



AMERICAN COLLEGE OF SURGEONS

SURGERY NEWS



BONNIE JOHNSTON/JAMES GRAHAM BROWN CANCER CENTER

Older women given hormonal therapy after breast-conserving surgery have an excellent prognosis, said Dr. Anees B. Chagpar.

Elderly May Safely Skip Radiation for Breast Ca

BY JANE SALODOF
MACNEIL

Elsevier Global Medical News

SANTA FE, N.M. — Elderly breast cancer patients who are given hormonal therapy may not need radiation therapy after breast-conserving surgery, according to a retrospective study of a randomized controlled trial.

Investigators who compared outcomes for patients 70 years of age and older in the North American Fareston [toremifene] Versus Tamoxifen Adjuvant (NAFTA) trial said that they saw no difference at a median follow-up of 56 months in local-regional recurrences, disease-free survival, or overall survival among 344 women who had ra-

diation therapy and 113 women who did not.

There were just two recurrences in the radiation cohort and one in the group that did not receive radiotherapy. The 5-year actuarial local-regional recurrence rates were calculated at 1.2% and 1.1%, respectively (odds ratio 1.0), Dr. Anees B. Chagpar reported at the annual meeting of the Western Surgical Association.

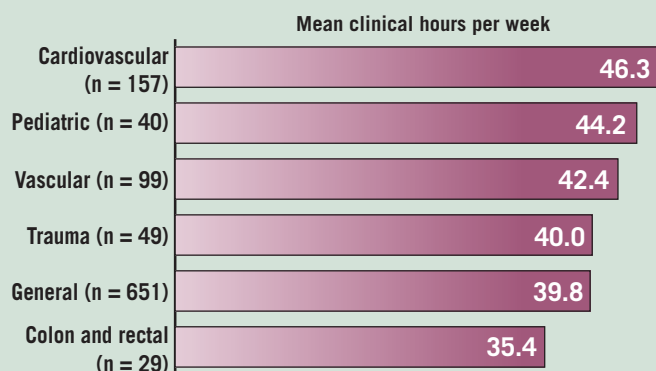
“Older women treated with hormonal therapy after breast-conserving surgery have an excellent prognosis,” said Dr. Chagpar, an ACS Fellow.

“In this population, adjuvant radiation therapy does not sig-

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VITAL SIGNS

Direct Patient Care Hours Varied Among Surgical Settings in 2007



Note: Clinical hours do not include time spent on administrative tasks.
Source: 2007 survey data, Medical Group Management Association

ELSEVIER GLOBAL MEDICAL NEWS

IOM Recommends Some Changes in Work Hours

Maximum 80-hour week retained.

BY DAMIAN McNAMARA
Elsevier Global Medical News

WEST PALM BEACH, FLA. — Changes in the maximum shift length for residents, increases in mandatory time off, and inclusion of all moonlighting in total work hours are among the recommendations put forth by the Institute of Medicine in early December.

The institute did not recommend changing the average weekly maximum of 80 hours, and it favored retention of the policy allowing a maximum of 88 hours for programs demonstrating a sound educational rationale, while continuing to restrict emergency department residents to a 60-hour work week that includes maximum 12-hour shifts followed by at least 12 hours off.

Release of the 323-page report, “Resident Duty Hours: Enhancing Sleep, Supervision,

and Safety,” coincided with the annual meeting of the Southern Surgical Association, where surgeons reacted with a call for a unified response.

“It is vital that all of us be informed about this. It’s important to the future of surgery quality in this country,” said Dr. James O’Neill Jr., an ACS Fellow and professor of surgery at Vanderbilt University, Nashville, Tenn.

In response to the report in a media release, the American College of Surgeons agreed that the 80-hour average maximum should be retained: “The ACS firmly believes that these work hours are important to provide surgical residents with the depth and variety of educational experiences that are essential for physicians to become competent surgeons.”

The ACS is concerned, however, about some of the details,

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‘Never Events’ on CMS Chopping Block

BY ALICIA AULT
Elsevier Global Medical News

The Centers for Medicare and Medicaid Services is proposing to refuse all payments related to so-called never-event surgical errors.

The agency is proposing a national coverage decision of nonpayment if an invasive procedure is performed on the wrong body part, if an incorrect invasive procedure is performed, or if a procedure is performed on the wrong patient. The proposal would affect payments not just to hospitals but also to physicians, other health care providers, and suppliers involved in the never events.

“These types of surgical errors can cause serious injury or

death to beneficiaries and result in increased costs to Medicare due to the need to treat the consequences of the errors,” Kerry Weems, CMS Acting Administrator, said in a statement.

The CMS proposal is not a surprise, but it came earlier than expected. During an August 2008 press briefing, Mr. Weems had said the CMS expected to issue three national

coverage decisions on surgical never events in February 2009.

The agency invited comments in midsummer, when it first considered the national coverage decision. At that time, the American Medical Association said that it objected to using the process, partly because there would appear to be no room for a provider to

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Early Experience With PQRI Spurs Improvements for 2009

BY ALICIA AULT

Elsevier Global Medical News

WASHINGTON — Data from the first 6 months of the Physician Quality Reporting Initiative (PQRI) are spurring improvements for the upcoming year, a Medicare official testified at a meeting of the Practicing Physicians Advisory Council.

In the summer of 2008, the CMS paid \$36 million in bonuses to 56,000 physicians for their 2007 reporting, said Dr. Michael T. Rapp, director of the quality measurement and health assessment group at the Centers for Medicare and Medicaid Services. The average payment was \$600 for 6 months of data; for 2008 reports, the 1.5% bonus is likely to be around \$800 on average, he said.

There will be a number of changes for reporting in 2009. In all, there will be 153 reportable measures. Fifty-two are new, and 18 are reportable only through registries. There are seven measures groups: diabetes mellitus, chronic kidney disease, preventive care, coronary artery bypass graft surgery, rheumatoid arthritis, perioperative care, and back pain. Each group contains a number of measures; physicians can report these only as groups.

There will be nine different ways physicians can qualify for the 2% PQRI bonus in 2009, said Dr. Rapp. Physicians also can receive an additional 2% bonus for satisfying requirements under the separate e-prescribing incentive program.

Under last year's Medicare Improvements for Patients and Providers Act, the CMS is required to eventually post on its Web site the names of physicians who satisfactorily report quality measures for 2009. That proposal has been controversial.

PPAC panelist Dr. Frederica Smith, an internist and rheumatologist in Albuquerque, called the idea a "terrifying concept," as it might appear that physicians who were not on the list did not care about quality.

And physicians had many problems complying with the CMS process for reporting measures in 2007, she noted.

Dr. Rapp agreed that the first phase of the program had been frustrating. But "the way it was for 2007 doesn't mean that's the way it will be for 2008," he said. The agency posted a detailed report on the 2007 experience at its Web site last month (www.cms.hhs.gov/PQRI/Downloads/PQRI2007Report-Experience.pdf).

Overall, there were submissions from 109,349 national provider identifier/tax identification numbers with at least one quality data code. Of those, about 93% (101,138) submitted at least one valid code. More than 14 million codes were reported; more than 50% of those (7.3 million) were validly submitted.

There were three major reasons for code nonvalidity: The provider did not adhere to the measure specification; the codes were not submitted with the same claim as the billing and diagnosis code submitted for the procedure; or

there was no national provider number (NPI) on the claim.

Many of the submission errors were for patients who did not meet reporting specifications for gender, age, or diagnosis or procedure code for a particular measure. For instance, the PQRI does not accept reports for diabetes measures on patients over age 75 said Dr. Rapp.

He said that the CMS plans to rerun reports for providers who did not qualify for the bonus, with the idea that mistakes could have been made and some providers could be found eligible for the bonus on reanalysis. If that is the case, the CMS will issue checks retroactively.

The agency also aims to make some changes that will hopefully reduce the number of rejected reports going forward. The CMS said that it would continue to conduct provider education and outreach to make sure that physicians understand the specifications for reporting each measure.

The agency also is working with local Medicare carriers to ensure that when claims get split—where the quality codes are separated—they will be "reconnected and counted," according to the agency.

Also, claims that were submitted to carriers for payment in 2008 without an NPI were automatically rejected. As a result, in the first half of 2008, less than 1% of claims submitted under the PQRI program were missing an NPI, according to the agency's report. The CMS expects less than 0.5% of PQRI claims to be without an NPI. ■

Criteria Still Unclear

Never Events • from page 1

appeal the nonpayment. The AMA is still standing by those comments.

In its submitted comments, the American Hospital Association also said an appeals process was necessary. Further, it questioned how the wrong-site events will be defined, how accountability would be assigned, and which costs or services would not be covered.

The agency also needs to consider scenarios such as a wrong-site surgery that is begun but corrected before there is any harm, said the AHA.

The comment period on the CMS proposal ended Jan. 2.

There are not a lot of data on the frequency of surgical never events. The CMS cited a 9-year study published in 2006 in Archives of Surgery that reported an incidence of 1 in 112,994 for wrong-site procedures not involving the spine.

Several states have recently launched initiatives to track wrong-site surgery.

The Pennsylvania Patient Safety Authority found that Pennsylvania facilities reported 286 wrong-site surgeries in 51 months, or 1 every 5.44 days, according to Dr. John Clarke, clinical director of the authority's reporting system. Pennsylvania facilities must report near-misses and actual incidents to the authority, so this is thought to be a fairly accurate estimate, he said in an interview.

Extrapolating the state data gives an estimated four to five wrong-site surgeries each day in the United States, he said.

The Pennsylvania data may be viewed on the Web site www.psa.state.pa.us. ■



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Obama Raises Hopes for Successful Health Reform

Economic woes will require us to 'also finally address our health care challenge,' he said.

BY MARY ELLEN SCHNEIDER
Elsevier Global Medical News

Early signals from the incoming Obama administration have many physicians feeling optimistic about the chances for comprehensive health reform.

The economy is one reason that health reform may have a greater chance for success now than it did in the Clinton administration, said Dr. Nancy H. Nielsen, president of the American Medical Association (AMA). As more Americans lose their jobs, they are also losing health insurance, driving policy makers to address the issue of the uninsured. "There may be more tension for change now than there has been in the past," she said.

President-elect Barack Obama addressed that tension during a press conference in December when he announced former Sen. Tom Daschle (D-S.D.) as his choice for Health and Human Services secretary.

The current state of health care in the United States—with rising premiums and the large number of uninsured Americans—is having a direct and negative impact on the U.S. economy, President-elect Obama said. "If we want to overcome our economic challenges, we must also finally address our health care challenge."

Mr. Obama tapped Sen. Daschle not only as HHS secretary, but also as director of a new White House Office on Health Care Reform. Jeanne M. Lam-

brew, Ph.D., a health policy expert who coauthored the health care book "Critical: What We Can Do About the Health-Care Crisis" with Sen. Daschle, was chosen as deputy director of the new White House office.

The AMA is pushing Congress and the administration to enact permanent Medicare physician payment reform by eliminating the Sustainable Growth Rate formula, which ties physician payments to the gross domestic product. Without congressional action on the payment formula within the next year, physicians will be faced with a projected 21% cut in Medicare payments starting in 2010, Dr. Nielsen said.

If Congress chooses to throw out the SGR formula, it likely will need to authorize some fast-track pilot projects to test some of the most promising models for new payment systems such as global and bundled payments, said Robert

Doherty, senior vice president of Governmental Affairs and Public Policy at the American College of Physicians.

ACP officials are hoping that the Obama health care reform proposal will include some of their top priorities—coverage of those who are uninsured and improving access to primary care physicians. The experience with the Massachusetts health reform law illustrates that expanding insurance coverage does not guarantee access to care if there are not enough primary care physicians to see all the new patients, said Mr. Doherty.

