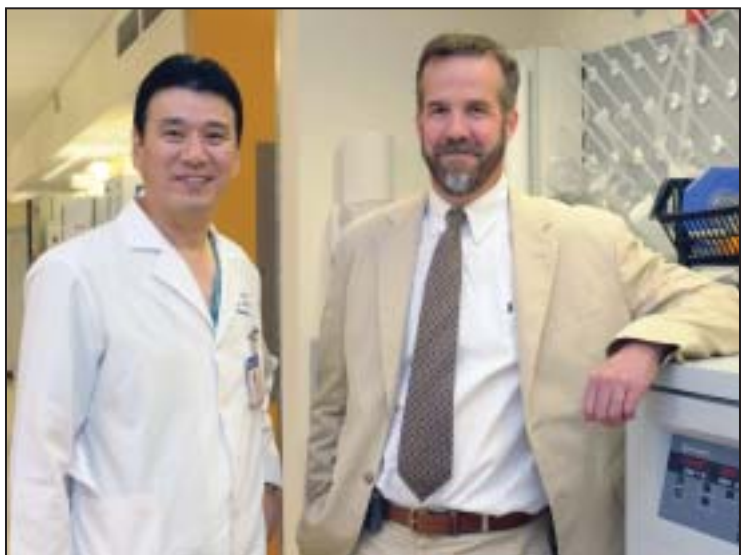




AMERICAN COLLEGE OF SURGEONS

SURGERY NEWS



MICHAEL MARSLAND/YALE UNIVERSITY

Tissue-engineered vascular grafts have been used in 25 children in Tokyo, said Dr. Toshiharu Shinoka (left) and Dr. Christopher Breuer.

New Vascular Grafts May Benefit Children

BY JANE ANDERSON
Elsevier Global Medical News

Tissue-engineered vascular grafts currently under development show promise as a substitute for prosthetic and bioprosthetic grafts used in pediatric patients, according to Dr. Christopher Breuer, one of the surgeons conducting the research.

Unlike prosthetic and bioprosthetic grafts, which must be replaced periodically because they do not grow as young patients mature, tissue-engineered vascular grafts are seeded with bone marrow cells and, as living vascular structures, may have the potential for growth, repair, and remodeling, said Dr. Breuer, as-

sistant professor of surgery at Yale University, New Haven, Conn., in an interview.

"We developed technology to seed a scaffold to provide the space for 3-D cell growth. We're very interested in getting this into children in the U.S.," he said, noting that the technology has been used in pediatric patients in Tokyo.

Dr. Breuer presented the results of an animal study at the annual meeting of the American Surgical Association (ASA) earlier this year. In that study, which was supported by a grant from the ASA, polyglycolic acid mesh tubes were statically seeded with mononuclear cells derived from

See **Vascular Grafts** • page 2

Capitol Hill Starts Strategizing for Health Reform

Committees crafting legislation.

BY ALICIA AULT
Elsevier Global Medical News

Democrats and Republicans are so confident about the chances of some type of health reform in the next administration that staff meetings and hearings geared toward crafting legislation have been going on in earnest in both the House and the Senate, with the goal of being ready to go in January, according to advocates and policy watchers.

Many health policy analysts have compared this election cycle with that of 1992, which sent Bill Clinton to the White House and launched the Clintons' health care reform efforts.

Both elections—1992 and 2008—feature a high level of public concern about access to health care and its costs, said Len Nichols, an analyst at the New America Foundation, a nonpartisan public policy institute.

For instance, a Harris Inter-

active survey conducted for the Commonwealth Fund in May found that 82% of Americans think the health care system should be fundamentally changed or completely rebuilt.

But the differences between the two elections are striking in a positive way, said Mr. Nichols in an interview.

First, the two major candidates have acknowledged that cost is an overriding concern, he said. Also, a common theme is the use of private markets, which he called "evidence, I would say, of moderation" and, perhaps, the proposals' better legislative traction.

