even physicians might be subject to the thousand natural shocks that other humans are heir to, Dr. Myers said at the American Psychiatric Association's Institute on Psychiatric Services.

Many patients are ambivalent about being treated by a physician with health issues, making an impaired physician even more leery about getting help. Even some psychiatrists are uncomfortable treating other physicians, he said.

For the physician established in practice, problems may go unaddressed until they have escalated to unmanageable levels and require intervention. The Joint Commission now requires accredited facilities to have a code of conduct defining acceptable behavior and specifying disruptive and inappropriate behaviors, and to have a process or action plan for managing disruptive staff members.

NEIL OSTERWEIL/IMNG MEDICAL MEDIA

Doctors worry that breaches in confidentiality could harm their careers, said Dr. Michael Myers.

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 didactics, 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 overextended and exhausted 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. ■

The Best of Times, the Most Demanding of Times

BY DR. SUHAIL RAOOF, FCCP

At 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 millennial 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 commenced 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 ACCP, 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 station and new Radiology Cases iPad® app with radiographic and pathology images
- 3-hour learning opportunities in the ACCP Simulation Center
- Incentives Spirometer, a fun but serious game
- a NetWorks Open House.

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

Leadership Development

"He who influences the thoughts of his times, 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 each of the six board meetings
- a full-day course of 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 mentorship stories. They exemplify the qualities that make ACCP mentors so magnanimous 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, Jeddah 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 March 2014 in Madrid, in collaboration with Spanish

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Immunosuppressive Therapy Guidelines in *CHEST*

The ACCP Guideline for Immunosuppressive Therapy was published in the November issue of *CHEST*. These guidelines represent the summation of several years of work by the members of the guideline panel, with the support of the ACCP. These guidelines were designed to provide the clinician with useful information to ensure awareness of potential adverse reactions to these drugs and to provide guidance that will allow these drugs to be used safely.

The rationale for creating this document was the perception that an increasing number of patients with pulmonary disease was receiving these drugs for various conditions that include lung transplantation, sarcoidosis, ANCA-associated pulmonary vasculitis, and connective tissue disorders with associated pulmonary fibrosis. As these drugs become more widely used and may not be managed by clinicians in centers that provide specialized care, pulmonary physicians and other caregivers have frequently become more responsible for monitoring the use of these drugs. Additionally, new drugs are being introduced that physicians may not have encountered in their training.

The ACCP guideline provides specific, evidence-based recommendations regarding the appropriate monitoring of patients who are receiving specific drugs, and the recommendations were based on available evidence that has been generated by clinical trials that were often double-blind and placebo-controlled. Although the panel reviewed all available trials for pulmonary disease or lung transplantation published in the medical literature, important evidence from well-conducted trials for nonpulmonary disease or transplantation for other solid organs was also used to develop these recommendations. Evidence tables are included in the guideline and provide researchers in the area an excellent source of supportive information.

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 is a well-known and 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 suggest 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 Ornelas, MS, PhD(c), ACCP Clinical Standards Specialist, at jornelas@chestnet.org. ■

This Month in *CHEST* – Editor's Picks

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

- Oral Treprostinil for the Treatment of PAH in Patients on Background Endothelin Receptor Antagonist and/or Phosphodiesterase Type 5 Inhibitor Therapy (The FREEDOM-C Study): A Randomized Controlled Trial. *By Dr. V. F. Tapson, FCCP et al.*

- Ventilator-Associated Pneumonia Is Characterized by Excessive Release of Neutrophil Proteases in the Lung. *By Dr. T. S. Wilkinson et al.*
- Monthly Follow-ups of Interferon-Gamma Release Assays Among Health-care Workers in Contact With Patients With TB. *By Dr. J. S. Park et al.*
- The Global Burden of Atrial Fibrillation and Stroke: A Systematic Review of the Epidemiology of Atrial Fibrillation in Regions Outside North America and Europe. *By Dr. Gregory Y. H. Lip et al.*

Ahead of the Curve

- Interdisciplinary Collaboration: The Slogan That Must Be Achieved for Models of Delivering Critical Care to Be Successful. *By Dr. R. S. Irwin, Master FCCP et al.*

Evidence-Based Medicine

- American College of Chest Physicians and Society of Thoracic Surgeons Consensus Statement for Evaluation and Management for High-Risk Patients With Stage I Non-small Cell Lung Cancer. *By Dr. J. Donington et al.* ■

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 74th 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 horizons, 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. ■

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.