Shoring up the primary care workforce will require an increase in payments for primary care services, an emphasis on primary care in graduate medical education funding, and the creation of programs that would allow primary care physicians to eliminate their medical school debt, he said. ■

Hormonal Therapy Suffices

Radiation • from page 1

nificantly affect local-regional recurrence or survival."

Dr. Chagpar said that she and her coinvestigators from the University of Louisville (Ky.) tackled the controversial issue because elderly patients often have indolent cancers and comorbidities that can make them more vulnerable to side effects.

Two previous trials—one involving patients 70 years and older (*N. Engl. J. Med.* 2004;351:971-7) and one involving patients 50 years and older (*N. Engl. J. Med.* 2004;351:963-70)—had shown lower recurrence rates with radiation therapy in women receiving adjuvant hormonal treatments after lumpectomy.

The NAFTA trial analyzed by Dr. Chagpar's group randomized 1,709 hormone receptor-positive patients from 1998 to 2002 to hormonal therapy with tamoxifen or toremifene. Within this population, the investigators identified 737 women aged 70 years and older, of whom nearly two-thirds had breast-conserving surgery. This postlumpectomy subgroup had a median age of 76 years and median tumor size of 1.2 cm. None had chemotherapy, and 91% were node negative.

The only factors associated with receiving radiation therapy were age (a median of 75 years vs. 76 years in women who did not have radiation therapy) and being lymph node positive (10.2% of the radiation group vs. 4.4% of those spared radiation). Both factors were controlled for in multivariate analyses of recurrence and survival data.

At 5 years, actuarial disease-free survival rates were 97.6% with radiation therapy and 95.9% with-

out; overall survival rates were about 90% in both groups, reported Dr. Chagpar, director of the multidisciplinary breast cancer program at the University of Louisville's James Graham Brown Cancer Center. She noted, however, that the study may have been underpowered to detect survival differences and that the two cohorts were not balanced.

These limitations could have resulted in a selection bias, said Dr. Amy C. Degnim, a discussant at the meeting. "It appears that the patients' treating physicians did succeed in identifying the low-risk patients in whom radiation therapy could be omitted," said Dr. Degnim, an ACS Fellow with the Mayo Clinic in Rochester, Minn., noting that two previous studies have shown benefit from radiation therapy.

Dr. Chagpar responded that the reference trials were done before 2000 and showed only small absolute benefits from radiation therapy. The NAFTA trial represents a more contemporary series, in which nearly two-thirds of patients had sentinel lymph node biopsies, she explained.

"Therefore, staging may be more accurate in our patients," she concluded.

Aromatase inhibitors have since been incorporated into adjuvant treatment, she added, suggesting that perhaps this will result in even lower recurrence rates with this population.

Dr. Chagpar disclosed no conflicts of interest.

Dr. Chagpar discusses her findings in a video interview available at <http://www.youtube.com/watch?v=jid3fXyANM>. ■

ACS Cites Patient Safety Concerns

Work Hours • from page 1

including a new recommendation to limit shifts to 16 hours. Since July 2003, when the Accreditation Council for Graduate Medical Education (ACGME) first implemented the work hour restrictions, residents have been allowed to work 30-hour shifts consisting of up to 24 hours for admitting patients and 6 hours for transitional and educational activities. In contrast, the Institute of Medicine (IOM) recommends that the 30 hours include 16 hours for admitting patients, followed by a 5-hour protected period for sleep between 10:00 p.m. and 8:00 a.m. The remaining time may be used for transitional and educational activities. A simpler, second option is a 16-hour shift with no protected sleep time.

"The IOM recommendation regarding 16-hour shifts could compromise the education of the residents and possibly affect the continuity of patient care that is essential to ensuring that all surgical patients receive safe, effective, and high-quality care before, during, and after surgical procedures," the ACS wrote in the statement, adding that shorter shifts for admitting patients could further exacerbate the shortage of surgeons in the United States.

Those concerns were echoed by Dr. Russell G. Postier, who commented on the report. "The IOM recommendations address one aspect of patient safety—resident fatigue—while ignoring communication issues related to the cross coverage necessary to implement work hour changes, supervision of residents, and lack of continuity of patient care," said Dr. Postier, an ACS Fellow who is Chair of the Surgery RRC and the department of surgery at the University of Oklahoma Health Sciences Center. He added that the ever-increasing coverage of patients with whom residents are unfamiliar would make their work environment even more stressful.

"I am very concerned that, if adopted, these recommendations will only further burden residents, who already stretched too thin, to cover even more patients while they are working," said Dr. Jacob Moalem, assistant professor at the University of Rochester (N.Y.) and chair of the ACS Resident/Associate Society,

who also commented on the report. "Alternatively, hospitals might be forced to create mechanisms that make resident coverage less indispensable—which would completely change the role of surgical residents and seriously undermine their education."

The IOM committee estimated it would cost about \$1.7 billion to hire support staff, other clinicians, or additional residents to cover the cost of current residents' excess time. Nearly one-quarter of the total amount would go toward bringing residency programs into compliance with the 2003 limits.

"One problem was the 24 plus 6—a lot of sleep literature shows that after 16 hours your performance falls off. So 16 hours is the line in the sand for these researchers," Dr. Tim C. Flynn, a surgeon and vice chair of the ACGME, said at the meeting. Dr. Flynn, an ACS Fellow who is also professor and associate dean of vascular surgery at the University of Florida in Gainesville, emphasized that his comments were his own and did not reflect the position of the ACGME.

The IOM also cited the compliance issue. "A lack of adherence to current limits on duty hours is common and underreported," committee authors wrote in an IOM Report Brief. "Therefore, the committee recommends changes to ACGME monitoring practices, including unannounced visits and strengthened whistleblower processes to encourage resident reporting of violations of limits and undue pressure to work too long."

The ACGME plans to meet in March 2009 to review the evidence, Dr. Flynn said.

Other IOM recommendations include confining in-house call to every third night without averaging; limiting the frequency of in-hospital night shifts to four nights, with 48 hours off after three or four consecutive nights of duty; and specifying mandatory time off as 5 days per month, 1 day per week, and at least one 48-hour period per month. ■

For a free summary of the report, visit www.iom.edu/CMS/3809/48553/60449/60469.aspx.

Study Compares Costs of Appendectomy Procedures

BY JANE SALODOF MACNEIL
Elsevier Global Medical News

SANTA FE, N.M. — A review of discharge data from nearly 1.5 million appendectomies found average hospital charges in nonperforated appendicitis cases were nearly \$4,000 higher for laparoscopic procedures than for open procedures, despite similar lengths of stay.

Conversely, charges were comparable for both types of procedures in perforated cases, but hospital stays were 1 day shorter when surgery was done laparoscopically.

"These data indicate that laparoscopic appendectomy should be reserved for perforated appendicitis while open appendectomy should be performed in nonperforated appendicitis," David Ludlow, a fourth-year medical student at the University of Utah, Salt Lake City, concluded in a presentation of the findings

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at the annual meeting of the Western Surgical Association.

Mr. Ludlow and senior author Dr. Raminder Nirula, an ACS Fellow and a surgeon at the University of Utah Hospitals, conducted the retrospective cohort study of appendectomies in the U.S. National Inpatient Sample (NIS) from 2001 to 2005. Using ICD-9 diagnosis and procedure codes, they identified 598,384 laparoscopic procedures and 871,605 open procedures.

During the years studied, the number of laparoscopic procedures increased by 24% for nonperforated appendicitis and by 19% for perforated appendicitis, while the number of open appendectomies decreased. By 2005, the discharge data showed nonperforated appendicitis was more likely to be treated laparoscopically than by open surgery. Open appendectomy was still more common in perforated cases by then, but the difference nationally was only about 5,000 cases (fewer than 30,000 laparoscopic procedures vs. fewer than 25,000 open procedures).

While hospital charges throughout the study period increased for laparoscopic and open procedures, by 2005 they were similar in perforated cases at \$26,399 and \$25,368, respectively. For nonperforated appendicitis, however, laparoscopic procedures in 2005 averaged \$18,479 vs. \$14,828 for open appendectomy.

Lengths of stay in nonperforated cases were similar, at 1.7 days for laparoscopic procedures and 2.1 days for open procedures, Mr. Ludlow reported. In perforated cases, however, laparoscopic patients were able to leave the hospital after 4.2 days on average versus 5.1

days after an open appendectomy.

Among the advantages offered by the NIS database, Mr. Ludlow noted its large size, objectivity, inclusion of all kinds of patients from all kinds of hospitals, and ability to stratify data by perforated vs. nonperforated appendicitis.

The NIS does not, however, include data on readmissions, wound infections, intraabdominal abscesses, or return to work.

Addressing these gaps, he cited single-

institution studies that have shown similar readmission and wound infection rates for laparoscopic and open procedures, but higher abscess rates by 1%-4% and faster return to work by 1-4 days after laparoscopic appendectomy.

In a discussion of the study, Dr. Fred Luchette, an ACS Fellow with Loyola University Medical Center in Maywood, Ill., praised the research but questioned the recommendations made solely on the basis of evidence from discharge

data. While hospital costs in nonperforated cases may be higher with laparoscopic procedures, the cost to society could be lower, he said, noting that such patients usually return to work sooner.

As for why an open procedure with longer length of stay would not cost more in perforated appendectomy cases, Dr. Nirula concurred with an audience suggestion that the added cost of equipment for laparoscopic cases probably was a balancing factor. ■



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COMMENTARY

Health Care 'Paradigm Shift' Needed

As the 17th Surgeon General of the United States (2002-2006) and chairperson of the Partnership to Fight Chronic Disease (www.fight-chronicdisease.org), I have been working for nearly 2 years with the presidential candidates' policy teams to help ensure that health and health care were among their top policy considerations. Today, I

continue that effort with President-elect Obama's staff, focusing on a vision of health care reform.

First, we have to consider this task as one that will require a cultural transformation of our nation. Our current health care system is a "sick care" system with perverse incentives. We have scores of billing codes to pay providers to make you better once you get sick, but there

are very few billing codes they can use to make a living if they want to keep you healthy. We need a paradigm shift that moves our nation to one that embraces health and wellness through appropriate prevention strategies.

That's not to say we still won't need surgeons, internists, gastroenterologists, and nephrologists. But we need to start this paradigm shift because the business

case has been made: The disease and economic burden that we have upon us—we currently spend more than \$2 trillion per year on health care, or 16% of our gross domestic product—is largely preventable. Chronic diseases account for 75% of our health care costs. Smoking, for instance, is the No. 1 preventable cause of death, yet we continue to sell cigarettes.

Currently, 9 million children are overweight or obese, some of them with diabetes and hypertension. As these youngsters get older and manifest cardiovascular disease and cancers at an earlier age, the economic burden of obesity and its effect on quality of life will be significant.

We have many well-respected thought leaders in this country who understand the factors that contributed to our predicament. We need to bring them together and have them figure out a way to accomplish the goal of ensuring that all Americans have access to a set of basic health services.

We also need to restructure our health care payment system, which is starting to

look like our tax system. It's almost impossible for the average person to navigate.

We have to start educating Americans about their responsibility. We can't afford to have adolescents start smoking,

because if they develop the habit, they will shorten their lives by 14 years and increase their lifetime health care costs astronomically because of pulmonary disease, cancer, and other related illnesses.

Every American can contribute by taking steps to improve his or her own health. The best mentors for our children are their parents. If children are routinely counseled about health, wellness, and prevention, they will grow up with those values.

