COC Director Thomas Frieden, shown here getting his flu shot, reminded physicians that community protection begins with them.

Physician, Vaccinate Thyself Against Flu

BY HEIDI SPLEMENT
Elsevier Global Medical News

WASHINGTON – Flu vaccination rates in the United States are up, and more health care professionals are leading by example, Dr. Thomas Frieden, director of the Centers for Disease Control and Prevention, said at a press conference at the end of September.

The annual flu vaccine is never perfect, but “we can say with certainty that the best way to protect yourself, your family, and your community is to get a flu shot,” Dr. Frieden said.

Approximately 90 million doses of vaccine are currently available, and 170 million doses are expected this year, Dr. Frieden said. Availability of the flu vaccine should not be a concern this year, and now is a great time for health care professionals and the public to get their flu vaccines, he added.

Last year, approximately 43% of Americans aged 6 months and older were vaccinated; 8 million more than the previous year, and more than ever before, Dr. Frieden said. The recommendations for flu vaccination remain the same as last year: “Everyone aged 6 months and older should get the flu vaccine, this year and every year,” Dr. Frieden said. He emphasized that flu shots are necessary each year, even though the strains of flu in this year’s vaccine and the viruses seen so far this year are the same as for the 2010-2011 season.

“You need this year’s flu shot to protect you against this year’s flu,” he said. One shot should protect against the flu for the duration of the season, but protection does wane and can’t be expected to carry over year to year, he explained.

This year, there are four types of flu vaccine available: the traditional intramuscular injection, a nasal spray, a high-dose injection for adults aged 65 years and older, and a new intradermal vaccine featuring a barely noticeable needle. The intradermal vaccine is only approved for use in individuals aged 18-64 years.

See Vaccinate • page 4

Endosonography For NSCLC Staging Effective, Cheaper
Patient quality of life scores higher.

BY MITCHEL L. ZOLER
Elsevier Global Medical News

AMSTERDAM – Initial endosonographic assessment of mediastinal lymph node metastases in patients with resectable non-small cell lung cancer surpassed initial surgical staging not just in clinical outcomes but also with lower cost and better quality of life in a controlled, head-to-head comparison of the two approaches.

“Given that assessment of lymph nodes by the endoscopic approach was more effective [and] better tolerated by patients, and seems cheaper than the surgical approach, we recommend that endoscopic tests be used, reserving surgical tests as a backup if endoscopy does not show evidence of cancer,” Dr. Robert C. Rintoul said in presenting the results of a follow-up analysis at the World Conference on Lung Cancer.

“We think this is the way forward, and that this will change practice globally,” said Dr. Rintoul, lead physician for thoracic oncology at Papworth Hospital in Cambridge, England.

He reported new data and addressed implications of the overall weight of evidence now available from ASTER (Assessment of Surgical Staging vs. Endoscopic Ultrasound in Lung Cancer: A Randomized Clinical Trial) that was conducted in patients with potentially resectable NSCLC.

Although the overall weight of evidence now in from ASTER uniformly favors endosonography first, perhaps the most noteworthy findings from the study were those included in a report in JAMA last November: Endosonography first cut the rate of unnecessary thoracotomies to 7% compared with an 18% rate in patients with potentially resectable NSCLC.

See Endosonography • page 8

Cardiothoracic Surgery Losing Ground

BY BRUCE JANCIN
Elsevier Global Medical News

COLORADO SPRINGS – Is the United States truly headed for a workforce crisis in cardiothoracic surgery by 2020, as many of the field’s leaders now warn? The U.S. cardiothoracic surgery workforce is relatively old. Many practitioners are nearing retirement at a time of unprecedented demand for their services, as the baby boomers hit their Medicare years. Meanwhile, the specialty’s popularity as a career choice has plummeted. It’s shaping up as a “perfect storm” set to crest at the end of this decade, Dr. Sean C. Grondin, FCCP, said at the annual meeting of the Western Thoracic Surgical Association.

But this storm is not inevitable. It can be averted through a multifaceted effort that includes better mentoring programs to attract talented young people to the specialty, more emphasis on preparing instructors in surgery to teach effectively, perhaps increased reliance upon international labor.
COMMENTARY
Just Stop Smoking

I give the Food and Drug Administration a “B” on their recent action to make cigarette packages more unattractive and to require truthful labeling. The FDA has not been given sufficient resources to accomplish this monumental task. Congress could have made the cigarette industry pay for the costs of implementing this legislation, but instead, they provided the FDA with the barest minimum of funding. The fact that the FDA was able to take this action at all is a testament to their dedication and hard work.

Plainly put, the United States is a Third World country when it comes to warning about cigarettes. Similar pictorial warnings have been used in China, Korea, Pakistan, and Argentina for almost a decade. Australia, almost all of the European Union countries, and even Uruguay have similar warnings. Having said that, we do know that pictures speak louder than words and may help motivate smokers to quit. But here is the hard reality: Even though nearly every available cigarette brand contains these warning signs, few people actually read the labels. One reason is that the warnings are not placed on the packs, but rather on the inside of the packages. Another reason is that the warnings are often covered up by the cigarettes themselves.

Thus, we are left with the question: What can be done to make cigarette packaging more effective? One solution is to require a pictorial warning on the front of each cigarette pack. This would allow people to see the warnings as they are about to purchase cigarettes, and it would help to remind them of the dangers of smoking. Additionally, requiring that the warnings be placed on the outside of the packages would make it easier for smokers to read them.

In conclusion, while the FDA’s recent action is a step in the right direction, more needs to be done to make cigarette packaging more effective. The FDA should be given the resources it needs to carry out this task, and the public should be educated about the dangers of smoking. Only then will we be able to make significant progress in reducing the number of smokers in this country.

Dr. Cummings is the director of the New York State Smokers’ Quitline and a senior research scientist at the Roswell Park Cancer Institute, Buffalo, N.Y.
Soviet-Era Drug Proved Effective in First Modern Study

Unlike other pharmacotherapies for smoking cessation, cytisine is inexpensive.

BY MARY ANN MOON Elsevier Global Medical News

The compound cytisine, an extract of acacia seeds that has been used in Eastern Europe for more than 40 years as an aid to smoking cessation, was found effective in the first placebo-controlled randomized trial of the agent that meets modern regulatory standards, according to a report in the Sept. 29 issue of the New England Journal of Medicine.

Cytisine is a partial agonist that binds with high affinity to a subtype of the nicotinic acetylcholine receptor, which is also the primary target of the smoking-cessation drug varenicline. It has been available across Eastern Europe under the brand name Tabex since 1964, said Robert West, Ph.D., of the Cancer Research U.K. Health Behavior Research Centre, department of epidemiology and public health, University College London, and his associates.

Because of its "unusual history of development," no preclinical studies, dosing studies, or large comparative trials have been reported to date. "We conducted a study to assess cytisine's efficacy and safety in a context that could be replicated globally, with a relatively short treatment course (25 days) and minimal contact with health professionals," they noted.

Their aim was to determine whether the agent would be particularly beneficial for the millions of smokers who live in "countries in which the average household income is less than $200 per week," who live in "countries in which the average smoker's household income is less than $200 per week," and who live in "countries in which the average smoker's household income is less than $200 per week," as defined in the 2005-2010 National Health Interview Survey.

This included a baseline clinic visit where the drug was dispensed, telephone calls from staff on the target quit day (day 5) and 1 week later, a clinic visit 1 month after the target quit date, further follow-up calls, and a clinic visit for those who remained abstinent at 6 and 12 months following the conclusion of treatment.

The study participants were adults who smoked 10 or more cigarettes per day and were willing to try to stop smoking permanently. At baseline, all reported heavy smoking and showed high concentrations of carbon monoxide in exhaled breath, and all scored high on the Fagerstrom Test for Nicotine Dependence. Approximately half the study subjects were manual workers, and more than 80% said they had tried to quit smoking previously.

The primary efficacy outcome was 12 months of smoking cessation and abstinence after the end of treatment. This rate was 8.4% with cytisine, significantly better than the 2.4% rate with placebo.

"The net improvement in the abstinence rate with cytisine was 6 percentage points. The relative rate of abstinence in the cytisine group as compared with that in the placebo group was 3.4," Dr. West and his colleagues said (N. Engl. J. Med. 2011;365:1193-200).

This 3.4 relative difference in smoking cessation between cytisine and placebo "was higher than previous studies have shown for varenicline (2.3) and nicotine-replacement therapy (1.6). However, the absolute difference in the rate of abstinence between participants receiving cytisine and those receiving placebo in this trial (6 percentage points) was lower than that shown for varenicline and similar to that shown for nicotine-replacement therapy," they noted.

The rates of drug discontinuation or dose reduction were similar between subjects taking the active drug and those taking placebo. There were no serious adverse effects attributed to cytisine. The incidence of minor gastrointestinal adverse effects, chiefly stomach ache, dyspepsia, and nausea, was higher with cytisine than with placebo.

Using more intensive behavioral support along with cytisine may improve absolute quit rates. "Also, the treatment period was only 4 weeks, as compared with 8 weeks for nicotine-replacement therapy and 12 weeks for varenicline, and it is possible that efficacy could be improved by a longer regimen," the investigators added.

CDC: Smokers Smoking Less

BY FRANCES CORREIA Elsevier Global Medical News

Adult smokers in the United States are smoking fewer cigarettes, according to a report released by the Centers for Disease Control and Prevention.

The proportion of smokers who said they smoked 30 or more cigarettes daily decreased from 12.7% to 8.3%, according to CDC data for 2005-2010. Also, more smokers said they were smoking nine or fewer cigarettes daily, with an increase from 16.4% to 21.8%. The number of adult smokers also declined from 20.9% to 19.3%, representing nearly 3 million fewer smokers.

Even as smoking prevalence has decreased overall, the data vary according to race/ethnicity, age, level of education, region, and poverty status (MMWR 2011;60:1-6). Smoking prevalence was lowest among Hispanics (12.5%) and Asians (9.2%), seniors (9.3%), those with a graduate degree (6.3%), and residents of the West (15.9%). The highest prevalence was among American Indians/Alaska Natives (25.4%) and adults aged 25-44 years (22%), General Education Development (GED) certificate recipients (45.2%), and residents of the Midwest (21.8%). Categorized by poverty status, 18.3% of those at or above the poverty level smoked, compared with 28.9% of those below the poverty level.

Although smoking appears to be decreasing nationwide, the CDC said the rates have decreased more slowly in the past 5 years. A lack of investment in antismoking programs reaps significant health care savings. For example, California has invested about $2.8 billion in antismoking efforts since 1988. During that same period, the state has saved nearly $86 billion in related health care costs and saw adult smoking rates decrease by about 50%, Dr. McAfee said.

Smoking costs the United States $193 billion annually, nearly equally divided between medical costs and loss of productivity, according to the CDC.

In addition to increased financial support for antismoking initiatives, the CDC recommends that more states place higher taxes on tobacco products and increase smoke-free policies and clinical interventions. As of 2011, 26 states and the District of Columbia have comprehensive smoke-free laws, according to the CDC. Another 18 states have smoking restrictions at work sites, in restaurants, or in bars. Also, 25 states have added clean air laws that make smoking in public more difficult, Dr. McAfee said.

The report is based on data from the CDC's 2005-2010 National Health Interview Surveys and the 2010 Behavioral Risk Factor Surveillance System survey. The analysis does not include data for underage smokers.
Still Room for Improvement on Flu Shot Goals

The 63.5% rate in health care personnel fell short of the Healthy People 2020 goal of 90%.

By Diane Mahoney

Despite recent improvements in influenza vaccination rates among U.S. health care personnel, their rates for the 2010-2011 flu season still fell short of national health objectives, a new survey has shown.

Similarly, although the record-high influenza vaccination levels among pregnant women during the 2009-2010 influenza season were sustained during the 2010-2011 season, vaccination levels in that group also remained well below the “Healthy People 2020” target of 80% coverage for pregnant women, Dr. Carolyn Bridges said during a telebriefing on the survey results.

Influenza vaccination among all health care personnel for the 2010-2011 season was 63.5%, representing an increase over the 61.9% reported for the previous year. But that rate still fell short of the Healthy People 2020 coverage goal of 90%, said Dr. Bridges of the National Center for Immunization and Respiratory Diseases.

The most recent season’s results come from an Internet-based survey of 1,931 health care personnel, which the Centers for Disease Control and Prevention and the Rand Corp. conducted in April 2011.

“The vaccination rates were highest among physicians, health care personnel working in hospital settings, and those aged 60 years and older,” Dr. Bridges reported.

Among the 13% of survey respondents whose workplace required influenza vaccination, the coverage rate was 98%, compared with 58% among the remaining respondents whose employers had no such requirement.

In the absence of mandatory workplace immunization, offering the vaccine onsite at work, free of charge, and on more than one day were associated with an increased likelihood of influenza vaccination, Dr. Bridges said.

Onsite vaccination in particular was a “key strategy,” she said, noting that the coverage rate among respondents who had the onsite option was 66%, compared with 38% among those who did not.

With respect to influenza vaccine during pregnancy, the CDC and Rand estimated coverage for the 2010-2011 season using data from an Internet panel survey, also conducted in April 2011, among 1,457 pregnant women who were pregnant any time between October 2010 and January 2011.

In all, 49% of respondents reported receiving the vaccine, including 32% who received it during pregnancy and 17% who received it before or after pregnancy,” said Dr. Bridges. The rate is comparable to the 50% coverage rate reported for the previous influenza season, in response to the 2009 H1N1 influenza pandemic. And it was significantly higher than the consistently low rates of approximately 15% reported in prior seasons, she said.

Pregnant women whose providers offered them the influenza vaccine were approximately five times more likely to get vaccinated than those whose providers did not, “which is consistent with other studies,” Dr. Bridges said.

Despite the fact that the influenza vaccine given during pregnancy has been shown to decrease illness in mothers and decrease the risk of influenza and hospitalization in newborns younger than 6 months old who are too young to get the vaccine, “out of 10 women reported not receiving an offer for vaccination from their providers,” she reported.

An assessment of pregnant women’s attitudes and beliefs about vaccination during pregnancy determined that their top two concerns were safety risks to the baby and the possibility of getting influenza from the vaccine, Dr. Bridges stated. “Women who were offered the vaccine by their providers were more likely to have a positive attitude about the vaccine and its safety, she said.

The findings of both studies are reported in Morbidity and Mortality Weekly Report (2011;60:1073-7; 1078-82). Dr. Bridges reported no conflicts of interest with respect to the data presented.

Lead by Example With a Flu Shot

Vaccinate • from page 1

Approximately 51% of children in the United States received a flu vaccine last year, Dr. Frieden noted, which represents a 7% increase over the previous year. Although the news on vaccination rates is encouraging, “it is critical to continue to make progress; there are too many illnesses and deaths from influenza each year,” he said.

Pediatric specialists have an important role to play in raising these rates higher, said Dr. O. Marion Burton, president of the American Academy of Pediatrics.

Pediatricians are normally the first, and sometimes the only contact that some families have with a health care provider,” Dr. Burton said. “Every child needs an influenza vaccine if they are 6 months of age or older,” he said. The only contraindication is for children who have had Guillain-Barré syndrome after an immunization in the past, he said.

And children with a moderate to high fever or febrile illness should not be vaccinated until subsides, he said. Young children aged 6 months to 8 years who received one dose of flu vaccine last year need only one dose this year, because the vaccine formula is the same, said Dr. Burton. But children aged 6 months to 8 years who are being vaccinated for the first time this year should receive two doses at least 4 weeks apart.

Dr. William Schaffner, president of the National Foundation for Infectious Diseases (NFID), noted that vaccination rates are up among health care workers and that doctors are getting better about recommending flu vaccination to their patients.

A total of 68% of adults said that a health care professional recommended that they get a flu vaccination this year, up from 58% in 2010 and 38% in 2008, according to a nationwide telephone survey of 1,006 adults conducted by the NFID. Approximately 60% of adults who were vaccinated last year said that they did so because a health care profession specifically recommended it.

Vaccination rates in health care professionals themselves are up to approximately 63%, Dr. Schaffner said, but there is room for improvement. “There are a lot of health care professionals who still don’t understand that it’s a patient safety issue,” he noted. “And among some health care professionals, there is that persistent myth that you can get the flu from the flu vaccine, which is incorrect,” he said.

Leadership from the top is essential to improving vaccination rates in health care professionals, Dr. Schaffner said. For example, “A strong senior administrator who makes it clear that we are going to make our hospital environment absolutely as safe as possible for our patients,” which means that flu vaccination is expected, “is essential for increasing flu vaccination among health care professionals,” he said.

To help encourage vaccination this year, the NFID introduced a “leading by example” initiative that calls on health care professionals as well as community and business leaders to get vaccinated themselves as an example to their employees and colleagues.

Dr. Frieden set an example by getting his flu shot live during the press conference. “It didn’t hurt a bit,” he said.

The press conference was sponsored by the NFID. For the latest information on the 2011-2012 flu season, visit www.cdc.gov/flu or www.flu.gov.
Unusual Swine Flu Cases Have H1N1 Links

BY SHARON WORCESTER
Elsevier Global Medical News

Two swine-origin influenza A (H1N2) virus strains that triggered febrile respiratory illness in two children this summer contain genetic material from the 2009 influenza A (H1N1) virus – a genetic reassortment that hasn’t been seen before, according to the Centers for Disease Control and Prevention.