©ACCP

(L-R) Glenview Village Board Trustee, Paul Detlefs; Immediate Past Chair of The CHEST Foundation, Dr. John C. Alexander Jr., FCCP; ACCP President, Dr. Darcy D. Marciniuk, FCCP; and ACCP EVP/CEO, Paul A. Markowski, CAE.

"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. ■

Critical Care Commentary

Cultural Bias as a Barrier to Recognition of Pain

"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 Canc 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 dyssynchrony, 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

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Pulmonary Perspectives

None Too Soon–Robotics, Screening, and Hope

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 15% 5-year survival is the result (Goldstraw et al. *J Thorac Oncol*. 2007;2[8]:706). 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 not a loser 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;135[2]:247).

Enter da Vinci: not the 15th century genius, but the robot, a four-armed, soldier-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.

A gimmick? 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[4]: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]:1598).

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 in or 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
Owensboro Medical Health System
Owensboro, Kentucky

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characteristics were explored (including age, gender, marital status, experience, degree, and culture), culture stood out against all the other factors in its association with predicting trends in pain perception and treatment. Based on our 40-question survey, providers of Asian descent tended to be more conservative with regard to perceiving and treating pain, and those of African-American and Caucasian descent tended toward more liberal patterns (Gupte et al. *Chest*. 2011;140[4]:877A; Raju et al. *Chest*. 2011;140 [4]: 343A). Adequate pain perception and treatment among the critically ill remain elusive and challenging facets of ICU care, and additional exploration in this area is essential and overdue.

Dr. Jennifer A. LaRosa, FCCP
Associate Director
Div of Pulmonary/Critical Care Med
Director, ICU
Newark Beth Israel Medical Center
Barnabas Health
Newark, NJ

The evaluation and treatment of pain in critical care still remain imperfect. The ability to adequately judge and interpret true pain is still elusive. Dr. LaRosa's fine commentary now introduces a further confounder, "us"; our own cultural bias adds to the confusion. Like all other aspects of care, we tend to ignore our own human component in the issue. As pain is still so imprecise in perception and evaluation, clear standards and interpretation leading to a more standard treatment approach would be advisable.

Dr. Peter Spiro, FCCP
Editor

For twice-daily maintenance treatment of COPD

With **the right fit**, they may get back into **daily living**

Not an actual patient.

The BROVANA® (arformoterol tartrate) basics

◉ Nebulized long-acting beta$_2$-agonist

BROVANA (arformoterol tartrate) should not be used with other medications containing long-acting beta$_2$-agonists.

◉ 12-hour bronchodilation, few daily troughs[1]

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 beta$_2$-agonists, BROVANA can produce paradoxical bronchospasm that may be life-threatening.

◉ Minimal coordination or dexterity required

◉ Covered under Medicare Part B*

◉ 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 beta$_2$-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 beta$_2$-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.

References: 1. Baumgartner RA, Hanania NA, Calhoun WJ, Sahn SA, Sciarappa K, Hanrahan JP. Nebulized arformoterol in patients with COPD: a 12-week, multicenter, randomized, double-blind, double-dummy, placebo- and active-controlled trial. *Clin Ther*. 2007;29(2):261-278. **2.** BROVANA [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; 2012.

Twice-Daily
Brovana® 15 mcg
(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 INHALATION ONLY

BRIEF SUMMARY

WARNING: ASTHMA RELATED DEATH

Long-acting beta$_2$-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 beta$_2$-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).

INDICATIONS AND USAGE

BROVANA (arformoterol tartrate) Inhalation Solution 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.

CONTRAINDICATIONS

BROVANA (arformoterol tartrate) Inhalation Solution is contraindicated in patients with a history of hypersensitivity to arformoterol, racemic formoterol 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**).