Our dysfunctional health care system is not a Democratic problem. It's not a Republican problem. It's an American problem, and we have to face it as Americans. Rather than arguing about who should pay for health care, let's start focusing on how to remove the preventable disease burden and related economic burden from society. Let's ensure that everybody has access to true health care, including prevention and wellness services.



BY RICHARD
CARMONA, M.D.

DR. CARMONA served as the 17th Surgeon General of the United States. He is currently vice chairman of Canyon Ranch, CEO of Canyon Ranch's health division, and president of Canyon Ranch Institute. He is also a Distinguished Professor of Public Health at the University of Arizona, Tucson.

BRIEF SUMMARY

Please see package insert for full prescribing information.

Azactam[®] aztreonam IV/IM 1g/2g

INDICATIONS AND USAGE: To reduce the development of drug-resistant bacteria and maintain the effectiveness of AZACTAM[®] (aztreonam for injection, USP) and other antibacterial drugs, AZACTAM should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Before initiating treatment with AZACTAM, appropriate specimens should be obtained for isolation of the causative organism(s) and for determination of susceptibility to aztreonam. Treatment with AZACTAM may be started empirically before results of the susceptibility testing are available; subsequently, appropriate antibiotic therapy should be continued.

AZACTAM is indicated for the treatment of the following infections caused by susceptible gram-negative microorganisms:

Urinary Tract Infections (complicated and uncomplicated), including pyelonephritis and cystitis (initial and recurrent) caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Enterobacter cloacae*, *Klebsiella oxytoca*, *Citrobacter* species* and *Serratia marcescens*.*

Lower Respiratory Tract Infections, including pneumonia and bronchitis caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Proteus mirabilis*, *Enterobacter* species and *Serratia marcescens*.*

Septicemia caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Proteus mirabilis*, *Serratia marcescens** and *Enterobacter* species.

Skin and Skin-Structure Infections, including those associated with postoperative wounds, ulcers and burns caused by *Escherichia coli*, *Proteus mirabilis*, *Serratia marcescens*, *Enterobacter* species, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae* and *Citrobacter* species.*

Intra-abdominal Infections, including peritonitis caused by *Escherichia coli*, *Klebsiella pneumoniae* including *K. pneumoniae*, *Enterobacter* species including *E. cloacae*,* *Pseudomonas aeruginosa*, *Citrobacter* species* including *C. freundii** and *Serratia* species* including *S. marcescens*.*

Gynecologic Infections, including endometritis and pelvic cellulitis caused by *Escherichia coli*, *Klebsiella pneumoniae*,* *Enterobacter* species* including *E. cloacae** and *Proteus mirabilis*.*

AZACTAM is indicated for adjunctive therapy to surgery in the management of infections caused by susceptible organisms, including abscesses, infections complicating hollow viscus perforations, cutaneous infections and infections of serous surfaces. AZACTAM is effective against most of the commonly encountered gram-negative aerobic pathogens seen in general surgery.

Concurrent Therapy: Concurrent initial therapy with other antimicrobial agents and AZACTAM is recommended before the causative organism(s) is known in seriously ill patients who are also at risk of having an infection due to gram-positive aerobic pathogens. If anaerobic organisms are also suspected as etiologic agents, therapy should be initiated using an anti-anaerobic agent concurrently with AZACTAM (see **DOSE AND ADMINISTRATION**). Certain antibiotics (e.g., cefoxitin, imipenem) may induce high levels of beta-lactamase *in vitro* in some gram-negative aerobes such as *Enterobacter* and *Pseudomonas* species, resulting in antagonism to many beta-lactam antibiotics including aztreonam. These *in vitro* findings suggest that such beta-lactamase inducing antibiotics not be used concurrently with aztreonam. Following identification and susceptibility testing of the causative organism(s), appropriate antibiotic therapy should be continued.

CONTRAINDICATIONS: This preparation is contraindicated in patients with known hypersensitivity to aztreonam or any other component in the formulation.

WARNINGS: Both animal and human data suggest that AZACTAM is rarely cross-reactive with other beta-lactam antibiotics and weakly immunogenic. Treatment with aztreonam can result in hypersensitivity reactions in patients with or without prior exposure. (See **CONTRAINDICATIONS**.)

Careful inquiry should be made to determine whether the patient has any history of hypersensitivity reactions to any allergens.

While cross-reactivity of aztreonam with other beta-lactam antibiotics is rare, this drug should be administered with caution to any patient with a history of hypersensitivity to beta-lactams (e.g., penicillins, cephalosporins, and/or carbapenems). Treatment with aztreonam can result in hypersensitivity reactions in patients with or without prior exposure to aztreonam. If an allergic reaction to aztreonam occurs, discontinue the drug and institute supportive treatment as appropriate (e.g., maintenance of ventilation, pressor amines, antihistamines, corticosteroids). Serious hypersensitivity reactions may require epinephrine and other emergency measures. (See **ADVERSE REACTIONS**.)

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including AZACTAM and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*. *C. difficile* produces toxins A and B, which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Rare cases of toxic epidermal necrolysis have been reported in association with aztreonam in patients undergoing bone marrow transplant with multiple risk factors including sepsis, radiation therapy and other concomitantly administered drugs associated with toxic epidermal necrolysis.

PRECAUTIONS: General: In patients with impaired hepatic or renal function, appropriate monitoring is recommended during therapy.

If an aminoglycoside is used concurrently with aztreonam, especially if high dosages of the former are used or if therapy is prolonged, renal function should be monitored because of the potential nephrotoxicity and ototoxicity of aminoglycoside antibiotics.

The use of antibiotics may promote the overgrowth of nonsusceptible organisms, including gram-positive organisms (*Staphylococcus aureus* and *Streptococcus faecalis*) and fungi. Should superinfection occur during therapy, appropriate measures should be taken.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenicity studies in animals have not been performed.

Genetic toxicology studies performed *in vivo* and *in vitro* with aztreonam in several standard laboratory models revealed no evidence of mutagenic potential at the chromosomal or gene level.

Two-generation reproduction studies in rats at daily doses up to 20 times the maximum recommended human dose, prior to and during gestation and lactation, revealed no evidence of impaired fertility. There was a slightly reduced survival rate during the lactation period in the offspring of rats that received the highest dosage, but not in offspring of rats that received five times the maximum recommended human dose.

Pregnancy: Pregnancy Category B: Aztreonam crosses the placenta and enters the fetal circulation.

Studies in pregnant rats and rabbits, with daily doses up to 15 and 5 times, respectively, the maximum recommended human dose, revealed no evidence of embryo- or fetotoxicity or teratogenicity. No drug induced changes were seen in any of the maternal, fetal, or neonatal parameters that were monitored in rats receiving 15 times the maximum recommended human dose of aztreonam during late gestation and lactation.

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, aztreonam should be used during pregnancy only if clearly needed.

Nursing Mothers: Aztreonam is excreted in human milk in concentrations that are less than 1 percent of concentrations determined in simultaneously obtained maternal serum; consideration should be given to temporary discontinuation of nursing and use of formula feedings.

Pediatric Use: The safety and effectiveness of intravenous AZACTAM (aztreonam for injection, USP) have been established in the age groups 9 months to 16 years. Use of AZACTAM in these age groups is supported by evidence from adequate and well-controlled studies of AZACTAM in adults with additional efficacy, safety, and pharmacokinetic data from non-comparative clinical studies in pediatric patients. Sufficient data are not available for pediatric patients under 9 months of age or for the following treatment indications/pathogens: septicemia and skin and skin-structure infections (where the skin infection is believed or known to be due to *H. influenzae* type b). In pediatric patients with cystic fibrosis, higher doses of AZACTAM may be warranted. (See **CLINICAL PHARMACOLOGY, DOSAGE AND ADMINISTRATION**, and **CLINICAL STUDIES**.)

Geriatric Use: Clinical studies of AZACTAM did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.^{1,10} In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Because elderly patients are more likely to have decreased renal function, renal function should be monitored and dosage adjustments made accordingly (see **DOSE AND ADMINISTRATION: Renal Impairment in Adult Patients and Dosage in the Elderly**).

ADVERSE REACTIONS: Local reactions such as phlebitis/thrombophlebitis following IV administration, and discomfort/swelling at the injection site following IM administration occurred at rates of approximately 1.9 percent and 2.4 percent, respectively.

Systemic reactions (considered to be related to therapy or of uncertain etiology) occurring at an incidence of 1 to 1.3 percent include diarrhea, nausea and/or vomiting, and rash. Reactions occurring at an incidence of less than 1 percent are listed within each body system in order of decreasing severity:

Hypersensitivity—anaphylaxis, angioedema, bronchospasm
Hematologic—pancytopenia, neutropenia, thrombocytopenia, anemia, eosinophilia, leukocytosis, thrombocytosis

Gastrointestinal—abdominal cramps; rare cases of *C. difficile*-associated diarrhea, including pseudomembranous colitis, or gastrointestinal bleeding have been reported. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment. (See **WARNINGS**.)

Dermatologic—toxic epidermal necrolysis (see **WARNINGS**), purpura, erythema multiforme, exfoliative dermatitis, urticaria, petechiae, pruritus, diaphoresis

Cardiovascular—hypotension, transient ECG changes (ventricular bigeminy and PVC), flushing

Respiratory—wheezing, dyspnea, confusion, vertigo, paresthesia, insomnia, dizziness

Hepatobiliary—hepatitis, jaundice

Nervous System—seizure, confusion, vertigo, paresthesia, insomnia, dizziness

Musculoskeletal—muscular aches

Special Senses—tinnitus, diplopia, mouth ulcer, altered taste, numb tongue, sneezing, nasal congestion, halitosis

Other—vaginal candidiasis, vaginitis, breast tenderness

Body as a Whole—weakness, headache, fever, malaise

Pediatric Adverse Reactions: Of the 612 pediatric patients who were treated with AZACTAM in clinical trials, less than 1% required discontinuation of therapy due to adverse events. The following systemic adverse events, regardless of drug relationship, occurred in at least 1% of treated patients in domestic clinical trials: rash (4.3%), diarrhea (1.4%), and fever (1.0%). These adverse events were comparable to those observed in adult clinical trials.

In 343 pediatric patients receiving intravenous therapy, the following local reactions were noted: pain (12%), erythema (2.9%), induration (0.9%), and phlebitis (2.1%). In the US patient population, pain occurred in 1.5% of patients, while each of the remaining three local reactions had an incidence of 0.5%.

The following laboratory adverse events, regardless of drug relationship, occurred in at least 1% of treated patients: increased eosinophils (6.3%), increased platelets (3.6%), neutropenia (3.2%), increased AST (3.8%), increased ALT (6.5%), and increased serum creatinine (5.8%).

In US pediatric clinical trials, neutropenia (absolute neutrophil count less than 1000/mm³) occurred in 11.3% of patients (8/71) younger than 2 years receiving 30 mg/kg q6h. AST and ALT elevations to greater than 3 times the upper limit of normal were noted in 15–20% of patients aged 2 years or above receiving 50 mg/kg q6h. The increased frequency of these reported laboratory adverse events may be due to either increased severity of illness treated or higher doses of AZACTAM administered.

Adverse Laboratory Changes: Adverse laboratory changes without regard to drug relationship that were reported during clinical trials were:

Hepatic—elevations of AST (SGOT), ALT (SGPT), and alkaline phosphatase; signs or symptoms of hepatobiliary dysfunction occurred in less than 1 percent of recipients (see above).

Hematologic—increases in prothrombin and partial thromboplastin times, positive Coombs' test.

Renal—increases in serum creatinine.

OVERDOSAGE: If necessary, aztreonam may be cleared from the serum by hemodialysis and/or peritoneal dialysis.

*Efficacy for this organism in this organ system was studied in fewer than ten infections.