The report coincides with the Food and Drug Administration’s approval of a new in vitro diagnostic kit for seasonal influenza and novel influenza A viruses with pandemic potential. The kit will be distributed at no cost to qualified international public health laboratories.

Both of the H1N2 cases were reported in August. There were no epidemiologic links between the cases, and no other human infections with the virus have been detected, although investigations are ongoing, according to the CDC’s report (MMWR 2011;60:1-4).

The first case involved a boy younger than 5 years, who has since recovered. The Indiana State Department of Health Laboratories reported the case Aug. 17.

The child, who had received flu vaccine in September 2010, presented in July 2011 with fever, cough, shortness of breath, diarrhea, and sore throat. A respiratory specimen taken at a local emergency department tested positive for influenza A (H1). Further testing of the specimen, including testing by the CDC, confirmed swine-origin influenza A (H1N2).

The child had no direct exposure to swine, but a caretaker of the child reported direct contact with asymptomatic swine in the weeks before onset of the boy’s illness.

On Aug. 24, the Pennsylvania Department of Health reported the second case, which involved a girl younger than 5 years who also has completely recovered. That child also had received influenza vaccine in September 2010, and presented in August 2011 with acute onset of fever, nonproductive cough, and lethargy. A nasopharyngeal swab at a local emergency department was positive for influenza A. Additional testing, including genome sequencing by the CDC, confirmed the virus as swine-origin influenza A (H1N2).

The girl had recently visited an agricultural fair, where she had direct exposure to swine and other animals.

The two viruses are similar but not identical, the CDC reported.

"Seven of the eight gene segments, including the hemagglutinin (HA) and neuraminidase (NA) genes, are similar to those of swine H1N2 influenza viruses circulating, among U.S. pigs since 1998 and previously identified in the eight other sporadic cases of human infections with swine-origin influenza A (H1N2) viruses in the United States since 2009," the authors of the report noted.

There’s a notable difference from those eight earlier cases, however: The two new viruses have a matrix gene from the 2009 influenza A (H1N1) virus, which has replaced the matrix gene found in the previous eight swine-origin infections in humans.

Although reassortment between swine influenza and 2009 influenza A (H1N1) had been reported in pigs, that particular genetic combination of swine influenza virus segments is unique, and has not been previously reported in swine or humans.

Researchers have since identified two additional influenza A (H1N2) isolates from swine containing the M gene from the 2009 influenza A (H1N1) virus. Those isolates are undergoing genome sequencing to characterize their genetic composition.

Although nothing is known about the new viral strains’ ability to transmit efficiently in humans or swine, or between swine and humans, they have been found to be resistant to amantadine and rimantadine. They are susceptible, however, to the neuraminidase inhibitor drugs oseltamivir and zanamivir.

The CDC offered clinicians the following diagnostic and treatment recommendations:

- If influenza virus infection is suspected in an individual with recent exposure to swine, a nasopharyngeal swab should be obtained for timely diagnosis at a state public health laboratory.
- Empiric neuraminidase inhibitor antiviral treatment should be considered to quickly limit potential human transmission.

New Test Could Speed Diagnosis

The newly approved diagnostic test – the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel – uses a three-module design that incorporates and streamlines previous versions of the CDC’s two separate FDA-cleared diagnostic test kits.

- The first module identifies and distinguishes influenza A and B viruses. The second module classifies influenza A viruses, including subtypes as H1N1, H3N2, or 2009 H1N1. The third module detects highly pathogenic avian influenza A (H5N1) viral infection in human respiratory tract specimens.

DATA WATCH

Pulmonologists’ Median Income Rose 4.1% in 2010

Note: 2010 figure based on survey data for 253 general pulmonologists in 107 group practices

Source: Medical Group Management Association

Most Children Who Died From Flu Weren’t Vaccinated

BY HEIDI SLEPTE
Elsevier Global Medical News

Nearly half the flu-related deaths in children last year occurred in those younger than 5 years, and only 23% of eligible children had been vaccinated, according to the Centers for Disease Control and Prevention.

A total of 115 flu-related deaths in children younger than age 18 years were reported to the CDC between September 2010 and August 2011. Of these, 56 (49%) had no known high-risk medical conditions as defined by the CDC’s Advisory Committee on Immunization Practices. Only 17 children (23%) had been fully vaccinated, based on data from the 74 children aged 6 months and older for whom vaccination information was available (MMWR 2011;60:1233-38).

The median age of the patients who died was 6 years, and 53 deaths (46%) occurred in children under 5 years. Overall, 71 cases (62%) were associated with influenza A viruses and 44 (38%) with influenza B viruses.

“Influenza B was identified in a disproportionate number of pediatric influenza-associated deaths,” although only 26% of the circulating viruses during the 2010-2011 flu season were influenza B, the researchers noted. The percentage of influenza B viruses in flu-related pediatric deaths has been equal or greater than the percentage of influenza B circulating virus for that season, they said.

The data are subject to the limitations of the current surveillance system, the researchers noted. But the report emphasizes the need for continued surveillance. The CDC continues to recommend annual flu vaccinations for all children aged 6 months and older.

The MMWR also included a report on flu activity in the United States and worldwide from May 22, 2011, through Sept. 3, 2011 (MMWR 2011;60:1239-41). In the United States, 122 respiratory specimens were positive for influenza, including 87 cases of influenza A and 35 of influenza B. Flu viruses were reported in 24 states during this period, and they were different from the currently circulating H1N2 virus.

Worldwide, the 2009 H1N1 virus was the dominant circulating virus in Australia, while influenza B viruses dominated in New Zealand. The 2009 H1N1 virus also dominated cases in southern Africa, while the influenza A H3N2 was the dominant virus in Asia during this period.

Dr. Burt Lesnick, FCCP comments: Every high-risk patient deserves timely administration of influenza vaccine. We should not lose opportunities to protect our patients by assuming that their primary care providers will do so.
SABR Ups Survival in Elderly With Early NSCLC

BY MITCHEL L. ZOLER
Elsevier Global Medical News

AMSTERDAM – Wide adoption of stereotactic ablative radiation as radiotherapy for elderly patients with stage 1 non-small cell lung cancer in the Netherlands produced a dramatic rise in overall survival during the last decade.

Dutch national data showed that median overall survival in patients aged 75 year or older with stage 1 NSCLC that was treated with radiation therapy jumped from 17 months in 2001-2003 to 26 months in 2007-2009 (P = .001), an improvement largely attributable to substantially increased use of stereotactic ablative radiation therapy (SABR), Dr. Cornelis J.A. Haasbeek said at the World Conference on Lung Cancer, which was sponsored by the International Association for the Study of Lung Cancer.

Dutch radiation oncologists began using SABR in 2003, and by 2009 more than 75% of early-stage NSCLC patients who received radiation therapy had it in the form of SABR.

“Our study provides high-level evidence to support the efficacy of modern SABR,” said Dr. Haasbeek, a radiation oncologist at Vrije Universiteit Medisch Centrum, Amsterdam.

SABR cut the number of treatments needed, compared with conventional radiotherapy, by 5- to 10-fold while also boosting efficacy, and is an option for patients who are too frail to undergo surgical resection of their cancer. SABR is also a reasonable option for selected operable patients, said Dr. Suresh Senan, professor and vice chairman of radiation oncology at Vrije Universiteit Amsterdam and senior investigator of the new report.

“The emerging data say that SABR is an option in patients who do not want to accept the risks of surgery.”

DR. SENAN

One drawback of SABR compared with surgery is less-extensive long-term experience. “We have no track record of more than 5 years in a substantial number of patients, so there may still be surprises on recurrences,” he said.

“Surgery has the advantages of allowing for accurate tissue diagnosis and intraoperative staging,” commented Dr. David A. Waller, a thoracic surgeon at Glenfield Hospital in Leicester, England.

“Surgical resections are generally performed in patients who have neither surgery nor radiation therapy. Patients with surgical resections had a median overall survival of 36 months in 2001-2003; median survival has not yet been reached in patients who had surgery between 2007-2009.

The better median survival in the surgery patients is due in part to the superior physical status of patients eligible for surgery, Dr. Haasbeek said.

Patients who had neither surgery nor radiation therapy had a similar, poor median survival of about 7 months.

Dr. Senan has received honoraria as a speaker for and his department received research support from Varian Medical Systems. Dr. Haasbeek had no disclosures.

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Elderly NSCLC Patients May Benefit From Doublet

Chemotherapy with a platinum-based doublet was associated with a highly significant 36% reduction in mortality, compared with monotherapy, among elderly patients with non-small cell lung cancer in a study published by the Lancet.

The combination of carboplatin and paclitaxel was associated with more toxicity than was single-drug vinorelbine or gemcitabine regimens in the phase III trial, but the investigators contended that this was outweighed by the survival benefit.

Median overall survival for patients receiving carboplatin plus paclitaxel was 10.3 months, compared with 6.2 months in those randomized to monotherapy (hazard ratio, 0.64; P less than .0001).

Although several guidelines currently recommend monotherapy for elderly patients, the current finding is “of such magnitude that we believe the treatment paradigm for elderly patients with advanced NSCLC should be reconsidered,” wrote Dr. Elisabeth Quoix of the Hôpitaux Universitaires de Strasbourg (France) and colleagues (Lancet 2011 Aug. 9 [doi:10.1016/S0140-6736(11)60780-0]).

The investigators from the IFCT (Inergroupe Francophone de Cancérologie Thoracique) looked at 451 patients aged 70-89 years (median age, 77 years) with unresectable stage IV NSCLC or stage III disease that was “unsuitable” for radical radiation therapy. Patients were followed for a median of 30.3 months. To be included in the study, patients had to have severe disease and a life expectancy of at least 12 weeks.

The 225 patients who were randomized to the doublet chemotherapy group received intravenous carboplatin (AUC [area under the curve] = 6), on day 1, plus 90 mg/m² of paclitaxel on days 1, 8, and 15 of 28-day cycles.

The 226-patient monotherapy cohort received 25 mg/m² vinorelbine (62 patients) on days 1 and 8 – or 1,150 mg/m² gemcitabine (164 patients) on days 1 and 8 – of 21-day cycles, with the choice of either vinorelbine or gemcitabine being made by the institution conducting the therapy.

By 1 year, the survival rate was 25.4% in the monotherapy group vs. 44.5% in the doublet therapy group (HR, 0.64; P less than .0001). The trend persisted at 2 years, with the probability of survival being 11.7% in monotherapy recipients and 22.4% in those receiving doublet therapy, wrote the authors.

Median progression-free survival also was significantly longer with the doublet (6 months vs. 2.8 months; P less than .0001). In 2009, an independent data-monitoring committee recommended stopping recruitment based on the second interim analysis.

“Grade 3-4 neutropenia, febrile neutropenia, thrombopenia, and anemia were significantly more frequent among patients in the doublet chemotherapy group than among those in the monotherapy group, as was grade 3-4 sensory neuropathy,” wrote the authors.

The protocol did not allow growth factor support in the first cycle, but it was authorized as secondary prophylaxis in patients who developed grade 3 or 4 neutropenia.

In all, 10 deaths in the doublet therapy group (4.4%) and 1 in the monotherapy group (1.3%) were related to treatment: Culprit diagnoses included sepsis, respiratory distress, and diarrhea related to renal insufficiency. But the percentage of deaths in the first 3 months after the start of therapy was “markedly lower” in patients who received carboplatin plus paclitaxel.

Although quality of life scores at week 18 were similar between groups, the authors pointed out that “role functioning and fatigue were worse in the doublet chemotherapy group than in the monotherapy group” (P = .026 and .039, respectively). Full quality of life data will be published separately, they said.

The 2009 American Society of Clinical Oncology guidelines (J. Clin. Oncol. 2009;27:6251-66) recommend that age “not be used as a criterion in the decision-making process about whether to treat a patient” and call for further research devoted to elderly patients, according to Dr. Quoix and colleagues. “Conversely,” they noted, “the European Organisation for Research and Treatment of Cancer Elderly Task Force and Lung Cancer Group and International Society of Geriatric Oncology highlighted in 2010 that monotherapy should be given to elderly patients with advanced NSCLC.”

“We believe that monthly carboplatin and weekly paclitaxel is a feasible option for first-line therapy of advanced NSCLC in patients older than 70 years with performance status scores of 0-2,” the authors wrote.

The study was funded by the IFCT and the French National Cancer Institute, with support by grants from Bristol-Myers Squibb, Roche, and Pierre Fabre. Several authors, including Dr. Quoix, disclosed financial relationships with the makers of chemotherapy drugs, including carboplatin (Bristol-Myers Squibb, Roche, and Lilly).

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Patients assessed by mediastinoscopy first (P = .02). In addition, patients considered high risk in the high-risk group. Only 18% underwent lobectomy and another 6% received segmentectomy, while 76% had a wedge resection.

"There were less than one-tenth as many segmentectomies as wedges in the high-risk patients. So, really, what you’ve shown is that a lesser operation – or you might even say our least good operation – can safely be done in high-risk patients. The question now is, is that lesser operation better than SBRT? Because if it’s not, then SBRT will probably win that argument. I have to say, I think we have a better chance of winning out over SBRT with surgery if we’re comparing it to segmentectomy than if we’re comparing it to wedge," said Dr. Shragar, professor and chief of the division of thoracic surgery at Stanford (Calif.) University.

Dr. Wolf replied that, like Dr. Shragar, she and her coinvestigators were "surprised" at the high rate of wedge resection because thoracic surgeons at Brigham and Women’s Hospital tend to promote anatomic resection whenever possible. She suspects some of the wedges were performed in an effort to spare parenchyma when a tumor bordered segmental boundaries.

Dr. Shragar also took the Boston surgeons to task for the fact that only 38% of high-risk patients in the series underwent lymph node sampling.

"Short of a proven survival advantage for surgery over SBRT, which we don’t have yet, all we can say is at least we’re providing better lymph node staging. So why not more lymph node sampling?" Dr. Shragar asked.

Dr. Wolf said this, too, came as a surprise to her and her colleagues. The most likely explanation is that in many instances patients and surgeons sought smaller, quicker operations in an effort to spare the patient. But given the compelling evidence showing that lymph node sampling is critical for accurate staging and for determining the need for adjunctive therapy, that’s not an adequate excuse.

"Going forward, we’re very interested in making sure patients are sampled, even with wedge resections," she said.

Dr. Wolf declared having no financial conflicts.

Noninvasive Staging

Endosonography • from page 1

patients assessed by mediastinoscopy first (P = .02). In addition, 45% of patients evaluated by endosonography first had positive lymph nodes and so avoided mediastinoscopy (JAMA 2010;304:2245-52).

"A few years ago, people said all these patients needed mediastinoscopy. What we’ve learned [from ASTER] is that about half never need mediastinoscopy. That is practice changing," commented Dr. Richard Gralla, chief of hematology oncology at North Shore–Long Island Jewish Health System in New Hyde Park, N.Y. "As a rule, patients find [endobronchial ultrasound–guided transbronchial needle aspiration] and EUS [transesophageal ultrasound–guided fine-needle aspiration] much simpler procedures," compared with mediastinoscopy, he noted at the meeting, which was sponsored by the International Association for the Study of Lung Cancer.

The ASTER results published last year proved so compelling that many surgeons and thoracic oncologists already switched to endosonography first, noted Dr. Joekie T. Annema, a thoracic surgeon at Leiden (the Netherlands) University and lead ASTER investigator.

"EBUS is the new standard," he said in an interview, noting that earlier this year the Dutch agency responsible for setting medical policy adopted endosonography as the preferred initial method for lymph node assessment in patients with resectable NSCLC. The National Institute for Health and Clinical Evidence (NICE), which sets U.K. health policies, did not name endosonography as the preferred initial staging method for lung cancer in its revised guidelines last April because the cost-effectiveness findings reported at the meeting had not yet been published, Dr. Rintoul said.

ASTER randomized 118 patients to initial mediastinoscopy and 123 to initial endosonographic staging at four medical centers in the United Kingdom, the Netherlands, and Belgium. Results showed that initial endosonography followed by surgical staging in patients initially found to be node negative had 94% sensitivity for positive lymph nodes, which was significantly better than the 79% sensitivity rate using mediastinoscopy first (P = .02).

The additional analyses reported by Dr. Rintoul used patient quality of life assessment by the EQ-5D (EuroQol five-domain) instrument at baseline, immediately after staging, and again at 2 and 6 months after staging. Researchers ran EQ-5D assessments on 144 of the study’s 241 patients at baseline, and on 124 patients after 6 months. The results showed similar average EQ-5D scores at baseline and after 2 and 6 months; however, immediately after staging, the endosonography-first patients had a statistically significant improvement in average quality of life (0.117 EQ-5D units), compared with those staged by mediastinoscopy first (P = .003).

Average medical costs rung up by patients over the 6 months of treatment after baseline were about $746 (about $1,200) less per patient using endosonography first, a difference that was not statistically significant but suggested that endosonographic staging produced better cost-effectiveness, Dr. Rintoul said. He also reported that initial endosonography led to an average of 0.015 quality-adjusted life-years, an advantage over initial surgical staging that just missed statistical significance (P = .052).

ASTER received no commercial support, and Dr. Rintoul said that he had no disclosures. He said that Papworth Hospital has received unrestricted educational grants and equipment loans from Olympus. Dr. Gralla and Dr. Annema had no disclosures.
Donor Lung Allocation Faulted

BY BRUCE JANCIN
Elsevier Global Medical News

COLORADO SPRINGS – A disproportionate share of donor lungs goes to local, low-priority recipients, according to an analysis of data from the United Network for Organ Sharing. The current lung allocation system results in a high proportion of donor organs being distributed to low-priority candidates who often receive little survival benefit from their transplant. Meanwhile, higher-priority candidates who might derive more benefit from transplantation continue to die at high rates on the waiting list, Dr. Alexander Iribarne said at the annual meeting of the Western Thoracic Surgical Association.