Both Sen. Barack Obama (D-Ill.) and Sen. John McCain (R-Ariz.) have also learned that "no president is going to send [to Congress] a 1,400-page health bill written in a hotel room by 300 wonks," Mr. Nichols said.

Instead, "Congress is going to own this [effort] far earlier and

See **Health Reform** • page 2

Noncovered 'Never' Events List Grows

BY MARY ELLEN SCHNEIDER

Elsevier Global Medical News

Starting Oct. 1, Medicare won't pay for a total of 11 preventable conditions acquired during a hospital stay, up from the current 8 such conditions.

Added to the list of noncovered preventable conditions are surgical site infections following certain elective procedures, such as orthopedic and bariatric surgery; manifestations of poor glycemic control; and deep vein thrombosis or pulmonary embolism following certain orthopedic procedures, such as total knee replacement and hip replacement. (See box, on p. 10, for current preventable conditions.)

The new conditions were included in the Acute Care Hospital Inpatient Prospective Pay-

ment final rule, which was published in the Federal Register on Aug. 19 and released earlier on the Centers for Medicare and Medicaid Services' Web site.

The expansion of the preventable conditions list was criticized by the American Medical Association for putting patient care at risk. The AMA said that Medicare officials are lumping together true "never" events such as wrong-site surgery with

"often unavoidable" conditions such as surgical site infections.

"Focusing on determining whether or not medical conditions exist when the patient enters the hospital will increase Medicare spending on tests and screenings with questionable benefit to patients," Dr. J. James Rohack, AMA president-elect, said in a statement. "A more ef-

See **Never Events** • page 10

VITAL SIGNS

Aggregate Hospital Costs of Select Diagnoses (in millions of dollars)

Complications of device, implant, or graft	\$9,404
Complications of surgical procedures	\$5,086
Intestinal obstruction without hernia	\$3,253
Gastrointestinal hemorrhage	\$2,863
Pancreatic disorders (not diabetes)	\$2,767
Appendicitis	\$2,449
Crushing injury or internal injury	\$1,947
Abdominal hernia	\$1,906
Colon cancer	\$1,837

Note: Based on 2006 data from the Nationwide Inpatient Sample.
Source: Agency for Healthcare Research and Quality

INSIDE

THE
20/20
VISION

Appreciation

Dr. Michael Ellis DeBakey was a pioneer heart surgeon and device innovator. • 4

Low Scores

A scorecard shows a decline in U.S. health care system performance since 2006. • 5



News From the College

New Leader

Dr. L.D. Britt becomes chair of the ACS Board of Regents. • 8

Practice Trends

High Price to Pay

Preventable surgical errors are likely costing insurers more than \$1 billion annually, a new study says. • 11

SURGERY NEWS
60 Columbia Rd., Bldg. B
Morristown, NJ 07960
CHANGE SERVICE REQUESTED

Presorted Standard
U.S. Postage
PAID
Permit No. 384
Lebanon Jct. KY

Tissue Engineering Takes Hold

Vascular Grafts • from page 1

autologous bone marrow. Eight grafts, including seven seeded and one unseeded control, were implanted as inferior vena cava interposition grafts in juvenile lambs. One of the seven seeded grafts was explanted after 1 month; all others were explanted 6 months after implantation.

All of the grafts explanted at 6 months were patent and increased in volume, according to Dr. Breuer and his colleagues. The tissue-engineered vascular grafts at explant averaged 126.9% (plus or minus 9.9%) of their volume at 1 month. The grafts resembled the native inferior vena cava histologically and had comparable collagen, elastin, and glycosaminoglycan contents. Testing showed that ephrin-B4, a determinant of normal venous development, was acquired in the seeded grafts 6 months after implantation.

The researchers found that tissue-engineered vascular grafts demonstrated evidence of growth and venous development when implanted in the inferior vena cava of a juvenile lamb model. "The vessels contract, and they grow," said Dr. Breuer.