AZACTAM is a trademark of Elan Pharmaceuticals, Inc.

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Bristol-Myers Squibb Company
Princeton, NJ 08543 U.S.A.

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Research Aims to Halt Resident Attrition

BY JANE ANDERSON
Elsevier Global Medical News

A survey-based research project underway at Yale University, New Haven, Conn., may shed light on why attrition is higher in surgical residency than in other residency programs, and ideally will help to identify preventive actions to change this trend, according to Dr. Heather Yeo, the study's principal investigator.

Dr. Yeo, a Yale Robert Wood Johnson Clinical Scholar and categorical surgical resident, became interested in surgical workforce issues during her first 2 years of residency, when several residents left the program. "We were losing a lot of really good people in training, and I wondered what the profession was doing wrong," said Dr. Yeo. "What we hope to do is identify the factors that help predict attrition so that we can intervene."



HEATHER YEO, M.D.

Most years, about 1,000 surgical residents enter training, which means there are 6,000-7,000 surgical residents active at any given time, Dr. Yeo said. One or two of every five surgical residents abandon training, a rate that is "much higher than in any other specialty that has published their own data," she said. Approximately 150 residents leave training programs in any given year, and the rate of attrition from individual programs ranges from 15% to 33%, according to published data.

The Surgical Resident Cohort Project, funded by the Robert Wood Johnson Clinical Scholars Program and the American Board of Surgery, seeks to determine the incidence of attrition, identify the factors associated with attrition, and define potential areas of policy- or program-based action.

The project, which began surveying residents in June 2007, will track surgical residents over 3 academic years. The survey is linked to the annual in-service examination, and looks at actual experiences and changing perceptions in surgical residency, Dr. Yeo said. It includes questions about the reasons for entering surgery and choosing a program; residents' expectations about training, fellowship, and surgical practice; and actual resident experiences and perceptions of the field, she explained.

Phase I involved in-depth retrospective interviews with surgery residents who left their programs, and the development of a survey on attrition issues.

In phase II, Dr. Yeo is looking prospectively at interns' expectations from surgical residency. She will survey surgical residents annually and will analyze the data to identify changes in expectations, changes in experience, and areas for potential intervention.

In initial interviews, the most common reasons for leaving surgical training were lifestyle issues (work hours and family life); economic issues and financial compensation; the changing face of surgery (increased specialization, and the fact that other specialties now are performing procedures that used to be in the realm of the general surgeon); personal factors; and the stress involved in taking care of surgical patients, she said. Women leave surgical training at much

higher rates than do men, she added.

People tend to leave programs after their first year or after their research time. Some have become urologists, anesthesiologists, or psychiatrists. Those who leave after their research time have been training for 4-5 years, so that represents a huge loss to the profession, she said.

Interventions could include a more supportive social structure and changes in program structure and teaching, ac-



According to Dr. Yeo. It may be necessary to increase the numbers of residents initially matched in order to compensate for attrition during the program's life cycle.

"I love surgery," Dr. Yeo said. "I think for people who love it and are reasonably good at it, we should make it easier for them to stay." ■

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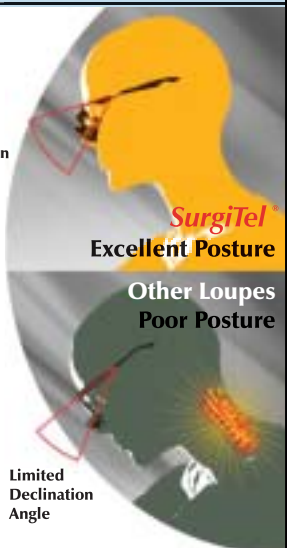
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Raymond L. Singer, MD

Limited Declination Angle

A Message From the Executive Director

As we begin the new year, I would like to provide you with an overview of a number of issues of concern to the surgical community. Let me assure you that the American College of Surgeons remains in great shape, despite the serious economic crises currently facing our nation.

Several important issues are playing out at this time. The Institute of Medicine (IOM) recently issued a report on resident work hours, which recommends some significant changes for training programs (see story on p. 1). A group spearheaded by L.D. Britt, M.D., FACS, Chair of the ACS Board of Regents, testified before the IOM in March 2008. Presently, we are gathering information from each of the surgical boards and academies to determine their respective views on the IOM report. We intend to share this information with the Accreditation Council for Graduate Medical Education. A small task force has been assembled for this purpose so that surgery can present a unified view during discussions with the council.

On another front, the College's Statement on Health Care Reform, which the ACS Health Policy Steering Committee developed and which was reviewed and approved by the Board of Governors and the Board of Regents, has been circulated to our

membership, to legislators on Capitol Hill, to the media, and to other surgical, medical, and health care organizations.

News stories on our health care reform proposal have appeared in *Congressional Quarterly*, an extremely important and well-read publication both on Capitol Hill and around the country, and, to date, on the Web sites of close to 100 business and daily newspapers in major cities from the East Coast to the West Coast, and on the Web sites of magazines like *Forbes*.

To assist in our efforts to advance the College's position on this and other issues, we have assembled a small committee of individuals who can respond to future requests and inquiries expeditiously. To that end, we have appointed members of some of our existing committees and leaders from the ACS Health Policy and Research Institute to serve on this central representative group.

As we seek to influence issues such as payment reform for physicians, potential health system reform, resident work hours, and so on, our governing bodies, as well as the general membership, will need to communicate with each other more consistently. SURGERY NEWS, the *Bulletin*, and *ACS NewsScope* all do

a good job of keeping the membership informed about issues of importance to surgeons and their patients, as well as about College efforts concerning those issues. However, our expanding technological capabilities are now making it possible for the College to present Webinars so that we can address pertinent issues in a very timely and immediate way. These teleconferences were initially intended solely for the Governors and Regents, but we think that this might well be a wonderful vehicle for communicating with the entire membership of the College. We are looking into the details of making this modern means of communication available to each and every one of you.

This will be a very interesting year. With the changes occurring in Washington, we have a wonderful opportunity to be a strong and positive partner in working together with other stakeholders on efforts to improve our health care delivery system, and, ultimately, the practice environment for our members and their patients. The best way to collaborate with others is to understand not only our own issues, but other people's problems as well—a goal that can be achieved through open communication.

I appreciate the continued support of so many of you in these times of change. Rest assured: We are ready to handle the tasks at hand in a very affirmative way. ■



BY THOMAS R. RUSSELL, M.D., FACS

Dr. Mary H. McGrath Appointed to Joint Commission

Mary H. McGrath, M.D., MPH, FACS, has been appointed to the Board of Commissioners of The Joint Commission. As an ACS representative, Dr. McGrath is one of five prominent health care leaders who were recently added to the 29-member board, which serves as The Joint Commission's governing body. The board includes representatives from each of The Joint Commission's Corporate Members—the American College of Surgeons, the American College of Physicians, the American Hospital Association, the American Medical Association, and the American Dental Association—six public members, one at-large representative of the nursing profession, and the Joint Commission president.

Dr. McGrath is professor of surgery in the division of plastic and reconstructive surgery at the University of California San Francisco and actively practices plastic surgery. She has held numerous leadership positions with the ACS, including serving as the Immediate Past First Vice-President, as a member of the Board of Regents for 9 years, and as Vice-Chair of the Board of Regents.

Dr. McGrath has been a panel member and consultant for the Food and Drug Administration for more than 20 years. She regularly serves on review panels at the National Institutes of Health, and is a frequent author of publications and books.

Dr. McGrath received her medical degree from St. Louis University and holds a Master's in Public Health in Health Policy and Management from The George Washington University.

LaMar S. McGinnis Jr., M.D., FACS, the current President-Elect of the College, and Kurt D. Newman, M.D., FACS, a past president of the Metropolitan Washington Chapter of the ACS, also serve on the Board of Commissioners as representatives of the College.

For more information, visit The Joint Commission's Web site at www.jointcommission.org. ■

Time Is Your Greatest Asset

For residents and younger members of the College, investing \$100 per month in an account with SDIF can make a tremendous difference over time.

The charted hypothetical example included with this article illustrates the difference between two investors who invest identical amounts, starting with \$100 per month, and increase their contributions by 10% each year. The chart assumes an average annual return of 6%, compounded monthly. The only difference is that one investor starts today and the other starts 10 years from now. Forty years later, the investor who started early has a portfolio of more than \$1 million. The investor who started later has only \$400,000. Past performance is no guarantee of future returns. The example is exclusive of taxes and fees.

Some members of the College have found SDIF to be the investment vehicle of choice for their annual Roth IRA contributions. As long as you have earned income and you fall under the adjusted gross income (AGI) range, the maximum allowable contribution for calendar year 2008 is \$5,000 (age 50 or older \$6,000).

The suggested minimum investment to participate in SDIF has been reduced to \$10,000. For those who find it feasible to participate in an automatic investment plan*, the minimum initial investment

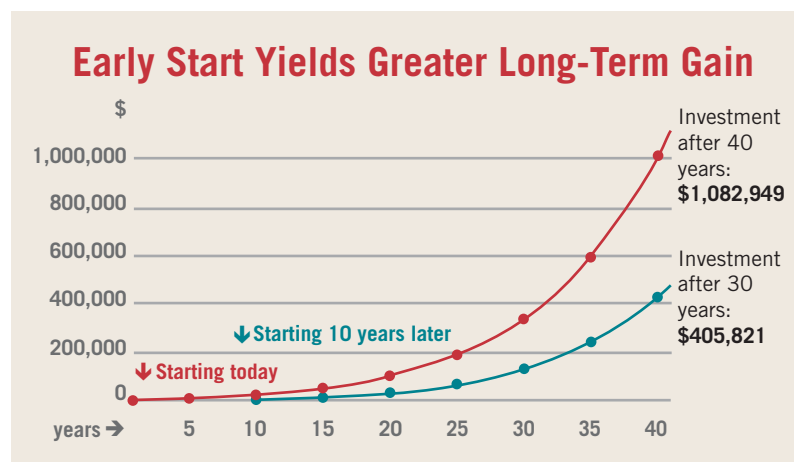
is \$5,000 assuming an automatic investment plan of at least \$100 per month is implemented; waivers of the minimum are possible. The minimum investment has been modified for Medical Student Members (\$500), Resident Members (\$1,000), and Associate Fellows (\$2,500) of the College.

For more information about SDIF or to discuss your specific situation, contact Savi Pai 312-202-5056, spai@facs.org; Tom Kiley 312-202-5019, tkiley@facs.org; or shareholder services at 800-208-6070. You may also visit the SDIF Web site at www.surgeonsfund.com.

An investor should consider the charges, risks, expenses, and investment objective carefully before investing. For a prospectus containing this and other information, please contact SDIF at 1-800-208-6070, or visit www.surgeonsfund.com. Read it carefully before you invest or send money.

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SDIF is distributed by Ultimus Fund Distributors, LLC, 225 Pictoria Dr., Suite 450, Cincinnati, OH 45246. The phone number is 513-587-3400. ■



* A program of regular investing does not ensure a profit or protect against depreciation in a declining market. Because a consistent investing program involves continuous investment in securities regardless of fluctuating prices, you should consider your financial ability to continue to purchase through periods of various price levels.

Late NSQIP Leader Given Codman Award

The late Shukri F. Khuri, M.D., FACS, has been honored by The Joint Commission for his leadership role in using performance measures to improve health care quality and safety. Dr. Khuri posthumously received the 2008 Ernest Amory Codman Award in the individual category last November.

At the time of his death on Sept. 26, 2008, Dr. Khuri had worked in the field of surgical quality improvement and risk-adjusted surgical outcomes for more than 20 years. He achieved national and international prominence in the fields of cardiac pathophysiology, cardiac surgery, medical informatics, quality improvement, and health policy research.