He presented an argument for the sharing of donor lungs over a broader geographical range in the United States. The analysis involved all 7,171 U.S. lung transplants done between May 2005 and the end of 2010.

May 2005 was chosen as the starting date because that’s when the Lung Allocation Score (LAS) was introduced as a measure for allocating organs on the basis of medical urgency rather than waiting time. An LAS score lower than 50 defines a transplant candidate as low priority; a score of 50-75 is considered intermediate, and an LAS greater than 75 is high priority.

Among the 5,544 transplants done in low-priority recipients, 54% of the donor organs were allocated locally, 17% regionally, and 29% nationally. In contrast, 40% of the 1,016 transplants in recipients with an LAS of 50-75 at the time of surgery were allocated locally; as were 33% of the donor organs used in patients with an LAS over 75.

What’s happening is that when an organ becomes available in one of the less-populated local donor service areas, there’s a lower likelihood that a suitable higher-priority candidate will be in place than in a more populous donor service area, said Dr. Iribarne of Columbia University, New York.

As a result, the organ often goes to a local patient with an LAS under 50. The UNOS data showed that in donor service areas with a population of fewer than 6.1 million, nearly 75% of locally allocated lungs went to patients with an LAS under 50. In local donor service areas with a population in excess of 10.3 million people, a greater percentage are allocated to higher-priority recipients, Dr. Iribarne said.

The next step should be to determine whether organ sharing across broader geographical areas results in higher rates of lung allocation to higher-priority candidates, he added. Dr. Iribarne declared having no financial conflicts.

Today, the incidence of asthma and complicated airway diseases in America is rising faster than nearly any other chronic disease. Tackling diseases that so significantly impact public health requires the most innovative clinical thinking and a dedication to discovering the underlying causes.

In addition to providing state-of-the-art clinical care, Yale-New Haven Hospital has teamed with Yale School of Medicine to create a research hub where industry-sponsored and investigator-initiated studies are continually underway. Our physicians in the Yale Center for Asthma and Airways Disease are at the forefront of groundbreaking research, such as studies that highlight the potential role of the chitinase-like protein YKL-40 as novel biomarkers in asthma. This research suggests that this protein could be useful to identify asthmatics or to characterize disease severity. Other studies have focused on the pathogenesis of refractory asthma, the vascular basis of asthma and the natural history of asthma.

With their research as the backbone for providing exceptional treatments, our physicians are making life better for our patients with complex airway diseases and for patients everywhere.

Yale New Haven Hospital is the primary teaching hospital of Yale School of Medicine. Pulmonology services at Yale-New Haven were ranked 22nd by U.S. News & World Report in 2011-12.
FDA Approves Arcapta Neohaler for COPD Patients

BY EMILY HAYES
Elsevier Global Medical News

The Food and Drug Administration has approved the Arcapta Neohaler for chronic obstructive pulmonary disease, albeit at a single and much lower dose than the two doses originally sought.

Novartis AG’s Arcapta (indacaterol inhalation powder) was approved at a 75-mcg once-daily dose for long-term maintenance treatment of airflow obstruction in COPD, including chronic bronchitis and/or emphysema, the FDA announced.

The long-acting beta2-adrenergic agonist helps muscles around the airways of the lungs stay relaxed in order to prevent symptoms of COPD.

As expected, a boxed warning in labeling and a medication guide note that the LABA class increases the risk of asthma-related death and that the bronchodilator is not indicated for asthma.

The approval was hard won, following much debate about the appropriate minimum dose for good efficacy and following a “complete” response letter in October 2009. Novartis had most recently been pushing for approval of two doses: 75 mcg and 150 mcg. But safety concerns for the LABA class in patients with asthma have been high on the agency’s radar.

The FDA’s Pulmonary-Allergy Drugs Advisory Committee voted in March for the approval of the 75-mcg dose only.

In its original New Drug Application in 2008, Novartis sought approval for 150-mcg and 300-mcg doses, which were subsequently approved in Europe. But the FDA’s “complete response” letter contended that these doses were high and questioned the supporting data.

In response, Novartis lowered its requested doses to 75 mcg and 150 mcg and submitted additional data from six confirmatory trials in more than 5,000 patients, who had a smoking history of at least a pack a day for 10 years and moderate to severe decreases in lung function, the FDA noted in its announcement of the approval. In the six trials, efficacy was measured based on changes in forced expiratory volume testing. With this measure, all doses tested (75 mcg, 150 mcg, 300 mcg, and 600 mcg) showed improvements in lung function at 12 weeks, compared with placebo, the label notes.

The label also notes that pooled data from the six studies show an improvement in health-related quality of life, based on patients’ results on the St. George’s Respiratory Questionnaire. Although the quality of life data showed an advantage for the higher dose, in the end, the FDA advisory committee was not persuaded that the 150-mcg dose had an efficacy advantage that would balance the higher risks.

Novartis intends to launch the drug in the first quarter of 2012.

Ms. HAYES is with “The Pink Sheet.” This newspaper and “The Pink Sheet” are published by Elsevier.
Smoking Speeds Loss of Lung Function in COPD

BY JEFFREY S. EISENBERG
Elsevier Global Medical News

The rate of change in forced expiratory volume in 1 second among current smokers, patients with COPD is highly variable, with the greatest rates of decline occurring among current smokers, patients with bronchodilator reversibility, and those with emphysema, according to an analysis of data from the ECLIPSE observational study.

Research in the 1970s established that patients with COPD experience an accelerated decline in FEV1, yet few longitudinal studies have provided detailed data about this decline.

Dr. Jørgen Vestbo of the University of Copenhagen and his colleagues analyzed data collected for the Evaluation of COPD Longitudinally to Identify Predictive Surrogate Endpoints (ECLIPSE) study, which included 2,163 patients aged 40-75 years who had a smoking history of 10 or more pack-years and 40% of the predicted value and ratio of FEV1 to forced vital capacity (FVC) of 0.7 or less (N. Engl. J. Med. 2011 Sept. 26 [doi:10.1056/NEJMoA1105482]). Specifically, the researchers analyzed changes in FEV1 after bronchodilator use at baseline, 3 months, 6 months, and then every 6 months for 3 years. They defined subgroups according to the presence of emphysema and chronic bronchitis, bronchodilator reversibility, and cardiovascular disease. They also obtained serum and plasma samples for the following biomarkers: C-reactive protein, interleukin-8, interleukin-6, fibrinogen, tumor necrosis factor-alpha, surfactant protein D, and Clara cell secretory protein 16 (CC-16).

The rate of FEV1 was highly variable during the 3-year period, the results showed. Overall, there was a mean decline of 33 mL/year. More specifically, 38% of patients had a decline of more than 40 mL/year, 31% had a decline of 21-40 mL/year, 23% had changes ranging from a decline of 20 mL/year to an increase of 20 mL/year, and 8% had an increase of more than 20 mL/year.

The researchers also found an inverse relationship between the declines in FEV1 and stage of disease, as defined by the Global Initiative for Chronic Obstructive Lung Disease (GOLD). Mean rates of decline were 35 mL/year in patients with severe disease (GOLD stage 2), 33 mL/year in patients with severe disease (GOLD stage 3), and 25 mL/year in patients with very severe disease (GOLD stage 4).

Smoking status was most strongly associated with the rate of decline, with current smokers experiencing a decline of 21 mL/year more than former smokers. However, cumulative exposure did not affect future decline.

Among the subgroups studied, FEV1 declined by 17 mL more per year in patients with bronchodilator reversibility at baseline, compared with those without reversibility. Also, FEV1 declined by an additional 13 mL/year in patients with clinically significant emphysema versus those with little or no emphysema. The presence of cardiovascular disease had no effect on FEV1.

Although several biomarkers were associated with FEV1, only CC-16 levels were significantly associated with the rate of change in FEV1, with an additional decline of 4 mL/year for each decrease of 1 standard deviation in the level of CC-16, but the association was weak, the researchers said.

The study findings call into question whether COPD is invariably progressive. “COPD may ‘burn out’ or at least stabilize for periods of 3 years or more, which would be good news for patients and could influence a variety of management decisions that depend on prognosis.” A limitation of the study was that it included only patients with moderate, severe, or very severe COPD, and therefore could not identify factors associated with rates of decline in early-stage COPD.

Also, the study was purely observational and did not include treatment. “Our results may not extend beyond this patient population for a variety of reasons, including the clinically determined care they received,” the researchers said.

The study was supported by grants from GlaxoSmithKline to Dr. Vestbo and several coauthors. Some of the coauthors are employees of and own stock in GlaxoSmithKline. All coauthors reported ties to numerous pharmaceutical companies.

INDICATION
Tyvaso is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability.

PULMONARY MEDICINE
For the treatment of PAH (WHO Group 1) to improve exercise ability

For your PAH patients on oral monotherapy, effective inhaled prostanooid add-on is ACHIEVABLE

Additional improvements in 6MWD when added to oral monotherapy

Four-times-daily dosing

Treatment timing can be adjusted for planned activities

Patient-friendly features with the lightweight, portable, handheld Tyvaso Inhalation System

The most common adverse events seen with Tyvaso in 24% 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.

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 CYP3A4 such as grapefruit 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 (9% vs 11%), flushing (5% 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
NYHA: New York Heart Association
WHO: World Health Organization

I'm a numbers guy. A picture paints a thousand words, then numbers, for me, equate to tens of thousands of words. Accordingly, we use numbers a lot at the College to track our progress. The ACCP strategic plan features rigorous key performance indicators for leaders and staff to readily see changes and trends and focus on what matters most. While numbers may not tell an entire story, they can tell us a lot. With that in mind, the following numbers illuminate the ACCP in a way that would be difficult to do with words alone.

- Total number of members in 2001: 15,256
- Total number of members: 18,172
- Total number of international members: 3,556
- Current number of members in India: 370
- Current number of members in Uganda: 1
- Total number of attendees at the CHEST 2000 annual meeting: 3,840
- Total number of attendees at the CHEST 2010 annual meeting: 4,721
- Total number of international attendees at the CHEST 2000 annual meeting: 768
- Total number of international attendees at the CHEST 2010 annual meeting: 1,383
- Number of staff working at ACCP headquarters in 2001: 62
- Current number of staff working at ACCP headquarters: 84
- CME credits offered in 2001: 268
- CME credits offered in 2010: 627
- Participants claiming CME in 2000: 2,131; in 2010: 3,794
- Percentage of lecture-based programming in 2001: 100
- Percentage of lecture-based programming in 2011: 49
- Number of manuscripts submitted to the CHEST journal in 2000: 1,980
- Number of manuscripts submitted to the CHEST journal in 2010: 3,300
- Ranking of the CHEST journal among respiratory journals in 2000: 8th (Journal Citation Reports®)
- Ranking of the CHEST journal among respiratory journals in 2010: 3rd (Journal Citation Reports®)
- Number of ACCP apps in 2008: 0
- Current number of ACCP apps: 3
- Fans on Facebook: 1,515
- Current number of fans on Facebook: 1,515

In summary, the ACCP is a national organization with a membership base that is growing rapidly. The College has made significant strides in recent years, and we have a clear path forward. The ACCP is committed to providing members with the tools and resources they need to succeed in their careers and to advance the field of pulmonary, critical care, and sleep medicine.
Product of the Month

ACCP-SEEK® App: Now Offered as CME Edition

Various volumes of ACCP-SEEK® have been available as an app for iPhone®, iPad®, and iPod touch® for 2 years, but, until now, the downside to the app as compared with the book has been the app’s lack of CME credit. The ACCP is pleased to release a new app that addresses this need: ACCP-SEEK®. The app features complete questions from the just-released ACCP-SEEK® Volume XXI: Pulmonary Medicine book and allows users to earn 50 CME credits on completion of all in-app questions and an online posttest. Like the print volume, the ACCP-SEEK® app costs $199.99—less than $4/credit. Users can download the app and sample 10 case-based questions for free via the App Store. The app retains all the same great features as the original: search and browse questions by keyword, star questions for follow-up, record text and audio notes, link to references in an online browser, and more.

The original, non-CME-eligible app has also been updated to include the same case-based questions from the ACCP-SEEK® Volume XXI: Pulmonary Medicine print book. Because CME is not available for any activities performed in this app, sets of 10 questions are available for the reduced price of $4.99.

Download ACCP-SEEK®, CME and start on your way to 50 CME credits at http://bit.ly/SEEKCMETCME.


This Month in CHEST: Editor’s Picks

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

Original Research

- Diagnosis of Pneumothorax by Radiography and Ultrasonography: A Meta-analysis. By Dr. W. Ding et al.
- Surgical Management and Outcomes of Elderly Patients With Early Stage Non-small Cell Lung Cancer: A Nested Case-Control Study. By Dr. C. Rivera et al.
- Mitral Annular Calcification Predicts Cardiovascular Morbidity and Mortality in Middle-aged Patients With Atrial Fibrillation: The Belgrano Atrial Fibrillation Study. By Dr. T. S. Potpara et al.

Point/COUNTERPOINT EDITORIALS

- Point: Should Tele-ICU Services Be Eligible for Professional Fee Billing? Yes. Tele-ICUs and the Triple Aim. By Dr. M. M. McCambridge et al.
- No. By Dr. S. Hoffman.

Vaccination Pocket Guides

Pocket guides for health professionals on the latest recommendations for influenza and pneumococcal vaccines are now available from the Immunization Action Coalition. The "2011-12 Influenza Vaccine Pocket Information Guide" reflects the most current recommendations and issues in use for the vaccine. These include (1) rationale for why it is important to get this year’s vaccine, even though the vaccine viruses did not change from the previous year; (2) which children need two doses of vaccine; (3) vaccination of persons with egg allergy; (4) the addition of an intradermal form of inactivated vaccine; and (5) the different age indications for the various vaccine products.

The “Pneumococcal Polyvalent Vaccine Pocket Guide” is also available. The card is the same as the card distributed last year, as there are no changes in the recommendations.

Both pocket guides are available at no cost. To order either or both pocket guides in quantity, go to http://www.immunize.org/pocketguides/.

For up-to-date information on influenza, visit the Web site of the National Influenza Vaccine Summit at www.preventinfluenza.org.
Suhail Raoof, MBBS, FCCP, will be inaugurated as the 74th President of the American College of Chest Physicians during the Convocation Ceremony at CHEST 2011. He is Professor of Clinical Medicine at Well Medical College of Columbia University and Chief of Pulmonary/Critical Care and Sleep Medicine, Medical Director of Respiratory Therapy, and Vice-Chairman of the Department of Medicine at New York Methodist Hospital in Brooklyn, New York.

Dr. Raoof obtained his medical degree from Maulana Azad Medical College, Delhi University, India. He completed his residency on Long Island Jewish Medical Center in New York, followed by a fellowship in pulmonary and critical care medicine at the State University of New York at Stony Brook and its affiliated hospitals.

Dr. Raoof has served the ACCP in many capacities, including Chair of the US and Canadian Council of Governors, Chair of the Membership Committee, member-at-large of the Board of Regents, Chair of the CHEST 2008 Annual Scientific Program Committee, Chair of the Council of Committees, Chair of the Global Education Track for CHEST 2010, ACCP representative to the American College of Radiology, and ACCP representative to the European Respiratory Society’s multisociety effort to develop noninvasive ventilation guidelines.

Dr. Raoof’s academic interests include mechanical ventilation and chest radiology for pulmonologists. Dr. Raoof is the recipient of many honors, including Master of the American College of Physicians (MACP). Dr. Raoof’s vision for the ACCP during his term will be to continue to promote the ACCP as a leader in clinical chest medicine and make available to the membership cutting-edge initiatives to deliver evidence-based medical education.

He plans to facilitate the development of problem-based learning modules for clinicians in chest radiology. He also endeavors to keep the membership informed of new and emerging health-care needs, so they can incorporate the latest medical practices in their day-to-day patient care and continue with the College for their recertification, licensure, and educational needs. Dr. Raoof will promote leadership development and mentorship within the College. He will continue to strengthen collaboration with strategic international partners. Finally, by promoting the OneBreath™ Campaign, he hopes to encourage virtual participation of the lay public through social media and increase awareness of pulmonary diseases and develop new partnerships with health-care societies and others.

We asked Dr. Raoof about his vision for this upcoming presidential year.

What would you like to accomplish as President of the ACCP?

The last 2 years have defined a new paradigm in how the ACCP Presidents operate. As part of a concerted 3-year plan that commenced when I was elected President Designate, I will continue to promote diversity in every aspect of the College, facilitate in redefining the work of the NetWorks and Governors, and foster transparency and openness. These are important projects that were initiated by our prior two Presidents—Drs. Guntupalli and Gutterman. Strengthening ties with targeted international partners (societies, individuals, and industry), and strategic international regions will continue to evolve. As the needs of our membership grow, the College will continue to retool and refine educational projects, including simulation, train-the-trainers, and certificate of completion programs, and provide multiple mediums of educational content to its members. It will also be my endeavor to strengthen our collaboration with sister organizations, such as the ATS, CTS, SCCM, ACP, AACN, and ERS. Perhaps the most important project that we have launched is “mentorship and leadership development.” As a College, we should strive to instill in our members the ability to act as agents of change and to inspire and mentor others to rise to the fullest potential. And finally, the infrastructure of the College requires a strong financial base. The EVP/CEO, Board of Regents, and the Presidents have the fiduciary oversight responsibility for the College, which I will take very seriously.