WARNINGS

- **ASTHMA RELATED DEATH**
  Long-acting beta$_2$-adrenergic agonists may increase the risk of asthma-related death. 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).
  - A 28-week, placebo-controlled US study comparing the safety of salmeterol with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in patients receiving salmeterol (13/13, 176 in patients treated with salmeterol vs. 3/13, 179 in patients treated with placebo; RR 4.37, 95% CI 1.25, 15.34). The increased risk of asthma-related death may represent a class effect of the long-acting beta$_2$-adrenergic agonists, including BROVANA. No study adequate to determine whether the rate of asthma related death is increased in patients treated with BROVANA has been conducted.
  - Clinical studies with racemic formoterol (Foradil® Aerolizer™) suggested a higher incidence of serious asthma exacerbations in patients who received racemic formoterol than in those who received placebo. The sizes of these studies were not adequate to precisely quantify the differences in serious asthma exacerbation rates between treatment groups.
- **The studies described above enrolled patients with asthma. Data are not available to determine whether the rate of death in patients with COPD is increased by long-acting beta$_2$-adrenergic agonists.**
- **BROVANA is indicated for the long term, twice daily (morning and evening) maintenance treatment for bronchoconstriction in chronic obstructive pulmonary disease (COPD), and is not indicated for the treatment of acute episodes of bronchospasm, i.e., rescue therapy.**
- **BROVANA should not be initiated in patients with acutely deteriorating COPD, which may be a life-threatening condition. The use of BROVANA in this setting is inappropriate.**
- **BROVANA should not be used in children as the safety and efficacy of BROVANA have not been established in pediatric patients.**
- **BROVANA should not be used in conjunction with other inhaled, long-acting beta$_2$-agonists. BROVANA should not be used with other medications containing long-acting beta$_2$-agonists.**
- **When beginning treatment with BROVANA, patients who have been taking inhaled, short-acting beta$_2$-agonists on a regular basis (e.g., four times a day) should be instructed to discontinue the regular use of these drugs and use them only for symptomatic relief of acute respiratory symptoms.**
- **See PRECAUTIONS and Information for Patients.**

Paradoxical Bronchospasm

As with other inhaled beta$_2$-agonists, BROVANA can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, BROVANA should be discontinued immediately and alternative therapy instituted.

Deterioration of Disease

COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If BROVANA no longer controls the symptoms of bronchoconstriction, or the patient's inhaled, short-acting beta$_2$-agonist becomes less effective or the patient needs more inhalation of short-acting beta$_2$-agonist than usual, these may be markers of deterioration of disease. In this setting, a re-evaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dosage of BROVANA beyond the recommended 15 mcg twice daily dose is not appropriate in this situation.

Cardiovascular Effects

BROVANA, like other beta$_2$-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, blood pressure, and/or symptoms. Although such effects are uncommon after administration of BROVANA at the recommended dose, if they occur, the drug may need to be discontinued. In addition, beta-agonists have been reported to produce ECG changes, such as flattening of the T wave, prolongation of the QT_c interval, and ST segment depression. The clinical significance of these findings is unknown. BROVANA, as with other sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension (see **PRECAUTIONS, General**).

Immediate Hypersensitivity Reactions

Immediate hypersensitivity reactions may occur after administration of BROVANA as demonstrated by cases of anaphylactic reaction, urticaria, angioedema, rash and bronchospasm.

Do Not Exceed Recommended Dose

Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. As with other inhaled beta$_2$-adrenergic drugs, BROVANA should not be used more often, at higher doses than recommended, or with other long-acting beta-agonists.

PRECAUTIONS

General

BROVANA (arformoterol tartrate) Inhalation Solution should not be used to treat acute symptoms of COPD. BROVANA has not been studied in the relief of acute symptoms and extra doses should not be used for that purpose. When prescribing BROVANA, the physician should also provide the patient with an inhaled, short-acting beta$_2$-agonist for treatment of COPD symptoms that occur acutely, despite regular twice-daily (morning and evening) use of BROVANA. Patients should also be cautioned that increasing inhaled beta$_2$-agonist use is a signal of deteriorating disease for which prompt medical attention is indicated (see **Information for Patients**).

BROVANA, like other sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually responsive to sympathomimetic amines. Clinically significant changes in systolic and/or diastolic blood pressure, pulse rate and electrocardiograms have been seen infrequently in individual patients in controlled clinical studies with arformoterol tartrate. Doses of the related beta$_2$-agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

Beta-agonist medications may produce significant hypokalemia in some patients, possibly though intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation.

Clinically significant changes in blood glucose and/or serum potassium were infrequent during clinical studies with long-term administration of BROVANA at the recommended dose.