Named for the physician regarded in health care as the “father of outcomes measurement,” the Ernest Amory Codman Award showcases the effective use of performance measurement by health care organizations to improve the quality and safety of health care. The Joint Commission also recognizes an individual who has played a significant leadership role in promoting the use of performance measures to improve health care services and for providing major contributions to the development and testing of performance measures and the science and art of quality improvement.

For 16 years, Dr. Khuri oversaw the National Surgical Quality Improvement Program (NSQIP) in the Department of Veterans Affairs (VA). NSQIP is the first national, validated, outcome-based, risk-adjusted, and peer-controlled program for the measurement and enhancement of the quality of surgical care. Since the inception of NSQIP, 30-day postoperative mortality and morbidity have dropped by 47% and 43%, respectively. Dr. Khuri was also instrumental in

implementing NSQIP in the private sector through collaboration with the American College of Surgeons. The American College of Surgeons created the ACS NSQIP, and Dr. Khuri served on the advisory and steering committees.

Dr. Khuri established the first automated data-management system in a surgical intensive care unit in the Northeast in 1978 and chaired the VA Surgery Specific Interest Users Group, which developed the first clinical module in the VA’s Decentralized Hospital Computer Plan. Today, the electronic patient record in the VA is the most advanced and comprehensive electronic medical record system in the world.

Dr. Khuri was a member of numerous professional organizations, and was vice-president of the American Surgical Association (2005-2006). He

authored more than 380 peer-reviewed publications and was awarded the Frank Brown Berry Prize, which identifies an outstanding physician in the U.S. federal health system; The American University of Beirut’s Stephen Penrose Award; the Brigham and Women’s Robert Matson Award; the American Heart Association’s Paul Dudley White Award; the Nicholas G. Berans Veterans Association’s Distinguished Service Award; the 2006 Philip Crosby Award for Quality; and the 2006 American Heart Association Mentorship Award in Surgery.

The five recipients of the 2008 awards were selected by a panel of national experts in quality measurement and improvement. Additional 2008 award recipients were Carolinas Medical Center, Charlotte, N.C.; Cincinnati (Ohio) Children’s Hospital Medical Center; Mission Hospital, Mission Viejo, Calif.; and Novant Health, Winston-Salem, N.C. ■



SHUKRI F. KHURI, M.D.

College To Host Symposia at the SESC and SWSC Annual Meetings

The ACS will host a half-day symposium at the Southeastern Surgical Congress in Atlanta, Ga., on Feb. 8. The panel, “Update from the American College of Surgeons,” will feature L.D. Britt, M.D., MPH, FACS; LaMar S. McGinnis Jr., M.D., FACS; Thomas R. Russell, M.D., FACS; and Ajit K. Sachdeva, M.D., FACS, FRC-SC. The second panel of the day, “The Shortage of General Surgeons: An Impending Crisis and Possible Solutions,” will feature Kirby I. Bland, M.D., FACS;

J. Wayne Meredith, M.D., FACS; J. David Richardson, M.D., FACS; and George F. Sheldon, M.D., FACS.

The Southwestern Surgical Congress in San Diego, which will take place March 22-25, will also feature a half-day symposium hosted by the College. More information on that session will be available in the near future; to learn more, visit the Web site at www.swscongress.org.

To register for the Southeastern Surgical Congress, call 1-800-558-8958 or visit www.sesc.org. ■

Manual Updates Bariatric Criteria

Last October, the Advisory Committee of the ACS Bariatric Surgery Center Network (ACS BSCN) Accreditation Program updated the criteria in the Bariatric Accreditation Manual regarding standard surgical procedures.

The committee clarified that elective revisional operations for failed weight loss may not be performed at Level 2 ACS-Accredited Bariatric Centers. The new language defines “elective revisional operations” for Level 2 Centers.

The committee also voted to approve adding an eighth standard surgical procedure. The eight procedures are:

1. Roux-en-Y Gastric Bypass
2. Laparoscopic Adjustable Gastric Banding

3. Vertical-Banded Gastroplasty
4. Biliopancreatic Diversion With Duodenal Switch
5. Biliopancreatic Diversion Without Duodenal Switch
6. Sleeve Gastrectomy
7. Revisional Surgery
8. Urgent or Emergent Surgery Due to Complications from Bariatric Operations (e.g., internal hernia)

The committee determined that procedures necessitated by complications from bariatric operations may be counted toward the facility’s and individual surgeons’ volume.

To learn more about the ACS BSCN Accreditation Program, visit the Web site at www.acsbscn.org/. ■

College Seeks Nominations For 2009 Volunteerism and Humanitarian Awards

The ACS, in association with Pfizer Inc., is accepting nominations for the 2009 Surgical Volunteerism Awards and Surgical Humanitarian Award, as well as the newly created Surgical Resident Volunteerism Award.

The ACS/Pfizer Inc. Surgical Volunteerism Award recognizes surgeons who have made significant contributions to surgical care through organized volunteer activities. This award is intended either for ACS Fellows in active surgical practice, whose volunteerism activities go above and beyond the usual professional commitments, or retired Fellows who have been involved in volunteerism during their active practice and into retirement. For the purposes of these awards, “volunteerism” is defined as professional work in which one’s time or talents are donated for charitable clinical, educational, or other worthwhile activities related to surgery—not to pro bono or uncompensated care provided as a matter of necessity.

The ACS/Pfizer Inc. Surgical Humanitarian Award is given in recognition of those surgeons who have dedicated a substantial portion of their career to ensuring the provision of surgical care to underserved populations without expectation of commensurate reimbursement. This award is intended for a surgeon who has dedicated a significant portion of his or her surgical career to full-time or near-full-time humanitarian efforts rather than routine surgical practice. This effort may reflect a career dedicated to missionary surgery, the founding and ongoing operations of a charitable organization dedicated to providing surgical care to the underserved, or a retirement characterized by surgical volunteer outreach. Having received compensation for this work does not preclude a nominee from consideration and, in fact, may be expected based on the extent of the professional obligation.

Candidates for the volunteerism awards have made contributions through clinical care, education, implementation of training programs, research, advocacy, or other meaningful undertakings in a domestic, international, or military setting. All surgical subspecialties are eligible for consideration.

The Surgical Resident Volunteerism Award, new in 2009, is intended for Resident Members of the College who have demonstrated an extraordinary commitment to addressing the unmet needs of surgical patients at home or abroad. Nominees for this award may have had extensive experience during their education in volunteer efforts, such as with international surgical missions or by working with free clinics in underserved areas, or may have made substantive contributions to surgical global health research and advocacy.

Nominations will be evaluated on the basis of the work’s sustainability, the volunteer’s collaboration with health care teams in areas where he or she serves, and any demonstrated impact of the contributions made.

Supplemental materials should be kept to a minimum and will not be returned; self-nominations are permissible but require an outside letter of support; and previous nominees may resubmit an updated application.

The deadline for nominations is Feb. 27, 2009. Nomination forms are available in the “Announcements” section of the Operation Giving Back Web site at www.operationgivingback.org. To obtain forms via mail, contact Uriah Melchizedek, OGB Program Coordinator. Send completed application forms to Michael Dalsing, M.D., FACS, Chair, Board of Governors’ Committee on Socioeconomic Issues, c/o Uriah Melchizedek, American College of Surgeons, 633 N. Saint Clair St., Chicago, IL 60611; 312-202-5458; fax 312-202-5021; ogb@facs.org. ■

Tissue-Engineered Trachea Transplanted in Woman

Autologous cells with the right biomaterials might provide functional solutions for clinical disorders.

BY MICHELE G. SULLIVAN
Elsevier Global Medical News

A woman in Barcelona has received the world's first tissue-engineered tracheal transplant, which has functioned for more than 4 months without the need for immunosuppression.

The graft was a decellularized cadaver trachea, which researchers seeded with the recipient's own epithelial cells and stem cells differentiated into chondrocytes. Dr. Paulo Macchiarini and his colleagues reported in the online issue of the *Lancet* (doi:10.1016/S0140-6736(08)61598-6). The decellularization, combined with the recolonization with autologous cells, greatly reduced the likelihood of rejection, they said.

"The results show that a cellular, tissue-engineered airway can be produced with mechanical properties that allow normal functioning and which is free from the risks of rejection," wrote Dr. Macchiarini, head thoracic surgeon at the Hospital Clinic Barcelona. "This patient provides new evidence that autologous cells combined with appropriate biomaterials might provide, in future, successful functional solutions for serious clinical disorders."

The patient, aged 30 years, with complications of tuberculous, received the transplant. She presented initially in 2004, with dysphonia and cough due to a tubercular infiltration of the cervical trachea and entire left main bronchus. Although the infection was successfully treated, she had a 3-cm stenosis of the left bronchus. Initially, a stent was implanted, but it was removed because of poor tolerance.

By March 2008, severe dyspnea made it impossible for her to carry on normal daily activities. The left main bronchus

had a diameter of only 4 mm; her lung function was severely abnormal.

The usual course of action would have been a left carinal total pneumonectomy, the researchers said. Because of the high rates of mortality and morbidity associated with the surgery, however, the team decided to replace the scarred bronchus with a tissue-engineered trachea.

The trachea was harvested from a 51-year-old woman who died of a cerebral hemorrhage. Over a 6-week period, the team removed all the graft's immunologically active cells with 25 cycles of a detergent-based enzymatic solution.

The researchers then harvested bronchial epithelial cells from the patient. The epithelial cells grew rapidly, and a population was soon ready for seeding the interior of the donor trachea. To secure chondrocytes for the outer trachea, the team harvested stem cells from bone marrow aspirate, and differentiated them into chondrocytes by a method developed at the University of Bristol, England, to treat osteoarthritis.

The cells were then seeded onto the matrix, which had been placed in a small bioreactor specially designed for the procedure. The rectangular device suspended the trachea on a rotating spindle, which constantly alternated the graft between the bath of culture medium and air. Separate compartments for the interior and exterior of the trachea contained growth media designed to stimulate the different cell types.

The surgery itself was uneventful. After a left posterolateral thoracotomy, surgeons removed the diseased left main bronchus, cut the graft to the required shape and length, and anastomosed it to existing tissue. The graft retained its na-

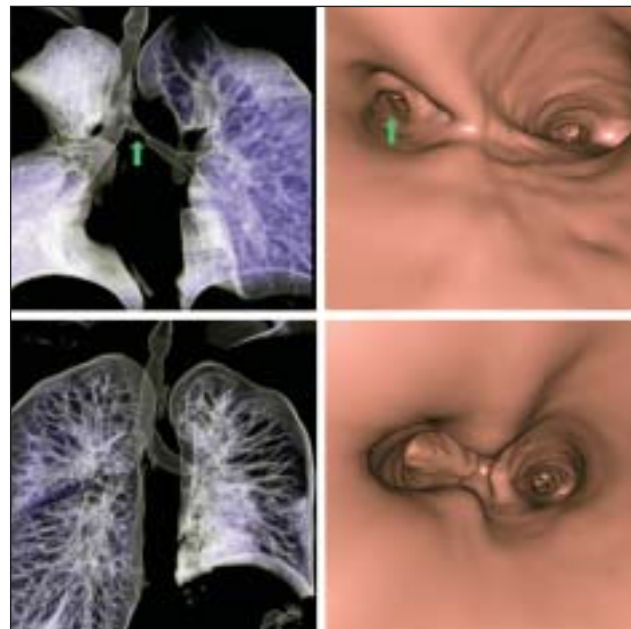
tive flexibility, which eased implantation greatly, the researchers noted. Immediate ventilation of the lung occurred. After 2 days in the intensive care unit, the patient was moved to a general ward; she was discharged on postoperative day 10.