Researchers led by Dr. Toshiharu Shinoka at the Heart Institute of Japan, Tokyo Women's Medical University, have implanted the tissue-engineered grafts in 25 patients thus far, Dr. Breuer said; the oldest graft has been in place for about 6 or 7 years.

Dr. Shinoka, who is now associate professor and director of pediatric cardiovascular surgery at Yale, is continuing his research with Dr. Breuer. They are seeking Food and Drug Administration approval to use the animal-tested tissue-engineered grafts to repair congenital heart defects in pediatric patients.

"We're in the lab developing the next generation of tissue grafts," Dr. Breuer

said. Using a mouse model, they are examining the potential for unseeded grafts that are coated with an immune system chemical to spur blood vessel growth.

"All along, we had this theory that we had been putting the cells on a scaffold, kind of like putting the bricks on the walls of a house—the cells are the bricks." The theory held that those seeded cells would survive and multiply to create the new venous graft, he said. Instead, the researchers realized something else was happening.

"The cells we were seeding actually disappeared, and were being replaced by cells from the animals themselves. So those cells, instead of being the building blocks, served as a kind of template. We leveraged the body's own ability to repair itself, and then improved it," Dr. Breuer explained.

The researchers identified an immune system chemical, MCP-1, which "is really critical to the whole process," Dr. Breuer said. "We were then able to redesign the scaffold so that it now releases MCP-1. If you can take that chemical and put it on a scaffold, it will be much more user friendly and available to everyone."

With their mouse model, the surgeons have created tissue-engineered vascular grafts without bone marrow cells by using MCP-1 on the mesh tubes, he said. "If you just take the regular scaffold without MCP-1, it doesn't work as well," he added.

The technology may work for angio-access in dialysis patients, for whom the current mostly synthetic grafts "work very poorly, with a lifetime of 1-2 years," Dr. Breuer said, and could be used in patients who do not have enough of their own graft material left to undergo lifesaving or limb-saving surgery, Dr. Breuer said.

He disclosed that funding for the clinical trial has been received from Gunze. ■

Key Players Identified

Health Reform • from page 1

deeper than before," he said, adding, "It's still going to require a lot of presidential leadership. But the Congress has to be an equal, more than it has before."

Several proposals are likely starting points for congressional negotiations with the new administration, he said. First is the Healthy Americans Act, introduced in January 2007 by Sen. Ron Wyden (D-Ore.) and Sen. Bob Bennett (R-Utah). It has 16 cosponsors from both parties, including Sen. Chuck Grassley (R-Iowa), the Finance Committee's ranking minority member.

The bill is being championed in the House by Rep. Debbie Wasserman Schultz (D-Fla.) and Rep. Jo Ann Emerson (R-Mo.). Rep. Wasserman Schultz is important "because she's a rising star and has impeccable liberal credentials," said Mr. Nichols.

In a paper published in the policy journal *Health Affairs*, Sen. Wyden and Sen. Bennett said they saw "signs of an ideological truce" on the Hill, with agreement that there is a need for the Democratic-backed universal coverage and the Republican-supported desire for market forces to promote competition and innovation. "The Healthy Americans Act strikes a balance between these ideals," they wrote (*Health Affairs* 2008;27:689-92).

The bill would require individuals to purchase insurance for themselves and their dependent children, and would require insurers to offer a prescribed package of benefits. It would subsidize coverage for Americans with incomes up to 400% of the federal poverty level. Employers would convert benefit dollars into salary; such compensation would be tax free, with the goal that the money

would be used to purchase coverage.

Sen. Wyden is likely to be front and center in crafting a bill, because he is a member of the finance and budget committees, which, along with the Health, Education, Labor and Pensions (HELP) Committee "will play very important roles," Mr. Nichols said.

Ron Pollack, executive director of the advocacy group Families USA, speculated that Sen. Max Baucus (D-Mont.) "is going to be as instrumental in the process as anyone."