What do you consider to be the greatest strengths of the ACCP, and how will you build upon these during your Presidency?

The greatest strengths of the College are its excellence in imparting clinically focused, high quality chest education globally, its networking opportunities; the continuous stream of new and innovative ideas that emanate in a timely fashion from the collaborative team efforts between dedicated physician membership and talented staff, and its warm and welcoming collegial atmosphere.

Simulation education, train-the-trainer, and certificate of completion courses, clinical practice guidelines, performance improvement modules, and Web-based educational content should be made available to the entire membership locally and globally. A new association management system (AMS) that supports and integrates with a new content management system (CMS) and learning management system (LMS) will leverage technology platforms to complement the vast educational content provided at our live courses for physicians and nonphysician health-care providers. Team-based training will enhance our members’ knowledge and equip them with tools to better provide patient-focused and evidence-based care to their patients. Incorporating social media will allow dissemination of information to diversified generations and groups throughout the cross-section of ACCP membership, and new ACCP e-communities will enhance communication among leadership, members, and sister organizations. It will be my utmost endeavor during my presidency to uphold the principles of governance dedicated to transparency, economic effectiveness, and commitment to the mission, vision, and core values of the ACCP.

What are some challenges facing the ACCP, and how will you address these challenges?

While there are several issues that confront the College, including shifting revenue streams, changing generational needs of the membership, retention of members and expansion of the membership base, health-care reform, workforce shortage, and redefinition of an integrated team approach, I would like to focus on the changing health-care landscape and poor public awareness of pulmonary diseases.

Health-care reform has introduced a sense of insecurity and “fear of the unknown” in our members, especially those in private practice. The College is poignantly aware that its members expect their professional society to have its ear to the ground so that it can monitor the changing health-care landscape and provide important and accurate information and balanced, well-thought-out remedial measures, so members can react appropriately, adapt proactively, and develop solutions expeditiously. We are in the process of setting up an intricate infrastructure under the Governors that will utilize grassroots education within the entire spectrum of College leadership, as well as designated staff for advocacy and regulatory issues. The members of the Chest Medicine Affairs Committee will energize and inform...
Saturation and POCs, New Role for Affiliates, Interventional Pulmonology

Airways Disorders
Saturation in Portable Oxygen Concentrators
AG is a 75-year-old woman diagnosed with COPD 2 years earlier. Her room air oxygen saturation is 90% to 91% at rest. Treadmill oxygen titration revealed desaturation below 88%. She was prescribed 3 L via nasal cannula with saturation increasing to 94% at rest and 92% with exercise. Her physician decides to prescribe 3L via nasal cannula. Oxygen equipment was delivered to her home. She wanted portable equipment for daily activity and traveling and chose a light piece (6 lbs) portable oxygen concentrator (POC) that delivers 3L via pulsed flow.

Today, she is complaining that the POC does not feel the same as her home equipment or the oxygen she received when the treadmill titration was performed.

This, unfortunately, is too common a situation that arises in practice. Many POCs deliver only pulsed oxygen with only a few delivering continuous flow, and these tend to be larger and heavier and not preferred by patients. Although the technology is improving, pulsed-dose oxygen does not deliver the same oxygen concentration as continuous flow. Thus, 3L delivered from wall oxygen is not the same as 3L from POC with pulsed flow.

Patients should have oxygen saturation tested during activity while receiving pulsed-dose oxygen. Moreover, pulsed flow should not be used during sleep. POC flow is measured by nasal inhalation, and mouth breathers will not get oxygen flow.

Most POCs also are not capable of delivering an adequate saturation level nocturnally for the patient. Continuous flow should generally be prescribed for sleep.

What matters are not the liters but the saturation, taking into account patients’ preferences.

Dr. Rubin Cohen, FCCP
NetWork Vice-Chair

Affiliate
New Role for the Affiliate NetWork
At its June meeting, the ACCP Board of Regents approved a recommendation to evolve the Affiliate NetWork into a standing committee of the ACCP. The new Training and Transitions (T&T) Committee will expand on the previous role of the Affiliate NetWork to oversee a greater number of educational activities within the College. These will include:

▶ Continue to provide a structure for Affiliate members to actively participate in the College.

▶ Overseer all fellows’ courses presented by the ACCP.

▶ Create and implement a successful Leadership Development program.

▶ Develop a sustainable mentoring and coaching program for Affiliate members.

▶ Monitor educational and resource needs of Affiliate members.

▶ Oversee the CHEST Challenge program.

▶ Create resources to assist members in career decisions and development of Affiliate members.

This new committee will work closely with NetWorks, the Education Committee, and other key groups within the ACCP to meet its educational mission. To ensure proper representation of our Affiliate members, the committee’s policy stipulates that at least three members of the Training and Transitions Committee be ACCP Affiliate members, and at least three members must be either Program Directors or Associate Program Directors at their home institution.

We are very excited to see this expanded role and value the ACCP’s recognition and support of training and developing our professional society’s future leaders.

If you have interest in getting involved in the ACCP’s Training and Transitions Committee, please contact Rachel Guterman at rsguterman@chestnet.org.

Dr. Jack Buckley, FCCP
NetWork Chair

Interventional Chest/Diagnostic Procedures
The Evolution of Interventional Pulmonology
What began as rigid bronchoscopy over 50 years ago has been transformed into interventional pulmonology (IP) this century. This domain largely falls under the purview of specialty-trained pulmonary medicine physicians and general thoracic surgeons. The field has evolved to include interventions directed toward the diagnosis, treatment, and staging of a variety of disease processes, including thoracic cancers, tracheobronchial obstruction, small airways disease, and pleural processes.

The field requires a multidisciplinary approach, as the problems are often quite complex and span several medical subspecialties. To this end, close collaboration between pulmonology and general thoracic surgeons trained in advanced IP techniques is essential.

Specifically, emerging technologies, such as endobronchial ultrasound and navigational bronchoscopy, are gaining widespread acceptance as important diagnostics that are routinely employed by IP practitioners.

More importantly, care centers interested in developing an IP program should focus not simply on IP technicians but also highly trained nursing, respiratory therapy, and anesthesia teams.

Dr. Sudish Murthy, FCCP
NetWork Chair

Pulmonary Vascular Disease
Exercise and Pulmonary Hypertension
The role of exercise in the diagnosis and treatment of pulmonary arterial hypertension (PAH) has evolved.

Years ago, patients were encouraged to minimize their activity to avoid overwhelming the stressed right ventricle. With the advent of agents to treat PAH, this approach has changed.

The benefits of pulmonary rehabilitation are well established for left ventricular systolic dysfunction. Recent studies suggest similar findings for right ventricular dysfunction. For example, Menees et al. (Circulation. 2006;114[14]1482) demonstrated that patients with PAH benefited from guided exercise training as measured by the 6-min walk test, VO2 max, workload at anaerobic threshold, and quality of life. This program utilized stationary cycling, walking, and low impact weight training and was closely supervised.

Pulmonary hemodynamic response to exercise may identify patients with PAH who have normal or modest elevation of pulmonary artery pressure (PAP) at rest.

Tolle and colleagues (Circulation. 2008;118[21]2183) identified a subset of patients with heightened pulmonary artery catheterization and cardiopulmonary exercise testing. They found a subset of patients with normal resting PAP who developed increased PAP and pulmonary vascular resistance with exercise.

Saggar and colleagues (Arthritis Rheum. 2010;62[12]:3741) examined patients with scleroderma and normal resting pulmonary hemodynamics. They found distinctive patterns that included normal response, pulmonary venous hypertension, and exercise-associated PAH.

These findings suggest that exercise may be beneficial to patients with known PAH and may help to diagnose PAH earlier in a patient’s course.

Dr. Victor Test, FCCP
NetWork Steering Committee Member
Pulmonary hypertension (PH) is a serious disease that arises from several different etiologies: pulmonary vascular, lung, or cardiac diseases. In addition to chronic disorders, acute events, such as acute respiratory distress syndrome (ARDS), pulmonary embolism, acute left ventricular dysfunction, or cardiovascular surgery, can also cause PH (Zamanian et al. Crit Care Med. 2007; 35(9):2037). PH occurs primarily through the down-regulation of endogenous vasodilators (nitric oxide and prostacyclin) and the up-regulation of the endogenous vasoconstrictor endothelin-1 (Weitzel and Chaouat). Pulmonary Circulation: Diseases and Their Treatment. 2nd Edition. New York, NY: Oxford University Press, 2004-376; Ishikawa et al. J Thorac Cardiovasc Surg. 1995; 110(1):271. The consequence of this imbalance is increased pulmonary vascular resistance (PVR), eventually leading to right ventricular hypertrophy and ischemia. Systemic vasodilators, while effective in decreasing pulmonary artery pressure (PAP) and PVR, may induce systemic hypotension and worsen right ventricular function. Local administration of vasodilators through inhalation can reduce PAP and PVR with minimal effects on systemic arterial pressure. In addition, inhaled vasodilators may improve arterial oxygenation by redistributing pulmonary blood flow to ventilated areas of the lung and reduce intrapulmonary shunt (Lowson. Anesthesiology. 2002;6(4):1504; Kemmig et al. Eur Surg Res. 2002;34(1-2):196).

Inhaled nitric oxide (iNO) was the first inhaled vasodilator investigated and has gained widespread off-label clinical use for PH due to various causes (Lowson. Anesthesiology. 2002;96(6):1504; Kemmig G. Eur Surg Res. 2002;34(1-2):196). Nitric oxide (NO) is a gaseous molecule that is synthesized endogenously from the amino acid L-arginine via nitric oxide synthase. The primary effects of NO include vasodilation of pulmonary vessels secondary to activation of soluble guanylate cyclase, inhibition of platelet aggregation and leukocyte adherence, and modulation of bronchomotor tone (Riddell and Owens. Vasa. 1999;57:25).

Hickey and Kubus. Exp Physiol. 1997;82(2):338. Giudic and Saleh. N Engl J Med. 1995;4(214). NO has a half-life of about 3 to 5 s, and standard doses used in clinical practice range from 3 to 40 ppm (Ignarro. Circ. Res. 1989;65(1):1; Dellinger et Crit Care Med. 1998;26(1):5). NO is inactivated via hemoglobin. Methemoglobinemia can be a byproduct, but this is uncommon with doses < 40 ppm (Jindal and Dellinger. J Lab Clin Med. 2000;136(21). Although several trials have evaluated iNO for acute lung injury (ALI), none have demonstrated significant mortality benefit (Taylor et al. JAMA. 2004;291(11):1609; Jindal and Dellinger. J Lab Clin Med. 2000;136:21). In addition, its use is limited by cost and need for special delivery equipment. As such, there is a growing interest in other alternative agents, such as aerosolized prostacyclin (prostaglandin I2, epoprostenol). Epoprostenol (PGI2), a prostacyclin derivative, is formed by arachidonic acid metabolism. It stimulates adenylate cyclase receptors to activate cyclic adenosine monophosphate and protein kinase A, resulting in smooth muscle relaxation and pulmonary vasodilation. PGI2 has a short half-life of 3 to 6 min, with the most common adverse effect from systemic administration being hypotension (see Fiolair® package insert). Epoprostenol can cause systemic adverse effects while effectively achieving pulmonary vasodilation (Siobal. Anesthesiology. 2002;96(6):640). Additionally, epoprostenol has no known toxic metabolites, and its inhalation could be considerably safer and cheaper than iNO (De Wet et al. J Thorac Cardiovasc Surg. 2004;127(1058).

**INO vs PGI2: Pulmonary Hypertension**

Inhaled PGI2 was compared with iNO for the management of primary (n=77) and secondary (n=5) PH. All patients received PGI2 at increasing doses of 15 to 50 ng/kg/min for a period of 20 min with a 10 min washout between doses, while eight patients received iNO at doses of 10 to 100 ppm, as well as IV prostacyclin at doses of 1 to 5 ng/kg/. Hemodynamic measurements were taken before, during, and after each treatment. Nebulized PGI2 produced greater decreases in PAP (54 ± 5 to 44 ± 5 mm Hg, P = 0.0005) compared with iNO (54 ± 5 to 48 ± 5 mm Hg, P = 0.02) as well as PVR (38% vs 12%, respectively, P = 0.001). A dose-dependent effect of inhaled PGI2 was identified, which suggests that lower doses could be used to attain significant response. There was no change in systemic arterial pressure with either agent (Michael. Eur Heart J. 1997;18(9):1499). Short-term effects of aerosolized PGI2 (52-115 mcg/kg/min), iNO (10-28 ppm), and iloprost were compared in six patients with PH. PGI2 was nebulized for 15 min and resulted in greater reduction in pulmonary hemodynamics: PAP (18%), PVR (41%) (P < .05). There was a significant improvement in CO and SvO2, and a nonsignificant change in systemic arterial pressure (Olshewski. Ann Intern Med. 1996;124(9):820). Another study evaluated short-term response after 10 min of aerosolized PGI2 (20-30 mcg via nebulization) compared with iNO (40 ppm) in 10 patients with PH awaiting heart transplantation. Both PGI2 and iNO had a similar effect on mean PAP (17% reduction) and PVR (49% vs 43% reduction, respectively), while PGI2 had a significantly greater effect on CO (11% increase vs 0%) (Haraldsson. Chest. 1998;114(3):780).

**INO vs PGI2: Following Cardiothoracic or Transplant Surgery**

Inhaled PGI2 (1 mcg/min) and iNO (20 ppm) were examined in 58 inpatients treated with mitral valve stenosis and elevated PVR after mitral valve surgery. Drugs were given for 30 min followed by a 15-min washout. PGI2 and iNO significantly reduced PVR (25% vs 17%, respectively), mean PAP (20% vs 19%, respectively), and transpulmonary gradient (TPG) (64% vs 62%, respectively) (Fattouch et al. J Surg Card. 2005;20(2):171). These authors also reported significant reductions in mean PAP and PVR with inhaled PGI2 and iNO compared with systemic therapy, as well as significant improvements in cardiac indices, weaning from cardiopulmonary bypass, and shorter intubation times and ICU stay (Fattouch et al. J Cardiovasc Med. 2006;7(2):119).

Inhaled PGI2 has also been evaluated following lung and heart transplantation in 25 patients who were randomized to inhaled PGI2 (20,000 ng/ml) or iNO (20 ppm) as initial therapy, followed by a crossover to the other agent after 6 h. Both PGI2 and iNO similarly improved hemodynamics (cardiac index [CI], central venous pressure [CVP], SvO2) and PAP initially and at the 6-h crossover trial (change in mean PAP: 13 ± 1 mm Hg, 95% CI 9-16 and 12 ± 1 mm Hg, 95% CI 9-15, respectively, P = .32). Neither agent affected the oxygenation index or systemic blood pressure (Khan. J Thorac Cardiovasc Surg. 2009;138(6):1417).

**INO vs PGI2: ARDS**

Five patients with hypoxemia secondary to ARDS were examined after receiving 30 min of either iNO (10 ppm) or aerosolized PGI2 (50 ng/kg/min) in a crossover study. The increase in PaO2 post PGI2 therapy (29%) compared with iNO (12%) was not statistically significant (P = .06). Hemodynamic parameters (mean arterial pressure, CI, CVP, pulmonary capillary wedge pressure) and shunt fraction did not change significantly (van Heerden et al. Anesth Analg. 1996;24(5):564). Inhalation of NO and PGI2 was compared in a dose-response study in eight patients with ARDS (1, 4, 8 ppm and 1, 10, 25 ng/kg/min for 15 min each, respectively). PGI2 resulted in significant, dose-dependent reduction in mean PAP while iNO did so only at 4 and 8 ppm. PGI2 reduced PVR by 20% at 10 ng/kg/min only, while iNO had no significant effect on PVR. Increases in PaO2 were significant with PGI2 doses of 10 (+18%) and 25 (+ 24%) ng/kg/min and all doses of iNO, with 8 ppm resulting in the greatest increase (+ 45%). Only iNO produced a significant decrease in intrapulmonary shunt (Zwissler. Am J Respir Crit Care Med. 1996;154(6):1671-1677; Lowson. Anesthesiology. 2002;96(6):1504). Both agents were investigated in a dose titration study for 48 h to find maximum improvement of arterial oxygenation and the lowest effective dose in 16 patients with ARDS. Mean doses of iNO and PGI2 that resulted in similar and significant increase in PaO2/FIO2 and significant decrease in intrapulmonary shunt were 17 ± 5.2 ppm.

**Comment from the Guest Editor**

Pulmonary hypertension is a life-threatening condition that, left untreated, portends a poor prognosis. Although the pathophysiology of PH is not fully understood, it is known that the condition involves an imbalance between endogenous vasodilators and vasoconstrictors. Several novel therapeutic strategies to combat PH are currently under investigation. Inhaled PGI2 demonstrates potential as an effective, yet safe, option for treating patients with PH. We look forward to further investigation and development of aerosolized prostacyclin for the treatment of PH.

**Dr. Marshallene Henriques-Forsythe**, Director, Pulmonary Hypertension Clinic, Morehouse School of Medicine, Atlanta, GA
and 7.5 ± 2.5 mg/kg/min, respectively. Inhaled PGI, produced a significantly greater decrease in mean PAP and PVR than iNO, with little impact on systemic arterial pressure. The use of iNO and inhaled prostacyclin in ARDS and ALI has been recently reviewed (Puri and Dellinger. Crit Care Clin. 2011; 27[3]:561-87; Siobal and Hess. Respir Care. 2010;55[2]:144).