By day 4, the graft was almost indistinguishable from adjacent normal bronchial mucosa, and laser Doppler readings confirmed an adjacent microvascular bed. At day 14, there was an adherent layer of mucus on the graft's surface, and no inflammatory cells were detected cytologically.

Because the new cells on the graft were phenotypically identical to the donor's native cells, however, "we cannot say whether these cells originated from those seeded or whether they grew in from an adjacent healthy airway," the researchers said.

By 1 month after transplant, the graft was indistinguishable from native trachea; local mucosal bleeding indicated full revascularization. That rapid growth of new blood vessels may be related to signaling by angiogenic cytokines that remained in the graft after decellularization, the investigators hypothesized.

After surgery, the patient rapidly regained normal lung function. Within 2 months, her forced vital capacity had increased from 62% at baseline to 100%. Similarly, her forced expiratory volume increased from 55% to 100%. As of October 2008, she had no sign of rejection.



CT images (left) and virtual bronchoscopic images (right) show before (top) and after (bottom) trachea grafting.

The experiment represents a major accomplishment in tissue engineering, Dr. Toshiko Sato and Dr. Tatsuo Nakamura of Kyoto (Japan) University wrote in a commentary in *Lancet* (doi:10.1016/S0140-6736(08)61599-8). However, they were not ready to recommend the procedure as a common one for airway replacement.

"Severe airway stenosis ... has been well managed by tracheal resection, although lengthy resections are still associated with anastomotic complications. Almost half of the adult trachea can be resected with a primary anastomosis, which means that the demand for tracheal replacement is limited," they said.

In addition, "some doubt remains about whether their results should be regarded as a fully tissue-engineered replacement or an allotransplantation of the trachea," Dr. Sato and Dr. Nakamura noted.

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The American College of Surgeons is pleased to announce its continued collaboration with the Southeastern and Southwestern Surgical Congresses, to develop and implement educational programs in the spring. The College looks forward to sponsoring half-day symposia at these prestigious events.

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Octogenarians Fare Well After Cardiac Surgery

BY MITCHEL L. ZOLER
Elsevier Global Medical News

NEW ORLEANS — Patients aged 80 years and older who underwent cardiac surgery had a subsequent life expectancy that was as good as the current average survival rate for similarly aged people in the general U.S. population, according to three separate reports presented at annual scientific sessions of the American Heart Association.

Cardiac surgery “is a viable option for selected patients aged 80 and older,” Dr. Paul Kurlansky said at the meeting. Chronologic age alone should not be a criterion for deciding whether an elderly patient should be offered cardiac surgery, added Dr. Kurlansky, an ACS Fellow who is a cardiothoracic surgeon and director of research at the Florida Heart Research Institute in Miami.



Postop actuarial survival closely matched the life expectancy for people aged 80 years and older.
DR. KURLANSKY

His report reviewed the experience of 1,062 consecutive patients aged 80-99 years who underwent coronary artery bypass grafting (CABG) during 1989-2001 at Mount Sinai Medical Center, a community hospital in Miami Beach. The average age of these patients was 83 years old, and all of them under-

went on-pump procedures. During a mean follow-up of 6 years, actuarial survival following surgery was about 6 years, which closely matches the current life expectancy for people aged 80 years in the United States.

“Without surgery, their survival would be very short. If survivorship is 5 or 6 years [with surgery], you are offering these patients something that they wouldn’t otherwise have,” he said.

In addition, a “very remarkable” finding was how they were doing overall and how they perceived their health. The Short Form-36 health-status questionnaire was completed by 545 of the patients during an in-person or telephone interview an average of 3 years after hospital discharge. The results showed that their self-rated physical- and mental-health scores very closely matched the scores of aged-matched norms for the U.S. population, Dr. Kurlansky reported.

His analysis also showed that during the 12-year period reviewed, the rate of in-hospital mortality in patients undergoing CABG at Mount Sinai steadily fell from a high of nearly 15% in 1989 to a rate of just over 2% by 2001.

The second report at the meeting reviewed 8,796 patients who underwent aortic valve surgery, with or without concurrent CABG, at eight medical centers in northern New England during 1989-2006. This included about 1,000 patients aged 80-84 years, and about 350 patients aged 85 years or older.

The median survival rate following surgery was about 7 years among both patients aged 80-84 years and those aged 85 years and older. Expected survival rates in the general U.S. population among people 80-84 years is also 7 years, and 5 years for those aged 85 and older, said Donald S. Likosky, Ph.D., a health policy analyst at Dartmouth Medical School in Lebanon, N.H. The survival rates in the elderly cardiac surgery patients were similar whether they under-

went valve surgery only or had combined valve surgery and CABG.

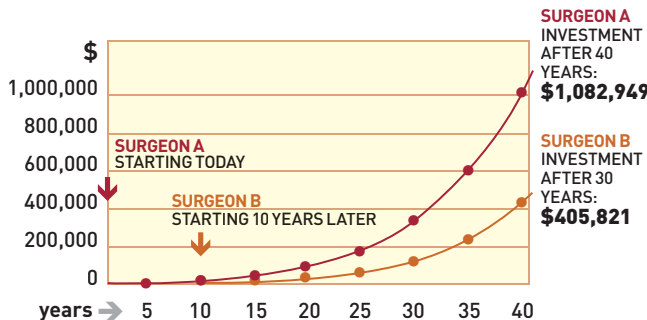
The third report at the meeting reviewed 203 patients aged 80 or older (average age 83 years) who underwent aortic valve surgery at the Methodist-DeBakey Heart Center in Houston during 1977-2008. A third of the patients also had concurrent CABG. The average perioperative mortality in these patients was about 6%, not significantly different from the average 4% perioperative mortality in 1,020 pa-

tients aged 79 or younger (average age 63 years) who also had aortic valve surgery, and in some cases CABG, at the Methodist-DeBakey Heart Center during the same period, Dr. Gerald M. Lawrie reported in a poster. He and his associates did not compare long-term mortality rates in their octogenarian patients with those of age-matched norms.

Dr. Kurlansky appears in a video interview at <http://www.youtube.com/watch?v=3wTCa2m3jeo>. ■

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BY LAZAR J. GREENFIELD, M.D., FACS

Life for the ancient Greeks prevailed through the four classical elements of earth, air, fire, and water. Then Xenocrates and Philostratus posited a fifth element, ether, to represent the cos-

mos. This was the stuff gods are made of, and it loftily defined the universe as a living creature. Plato called the fifth element quintessence, a term later used by Shakespeare in "Hamlet" to define the essential quality of a thing.

So as we enter our fifth year of publication, we should think about the quintessence of SURGERY NEWS. It must include our goals: to be timely, by

reporting on the most recent papers presented at peer-reviewed meetings; accurate, by fact checking the material presented; comprehensive, by including critiques of the studies by meeting discussants or our editors; relevant, by being pertinent to the practice and science of surgery; and unbiased, by disclosing conflicts of interest and excluding industrial hype or advertorials.

If these goals are not sufficient to define our essence, we must concede that we are defined by the ultimate goal of quality in all that we print. The "we" includes Elizabeth Wood, the publication editor; and the staff of Elsevier. But we are just half of the equation. The critical half is you, the reader; your satisfaction determines the publication's success.

Of course, advertising is also a critical component. The latest readership scores rate SURGERY NEWS as the second most widely read surgical publication among general surgeons. Informal conversations suggest that our readers find our condensed reporting useful, but what's missing? What would you like to see, or to see more of? How do the print and online versions of SURGERY NEWS fit into your desire to stay informed?

In fact, the future of major print newspapers is currently in doubt, as evidenced by the bankruptcy announcement by the Chicago Tribune. In October 2008, the Christian Science Monitor announced that it would abandon print except for a small weekly edition. As of April 2009, it will be available mostly online.

Many more people are reading the news online, but newspapers have yet to figure out a profitable business model for their online versions. The disappearance of newspapers in print may seem as noteworthy as the loss of the tape recorder, but remember that radio and television only tell you what is happening currently, and magazines or journals take months to bring news to print. It takes a newspaper reporter to follow the paper trail of a shady deal, document kickbacks, and identify conflicts of interest. Therefore, we all have a big stake in this experiment by the Monitor.

In science, an exclusively online publication called the Public Library of Science (PLOS ONE) uses peer review, but is not concerned with a paper's importance to the field. It only judges whether research was done "rigorously and astutely," allowing subsequent debate and comment to judge its importance. The \$1,300 fee to publish an article is waived if funds are not available.

Bentham Science Publishers has more than 200 peer-reviewed open-access journals (bentham.org/open). Its individual membership fee of \$1,600 provides a 5% discount on the article publication fee of \$800, but institutional memberships provide higher discounts.

We have selected some reports for online-only publication in SURGERY NEWS as an experiment. Do you have a preference between the print and online versions? Share your opinions with us, and you may wind up in print yourself, free of charge.

Effective communication should be two way; otherwise it's like one hand clapping. As George Bernard Shaw said, "The single biggest problem in communication is the illusion that it has taken place." ■

DR. GREENFIELD is editor in chief of SURGERY NEWS.

EDITORIAL

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New Advisers Join Board

SURGERY NEWS welcomes the individuals below to the Editorial Advisory Board in 2009. Our advisers offer the insights and perspectives that inform our content. Board members are asked to review stories pertaining to their specialties prior to publication in SURGERY NEWS. They are sometimes asked to provide commentary or write an opinion piece on a particular topic, and they regularly critique the newspaper, helping us to direct future coverage toward the areas of greatest interest to surgeons. The arrival of these new members marks the end of service for several individuals who have given SURGERY NEWS their time and attention since its inception: Dr. James Neifeld, Dr. Thomas Tracy, and Dr. Patricia Turner, along with Dr. Ted James, who for the past year was the Resident/Associate Society representative on the board.



JAY L. GROSFELD, M.D.

Jay L. Grosfeld, M.D., Lafayette Page Professor of Pediatric Surgery and chairman emeritus; department of surgery, Indiana University, Indianapolis



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Jacob Moalem, M.D., assistant professor, division of surgical oncology, University of Rochester, N.Y.

LETTERS

MS 1.20: Maintaining Quality Standards

The Joint Commission is on the right track with the revised MS 1.20 standard ("Is the Joint Commission's MS 1.20 a step in the right direction?" *Point/Counterpoint*, October 2008, p. 6). Hospital administrators and boards have way too much decision-making power about who should and should not be on a medical staff. By fiat they are able to declare an individual or an entire class of physicians "ineligible

for membership," and there's nothing the medical staff can do about it.

Without the changes in MS 1.20, medical staffs will be unable to maintain quality standards and continuity of care. If the administration persuades the board to award an exclusive contract to an out-of-town company to provide anesthesiologists, and that company tries to force all the current anesthesiologists to become their employees and hand over their private practices to the company without compensation

or be forced off the staff, how can the staff maintain quality surgical services?

Or if emergency department physicians are replaced with nurse practitioners or physician assistants, how can the medical staff react? Patients deserve to be seen and cared for by a physician.

MS 1.20 will require hospital boards and administrators to engage in meaningful dialogue with their medical staff. Without the standard, hospitals will rule by decree, and medicine—and patients—will suffer because of it.

Sandra D. Dickerson, M.D., FACS
Lubbock, Tex.

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CEA Considered Safer Than CAS for Elderly

BY NANCY WALSH
Elsevier Global Medical News

NEW YORK — Carotid endarterectomy is safer than carotid artery stenting for patients with severe, symptomatic carotid artery stenosis who are older than 68 years, according to a subanalysis of a prospective multicenter trial.