Sen. Baucus, chairman of the Finance Committee, held a health care summit in mid-June. Staff from the Finance Committee and the HELP Committee, led by Sen. Edward M. Kennedy (D-Mass.), have been coordinating meetings with those two panels and the Budget Committee, Mr. Pollack said in an interview.

Committee chairs have the greatest influence on the legislative process, he said. Both Mr. Pollack and Mr. Nichols also expect Sen. Kennedy to play a very significant part in creating the legislation, as much as his cancer will allow.

Even so, "to pass anything of significance will require bipartisanship," said Mr. Pollack.

The House is not as far along in preparing for health reform, but staffers on the four relevant committees with jurisdiction over health care have been meeting, said Mr. Pollack.

"I don't think any of the proposals that have come out so far are going to be the proposals [for health care reform]," said Mr. Pollack.

Instead, the expectation is that a health reform bill will be developed during the transition period between November and January, he said. ■



SURGERY NEWS

Editor in Chief, SURGERY NEWS Lazar J. Greenfield, M.D., FACS
ACS Director of Communications Linn Meyer

EDITORIAL ADVISORY BOARD

- Anesthesiology:** Robert Morell, M.D., Clinical Associate Professor of Anesthesia, Fort Walton Beach Medical Center
Bariatric: Myriam J. Curet, M.D., FACS, Professor of Surgery, Stanford University
Cardiothoracic: Mark S. Allen, M.D., FACS, Professor of Surgery, Mayo Clinic
Cardiothoracic: Fred A. Crawford, Jr., M.D., FACS, Chief, Division of Cardiothoracic Surgery, Medical University of South Carolina
Colorectal: Robert Madoff, M.D., FACS, Professor of Surgery, University of Minnesota
Endocrine Surgery: Robert Udelsman M.D., FACS, Chairman, Department of Surgery, Yale University
Ethics: James W. Jones, M.D., Ph.D., FACS, Visiting Professor of Medicine and Medical Ethics, Baylor University
Information Technology: Patricia L. Turner, M.D., FACS, Assistant Professor of Surgery, University of Maryland
Minimally Invasive and Gastrointestinal: Gerald M. Fried, M.D., FACS, Professor of Surgery, McGill University
Neurological: Hunt Batjer, M.D., FACS, Michael J. Marchese Professor, Northwestern University
Obstetrics and Gynecology: William J. Hoskins, M.D., FACS, Executive Director of Surgical Activities, Memorial Sloan-Kettering Cancer Center
Ophthalmology: Natalie C. Kerr, M.D., FACS, Chief, Pediatric Ophthalmology Service, University of Tennessee
Orthopedic: Mark R. Belsky, M.D., FACS, Chief of Orthopedic Surgery, Newton-Wellesley Hospital
Otolaryngology: Mark Weissler, M.D., FACS, J.P. Riddle Distinguished Professor, University of North Carolina
Pediatric Surgery: Thomas F. Tracy, Jr., M.D., FACS, Pediatric Surgeon-in-Chief, Hasbro Children's Hospital
Plastic Surgery: Linda Phillips, M.D., FACS, Truman G. Blocker Jr., M.D. Distinguished Professor, University of Texas
Resident/Associate Society: Ted A. James, M.D., Assistant Professor of Surgery, University of Vermont
Surgical Oncology: James P. Neifeld, M.D., FACS, Chairman, Department of Surgery, Virginia Commonwealth University
Transplantation: Jeffrey Punch, M.D., FACS, Associate Professor of Surgery, University of Michigan
Trauma (Burns and Mass Casualties): Steven E. Wolf, M.D., FACS, Professor of Surgery, University of Texas
Trauma and Critical Care: Grace S. Rozycki, M.D., FACS, Professor of Surgery, Emory University
Urology: Badrinath R. Konety, M.D., FACS, Vice Chair, Dept. of Urology, University of California at San Francisco
Vascular: Linda Harris, M.D., FACS, Associate Professor of Surgery, Millard Fillmore Hospital

SURGERY NEWS

SURGERY NEWS is the official newspaper of the American College of Surgeons and provides the practicing surgeon with timely and relevant news and commentary about clinical developments and about the impact of health care policy on the profession and on surgical practice today. Content for **SURGERY NEWS** is provided by International Medical News Group and Elsevier Global Medical News. Content for the NEWS FROM THE COLLEGE is provided by the American College of Surgeons.