Information for Patients

Patients should be instructed to read the accompanying Medication Guide with each new prescription and refill. Patients should be given the following information:

1. Patients should be informed that long-acting beta$_2$-adrenergic agonists, such as BROVANA, increase the risk of asthma-related death. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication (see **CONTRAINDICATIONS**).
2. BROVANA is not indicated to relieve acute respiratory symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting, beta$_2$-agonist (the health-care provider should prescribe the patient with such medication and instruct the patient in how it should be used). Patients should be instructed to seek medical attention if their symptoms worsen, if BROVANA treatment becomes less effective, or if they need more inhalations of a short-acting beta$_2$-agonist than usual. Patients should not inhale more than one dose at any one time. The daily dosage of BROVANA should not exceed one ready-to-use vial (15 mcg) by inhalation twice daily (30 mcg total daily dose).
3. Patients should be informed that treatment with beta$_2$-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 stored under refrigeration between 2ºC and 8ºC (36º–46ºF). They should not be used after the expiration date stamped on the container. After opening the pouch, unused ready-to-use vials should be returned to, and stored in, the pouch. An opened ready-to-use vial should be used right away. Discard any ready-to-use vial if the solution is not colorless.
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. Women should be advised to contact their physician if they become pregnant or if they are nursing.
8. It is important that patients understand how to use BROVANA appropriately and how it should be used in relation to other medications to treat COPD they are taking.

Drug Interactions

If additional adrenergic drugs are to be administered by any route, they should be used with caution because the pharmacologically predictable sympathetic effects of BROVANA may be potentiated.

When paroxetine, a potent inhibitor of CYP2D6, was co-administered with BROVANA at steady-state, exposure to either drug was not altered. Dosage adjustments of BROVANA are not necessary when the drug is given concomitantly with potent CYP2D6 inhibitors.

Concomitant treatment with methylxanthines (aminophylline, theophylline), steroids, or diuretics may potentiate any hypokalemic effect of adrenergic agonists.

The ECG changes and/or hypokalemia that may result from the administration of non-potassium sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the co-administration of beta-agonists with non-potassium sparing diuretics.

BROVANA, as with other beta$_2$-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QT_c interval because the action of adrenergic agonists on the cardiovascular system may be potentiated by these agents. Drugs that are known to prolong the QT_c interval have an increased risk of ventricular arrhythmias. The concurrent use of intravenously or orally administered methylxanthines (e.g., aminophylline, theophylline) by patients receiving BROVANA has not been completely evaluated. In two combined 12-week placebo controlled trials that included BROVANA doses of 15 mcg twice daily, 25 mcg twice daily, and 50 mcg once daily, 54 of 873 BROVANA-treated subjects received concomitant theophylline at study entry. In a 12-month controlled trial that included a 50 mcg once daily BROVANA dose, 30 of the 528 BROVANA-treated subjects received concomitant theophylline at study entry. In these trials, heart rate and systolic blood pressure were approximately 2-3 bpm and 6-8 mm Hg higher, respectively, in subjects on concomitant theophylline compared with the overall population.

Beta-adrenergic receptor antagonists (beta-blockers) and BROVANA may interfere with the effect of each other when administered concurrently. Beta-blockers not only block the therapeutic effects of beta-agonists, but may produce severe bronchospasm in COPD patients. Therefore, patients with COPD should not normally be treated with beta-blockers. However, under certain circumstances, e.g., as prophylaxis after myocardial infarction, there may be no acceptable alternatives to the use of beta-blockers in patients with COPD. In this setting, cardioselective beta-blockers could be considered, although they should be administered with caution.

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 carcinogenicity study in CD-1 mice, arformoterol caused a dose-related increase in the incidence of uterine and cervical endometrial stromal polyps and stromal cell sarcoma in female mice at oral doses of 1 mg/kg and above (AUC exposure approximately 70 times adult exposure at the maximum recommended daily inhalation dose).

In a 24-month carcinogenicity study in Sprague-Dawley rats, arformoterol caused a statistically significant increase in the incidence of thyroid gland c-cell adenoma and carcinoma in female rats at an inhalation dose of 200 mcg/kg (AUC exposure approximately 130 times adult exposure at the maximum recommended daily inhalation dose). There were no tumor findings with an inhalation dose of 40 mcg/kg (AUC exposure approximately 55 times adult exposure at the maximum recommended daily inhalation dose).

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 10 mg/kg (approximately 2700 times the maximum recommended daily inhalation dose in adults on a mg/m^2 basis).