The Stent-Protected Angioplasty versus Carotid Endarterectomy in Symptomatic Patients (SPACE) trial tested the hypothesis that carotid artery stenting (CAS) was not inferior to carotid endarterectomy (CEA) in preventing ipsilateral ischemic stroke or death in the first 30 days post procedure.

In the SPACE trial, 1,200 patients were randomly assigned within 180 days of a transient ischemic attack or moderate ischemic stroke to undergo carotid stenting (n=605) or carotid endarterectomy (n=595). To be eligible, patients had to have carotid stenosis, to correspond to more than 50% of North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria, or more than 70% of the European Carotid Surgery Trial (ECST) criteria.

The trial was carried out in 35 centers in Germany, Austria, and Switzerland, with neurologists, vascular surgeons, and interventionalists participating from each center.

The trial failed to prove noninferiority of stenting, with event rates of 6.8% and 6.3% in the CAS and CEA groups, respectively (Lancet 2006;368:1239-47).

“However, in a subgroup analysis there was one variable—age—that had a significant impact on the 30-day outcomes of ipsilateral stroke and death,” said Dr. Dittmar Boeckler of the department of vascular surgery, University of Heidelberg (Germany).

The periprocedural risk of ipsilateral stroke or death increased significantly with age in the CAS group but not in the CEA group. Classification and regression tree analysis showed that an age of 68 years gave the greatest separation between high- and low-risk populations with CAS, with an event rate of 2.7% in patients aged 68 or younger and 10.8% in those who were older, Dr. Boeckler explained at the Veith symposium on vascular medicine sponsored by the Cleveland Clinic.

At 2 years post procedure, no differences have been seen in rates of ipsilateral stroke or death on intent-to-treat analysis, at 9.5% and 8.8% in the CAS and CEA groups, respectively. However, recurrent stenosis of 70% or more was seen in 10.7% of CAS patients, compared with 4.6% of CEA patients (Lancet Neurol. 2008;7:893-902).

SPACE 2, which is being funded by the German Federal Ministry for Education and Research, will take place at 135 centers over an 8-year period. With enrollment beginning in December, investigators plan to recruit 3,640 patients, of which 1,550 would be randomized to each surgical group and 540 to the medical group. ■

Long-Term EVAR Outcomes Still Under Investigation

BY NANCY WALSH
Elsevier Global Medical News

NEW YORK — The early promise of endovascular repair of abdominal aortic aneurysms may not be borne out over the long term, according to ongoing follow-up of a randomized Dutch trial suggesting that mortality may be higher at 4 years after endovascular repair than after open surgery.

Initial experience showed a survival advantage during the first month after endovascular repair (EVAR) of abdominal aortic aneurysms compared with open repair. In the Dutch Randomized Endovascular Aneurysm Management (DREAM) trial, which included 345 patients, the combined rate of operative mortality and severe complications was 10% in the open repair group and 5% in the EVAR group.

In their first report the investigators wrote, “The findings of this randomized trial comparing open and endovascular aneurysm repair suggest that in patients who qualify for either procedure, endovascular repair is preferable to open repair over the first 30 days after the procedure” (N. Engl. J. Med. 2004;351:1607-18).

However, that advantage was lost at 2 years, when the survival curves for the two groups converged, according to lead investigator Jan D. Blankensteijn, chief of vascular surgery, Radboud University Nijmegen (the Netherlands)

Medical Centre. At that point the cumulative survival rate was 90% in both groups (N. Engl. J. Med. 2005;352:2398-405).

“Four years after discharge, with 62% of patients remaining alive and only 10% having been censored, overall survival shows a clear and highly significant difference between the groups, with a higher mortality rate as of discharge in the endovascular group,” Dr. Blankensteijn said at the Veith symposium on vascular medicine sponsored by the Cleveland Clinic.

“The data are preliminary and incompletely analyzed, and in particular, the causes of death need further analysis before any interpretation can be given,” he explained in an interview. “For instance, were there more aneurysm ruptures in the EVAR group? Was there greater mortality associated with reinterventions? We don’t know.”

All patients will continue to be followed for 5 years. “We need to figure out if the apparent trend holds up in the long-term analysis of all randomized trials, why it is so, and whether this accounts for all patients or just particular subgroups,” he said. “This may be conceived as a disappointment to some, and in the long term it may jeopardize the perioperative survival advantage of EVAR,” he concluded.

DREAM was supported by a grant from the Netherlands National Health Insurance Council. Dr. Blankensteijn declared no conflicts of interest. ■

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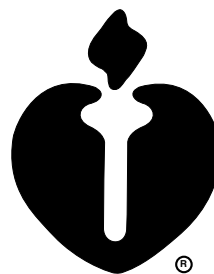
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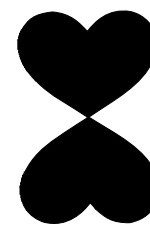
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Report Card Gives U.S. Low Marks in Emergency Care

BY DENISE NAPOLI
Elsevier Global Medical News

WASHINGTON — The United States gets a C- in support of emergency care, according to a report released in December 2008 by the American College of Emergency Physicians.

And in a state-by-state comparison, Massachusetts received the highest mark, B, while Arkansas received the lowest, D-. After Massachusetts, the four states with the highest overall grades were the District of Columbia (B-), Rhode Island (B-), Maryland (B-), and Nebraska (C+). After Arkansas, the four states with the lowest overall grades were Oregon (D), Nevada (D), New Mexico (D), and Oklahoma (D).

The report card “does not measure the quality of care provided in individual hospitals or by individual emergency providers—rather, it considers the legislative and regulatory environment, the existing infrastructure, and the available workforce that constitute the emergency care system we all rely upon every day,” according to an executive summary of the report.

The report committee, made up of 14 physicians and ACEP regional heads, drew on unpublished medical reports, as well as data from the Centers for Disease Control and Prevention, the National Highway Traffic Safety Administration, the Centers for Medicare and Medicaid Services, the American Medical Association, other physician associations, and a survey of state health officials.

The report reviewed five major categories affecting care and weighed them according to their importance to the overall delivery of emergency services: access to care (30%); the quality and patient safety environment (20%); the medical liability environment (20%); public health and injury prevention legislation (15%); and disaster preparedness (15%).

The nation’s overall grade of C- reflects an especially low grade in the access-to-care category: a D-, according to the report. That’s due primarily to the combined effect of an aging population and a shortage of emergency departments and emergency care workers.

“While national data for hospital crowding, emergency department patient boarding, ambulance diversions, and shortages of on-call specialists are available, there is a critical lack of detailed and state-specific data related to these and other major emergency care

access issues,” the report’s authors said.

Nationally, the areas receiving the highest grades (C+) were in the quality and patient safety environment category, which “has benefited from extensive efforts to continually improve the quality of care provided,” according to the report, and in the disaster preparedness category.

The report card outlined eight recommendations to improve the nation’s overall grade:

1. Alleviate boarding in emergency de-

partments and hospital crowding.

2. Pass the Access to Emergency Medical Services Act.
3. Enact federal and state medical liability reforms.
4. Increase federal funding and support of disaster preparedness.
5. Increase support for the nation’s health care “safety net” (i.e., enact federal policies to reimburse hospitals for uncompensated emergency and trauma care, to address uninsured citizens.

6. Foster greater coordination of emergency services.

7. Maximize the use of information technologies to track and enhance the quality and patient safety environment.

8. Strengthen emergency departments through national reform.

Financial support for the report card was provided by the Emergency Medicine Foundation, with grants from the WellPoint Foundation and the Robert Wood Johnson Foundation. ■

TYGACIL® (tigecycline) Brief Summary

See package insert for full Prescribing Information. For further product information and current package insert, please visit www.wyeth.com or call our medical communications department toll-free at 1-800-934-5556.

CONTRAINDICATIONS

TYGACIL is contraindicated for use in patients who have known hypersensitivity to tigecycline.

WARNINGS

Anaphylaxis/anaphylactoid reactions have been reported with nearly all antibacterial agents, including tigecycline, and may be life-threatening.

Glycylcycline class antibiotics are structurally similar to tetracycline class antibiotics and may have similar adverse effects. TYGACIL should be administered with caution in patients with known hypersensitivity to tetracycline class antibiotics.

TYGACIL may cause fetal harm when administered to a pregnant woman. If the patient becomes pregnant while taking tigecycline, the patient should be apprised of the potential hazard to the fetus. Results of animal studies indicate that tigecycline crosses the placenta and is found in fetal tissues. Decreased fetal weights in rats and rabbits (with associated delays in ossification) and fetal loss in rabbits have been observed with tigecycline. (See **PRECAUTIONS, Pregnancy**.)

The use of TYGACIL during tooth development (last half of pregnancy, infancy, and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). Results of studies in rats with TYGACIL have shown bone discoloration. TYGACIL should not be used during tooth development unless other drugs are not likely to be effective or are contraindicated.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including TYGACIL, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

PRECAUTIONS

General

Caution should be exercised when considering TYGACIL monotherapy in patients with complicated intra-abdominal infections (cIAI) secondary to clinically apparent intestinal perforation. (See **ADVERSE REACTIONS**.) In Phase 3 cIAI studies (n=1642), 6 patients treated with TYGACIL and 2 patients treated with imipenem/cilastatin presented with intestinal perforations and developed sepsis/septic shock. The 6 patients treated with TYGACIL had higher APACHE II scores (median = 13) vs the 2 patients treated with imipenem/cilastatin (APACHE II scores = 4 and 6). Due to differences in baseline APACHE II scores between treatment groups and small overall numbers, the relationship of this outcome to treatment cannot be established.

Glycylcycline class antibiotics are structurally similar to tetracycline class antibiotics and may have similar adverse effects. Such effects may include: photosensitivity, pseudotumor cerebri, and anti-anabolic action (which has led to increased BUN, azotemia, acidosis, and hyperphosphatemia). As with tetracyclines, pancreatitis has been reported with the use of TYGACIL.

The safety and efficacy of TYGACIL in patients with hospital acquired pneumonia have not been established. In a study of patients with hospital acquired pneumonia, patients were randomized to receive TYGACIL (100 mg initially, then 50 mg every 12 hours) or a comparator. In addition, patients were allowed to receive specified adjunctive therapies. The sub-group of patients with ventilator-associated pneumonia who received TYGACIL had lower cure rates (47.9% versus 70.1% for the clinically evaluable population) and greater mortality (25/131 [19.1%] versus 15/122 [12.3%]) than the comparator.

As with other antibacterial drugs, use of TYGACIL may result in overgrowth of non-susceptible organisms, including fungi. Patients should be carefully monitored during therapy. If superinfection occurs, appropriate measures should be taken.

Prescribing TYGACIL 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.

Information for Patients

Patients should be counseled that antibacterial drugs including TYGACIL should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When TYGACIL is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by TYGACIL or other antibacterial drugs in the future. Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

Drug Interactions

Prothrombin time or other suitable anticoagulation test should be monitored if tigecycline is administered with warfarin. (See **CLINICAL PHARMACOLOGY, Drug-Drug Interactions** in full prescribing information.)

Concurrent use of antibacterial drugs with oral contraceptives may render oral contraceptives less effective.

Drug/Laboratory Test Interactions

There are no reported drug-laboratory test interactions.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Lifetime studies in animals have not been performed to evaluate the carcinogenic potential of tigecycline. No mutagenic or clastogenic potential was found in a battery of tests, including in vitro chromosome aberration assay in Chinese hamster ovary (CHO) cells, in vitro forward mutation assay in CHO cells (HGPRT locus), in vitro forward mutation assays in mouse lymphoma cells, and in vivo mouse micronucleus assay. Tigecycline did not affect mating or fertility in rats at exposures up to 5 times the human daily dose based on AUC. In female rats, there were no compound-related effects on ovaries or estrous cycles at exposures up to 5 times the human daily dose based on AUC.