The ideas and opinions expressed in **SURGERY NEWS** do not necessarily reflect those of the College or the Publisher. The American College of Surgeons and Elsevier Inc., will not assume responsibility for damages, loss, or claims of any kind arising from or related to the information contained in this publication, including any claims related to the products, drugs, or services mentioned herein.

POSTMASTER: Send changes of address (with old mailing label) to Circulation, **SURGERY NEWS**, 60 B Columbia Rd., 2nd fl., Morristown, NJ 07960.

The American College of Surgeons' headquarters is located at 633 N. Saint Clair St., Chicago, IL 60611-3211.

SURGERY NEWS (ISSN 1553-6785) is published monthly for the American College of Surgeons by Elsevier Inc., 60 B Columbia Rd., 2nd fl., Morristown, NJ 07960; 973-290-8200; fax 973-290-8250.

EDITORIAL OFFICES 5635 Fishers Lane, Suite 6000, Rockville, MD 20852, 240-221-4500, fax 240-221-2541.

Letters to the Editor: surgerynews@facs.org

©Copyright 2008, by the American College of Surgeons

ELSEVIER SOCIETY NEWS GROUP, A DIVISION OF INTERNATIONAL MEDICAL NEWS GROUP

President, IMNG Alan J. Imhoff
Director, ESGN Mark Branca
Executive Director, Editorial Mary Jo M. Dales
Executive Editor, IMNG Denise Fulton
Executive Editor, EGMN Kathy Scarbeck
Publication Editor Elizabeth Wood
Publication Associate Editor Jay C. Cherniak
VP, Medical Education Sylvia H. Reitman
Senior Director, Marketing and Research Janice Theobald
Circulation Analyst Barbara Cavallaro
Executive Director, Operations Jim Chicca
Director, Production and Manufacturing Yvonne Evans
Production Manager Judi Sheffer
Creative Director Louise A. Koenig