Conclusion

Based on the available evidence, it appears that inhaled PGI, is as effective as iNO for short-term management of PH and impaired oxygenation with potentially fewer side effects, lower costs, and greater ease of administration. However, further randomized, controlled studies are needed to prove the efficacy of inhaled PGI, and determine its place in therapy for patients with PH.

Marina Rabkovich, PharmD; Derek Barden, PharmD; Vusum Liian, PharmD; and Prasad Abraham, PharmD
Grady Health System
Atlanta, GA

Sample Checklist for Physician Retirement

BY DONNA K. KNAPP, MA, FACMPE
Vice-Chair, Practice Management Committee

Preparations for retirement should start on your first job. All of the details to create a successful retirement can take as little as a minute or as long as decades to accomplish properly. The following is a general list of issues to consider when planning your retirement. The list is not all inclusive and is not to be considered legal advice.

All individual life, health, and family situations should be considered from a personal perspective. It is important to speak to an expert in financial planning and an estate advisor as early in your career as possible and on a regular basis. Addressing the following issues will get you started on the road to a comfortable living in your retirement years:

Personal Living Issues

- A home free of debt, in good repair, with low maintenance upkeep, easily maneuvered and with enough room for an in-house caretaker
- Transportation free of debt, in good repair, with low maintenance upkeep, easily maneuvered, and with adequate storage capacity for personal living equipment

Insurances

- Long-term care bought at the peak time for the best lifetime rate—consult your insurance broker
- Enough life insurance to cover all debts and provide for surviving spouse
- Health insurance with coverage options when traveling
- Vision, dental
- Long-term and/or short term disability if still working or plan to work part-time
- Home, auto, general liability, and umbrella coverage

Physician Practice

- Profit sharing, pension, and/or 401K
- Retiree benefits
- Small group insurance
- Medicare, Medicaid
- Other income
- Financial planning
- Will

Physicians should start early, be vigilant throughout your career, and always be working toward the retirement goals that you have set for you and your family.

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10.1 Signs and Symptoms

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

Mometasone Furoate: Chronic overdosage may result in signs/symptoms of hypertension (see Warnings and Precautions (5.3)). Single oral doses up to 8000 mcg of mometasone furoate have been studied on human volunteers with no adverse reactions reported.

Formoterol Fumarate: The expected signs and symptoms with overdosage of formoterol are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the following signs and symptoms: angina, hypertension or hyper tension, tachycardia, with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, seizures, muscle cramps, dry mouth, palpitation, nausea, diarrhea, fatigue, malaise, hypokalemia, hyperglycemia, and insomnia. Metabolic acidosis may also occur. Cardiac arrest and even death may be associated with an overdose of formoterol.

The minimum acute lethal inhalation dose of formoterol fumarate in rats is 156 mg/kg approximately 65,000 times the MRHD on a mg/m2 basis. The median lethal oral doses in Chinese hamsters, rats, and mice provide even higher multiples of the MRHD.

10.2 Treatment

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

Manufactured by 3M Health Care Ltd., Loughborough, United Kingdom. Manufactured for Schering Corporation, a subsidiary of Merck & Co., Inc.

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All rights reserved. U.S. Patent Nos. 5898915; 6057307; 6677323; 6066392; 7085732; and 7568705. The trademarks depicted in this piece are owned by their respective companies.
Patients in the ICU face a number of health transitions from the time they enter the hospital until they are discharged. A transition is defined as a "process or period in which something undergoes a change and passes from one state, form, function, or activity to another" (Encarta World Dictionary, 1999). While transitions may involve new roles, such as becoming a mother or starting a new job, health transitions are complex and multidimensional. This is especially so in the transition from being a regular family member to being a regular patient experiencing acute illness in a hospital setting. Such transitions are significant, and health professionals and families are often unprepared to undertake this research because such admissions are often unplanned. Once patients are in the ICU, however, they, and their family members, have a profound need to "feel safe." They need to overcome the ICU-engendered anxiety, depression, fear, and high stress levels (acute stress disorder, posttraumatic stress disorder, and posttraumatic stress reaction) (McAdams and Puntillo, Am J Crit Care. 2009;18[3]:200). Research has also shown that the ICU environment is so unexpected and difficult that families are affected both socially and economically (Agard and Harder. Heart Lung. 2005;29[1]:68). Deterioration may be related to the day of ICU discharge, with increased mortality associated with after-hours ICU discharge (Lin et al. Crit Care Med. 2009;37[1]:29), although this relationship is not universally accepted.

From the health service perspective, this body of work complements two recent patient safety initiatives, clinical handover and recognizing and responding to the deteriorating patient. Clinical handover (or hand-offs) is much more than the transfer of information; it also involves transferring responsibility and accountability for patient care (The OSSIE Handbook of Health Psychology; 2001) when

Critical Care Commentary

ICU Transitions: Patients, Families, and Staff

Emergency teams (CCOT) in the United Kingdom and ICU Liaison Nurses (LN) in Australia are but two examples. These nurse-led services focus on the physical, psychosocial, and practical support to the patient and family in addition to physical support to the patient. The next major transition ICU patients face is their transition out of the hospital. A recent review of long-term complications of critical care identified that physical, psychiatric, and cognitive complications can last for 3 to 10 years (Desai et al. Crit Care Med. 2011;39[2]:371). These limitations are pulmonary, neuromuscular, and physical in nature, whereas others reflect depression, anxiety, posttraumatic stress disorder, and delirium. Deficits in most quality of life domains have also been consistently identified and have resulted in hospital and outpatient initiatives. For example, avoidance of medications, such as corticosteroids and neuromuscular blocking agents, and glycemic control have been advocated to address critical care illness neuromyopathy. Early mobility and rehabilitation in the ICU and its continuation throughout the recovery period have also been suggested to promote better physical functioning and prevent muscle atrophy, as has limiting deep sedation. Lighter sedation or daily sedation interruption have also been advocated to limit psychiatric complications. But, as Desai and colleagues note (Crit Care Med. 2011;39[2]:371), the evidence for most of these initiatives is only beginning to emerge. Health-care professionals may benefit from using the "theory of illness representations" (Leyshelf et al. Handbook of Health Psychology. Mahwah, NJ: Lawrence Erlbaum Associates Publishers; 2001) when helping patients and families adjust to these transitions. Illness representations are reflections of how people develop and use their own interpretation of their illness conditions. Both cognitive and emotional representations are used to determine individuals’ illness-related behaviors in response to health threats and their adjustments and coping with these changes. In numerous patient populations, illness representations have been associated with quality of life and functional outcomes. Application of this theory may assist health professionals in gaining an understanding of their patients’ illness perceptions and develop more accurate perceptions, if required. Techniques, such as cognitive behavioral therapy, can be used to reshape erroneous perceptions. As more patients are being admitted to the ICU and also surviving their ICU experiences, it seems important to continue investigating not only their recovery but also their transitions and how we can help patients and their families in this endeavor. And, if we really want to understand the patient and family journeys, we will have to undertake this research with their collaboration, extending their right to participate in their care to their right to be active members of the research team. Ultimately, this paradigm shift reflects the simple idea that patient safety has been advocating—"It’s about me, not without me."
Specialty Not Filling Match Slots

Dr. Joseph B. Barney, FCCP, comments: This is important and timely research, given the disparity between patients needing lung transplants and availability of acceptable organs. Many guidelines in existence are from experiences with the initial years of transplantation and are in need of review by scientific inquiry. Clearly we need a better, more comprehensive way of evaluating donor lungs. A larger, more prospective investigation is needed to decide if we need to fundamentally change the way we utilize available organs.

Dr. Richard Fischel, FCCP, comments: The numbers don’t lie, and the suggestion of the most competitive and highly respected professions to enter, cardiothoracic surgery in the United States is facing a very troubling future with significant implications for health care in our aging population. We should be very concerned that nationwide only 55 applicants applied for 102 residency spots in 2011. While consolidation of services such as that seen in the Canadian system may provide a beneficial model, we will still be in significant trouble if nobody wants to train in the field. This paper discusses an issue that should be front and center to every discussion about the future of medicine. We must act and act soon to address the problems in the residencies and the profession if we want any hope of quality cardiovascular and thoracic care when we will need it most.
Eplerenone Cut Events in Mild Heart Failure

BY PATRICE WENDLING
Elsevier Global Medical News

PARIS The aldosterone antagonist eplerenone cut cardiovascular events and the need for hospitalization significantly across all risk levels in patients with mild heart failure, according to a subanalysis of the EMPHASIS-HF trial. Eplerenone (Inspra) was also shown to trim troublesome and costly repeat heart failure hospitalizations in a subset of patients followed for up to 10 additional months after the pivotal, phase III trial closed, Dr. Bertram Pitt reported at the annual congress of the European Society of Cardiology.

“Overall efficacy, no matter where we looked, was about the same, and we had the same safety,” Dr. Pitt told reporters.

EMPHASIS-HF (Eplerenone in Mild Patients Hospitalization and Survival Study in Heart Failure) was stopped prematurely last spring after eplerenone in addition to standard therapy demonstrated a 37% (hazard ratio, 0.63) improvement over placebo in the primary end point of death from cardiovascular causes or heart failure hospitalization in 2,637 patients with mild New York Heart Association class II systolic heart failure (N. Engl. J. Med. 2011;364:11-21).

Among 1,597 patients who remained on double-blind therapy after study closure, the primary end point occurred in 21% on eplerenone and 29% on placebo (HR 0.66, Pless than .0001), reported Dr. Pitt, of the University of Michigan in Ann Arbor.

Repeat hospitalization for heart failure was significantly reduced with eplerenone (rate ratio 0.62, P less than .001).

“This suggests, to us at least, that this is going to have important cost implications, quality of life implications, as well as important implications on survival, since we know that heart failure hospitalization relates to target-organ damage and survival,” Dr. Pitt said.

The benefits of eplerenone were particularly compelling in elderly patients and those with diabetes and renal dysfunction, three high-risk populations in whom clinicians are hesitant to use aldosterone blocker because of fears of inducing hyperkalemia, he said.

He pointed out that recent head-to-head data showed that the aldosterone antagonist spironolactone (Aldactone) increases hemoglobin A1c and cortisol levels and reduces adiponectin in patients with diabetes, whereas eplerenone does not.

When Dr. Pitt and colleagues looked at patients with diabetes in the subanalysis, the benefit was better than that observed in the overall EMPHASIS-HF cohort, with a 46% reduction in the primary end point (HR 0.54, P less than .0001).

Dr. Pitt noted that the current American Heart Association, American College of Cardiology, and European guidelines for aldosterone blockade don’t specify a particular agent, but look at the agents as a class.

“We believe with [these] data, that in the next guidelines there should at least be some consideration for the specific use of eplerenone, at least in the subset of patients with diabetes,” he said.

Among patients with an estimated glomerular filtration rate less than 60 mL per minute per 1.73 m², the improvement in the primary outcome reached 38% with eplerenone over placebo (HR 0.62, P less than .0001).

The study excluded patients with a baseline serum potassium level above 5.0 mmol/L and estimated GFR below 30 mL per minute per 1.73 m² in an attempt to minimize the risk of hyperkalemia. Despite this, the positive results remain applicable, Dr. Pitt said in an interview. Among elderly patients at least

**Important safety information**

Because of the risks of liver injury and birth defects, Tracleer may be prescribed and dispensed only through the Tracleer Access Program (T.A.P.), a restricted distribution program, by calling 1-866-228-3546. Only prescribers and pharmacies registered with T.A.P. may prescribe and distribute Tracleer. Tracleer may be dispensed only to patients who are enrolled in and meet all conditions of T.A.P.

**Liver injury**

Elevations of liver aminotransferases (ALT, AST) and liver failure have been reported with Tracleer. In a setting of close monitoring, rare cases of liver failure and unexplained hepatic cirrhosis were observed after prolonged treatment. In general, avoid using Tracleer in patients with elevated aminotransferases (>3 × ULN). Measure liver aminotransferases prior to initiation of treatment and then monthly. Discontinue Tracleer if aminotransferase elevations are accompanied by signs or symptoms of liver dysfunction or injury or increases in bilirubin >2 × ULN.

**Teratogenicity**

Based on animal data, Tracleer is likely to cause major birth defects if used during pregnancy. Exclude pregnancy before and during treatment. To prevent pregnancy, females of childbearing potential must use 2 reliable forms of contraception during treatment and for 1 month after stopping Tracleer unless the patient has a tubal sterilization or Copper T 380A IUD or LNG-20 IUS inserted, in which case no other contraception is needed. Monthly pregnancy tests should be obtained.

**Contraindications**

Tracleer is contraindicated with cyclosporine A, glyburide, in females who are or may become pregnant, or in patients who are hypersensitive to bosentan or any component of Tracleer.

**Warnings and precautions**

In clinical trials, Tracleer caused ALT/AST elevations (>3 × ULN) in 11% of patients accompanied by elevated bilirubin in a few cases. The combination of hepatocellular injury (increases in aminotransferases of >3 × ULN) and increases in total bilirubin (>3 × ULN) is a marker for potential serious liver injury. Liver aminotransferase levels must be measured prior to initiation of treatment and then monthly. Avoid using Tracleer in patients with moderate or severe liver impairment or elevated ALT/AST >3 × ULN.

If clinically significant fluid retention develops, with or without associated weight gain, the cause, such as Tracleer or underlying heart failure, must be determined. Patients may require treatment or Tracleer therapy may need to be discontinued.

Preclinical data and an open-label safety study (N=25) showed a decline in sperm count of >50% in 25% of Tracleer-treated patients after 3 or 6 months. After 6 months, sperm count remained in normal range, with no changes in sperm morphology or motility, or hormone levels. Endothelin receptor antagonists such as Tracleer may adversely affect spermatogenesis.

Treatment with Tracleer can cause a dose-related decrease in hemoglobin (Hgb) and hematocrit. Hgb should be checked after 1 and 3 months, and then every 3 months. Upon marked decrease in Hgb, determine the cause and need for specific treatment.

If signs of pulmonary edema occur, the possibility of associated pulmonary veno-occlusive disease should be considered. Tracleer should be discontinued.

**Adverse events**

In Tracleer pivotal trials, the most common adverse events occurring more often in Tracleer-treated patients than in patients taking placebo (≥2%) were respiratory tract infection, edema, hypotension, sinusitis, arthralgia, liver function test abnormal, palpitations, and anemia.
Tracleer is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital systemic-to-pulmonary shunts (18%). Patients with WHO class II symptoms showed reduction in the rate of clinical deterioration and a trend for improvement in walk distance. Physicians should consider whether these benefits are sufficient to offset the risk of liver injury in WHO class II patients, which may preclude future use as their disease progresses.

Please see accompanying brief summary of prescribing information, including BOXED WARNING about liver injury and pregnancy, on following pages.

*Patients ineligible for the Tracleer Patient Coupon Program include any patients whose prescriptions are paid for by the government, Medicare, Medicaid, VA/DOD (Tricare), or Indian Health Service, patients in Massachusetts and Puerto Rico, or where prohibited by law.

www.Tracleer.com
Algorithm Helps Tell MI From Noncoronary Disease

By Sherry Boschert
Elsивer Global Medical News

PARIS – A new algorithm incorporating high-sensitivity cardiac troponin T values in patients with ST-segment elevation seems to differentiate between MI and cardiac but noncoronary disease in patients with acute chest pain. The algorithm helped triage patients in the first hour of presentation so that the patients who need coronary angiographies get them quickly and unnecessary angiographies are minimized, Dr. Philip Haaf said in a press briefing at the annual congress of the European Society of Cardiology.

Troponins are increased in cardiovascular disorders including tachyarrhythmia, heart failure, hypertensive urgency or emergency, Takotsubo cardiomyopathy, and myocarditis in patients without a coronary obstruction. The introduction of high-sensitivity assays for cardiac troponins has allowed earlier diagnosis of acute MI in many patients. But the assays also have caused “considerable confusion among treating physicians” because mildly elevated troponins can be seen in some patients who do not have a coronary obstruction but have tachyarrhythmia, hypertensive urgency, or heart failure, said Dr. Haaf of University Hospital Basel.

He and his associates analyzed data on the first 887 patients who presented with acute chest pain in the APACHE (Advantageous Prediction of Acute Coronary Syndrome Evaluation) study. The ongoing, multicenter study has enrolled close to 2,000 patients so far, obviating a morbidly ill patient history, ECG analysis, and measures of novel cardiac biomarkers from a blinded, random assignment and trial entrance after a selection process.

Desired sensitivity, specificity, and positive predictive value of this algorithm were high enough to consider it a valuable addition, said Dr. Haaf.

The algorithm helps to stratify patients into three groups.

1. A group of patients with acute MI
2. A group of patients with ischemic heart disease
3. A group of patients with atypical presentations

This algorithm has the potential to spare hospital space and to reduce costs and morbidity, Dr. Haaf said. It also can potentially be expanded to include patients with unstable coronary syndromes, said Dr. Haaf.

Use in Females of Childbearing Potential

Females of childbearing potential must use two reliable methods of contraception unless the patient has a tubal sterilization or Copper T 380A. Contraceptives should not be started during treatment and for one month after stopping Tracleer, unless the patient has a hysterectomy or copper intrauterine device. Therefore, pregnancy must be excluded before the start of treatment with Tracleer. Patients required intervention (82 mg film-coated tablets, concordant tablets for oral administration, 5 mg film-coated tablets, film-coated, round, licorice, orange-white tablets, embossed with identification marking “152”) as measured at pre- and post-treatment levels.