Pregnancy: Teratogenic Effects

Pregnancy Category C

Arformoterol has been shown to be teratogenic in rats based upon findings of omphalocele (umbilical hernia), a malformation, at 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 at birth and during lactation and decreased pup weights were observed in rats at oral doses of 5 mg/kg and above (AUC exposure approximately 1100 times adult exposure at the maximum recommended daily inhalation dose). Delays in development were evident with an oral dose of 10 mg/kg (AUC exposure approximately 2400 times adult exposure at the maximum recommended daily inhalation dose).

Arformoterol has been shown to be teratogenic in rabbits based upon findings of malpositioned right kidney, a malformation, at oral doses of 20 mg/kg and above (AUC exposure approximately 8400 times adult exposure at the maximum recommended daily inhalation dose). Malformations including brachydactyly, bulbous aorta, and liver cysts were observed at doses of 40 mg/kg and above (approximately 22,000 times the maximum recommended daily inhalation dose in adults on a mg/m^2 basis).

There are 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 human 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

In reproductive studies in rats, arformoterol was excreted in the milk. It is not known whether arformoterol is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when BROVANA is administered to a nursing woman.

Pediatric

BROVANA is approved for use in the long term maintenance treatment of bronchoconstriction associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. This disease does not occur in children. The safety and effectiveness of BROVANA in pediatric patients have not been established.

Geriatric

Of the 873 patients who received BROVANA in two placebo-controlled clinical studies in adults with COPD, 391 (45%) were 65 years of age or older while 96 (11%) were 75 years of age or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Among subjects age 65 years and older, 129 (33%) received BROVANA at the recommended dose of 15 mcg twice daily, while the remainder received higher doses. ECG alerts for ventricular ectopy in patients 65 to ≤75 years of age were comparable among patients receiving 15 mcg twice daily, 25 mcg twice daily, and placebo (3.9%, 5.2%, and 7.1%, respectively).

A higher frequency (12.4%) was observed when BROVANA was dosed at 50 mcg once daily. The clinical significance of this finding is not known. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

Experience in Adult Patients with COPD

Of the 1,456 COPD patients in the two 12-week, placebo-controlled trials, 288 were treated with BROVANA (arformoterol tartrate) Inhalation Solution 15 mcg twice daily and 293 were treated with placebo. Doses of 25 mcg twice daily and 50 mcg once daily were also evaluated. The numbers and percent of patients who reported adverse events were comparable in the 15 mcg twice daily and placebo groups.

The following table shows adverse events where the frequency was greater than or equal to 2% in the BROVANA 15 mcg twice daily group and where the rates of adverse events in the BROVANA 15 mcg twice daily group exceeded placebo. Ten adverse events demonstrated a dose relationship: asthenia, fever, bronchitis, COPD, headache, vomiting, hyperkalemia, leukocytosis, nervousness, and tremor.

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 their expertise to assist our members and advance the mission of the College.*


DR. BENTON

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'll 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 those 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

Continued from previous page

others have done in your community, especially and specifically the specialists who have successfully implemented systems.

It is essential that you understand that while no one wants to spend more than necessary for an EMR, getting a suboptimal system because of cost-containment issues can cost immeasurably more than spending more money up front and getting the right system for you.

The ACCP does not endorse specific EMR products.

I am not aware of any currently available product that incorporates a fully developed suite of pulmonary and sleep templates. This would be extremely difficult to do, because the individual and regional preferences regarding content and workflow are so varied (they're usually quite diverse even within a single practice) that it's almost impossible to invest the effort in creating something to please everyone.

As such, something user-friendly, easy to modify, simple (simple simple simple), and relatively easy to learn, with good support from the vendor, is usually the best you can hope for. Cheap is nice also, if you can find it. This is notwithstanding many important and often mysterious issues related to hardware needs, on-site vs off-site hosting, data backup, etc.

My personal experience (and this information is not endorsed by the ACCP or anyone else) includes eClinicalWorks (pretty easy to use and customize, but with many limitations; inexpensive; widely used; offering decent support); NextGen (more rigidly templated and harder to use, lots of bells and whistles, expensive); athenahealth (expensive but you get tremendous back-office support, EMR still being developed, clearly one of the most intelligently designed systems); and Allscripts (I hear lots of good and bad things, no personal experience yet). These things can change in an instant, so be aware that some of this information may be very inaccurate by the time you see it.