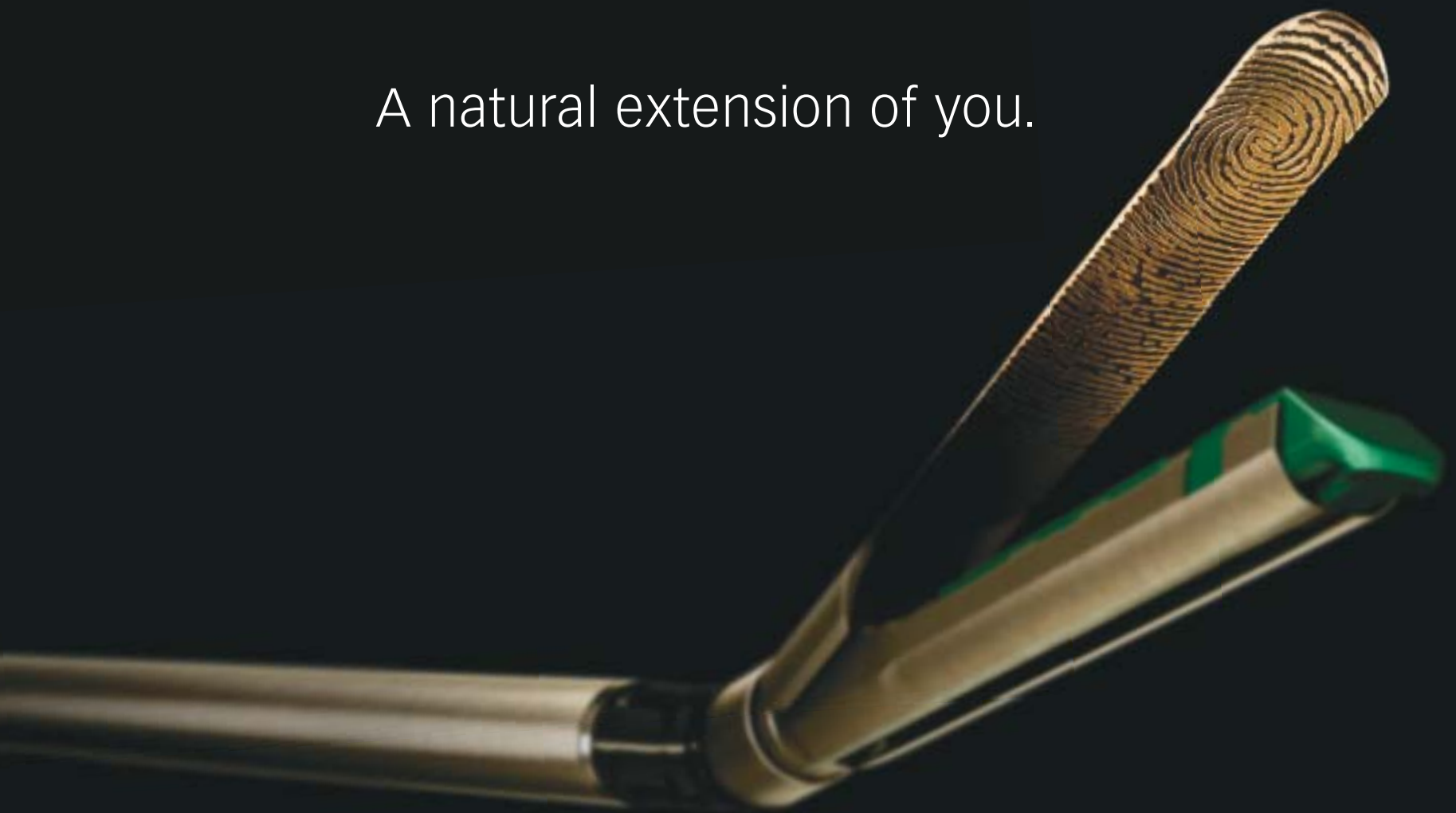
National Account Manager Stephen H. Close, 973-290-8223, fax 973-290-8250, s.close@elsevier.com
Classified Sales Manager Danny Wang, 212-633-3158, fax 212-633-3820, d.wang@elsevier.com
Address Changes: Fax change of address (with old mailing label) to 973-290-8245 or e-mail change to subs@elsevier.com

ADVERTISING OFFICES 60 B Columbia Rd., 2nd fl., Morristown, NJ 07960, 973-290-8200, fax 973-290-8250

CLASSIFIED ADVERTISING OFFICES 360 Park Ave. South, 9th Floor, New York, NY 10010, 800-379-8785



A natural extension of you.



Experience the freedom of true one-handed natural articulation, with an 18% higher angle of articulation than Endo GIA™*. To try ECHELON FLEX™ in your next case, contact your EES representative or call 1-800-USE-ENDO. For complete product details, see Instructions For Use.

FEEL THE CONNECTION.

echelonflex™
ENDOPATH® STAPLER



*ECHELON FLEX™ = 45° Endo GIA Roticulator™ Stapler = 36° Endo GIA Roticulator™ Stapler is a trademark of Covidien Ltd.

 ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

© Ethicon Endo-Surgery, Inc. 2008 DSL# 08-0865

THE 20/20 VISION

Evolutionary Changes in Surgical Practice

Appreciation

Dr. DeBakey, Cardiovascular Surgery Pioneer

BY MARK S. LESNEY
Elsevier Global Medical News

Dr. Michael Ellis DeBakey, pioneer heart surgeon and medical device innovator, died July 11, 2008, in Houston.