Tracleer should be stopped. There is no experience with the re-introduction of Tracleer in these circumstances.”

Use in Women with Low Body Weight

In patients with a body weight < 50 kg but who are over 12 years of age, the recommended initial and maintenance dosage is 25 mg twice daily.

Use in Patients with Pre-existing Hepatic Impairment

Tracleer should generally be avoided in patients with moderate or severe liver impairment. There are no specific data on dosing in heparinized patients; caution should be exercised in patients with mildly impaired liver function (see Warnings and Precautions).

Co-administration of Tracleer in Patients on Tracleer

Dosage and Administration

Tracleer should be provided at a dose of 25 mg twice daily for 4 weeks and then increased to the maintenance dose of 125 mg twice daily. Doses above 125 mg twice daily do not appear to confer additional benefit sufficient to offset the increased risk of liver injury. Tablets should be administered every morning and evening without or with food. Treatment should be stopped and re-introduction of Tracleer should not be attempted in these cases.

Use in Drug Interactions

Tracleer is contraindicated in patients who are hypersensitive to any component of the product. Observed reactions include rash and angioedema (see Adverse Reactions).
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If clinically significant fluid retention develops, with or without associated symptoms, refer to Chapter 11 for recommendations on management. New or worsening symptoms of fluid retention may necessitate further evaluations. For example, if the patient becomes edematous, refer the patient for an echocardiogram to determine whether there is significant fluid overload.

Decreased Spontaneous Count

The estimated increase in spontaneous count per hour of bosentan therapy is 12% in patients with PAH and 4% in those with PAH who have a history of heart failure. The spontaneous count was observed to increase by 12% in patients with PAH and 4% in those with PAH who have a history of heart failure.

Decreased in Hemoglobin and Hematocrit

The most common adverse reactions reported in patients treated with bosentan were anemia and decreased hematocrit. The most common adverse reactions reported in patients treated with bosentan were anemia and decreased hematocrit. The most common adverse reactions reported in patients treated with bosentan were anemia and decreased hematocrit. The most common adverse reactions reported in patients treated with bosentan were anemia and decreased hematocrit. The most common adverse reactions reported in patients treated with bosentan were anemia and decreased hematocrit.

Pulmonary Venous-Occlusive Disease

Signs of pulmonary edema occur more commonly in patients who have a history of heart failure. Pulmonary venous-occlusive disease is the most common adverse reaction reported in patients treated with bosentan. Pulmonary venous-occlusive disease is the most common adverse reaction reported in patients treated with bosentan. Pulmonary venous-occlusive disease is the most common adverse reaction reported in patients treated with bosentan. Pulmonary venous-occlusive disease is the most common adverse reaction reported in patients treated with bosentan.

Hypertension

Hypertension is the most common adverse reaction reported in patients treated with bosentan. Hypertension is the most common adverse reaction reported in patients treated with bosentan. Hypertension is the most common adverse reaction reported in patients treated with bosentan. Hypertension is the most common adverse reaction reported in patients treated with bosentan.

Anemia

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Hypersensitivity

The incidence of hypersensitivity reactions in patients treated with bosentan is less than 1% and is the most common adverse reaction reported in patients treated with bosentan. The most common adverse reaction reported in patients treated with bosentan was anaphylaxis. The most common adverse reaction reported in patients treated with bosentan was anaphylaxis. The most common adverse reaction reported in patients treated with bosentan was anaphylaxis. The most common adverse reaction reported in patients treated with bosentan was anaphylaxis.

Hypothyroidism

Hypothyroidism is the most common adverse reaction reported in patients treated with bosentan. Hypothyroidism is the most common adverse reaction reported in patients treated with bosentan. Hypothyroidism is the most common adverse reaction reported in patients treated with bosentan. Hypothyroidism is the most common adverse reaction reported in patients treated with bosentan.

Atrial Fibrillation

Atrial fibrillation is the most common adverse reaction reported in patients treated with bosentan. Atrial fibrillation is the most common adverse reaction reported in patients treated with bosentan. Atrial fibrillation is the most common adverse reaction reported in patients treated with bosentan. Atrial fibrillation is the most common adverse reaction reported in patients treated with bosentan.

Hypokalemia

Hypokalemia is the most common adverse reaction reported in patients treated with bosentan. Hypokalemia is the most common adverse reaction reported in patients treated with bosentan. Hypokalemia is the most common adverse reaction reported in patients treated with bosentan. Hypokalemia is the most common adverse reaction reported in patients treated with bosentan.

Potential liver injury [see Boxed Warning, Warnings and Precautions]

Bosentan is an inducer of CYP3A and CYP2C9. Consequently, plasma concentrations of bosentan may be affected by other drugs that are metabolized by these enzymes. Bosentan is an inducer of CYP3A and CYP2C9. Consequently, plasma concentrations of bosentan may be affected by other drugs that are metabolized by these enzymes. Bosentan is an inducer of CYP3A and CYP2C9. Consequently, plasma concentrations of bosentan may be affected by other drugs that are metabolized by these enzymes. Bosentan is an inducer of CYP3A and CYP2C9. Consequently, plasma concentrations of bosentan may be affected by other drugs that are metabolized by these enzymes.

Hormonal Contraception

Hormonal contraception, including oral, injectable, transdermal, and implantable forms, may be unreliable when Tracleer is co-administered. Females should practice alternative methods of contraception and not rely on hormonal contraception alone when taking Tracleer (see Boxed Warning, Contraindications). Hormonal contraception, including oral, injectable, transdermal, and implantable forms, may be unreliable when Tracleer is co-administered. Females should practice alternative methods of contraception and not rely on hormonal contraception alone when taking Tracleer (see Boxed Warning, Contraindications). Hormonal contraception, including oral, injectable, transdermal, and implantable forms, may be unreliable when Tracleer is co-administered. Females should practice alternative methods of contraception and not rely on hormonal contraception alone when taking Tracleer (see Boxed Warning, Contraindications). Hormonal contraception, including oral, injectable, transdermal, and implantable forms, may be unreliable when Tracleer is co-administered. Females should practice alternative methods of contraception and not rely on hormonal contraception alone when taking Tracleer (see Boxed Warning, Contraindications).

Cyclosporine PPS Summary

Bosentan is metabolized by CYP3A4 and CYP2C9. Inhibitors of these enzymes may increase the plasma concentrations of bosentan (see Contraindications). Bosentan has an additive effect on the CYP450 3A4 and CYP2C9 isozymes in vitro. bosentan-induced hypotension was more common in patients taking tracleer than in patients taking placebo. boventan-induced hypotension was more common in patients taking tracleer than in patients taking placebo. boventan-induced hypotension was more common in patients taking tracleer than in patients taking placebo. boventan-induced hypotension was more common in patients taking tracleer than in patients taking placebo.

Dr. Jun Chiong, FCCP, comments: This will help cardiologists and ED specialists sort out elevated troponin, as troponin is simply indicative of myocardial injury. It’s up to the physicians to determine if the cause is coronary.

National Science Foundation, the Swiss Heart Foundation, Abbott, Roche, Nanosphere, Siemens, and University Hospital. No disclosures were reported.
Infarct Size Not Reduced With Balloon Therapy

PARIS - Intra-arterial balloon counterpulsion ballooning, a promising new percutaneous coronary intervention did not reduce infarct size in patients with ST-elevation MI without shock in the multicenter, intermediate CRISPI-AMI trial. The trial did not, however, close the door on this widely used therapy, Dr. Manesh Patel said.

"Clinicians should continue to be vigilant about identifying patients who are at risk for rapid deterioration or hyper-tension that may still benefit from supra-aortic cross in this trial," he said at the annual congress of the European Society of Cardiology. In all, 8.5% of patients randomized to percutaneous coronary intervention (PCI) alone did not cross on to balloon counterpulsion (IABC) in the CRISPI-AMI (Counterpulation to Reduce Infarct Size Pre-PCI Acute Myocardial Infarction) study (JAMA 2011;306:1129-37).

Among all 337 patients in the trial, mean infarct size was 42% of the left ventricle in patients randomized to IABC prior to PCI and continued for at least 12 hours and 37.5% in the PCI-alone group (P = .06), said Dr. Patel of the Duke Clinical Research Institute in Durham, N.C. In patients who crossed to PCI from proximal left anterior descending and thrombolysis in myocardial infarction flow scores of 0 or 1, the mean infarct size was 46.7% of the left ventricle vs. 42.3% respectively (P = .11).

Invited discussant Dr. Kurt Huber, director of the department of medicine, cardiology, and emergency medicine at Wilhelminenspital in Vienna, said, "I'm sure that this method is still important for certain patient groups.

At 6 months, three patients in the IABC plus PCI group had died vs. nine in the PCI-alone group (P = .12).

An exploratory composite end point of time to death, shock, or new or worsening heart failure also favored the counterpulsion therapy plus PCI group over the PCI-alone group (8 vs. 21 events, P = .03).

There was a nonsignificant rise in side effects, particularly vascular complications.

At 30 days, major vascular complications occurred in seven patients in the IABC plus PCI group vs. only two in the PCI-alone group (P = .09). Major bleeding or transfusion occurred in five patients vs. three patients, respectively, Dr. Patel said.

Dr. Huber said other studies are needed to define which patients might benefit from IABC. He highlighted the only other prospective trial of IACP the TAC-CSCT trial failed to offer a survival benefit when added to fibri-nolysis for patients with MI who were hemodynamically unstable, but suggested a possible benefit for patients with the most severe myocardial injury on admission (J. Thoromb Thrombolysis 2005;19:13-9).

Session co-moderator Dr. Christodoulos Stefanadis of Athens University Medical School said in an interview that it is still acceptable to use IACP in both stable and unstable patients, but agreed that other studies are needed to resolve the issue.

"In unstable patients, I personally believe that the use of the intra-arterial balloon counterpulsion is a reasonable approach. The question is what happens in stable patients without low blood pressure or shock."

At baseline, CRISPI-AMI patients were hemodynamically stable, with a median systolic blood pressure of 125 mm Hg in the IABC plus PCI group and 115 mm Hg in the PCI-alone patients.

The time required to insert the intra-arterial balloon added just 9 minutes to the procedure, making it unlikely that this delayed the potential benefits of counterpulsion therapy, Dr. Patel said in an interview.

Dr. Patel reported receiving grant funding from the sponsor of this study, the sponsor of IAP

Dr. Jan Chiang, FCCP, comments: The outcome is quite a surprise. This is also why we need to be reminded that randomized trials are the gold standard in evidence-based medicine. The current clinical trial called SHOCK, presented 4 years ago, also had neutral results. However, subanalyses have to be done to determine the fraction of patients who will strongly benefit.
Adjuvant Colchicine Halves Pericarditis Recurrences

BY PATRICE WENDLING
Elsevier Global Medical News

PARIS – In patients with a first recurrence of pericarditis, adding low-dose colchicine to standard therapy halved the risk of subsequent episodes.

Among 120 patients with a first recurrence of pericarditis in the Study of Colchicine to Treat and Prevent Recurrent Pericarditis (CORP) trial, the rate at 18 months of another recurrence was 24% with colchicine and standard therapy and 55% with standard therapy alone (P less than .001).

The relative risk reduction associated with adjuvant colchicine was 56% and the number needed to treat to prevent one recurrence was three, Dr. Massimo Imazio reported at the annual congress of the European Society of Cardiology.

Colchicine (Colcrys) has been used for years to treat gout and is the first drug to be shown in a double-blind, randomized, placebo-controlled trial to prevent recurrent pericarditis.

“Following an initial episode of recurrent pericarditis, colchicine, as an adjunct to anti-inflammatory therapy, appears to be an inexpensive and safe means to hasten symptom resolution, improving remission rates by 1 week, and to reduce further recurrences,” said Dr. Imazio of the Maria Vittoria Hospital in Turin, Italy.

Invited discussion Dr. Andre Keren, of the Heart Institute at Hadassah University Hospital in Jerusalem, described CORP as a well-designed and carefully performed trial. Its results strongly support the use of low-dose colchicine in adjuvant pericarditis patients.

“I really believe that the time has arrived that colchicine should be more freely used,” he said.

Both Dr. Imazio and Dr. Keren observed that the results may not be applicable to all patients with pericarditis since the trial excluded those with neoplastic or bacterial etiologies as well as those with multiple recurrences.

In addition, the drug’s “remarkable safety and tolerability profile might have been influenced by the study design,” said Dr. Keren.

Based on nonrandomized observations and expert opinion, the European Society of Cardiology guidelines recommend colchicine 2 mg/day for 1-2 days, followed by a maintenance dose of 0.5 mg/day for 1 year for recurrent pericarditis.

The CORP investigators randomized patients from four Italian centers to conventional therapy plus placebo or colchicine for 6 months at the recommended doses for patients weighing at least 70 kg, but reduced the initial dose to 1 place (<70 kg) to 0.5 mg/day for those weighing less than 70 kg.

Conventional therapy was aspirin 800-1,000 mg or ibuprofen 600 mg every 8 hours for 7-10 days, with the second choice being prednisone 0.2-0.5 mg/kg of body weight per day for 4 weeks and then gradually tapered.

Dr. Keren pointed out that the dose as well as the frequency of corticosteroids was lower in CORP than the researchers’ earlier CORE trial, in which prednisone was dosed at 1.0-1.5 mg/kg of body weight per day for 4 weeks, and 35% of patients had received steroids during the initial episode of pericarditis.

In contrast, only 10% of placebo and 8% of colchicine patients in CORP had previously received corticosteroids.

“This might also reflect, in my view, a change in our perception that steroids can actually be deleterious in decreasing the recurrence rate,” Dr. Keren said.

Symptom persistence at 72 hours was significantly lower in the colchicine group than in the placebo group (23% vs. 53%, P = .001), as was the rate of admission at 1 place (38% vs. 82%, P less than .001), Dr. Imazio said.

The mean number of recurrences was significantly lower in the colchicine-treated group than in the placebo group (0.1 vs. 1.0), and the time to first recurrence was also significantly longer at 2.5 months vs. 1 month (P less than .001).

No significant differences were observed between the two groups in rates of readmission (5% vs. 13%), tamponade (0% vs. 2%), or mortality (0% vs. 1%).

Gastrointestinal intolerance was the most common side effect, reported in four colchicine and five placebo patients. No serious side effects were observed in either group. Treatment discontinuation occurred in five colchicine and four placebo patients, Dr. Imazio said.

Dr. Imazio and his coauthors report no study sponsorship or conflicts. Dr. Keren reports no disclosures.
Are Benchmarks the Problem for High VAP Rates?

By Richard M. Kirkner, Elsevier Global Medical News

CHICAGO—Payers are relying ever more on tying physician and hospital payments to quality measures, but what happens if the benchmarks they use vary among institutions or are flawed? Such may be the case with ventilator-associated pneumonia and large trauma centers, as a recent study shows VAP rates at such facilities exceed national benchmarks, which some say are inadequate for comparison.

Dr. Christopher P. Michetti of Inova Fairfax Hospital in Falls Church, Va., presented a retrospective study designed to determine VAP rates at major trauma centers and to lay groundwork for more accurate benchmarking that relies less on National Health Safety Network data, he said. He spoke at the annual meeting of the American Association for Surgery in Trauma. The study was performed through the AAST Multi-Institutional Trials Committee.

“Hospitals are under pressure to reduce their VAP rates, yet a direct association between VAP rates and quality of care or outcomes has not been demonstrated,” he remarked.

“VAP rates … are remarkably variable,” Dr. Michetti said. “It is not appropriate to measure all trauma centers against a single benchmark, nor does an actual benchmark appear to exist at this point.” Comparing VAP rates between different trauma centers is “like comparing apples and oranges,” he said.

The study looked at VAP rates at 47 level I and II trauma centers for 2008 and 2009 with an average of 3,000 trauma evaluations a year. The average VAP rate for the study group was 17.2/1,000 ventilator days, compared with 8.1/1,000 for NHSN data. “In fact, the 90th-percentile rate for NHSN was still below the mean rate from our study,” Dr. Michetti said. Across all 47 centers in the study, VAP rates ranged from a low of 1.8/1,000 ventilator days to a high of 57.6/1,000 ventilator days.

The case mix at the trauma centers did not auger well for lower VAP rates, as 88% of the cases were blunt trauma, Dr. Michetti noted. “VAP rates are generally higher for blunt-trauma patients, at about 17/1,000 ventilator days, compared with penetrating trauma at 11/1,000,” he said.

Most other variables among the centers in the study—such as having a closed or open ICU, or using a bacteriologic vs. a clinical strategy to diagnose VAP—showed little impact on the pneumonia rates. VAP rates did not correlate with the size or level of trauma center, injury severity, or type of ICU, he said.

Among the problems he noted with the NHSN data on VAP rates are the lack of source hospital identification, population risk, or injury severity stratification.

“In addition, the NHSN rates are substantially lower than other published rates among trauma patients,” he said.

However, the investigators did isolate a few variables that may influence VAP rates: Among centers where the trauma service alone made the diagnosis, the average VAP rate was 27.5/1,000 ventilator days. When the infection control, quality, or epidemiology department made the call, the average VAP rate was 11.9/1,000 days. Centers that excluded patients also had rates about 30% lower than those that did not. This variability raises questions about using VAP as a quality measure, Dr. Michetti said. “Before we take that leap, diagnostic and reporting standards are necessary.”