Pregnancy

Teratogenic Effects—Pregnancy Category D

Tigecycline was not teratogenic in the rat or rabbit. In preclinical safety studies, ¹⁴C-labeled tigecycline crossed the placenta and was found in fetal tissues, including fetal bony structures. The administration of tigecycline was associated with slight reductions in fetal weights and an increased incidence of minor skeletal anomalies (delays in bone ossification) at exposures of 5 times and 1 times the human daily dose based on AUC in rats and rabbits, respectively. An increased incidence of fetal loss was observed at maternotoxic doses in the rabbits with exposure equivalent to human dose.

There are no adequate and well-controlled studies of tigecycline in pregnant women. TYGACIL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (See **WARNINGS**.)

Labor and Delivery

TYGACIL has not been studied for use during labor and delivery.

Nursing Mothers

Results from animal studies using ¹⁴C-labeled tigecycline indicate that tigecycline is excreted readily via the milk of lactating rats. Consistent with the limited oral bioavailability of tigecycline, there is little or no systemic exposure to tigecycline in nursing pups as a result of exposure via maternal milk.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TYGACIL is administered to a nursing woman. (See **WARNINGS**.)

Use in Patients with Hepatic Impairment

No dosage adjustment is warranted in patients with mild to moderate hepatic impairment (Child Pugh A and Child Pugh B). In patients with severe hepatic impairment (Child Pugh C), the initial dose of tigecycline should be 100 mg followed by a reduced maintenance dose of 25 mg every 12 hours. Patients with severe hepatic impairment (Child Pugh C) should be treated with caution and monitored for treatment response. (See **CLINICAL PHARMACOLOGY, Special Populations, Use in Patients with Hepatic Impairment and DOSAGE AND ADMINISTRATION** in full prescribing information.)

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 18 years have not been established. (See **WARNINGS**.) Therefore, use in patients under 18 years of age is not recommended.

Geriatric Use

Of the total number of subjects who received TYGACIL in Phase 3 clinical studies (n=1415), 278 were 65 and over, while 110 were 75 and over. No unexpected overall differences in safety or effectiveness were observed between these subjects and younger subjects, but greater sensitivity to adverse events of some older individuals cannot be ruled out.

ADVERSE REACTIONS

Because clinical studies are conducted under varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. The adverse reaction information from clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Phase 3 clinical studies enrolled 1415 patients treated with TYGACIL. TYGACIL was discontinued due to treatment-emergent adverse events in 5.0% of patients compared to 4.7% for all comparators (5.3% for vancomycin/aztreonam and 4.4% for imipenem/cilastatin). Table 4 shows the incidence of treatment-emergent adverse events through test of cure reported in ≥2% of patients in these studies regardless of causality.

Table 4. Incidence (%) of Treatment-Emergent Adverse Events Through Test of Cure Reported in ≥2% of Patients Treated in Phase 3 Clinical Studies

Body System Adverse Events	TYGACIL ^a (N=1415)	Comparators ^b (N=1382)
Body as a Whole		
Abdominal pain	6.8	5.7
Abscess	3.2	2.6
Asthenia	2.5	1.7
Back Pain	1.2	2.3
Fever	7.1	9.8
Headache	5.9	6.5
Infection	8.3	5.4
Pain	3.7	2.9
Cardiovascular System		
Hypertension	4.9	5.6
Hypotension	2.3	1.7
Phlebitis	1.8	3.8
Digestive System		
Constipation	2.8	4.1
Diarrhea	12.7	10.8
Dyspepsia	2.9	1.6
Nausea	29.5	15.8
Vomiting	19.7	10.8
Hemic and Lymphatic System		
Anemia	4.2	4.8
Leukocytosis	3.7	2.5
Thrombocytopenia	6.1	6.2
Metabolic and Nutritional		
Alkaline Phosphatase Increased	3.5	2.6
Amylase Increased	3.1	1.4
Bilirubinemia	2.3	0.9
BUN Increased	2.1	0.2
Healing Abnormal	3.5	2.6
Hyperglycemia	1.8	2.9
Hypokalemia	2.1	2.9
Hypoproteinemia	4.5	3.0
Lactic Dehydrogenase Increased	4.0	3.5
Peripheral Edema	3.3	3.3
SGOT Increased ^c	4.3	4.4
SGPT Increased ^c	5.6	4.7
Nervous System		
Dizziness	3.5	2.7
Insomnia	2.3	3.3
Respiratory System		
Cough Increased	3.7	3.8
Dyspnea	2.9	2.7
Pulmonary Physical Finding	1.9	2.2
Skin and Appendages		
Pruritus	2.6	4.1
Rash	2.4	4.1
Sweating	2.3	1.6
Other		
Local Reaction to Procedure	9.0	9.1

^a 100 mg initially, followed by 50 mg every 12 hours.

^b Vancomycin/Aztreonam, Imipenem/Cilastatin, Linezolid

^c LFT abnormalities in TYGACIL-treated patients were reported more frequently in the post therapy period than those in comparator-treated patients, which occurred more often on therapy.

In Phase 3 cSSSI and cIAI studies, death occurred in 2.3% (32/1383) of patients receiving TYGACIL and 1.6% (22/1375) of patients receiving comparator drugs; this difference is not statistically significant and relationship to treatment cannot be established. In all treatment groups, mortality was associated with higher baseline comorbidity and/or greater severity of baseline infections.

In Phase 3 clinical studies, infection-related serious adverse events were more frequently reported for subjects treated with TYGACIL (6.7% vs comparators (4.6%). Significant differences in sepsis/septic shock with TYGACIL (1.5% vs comparators (0.5%)) were observed. Due to baseline differences between treatment groups in this subset of patients, the relationship of this outcome to treatment cannot be established. (See **PRECAUTIONS**.) Other events included nonsignificant differences in abscess (1.8% vs 1.6%) and infections, including wound infections (1.7% vs 1.1%) for TYGACIL vs comparators, respectively.

The most common treatment-emergent adverse events were nausea and vomiting which generally occurred during the first 1 – 2 days of therapy. The majority of cases of nausea and vomiting associated with TYGACIL and comparators were either mild or moderate in severity. In patients treated with TYGACIL, nausea incidence was 29.5% (19.6% mild, 8.5% moderate, 1.4% severe) and vomiting incidence was 19.7% (12.3% mild, 6.3% moderate, 1.1% severe). In patients treated for cSSSI, nausea incidence was 35.0% for TYGACIL and 8.9% for vancomycin/aztreonam; vomiting incidence was 20.0% for TYGACIL and 4.2% for vancomycin/aztreonam. In patients treated for cIAI, nausea incidence was 25.3% for TYGACIL and 20.5% for imipenem/cilastatin; vomiting incidence was 19.5% for TYGACIL and 15.3% for imipenem/cilastatin.

Discontinuation from tigecycline was most frequently associated with nausea (1.3%) and vomiting (1.0%). For comparators, discontinuations were most frequently associated with rash (1.1%), vancomycin/aztreonam and nausea (1.0%, imipenem/cilastatin).

The following drug-related adverse events were reported infrequently (≥0.2% and <2%) in patients receiving TYGACIL in Phase 3 clinical studies:

Body as a Whole: injection site inflammation, injection site pain, injection site reaction, septic shock, allergic reaction, chills, injection site edema, injection site phlebitis
Cardiovascular System: thrombophlebitis, bradycardia, tachycardia, vasodilatation
Digestive System: anorexia, dry mouth, jaundice, abnormal stools
Metabolic/Nutritional System: increased creatinine, hypocalcemia, hypoglycemia, hyponatremia
Nervous System: somnolence
Special Senses: taste perversion
Hemic and Lymphatic System: prolonged activated partial thromboplastin time (aPTT), prolonged prothrombin time (PT), eosinophilia, increased international normalized ratio (INR), thrombocytopenia
Urogenital System: vaginal moniliasis, vaginitis, leukorrhea

Post-Marketing Experience

Worldwide post-marketing adverse events not previously listed in the product label include: anaphylaxis/anaphylactoid reactions, acute pancreatitis.

OVERDOSAGE

No specific information is available on the treatment of overdosage with tigecycline. Intravenous administration of TYGACIL at a single dose of 300 mg over 60 minutes in healthy volunteers resulted in an increased incidence of nausea and vomiting. In single-dose IV toxicity studies conducted with tigecycline in mice, the estimated median lethal dose (LD₅₀) was 124 mg/kg in males and 98 mg/kg in females. In rats, the estimated LD₅₀ was 106 mg/kg for both sexes. Tigecycline is not removed in significant quantities by hemodialysis.

This Brief Summary is based on TYGACIL direction circular W10521C002 ET01, revised 06/07.

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Expanded broad-spectrum
coverage is on your side^{1*†}

Gram positives
Gram negatives
Anaerobes
Resistant gram positives
Resistant gram negatives



* The clinical significance of in vitro activity is unknown.

† TYGACIL does not cover *Pseudomonas aeruginosa*.

TYGACIL is indicated for

- The treatment of adults with complicated skin and skin structure infections caused by *E. coli*, *E. faecalis* (vancomycin-susceptible isolates only), *S. aureus* (methicillin-susceptible and -resistant isolates), *S. agalactiae*, *S. anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *S. pyogenes*, and *B. fragilis*
- The treatment of adults with complicated intra-abdominal infections caused by *C. freundii*, *E. cloacae*, *E. coli*, *K. oxytoca*, *K. pneumoniae*, *E. faecalis* (vancomycin-susceptible isolates only), *S. aureus* (methicillin-susceptible isolates only), *S. anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *B. fragilis*, *B. thetaiotaomicron*, *B. uniformis*, *B. vulgatus*, *C. perfringens*, and *P. micros*

Important Safety Information

- To reduce the development of drug-resistant bacteria and maintain the effectiveness of TYGACIL and other antibacterial drugs, TYGACIL should be used only to treat infections proven or strongly suspected to be caused by susceptible bacteria
- Anaphylaxis/anaphylactoid reactions have been reported with nearly all antibacterial agents, including tigecycline, and may be life-threatening
- TYGACIL is contraindicated in patients with known hypersensitivity to tigecycline
- TYGACIL should be administered with caution in patients with known hypersensitivity to tetracycline class antibiotics
- Glycylcycline class antibiotics are structurally similar to tetracycline class antibiotics and may have similar adverse effects. Such effects may include: photosensitivity, pseudotumor cerebri, and anti-anabolic action (which has led to increased BUN, azotemia, acidosis, and hyperphosphatemia). As with tetracyclines, pancreatitis has been reported with the use of TYGACIL
- The safety and efficacy of TYGACIL in patients with hospital-acquired pneumonia have not been established
- In clinical trials, the most common treatment-emergent adverse events in patients treated with TYGACIL were nausea (29.5%) and vomiting (19.7%)
- **TYGACIL may cause fetal harm when administered to a pregnant woman**
- The safety and effectiveness of TYGACIL in patients below age 18 and lactating women have not been established
- *Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including TYGACIL, and may range in severity from mild diarrhea to fatal colitis
- **The use of TYGACIL during tooth development may cause permanent discoloration of the teeth.** TYGACIL should not be used during tooth development unless other drugs are not likely to be effective or are contraindicated

Please see brief summary of Prescribing Information on adjacent page.

Reference: 1. TYGACIL® (tigecycline) Prescribing Information, Wyeth Pharmaceuticals Inc.

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Tygacil[®]
tigecycline IV

Expanded coverage for resistant pathogens