This is one of those situations where it is essential that someone in your practice needs to assume a substantial burden of responsibility in performing the due diligence necessary to make some difficult decisions. It will be time very well spent. ■

In Remembrance

Harold Clifton Urschel Jr., MD, FCCP, a 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 to 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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Email CV: **cindy.baeder@piedmont.org** or call 770-801-2703, **www.piedmont.org**

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University of South Carolina School of Medicine

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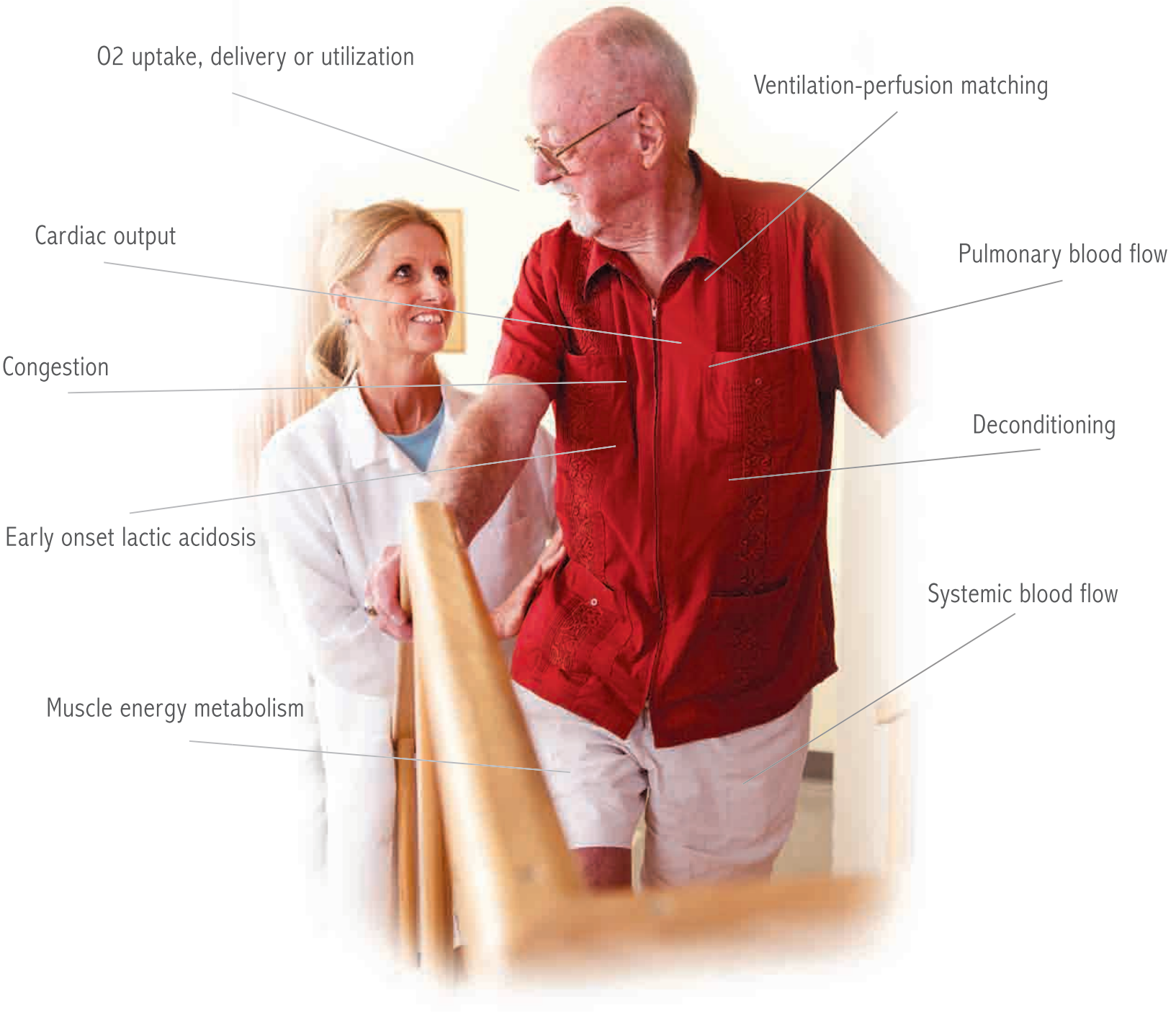

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