The heightened attention on VAP as a quality measure for critical care is having other implications, he said. “As pressure to reduce VAP rates grows, an increasing number of patients are being labeled as having ventilator-associated tracheobronchitis or excluded for reasons such as aspiration,” he said.

Discussant Dr. Karen J. Bresal of the Medical College of Wisconsin, Milwaukee, acknowledged the need for the study, but raised the question: “Are the benchmarks the problem, or are we the problem?”

“I think the answer is yes, both,” Dr. Michetti said. “I’m not sure that an adequate benchmark exists probably because no representative sample of trauma centers has been done to set that benchmark.” He noted that the CDC’s Healthcare Infection Control Practices Advisory Committee does not recommend reporting of VAP, which argues against using that as a benchmark. Meanwhile, across individual centers no reporting standards exist, “so centers can’t agree on what is VAP,” he said.

Pneumonia Hospitalization Risk Higher in ESRD Patients

By Susan London, Elsevier Global Medical News

CHICAGO—Patients with end-stage renal disease have sharply elevated rates of hospitalization for pneumonia throughout the renal transplantation trajectory, researchers reported at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

The findings underscore the importance of vaccinating this group against pneumococcal and other diseases, lead investigator Lise Haaberg Nielsen said in an interview. Pneumonia “is a big economic burden for society and it is a huge source of mortality for these patients.”

In a Danish nationwide population-based cohort study among more than 90,000 individuals, those with end-stage renal disease (ESRD) had an 8- to 14-fold higher incidence of such hospitalization, depending on whether they were wait-listed, post transplant, or post graft failure, when compared with their counterparts in the general population. About one-third of the post-transplant group was hospitalization for pneumonia. Male sex and older age were among the significant risk factors for pneumonia hospitalization at this stage. On the other hand, risk fell after the first year post transplant.

The marked increase in post-transplant risk was expected, given patients use more immunosuppressors, according to Ms. Nielsen, who is a medical student undertaking a research year in the department of infectious diseases at Aarhus University Hospital, Skejby.

However, the fact that the elevations seen before and after transplantation were even greater was the clinical surprise, she said at the meeting, which was sponsored by the American Society for Microbiology.

The increase in pretransplant risk was probably caused by patients’ uremic state, while that post-graft failure “could also be just a reflection of patients being more sick than the general population,” she speculated.

The investigators analyzed data from the Danish National Hospital Registry, identifying all ESRD patients since 1997, patients having a discharge diagnosis of pneumonia, regardless of whether the infection was community or hospital acquired. They assessed the rates and why they occurred in the first two years post transplantation.

The incidence of first pneumonia hospitalization was 46, 32, and 63 per 1,000 person-years among wait-listed patients, renal transplant recipients, and patients who experienced graft loss, respectively.

These groups had correspondingly higher—8- to 14-fold increases in the incidence of such hospitalization compared with the general population, according to Ms. Nielsen.

Ms. Nielsen reported that she had no recent conflicts of interest.
TEFLARO is indicated for the treatment of community-acquired bacterial pneumonia (CABP) caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms:

- *Streptococcus pneumoniae* (including cases with concurrent bacteremia),
- *Staphylococcus aureus* (methicillin-susceptible isolates only),
- *Haemophilus influenzae*,
- *Klebsiella pneumoniae*,
- *Klebsiella oxytoca*, and
- *Escherichia coli*.

TEFLARO is also indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms:

- *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates),
- *Streptococcus pyogenes*,
- *Streptococcus agalactiae*,
- *Escherichia coli*,
- *Klebsiella pneumoniae*, and
- *Klebsiella oxytoca*.

**INDICATIONS**

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

When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

**IMPORTANT SAFETY INFORMATION**

**Contraindications**

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

Please see additional Important Safety Information throughout and brief summary of Prescribing Information on last page of this advertisement. Please also see full Prescribing Information at www.TEFLARO.com.
INDICATIONS AND USAGE

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

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

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

IMPORTANT SAFETY INFORMATION

**Warnings and Precautions**

**Hypersensitivity Reactions**

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

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

**Clostridium difficile-associated Diarrhea**

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

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

- CABP
- ABSSSI

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

**IMPORTANT SAFETY INFORMATION**

Direct Coombs' Test Seroconversion

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

Development of Drug-Resistant Bacteria

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

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

Day 4 Population (mITT)*
A microbiological intent-to-treat population (mITT population) containing only subjects with a confirmed bacterial pathogen at baseline.

Test of Cure (TOC) Populations†
- MITT Modified Intent-to-treat: All randomized subjects who received any amount of study drug.
- MITTE Modified Intent-to-treat Efficacy: All subjects in the MITT population who were in PORT Risk Class III or IV at baseline.
- CE Clinically Evaluable: All subjects in the MITTE population who demonstrated sufficient adherence to the protocol. Sufficient adherence is defined as patients who met the minimal disease criteria for CABP and for whom sufficient information regarding the CABP was available to determine the patient’s outcome.
- ME Microbiologically Evaluable: All subjects in the CE population who had at least one typical bacterial pathogen identified at baseline from an appropriate microbiological specimen (eg, blood, sputum, or pleural fluid).

* To evaluate the treatment effect of ceftaroline, an analysis was conducted in CABP patients for whom the treatment effect of antibacterials may be supported by historical evidence. This analysis endpoint required subjects to meet sign and symptom criteria at Day 4 of therapy: a responder had to be in stable condition according to consensus treatment guidelines, and (b) show improvement from baseline on at least one symptom of cough, dyspnea, pleuritic chest pain, or sputum production, while not worsening on any of these four symptoms.

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

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

IMPORTANT SAFETY INFORMATION

Adverse Reactions
- In the four pooled Phase 3 clinical trials, serious adverse events occurred in 98/1300 (7.5%) of patients receiving TEFLARO and 100/1297 (7.7%) of patients receiving comparator drugs. Treatment discontinuation due to adverse events occurred in 35/1300 (2.7%) of patients receiving TEFLARO and 48/1297 (3.7%) of patients receiving comparator drugs with the most common adverse events leading to discontinuation being hypersensitivity for both treatment groups at a rate of 0.3% in the TEFLARO group and 0.5% in the comparator group.
- No adverse reactions occurred in greater than 5% of patients receiving TEFLARO. The most common adverse reactions occurring in ≥2% of patients receiving TEFLARO in the pooled Phase 3 clinical trials were diarrhea, nausea, and rash.

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

### TEFLARO Demonstrated Clinical Response at Day 4 (mITT) in Community-Acquired Bacterial Pneumonia

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Clinical response, % (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FOCUS 1</strong></td>
<td></td>
</tr>
<tr>
<td>TEFLARO</td>
<td>69.6% (48/69)</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>58.3% (42/72)</td>
</tr>
<tr>
<td>Treatment</td>
<td>11.2 (95% CI: -4.6, 26.5)</td>
</tr>
<tr>
<td><strong>FOCUS 2</strong></td>
<td></td>
</tr>
<tr>
<td>TEFLARO</td>
<td>69.0% (58/84)</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>61.4% (51/83)</td>
</tr>
<tr>
<td>Treatment</td>
<td>7.6 (95% CI: -6.8, 21.8)</td>
</tr>
</tbody>
</table>

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

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

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

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

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

*FOCUS = Ceftaroline Community-Acquired Pneumonia Trial vs Ceftriaxone in Hospital Patients. FOCUS 1 = CABP Trial 1, FOCUS 2 = CABP Trial 2.

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

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**IMPORTANT SAFETY INFORMATION**

### Drug Interactions

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

**Day 3 Population**

The analysis evaluated patients with lesion size ≥75 cm² and having one of the following infection types:

- Major abscess with ≥5 cm of surrounding erythema
- Wound infection
- Deep/extensive cellulitis

**Test of Cure (TOC) Populations**

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

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

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

### INDICATION AND USAGE

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

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

### IMPORTANT SAFETY INFORMATION

**Use in Specific Populations**

- TEFLARO has not been studied in pregnant women. Therefore, TEFLARO should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.
- It is not known whether ceftaroline is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TEFLARO is administered to a nursing woman.
- Safety and effectiveness in pediatric patients have not been established.
- Because elderly patients, those ≥65 years of age, are more likely to have decreased renal function and ceftaroline is excreted primarily by the kidney, care should be taken in dose selection in this age group and it may be useful to monitor renal function. Dosage adjustment for elderly patients should therefore be based on renal function.
- Dosage adjustment is required in patients with moderate (CrCl 30 to ≤50 mL/min) or severe (CrCl ≥15 to ≤30 mL/min) renal impairment and in patients with end-stage renal disease (CrCl <15 mL/min).
- The pharmacokinetics of ceftaroline in patients with hepatic impairment have not been established.
TEFLARO Demonstrated Clinical Response at Day 3 in Acute Bacterial Skin and Skin Structure Infections

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Clinical responders, % (n/N)</th>
<th>Treatment Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEFLARO monotherapy</td>
<td>74.0% (148/200)</td>
<td>9.4 (0.4, 18.2)</td>
</tr>
<tr>
<td>Vancomycin + aztreonam</td>
<td>64.6% (135/209)</td>
<td>-5.9 (-18.2, 6.4)</td>
</tr>
</tbody>
</table>

* CI = confidence interval.

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

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

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Clinical cure rates, % (n/N)</th>
<th>Treatment Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEFLARO monotherapy</td>
<td>91.1% (288/316)</td>
<td>-2.2 (-6.2, 1.8)</td>
</tr>
<tr>
<td>Vancomycin + aztreonam</td>
<td>93.3% (280/300)</td>
<td>0.1 (-4.4, 4.5)</td>
</tr>
</tbody>
</table>

* CI = confidence interval.

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

Please see brief summary of Prescribing Information on following page.
Please also see full Prescribing Information at www.TEFLARO.com.
A gray market of secondary pharmaceutical suppliers is driving up the price of lifesaving drugs that are in short supply, with markups ranging from 100% to 4,500%. An analysis released by the Premier Healthcare Alliance found that, on average, drugs are being marked up 65% on the gray market. Premier compiled and analyzed 636 unsolicited sales offers received by acute care facilities in its network. All of the drugs offered were either back-ordered or unavailable through the manufacturer. The average markup for these drugs was 65%, with the top 10 highest markups more than 1,000% over base contract prices.

The top 10 highest markups were seen in pharmaceuticals used in cardiac cedation, critical care, and oncology:

- Labeletal (4,533%)
- Cytrabine (3,980%)
- Dexamethasone 4-mg injection (3,857%)
- Leucovorin - 3,170%)
- Propofo (3,161%)
- Papavetamine - 2,979%)
- Prostamine sulfate - 2,712%)
- Levedep - 2,642%)
- Sodium chloride concentrate - 2,350%)
- Furosine injection - 1,721%)

Gray market vendors generally advertise through e-mails and faxes that tout the shortage of the products, Premier officials said, with language such as “we only have 20 [percent of] this drug left and quantities are going fast.” The reported price gouging comes as the country faces an unprecedented shortage of drugs. By the end of 2011, there could be more than 300 drugs in short supply, according to projections by Premier.

Hospitals and pharmacies must beware when purchasing drugs on the gray market, not just because of the inflated price, but also because of safety risks, Premier officials warned. Products sold on the gray market may have been mishandled, rendering them ineffective or harmful, or they could also be counterfeit.

Stolen, counterfeit, and mishandled drugs are also difficult to recognize. Even the original manufacturers may not be able to spot fake drugs, according to analysts for Premier. And hospitals that try to avoid gray market vendors may encounter problems because these vendors have sophisticated methods of impersonating legitimate, licensed distributors, according to Premier.

Drug shortages are also getting increased attention in Washington, where a bipartisan group of senators has been urging the Food and Drug Administration to do more to address these shortages. The FDA held a public workshop on the issue on Sept. 26, where increased oversight of drug manufacturers was called for (www.fda.gov/Drugs/ NewsEvents/ucm265968.htm).

Sen. Amy Klobuchar (D-Minn.), a member of the bipartisan group, told reporters that one short solution that would be for drug manufacturers to alert the FDA to any problems that could result in a drug shortage; she is sponsoring a bill (S. 296, the Preserving Access to New and Existing Drugs Act of 2011) that would require manufacturers to do so.

The FDA told the ADMA that the FDA will add the gray market to the FDA’s Additional Drug and Alternative Manufacture (ADA) Program, which allows for access to alternative drugs before a shortage occurs. Sen. Klobuchar said, adding that a price range of options needs to be on the table to address drug shortages before a price gouging charge comes from the gray market.

“I don’t care how much fighting is going on in Congress,” she said. “I don’t think anyone wants to be responsible for a little kid dying because he doesn’t get his cancer drug because we haven’t been able to figure out the bureaucracy.”
Frequent Use of CPOE Shown to Save Lives

By Mary Ellen Schneider

Current government thresholds for reportable “serious error” of computerized provider order entry in the hospital may not be high enough to actually save lives, according to a simulation conducted by researchers at the Rand Corporation.

The researchers estimated the impact on mortality in a sample of more than 2,500 hospitals using computerized provider order entry (CPOE) for 26%-50% of patients, and found that that level of use could reduce mortality for heart failure and acute MI among hospitalized Medicare beneficiaries by 1.2%—not a statistically significant reduction.

But a second simulation found that mortality could be significantly reduced (2.1%) if CPOE were used for 51%-90% of patients hospitalized for those conditions (Health Affairs 2011 Sept. 14; doi:10.1377/hlthaff.2011.0245).

The results could help influence policy makers as they set standards for the later stages of the electronic health records (EHR) incentive program, the authors noted. The program was authorized by Congress in the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act and will provide about $27 billion in payments to physicians, hospitals, and other providers by the end of 2016.

Under stage 1 of the program, hospitals are required to use CPOE on medication orders for at least 30% of their eligible patients; under initial regulations governing the program, the threshold could rise to 60% in stage 2 and 80% in stage 3 of the program.

However, even the initial requirements for CPOE have been criticized by health care providers as being too strict. And recently, the Health Information Technology Policy Committee convened by the Health and Human Services department to help implement the incentive program recommended delaying the implementation of stage 2 requirements by a year.

The Rand study results could be ammunition for policy makers seeking to make the program more robust. “Our study should reassure policy makers at HHS and other stakeholders that high levels of use of computerized provider order entry and other health information technology have value and are likely to yield tangible health benefits for patients,” said Spencer S. Jones, an associate information scientist at Rand in Boston and lead author of the study, said in an interview.

But Mr. Jones added that there is currently no research setting out the optimal pace for EHR adoption. While proceeding at a cautious pace may be an appropriate strategy, maintaining parallel paper and electronic systems could lead to unneeded adverse consequences, he said.

The study, which relied on data from 2,543 privately owned general acute hospitals, also compared the impact of any use of CPOE to no use and found that hospitals that used CPOE even a small amount achieved lower mortality rates for heart failure, acute MI, and pneumonia among Medicare beneficiaries. However, when the researchers adjusted for potential confounding factors that might affect mortality, there was a statistically significant relationship between CPOE use and lower mortality only for acute MI and heart failure. It could be that CPOE is more helpful in reducing medication errors for such complex chronic conditions as heart failure than for acute conditions like pneumonia, the researchers wrote.

The researchers analyzed data from the 2007 American Hospital Association annual survey database and the AHA’s Information Technology Supplement from the same year. Mortality data are from the CMS’s Hospital Compare database.

The researchers disclosed no conflicts of interest. The study was funded by philanthropic contributions from members of the Rand health board of advisers.

Dr. Jeana O’Brien, FCCP, comments: This study by the Rand Corporation supports the previous evidence regarding the mortality benefit to patients through use of CPOE. While institutions and care providers ultimately need to move to complete use of CPOE, there must also be time to safely develop processes around handling of the electronic orders and ensuring appropriate technology training and safeguards.

It is almost certain the later stages of meaningful use will require high levels of CPOE use. The pace at which this occurs must take into consideration the operational details and magnitude of CPOE, as well as the impact of other simultaneous meaningful use requirements.

Medicare to Begin Testing Bundled Payments

Physicians and hospitals now have the chance to test bundled payments on a range of conditions under a new Medicare initiative.

In late August, the Centers for Medicare and Medicaid Services released a request for applications (RFA) inviting physicians, hospitals, and other health care providers to participate in the Bundled Payments for Care Improvement program. The program, which was mandated under the Affordable Care Act, offers a variety of options for bundling payments for a hospital stay, for postdischarge services, or for both the hospital stay and the postdischarge care.

The move toward bundled payments is a major shift in how the government pays for medical care. Instead of paying hospitals, physicians, and other providers separately, this initiative would combine the payment over an episode of care for a specific condition. The aim of the program is to incentivize clinicians to work together and provide better continuity of care, resulting in better quality and lower costs.

“Today, Medicare pays for care the wrong way,” Health and Human Services Secretary Kathleen Sebelius said during a teleconference to announce the bundling program. “Payments are based on the quantity of care, the amount of services delivered, not the quality of that care. And that leaves us too often with a system that actually can punish the providers that are most successful at getting and keeping their patients healthy.”

The new bundling program offers four ways that health care providers can receive a bundled payment, three of which provide payment retrospectively and one that offers a prospective payment. For example, under some of the retrospective payment models, CMS and the providers would agree on a target payment amount for the episode of care and providers would be paid under the original fee-for-service system, but at a negotiated discount of 2%-3% or greater. At the end of the care episode, the total payment would be compared with the target price and providers would share in the savings, according to CMS.

The prospective payment model would work differently. Under that option, CMS would make a single bundled payment to the hospital to cover all services provided during the inpatient stay by the hospital, physicians, and other providers. That payment would offer at least a 3% discount to Medicare. Under this arrangement, physicians and other providers would submit “no pay” claims to Medicare and the hospital would pay them out of the single bundled payment.

In addition to the options of prospective or retrospective payment, providers could choose how long the episode of care will be and what conditions they want to bundle payment for, and what services would be included in the payment. CMS officials said they wanted to make the program flexible so that a range of hospital, physicians, and other providers could participate.

Although the application period has closed for organizations interested in Model 1, those interested in applying for Models 2, 3, and 4 have until Nov. 4 to do so. More information is available at www.innovations.cms.gov/areas-of-focus/patient-care-models/bundled-payments-for-care-improvement.html.

Dr. Richard Gillfian, the acting director of the CMS Innovation Center, which is overseeing the bundling initiative, said he expects that hundreds of organizations will apply. CMS will consider a number of factors in choosing participants for the program including the best proposals for care improvement, the number of patients involved, and the costs addressed, and the price discounts offered, he said.

The program is a unique opportunity for hospitals to redesign their systems to promote better care coordination, Dr. Gillfian said, and have that effort supported through Medicare payments.

The idea is to eliminate the traditional barriers between physicians and other providers—both inpatient and outpatient—all of whom may be involved in the care of a single condition, said Dr. Nancy Nelson, senior adviser to the CMS Innovation Center and past president of the American Medical Association. “I do believe that both physicians and hospitals will find this [to be] an opportunity that’s flexible enough to give them the opportunity to begin to learn how to get paid for care differently,” she said.

The AMA was still reviewing the bundled payment details at press time, but praised CMS for making the program flexible. Dr. Cecil B. Wilson, AMA immediate past president, said the organization will urge federal officials to encourage applications for physician-led bundling projects. “For this to be successful, and for physicians to participate actively, then they need to be a part of that process rather than just some larger corporation or larger hospital system or health plan that’s organizing these,” he said. “We think those are important as well, but we also think it’s important that physicians be a part of that leadership.”

While physicians working in large group practices have had some experience with bundled payments, most doctors aren’t prepared for these types of changes, Dr. Wilson said. So the AMA is also recommending that CMS provide technical assistance to interested physicians.
CMS Eases Requirements for E-Prescribing

BY FRANCES CORREA
Elsevier Global Medical News

Based on feedback from physicians and health care providers, the final federal e-prescribing regulations are more flexible and contain more exemptions, the Centers for Medicare and Medicaid Services announced.

The changes come after concern that the program criteria should be more aligned with the Medicaid incentive program for electronic health records, according to CMS officials. “[The changes] will encourage more doctors and other health care professionals to adopt this technology and give them the added flexibility to help them succeed,” Dr. Patrick Conway, chief medical officer at CMS and director of the agency’s Office of Clinical Standards and Quality, wrote in a blog post announcing the change.

“With electronic prescribing, providers can better manage patient prescriptions, reducing drug interactions or other preventable prescription errors.”

Under the Medicare Electronic Prescribing Incentive Program, eligible prescribers who meet the e-prescribing criteria will get a 1% bonus payment for 2011 and 2012 and a 0.9% bonus in 2013. Those who do not meet the criteria in 2012 will be penalized 1% of Medicare payments; the penalty will escalate in 2013 and 2014.

Under the final rule, prescribers who use certified electronic health records can claim this as a “qualified” e-prescribing system. This move was designed to more closely align the e-prescribing program with the program that offers incentives for meaningful use of electronic health records, CMS officials said.

The final rule contains hardship exemptions for those who live in a rural area without high-speed Internet access and those who work where there are not enough pharmacies that can take electronic prescriptions. In addition, the final rule creates additional hardship exemption categories. Eligible professionals have to demonstrate that they have registered to participate in the Medicare or Medicaid EHR incentive program and have adopted certified EHR technology, an inability to electronically prescribe due to local, state, or federal law (this primarily applies to prescribing of narcotics); very limited prescribing activity; or insufficient opportunities to report the e-prescribing measure.

The deadline to apply for a hardship exemption has been extended until Nov. 1, 2011, according to CMS officials.

Even with the changes, however, some physicians still have concerns. The American Medical Association said it is worried about the amount of time physicians will have to apply for the exemptions.

“We remain concerned that physicians will be hit with a penalty and are not being given enough time to comply with the e-prescribing program criteria to avoid this penalty,” said Dr. Cecil Wilson, AMA immediate past president.

Medicaid Spending Varies Widely

BY MARY ELLEN SCHNEIDER
Elsevier Global Medical News

A look at Washington state’s Medicaid program could provide some clues for how to control costs as states prepare for the massive 2014 expansion of Medicaid under the Affordable Care Act.

Washington has been able to provide widespread access to outpatient services and prescription drugs, while keeping down spending on inpatient care, according to an analysis in Health Affairs (doi: 10.1377/hlafail.2011.0106).

The per beneficiary cost for inpatient stays was about 35% below the national average in Washington state, while outpatient visits and prescriptions were each 15% above the national average, according to authors Todd P. Gilmer, Ph.D., and Richard G. Kronick, Ph.D., who were both at the University of California, San Diego, when the article was written. Dr. Kronick is now a deputy assistant secretary for health policy at the Department of Health and Human Services.

Dr. Gilmer and Dr. Kronick analyzed Medicaid claims data from 2001 to 2005 to see how the volume and the price of services affected the variation in spending across the states. They limited the analysis to claims for Medicaid-only, disabled beneficiaries receiving cash assistance.

Several states are using their Medicaid resources in a way that’s helping to reduce the need for more expensive hospital care,” Dr. Gilmer said in a statement. “This suggests that there is a great deal of room for innovation in Medicaid. By increasing access to primary care and experimenting with team-based delivery models and low-cost providers, states may be able to improve quality while reducing Medicaid spending.”

For example, the Medicaid programs in Connecticut, Massachusetts, New Hampshire, and Vermont spent more than most on prescription costs and outpatient visits, but had a lower-than-average number of hospital days. The inpatient and outpatient spending offset each other, the researchers wrote, resulting in average overall spending that was just below the mean among all states.

The researchers also found that having a large primary care workforce was associated with reduced hospital stays for some chronic conditions. The authors received funding from the Robert Wood Johnson Foundation’s Changes in Health Care Financing and Organization initiative.

Medicare Aims to Cut Paperwork

BY MARY ELLEN SCHNEIDER
Elsevier Global Medical News

Physicians and their staffs may have a less burdensome paperwork load to do thanks to a new Medicare regulation.

The interim final rule, now published in the Federal Register, places two rules on electronic health care transactions: one to make it easier to determine patients’ health care coverage and the other to ascertain the status of a submitted claim.

Currently, when a physician’s office staff seeks information on patient health care coverage, they may have to make the request in a different format for each health plan, but under the operating rules set out by Medicare the format will be standardized across all health plans. The changes mandated under the Affordable Care Act, will go into effect Jan. 1, 2013. The new requirements are based largely on operating rules developed by the Council for Affordable and Quality Healthcare’s Committee on Operating Rules for Information Exchange (CAQH CORE), an industry coalition that works on administrative simplification issues. The CAQH CORE rules are currently in use on a voluntary basis, Centers for Medicare and Medicaid Services officials said.

The CMS estimates that the adoption of these rules will save physicians and health plans about $12 billion over the next decade, largely because of fewer phone calls between physicians and health plans, reduced paperwork and postage costs, increased opportunities to automate the claims process, and fewer denials.

—Mary Ellen Schneider
Hospitalization Linked to Stoppage of Chronic Meds

BY MARY ANN MOONEY
Elsevier Global Medical News

Hospitalization raises the risk of long-term medications for chronic diseases will be discontinued unintentionally, according to a report.

That risk is further heightened with ICU care, which suggests that the more patients are transitioned from site to site and from clinician to clinician, the greater the chance that their long-term medications (statins, antplatelet or anticoagulant agents, levotyroxine, respiratory inhalers, and gastric acid-suppressing drugs) will get lost in the shuffle.

Discontinuing these necessary medications appears to raise patients’ risk of death, further hospitalization, and ED visits for up to 1 year after discharge, said Dr. Chaim M. Bell of St. Michael’s Hospital, Toronto, and his associates.

“These findings emphasize the importance of a systematic approach to transitions in health care to ensure medication continuity,” they noted.

The investigators conducted a population-based cohort study of all hospitalizations of patients aged 66 years and older in Ontario between 1997 and 2009 to examine medication continuity. They reviewed the records of 396,036 patients who had been taking any of five types of medications for chronic disease listed above for at least 1 year. In all, 160,568 of these study subjects were hospitalized during the study period, including 16,474 who were admitted to the ICU; the remaining 208,468 were not hospitalized served as control subjects. The rate of patients who failed to refill prescriptions of the five categories of medication within 90 days of discharge was calculated.

The study investigators excluded cases in which patients developed complications or contraindications to their medications, or otherwise had a clear reason for discontinuing a drug. They also controlled for confounding factors that could influence stopping a medication, such as comorbid disease burden and the number of physician contacts that occurred during the year preceding hospitalization.

Drugs in all five medication categories were significantly more likely to be discontinued after hospitalization than in the controls. Rates of unintentional discontinuation were highest for antplatelet/anticoagulants (19.4%), followed by statins (13.6%), gastric acid suppressors (12.9%), and respiratory inhalers (4.5%). The corresponding rates for control subjects were 11.8%, 10.7%, 9.4%, 11%, and 3%, respectively.

Rates of unintentional discontinuation were even higher among ICU patients in four of the five medication categories (22.8% for antplatelet/anticoagulants, 15.4% for gastric acid suppressors, 15% for levothyroxine, and 14.6% for statins).

In a secondary analysis, the unintentional discontinuation of antplatelet/anticoagulants and of statins was associated with higher risk of the combined outcome of death, further hospitalization, or emergency admission for up to 1 year after hospital discharge.

“This underscores the widespread prevalence of potential errors of omission and the risk for long-term harm following hospitalization,” Dr. Bell and his colleagues said (JAMA 2011;306: 840-7).

Although this study was not designed to assess how it is that necessary medications get “dropped” unintentionally, previous studies have suggested that miscommunication during transitions of care is not the only contributor. Many medications for chronic diseases are prescribed during a critical illness, but restarting them is forgotten or overlooked after the acute event resolves.

Previous research also found that unintentional discontinuation of medications is common, but they were primarily single-site, cross-sectional studies. In contrast, “our study examined personnel errors of omission during a systemic basis for an extended period in a diverse patient population with a focus on long-term medications for chronic diseases,” the investigators wrote.

“Even though our study cohort only included elderly patients (aged 66 and older), the findings are likely generalizable to the general population,” Dr. Bell and his colleagues concluded.

The study was funded by the Canadian Institutes of Health Research, the Institute for Clinical and Evaluative Sciences, and the Ontario Ministry of Health and Long-Term Care.

Beware of Curtain! Pathogens Plentiful on Hospital Partitions

BY DOUG BRUNK
Elsevier Global Medical News

CHICAGO – If you think the privacy curtains at your health care facility are free of potentially harmful bacteria, think again.

Within 1 week of being laundered, 92% of hospital curtains were contaminated with pathogens that included methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant Enterococcus (VRE) species, results from a single-center study showed.

“Usually when health care workers walk into a patient room, they’ll wash their hands, grab the curtain, pull it aside, and then touch the patient, without realizing that they touched the curtain,” Marion L. Schweizer, Ph.D., commented in an interview during a poster session at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

“The message here is that health care workers should wash their hands after touching privacy curtains and before touching the patient.”

Over a 3-week period, Dr. Schweizer and her associates obtained 180 swab cultures from 43 privacy curtains in 30 rooms at the University of Iowa Hospitals and Clinics. They obtained the cultures twice weekly from an 800-cm2 area on the leading edge of each curtain, and marked each curtain to determine when it was changed.

Standard microbiologic methods, including broth enrichment, were used to determine contamination. To distinguish persistence of pathogens on curtains from recontamination, all MRSA and VRE were typed using pulsed-field gel electrophoresis.

Of the 13 curtains placed during the study, 12 (92%) showed contamination within 1 week, while 41 of the 45 curtains (95%) showed contamination on at least one occasion.

“We thought the prevalence would be high, but we didn’t think it would be that high,” commented Dr. Schweizer of the department of general internal medicine at the University of Iowa, Iowa City.

She went on to report that VRE and MRSA were isolated from 42% and 21% of the curtains, respectively. Eight curtains were contaminated with VRE at more than one time point: three with persistence of a single genetic type and five with genetic types over time. “This shows that there are lots of pathogens on the curtains,” Dr. Schweizer said. “They stick around for a long time and they’re constantly being recontaminated.”

Two-thirds of all swab cultures (66%) were positive for either S. aureus, Enterococcus spp. (44%), or gram-negative rods (22%).
Division Chief, Pediatric Pulmonology

Phoenix Children’s Hospital is seeking a Chief of Pediatric Pulmonology. The desired candidate should be a board certified pediatric pulmonologist with demonstrated excellence in administration, clinical care, teaching and academics. The successful candidate should also have strong leadership and interpersonal communication skills.

Phoenix Children’s Hospital is the only free-standing children’s hospital in the state of Arizona, located in the fifth largest metropolitan region in the country. Phoenix Children’s Hospital just completed a major physical expansion growing its licensed beds to 600 with the opening of a new, state of the art inpatient facility. In addition, brand new, luxurious ambulatory space has also been developed to meet our growing numbers of children.

The new division chief will have the opportunity to mentor our six current physicians, expand the hospital’s current Cystic Fibrosis and Sleep programs, identify and develop new programs, and recruit faculty to help achieve the institutional goals of pursuing a fellowship and collaborative research. Academic appointments with the University of Arizona College of Medicine Phoenix and the Mayo Clinic are available.

Phoenix Children’s Hospital is an equal opportunity employer.

Interested Candidates should contact:

David Bank, MD MBA
Physician in Chief
Phoenix Children’s Medical Group
(w) 602-546-1905
(c) 602-361-0359
dbank@phoenixchildrens.com

BC/BE Pulmonary/ Critical Care Physician

Pulmonary/Critical Care Physician

Metro Atlanta

Established, 18 physician Pulmonary Medicine practice in suburban Atlanta, looking for a BC/BE Pulmonary/Critical Care Physician. Sleep certification a plus. Practice includes all aspects of pulmonary medicine including: critical care, sleep medicine, pulmonary rehab, clinical research, and interventional pulmonology. Practice located at three large acute-care hospitals. Practice has a team of 14-advanced practitioners. Competitive salary with aggressive bonus structure. Malpractice coverage and generous benefits package including 401(k) and defined pension plan. Please contact Provider.Positions@wellstar.org or 770-792-7539.

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Reply to: Administrator
4741 C NW 8 Avenue, or by fax to 352-379-1928, or by email to info@pulmonaryphysicians.net

New York - Nassau County, Long Island

Hospital Affiliated-Private Practice seeking FT and PT BC/BE Pulmonologist. Successful candidate(s) to join our existing five Physician single-specialty group. We offer a generous mix between office, hospital and a nursing home based practice, we are affiliated with a large university hospital and provide services at local community hospitals as well. Practice includes Directors of a large ventilator unit, critical care, medicine, sleep and pulmonary departments. We are also affiliated with two state of the art sleep labs and rehabilitation centers. We offer a competitive salary, excellent benefits and on call lifestyle. Immediate openings are available as well as openings for July 2012. This is not a J-1 visa opportunity. Motivated, qualified candidates should fax CV to 516-796-3208 or Cindy Strain or email to Cindy65@aol.com Call 516-796-3700 for further information on this exciting opportunity.

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North Shore-Long Island Jewish Health System (NSLIJHS) and Hofstra University School of Medicine are conducting a national search for a Chief, Division of Pulmonary Critical Care and Sleep Medicine for North Shore University Hospital (NSUH) and Long Island Jewish Medical Center (LIJMC).

This position is an opportunity for a highly distinguished physician to provide leadership and direction for the Division of Pulmonary Critical Care and Sleep Medicine at NSUH and LIJMC in addition to developing the Division at the new medical school. The ideal candidate will have national and/or international recognition as well as experience working in an academic medical center or health system. The candidate must have a strong clinical orientation, be familiar with medical school curricular needs, the conduct of translational and clinical research, and have the capability to manage the financial/business affairs of a complex multi-site department. Candidates for this position must be board-certified and eligible for a NY State medical license.

North Shore-LIJ Health System provides compassionate, high-quality healthcare in the greater Long Island region through its 16 hospitals and more than 38,000 employees. NSLIJHS is the 3rd largest, non-profit, secular healthcare system in the U.S. and the 9th largest employer in the New York City metropolitan area.

The Chief’s primary role at the Hofstra University School of Medicine will be to build and grow a top-tier academic Division of Pulmonary Critical Care and Sleep Medicine, including building a strong collaborative effort with the Feinstein Institute of Research, and be responsible for all educational activities, including the development of a comprehensive curriculum, oversight of medical student training, and recruitment of faculty. At the Health System, the Chief will have direct responsibility for medical services at NSUH and LIJMC. The incoming Chief will oversee the combined faculty members, voluntary physicians and fellows across both campuses.

Interested individuals should submit a letter or email expressing interest with a curriculum vitae to:

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