Renowned for his immense contributions to the progress of medical science, Dr. DeBakey was declared a "living legend" by the Library of Congress and was this year awarded a Congressional Gold Medal for his lifetime achievements, in particular his pioneering work as a heart surgeon.

Even before receiving his medical degree from Tulane University in 1932, he developed a small continuous flow-roller pump designed to improve blood transfusion. And in 1939, with his mentor, Dr. Alton Ochsner, Dr. DeBakey suggested a strong link between smoking and lung cancer.

During World War II, while assigned to the U.S. Army Surgeon General's office, Dr. DeBakey persuaded the surgeon general to form what would become the mobile army surgical hospitals (MASH units)—an innovation that gained him the U.S. Army Legion of Merit in 1945.

He helped to establish the Veterans Administration medical center research system, and he initiated the movement that in 1956 took the Army's poorly housed medical library and used it to create the National Library of Medicine.



©BAYLOR COLLEGE OF MEDICINE

According to the Web site of Baylor College of Medicine's department of surgery, where he spent almost his entire postwar career, Dr. DeBakey operated on more than 60,000 patients in the Houston area alone. In 1953, he performed the first successful carotid endarterectomy, as well as the first successful removal and graft replacement of a fusiform thoracic aortic aneurysm, and in 1954, the first successful resection and graft replacement of an aneurysm of the distal aortic arch and upper descending thoracic aorta.

In 1955 he performed the first successful resection of a thoracoabdominal aortic aneurysm using the DeBakey Dacron graft—the first artificial arterial graft of its kind.

"If we now tried to develop the Dacron

graft the way we developed it, I am not sure we would have it today with the way they regulate things. ... When I went down to the department store ... they said 'We are fresh out of nylon, but we do have a new material called Dacron.' I felt it, and it looked good to me. So I bought a yard of it. ... I took this yard of Dacron cloth, I cut two sheets the width I wanted, sewed the edges on each side, and made a tube out of it. ... We put the graft on a stent, wrapped nylon thread around it, pushed it together, and baked it. ... After about two or three years of laboratory work on my own [including experiments in dogs], I decided that it was time to put the graft in a human being. I did not have a committee to approve it. ... In 1954, I put the first one in during an abdominal aortic aneurysm. That first patient lived, I think, for 13 years and never had any trouble," Dr. DeBakey related in an interview published in 1996 in the *Journal of Vascular Surgery*.

In 1964, Dr. DeBakey was the first to perform a successful coronary artery bypass in what is now a common procedure: coronary artery bypass grafting. He was a pioneer of devices such as the left ventricular assist device, the extracorporeal pneumatic pump, and the total artificial heart model.

In his death, Dr. DeBakey was the first Houston resident given the honor of lying in state at City Hall, where he was viewed by long lines of the general public. ■

PHR Criteria Identified for Certification

BY MARY ELLEN
SCHNEIDER
Elsevier Global Medical News

Privacy should be the top priority when developing certification criteria for personal health records, a task force created by the Certification Commission for Healthcare Information Technology has recommended.

Adequate security and interoperability also must be included in certification efforts, according to the task force.

The Certification Commission for Healthcare Information Technology (CCHIT) will use these recommendations as it prepares to begin certifying personal health records (PHRs) next summer.

The task force recommended that the voluntary certification process should apply to any products or services that collect, receive, store, or use health information provided by consumers. Certification should also apply to products or services that transmit or disclose to a third party any personal health information.

This would allow the CCHIT to offer certification to a range of products and applications. CCHIT hopes that, just as it did in the EHR field, certification will create a floor of functionality, security, and interoperability, said Dr. Paul Tang, cochair of the PHR Advisory Task Force and vice president and chief medical information officer for the Palo Alto (Calif.) Medical Foundation.

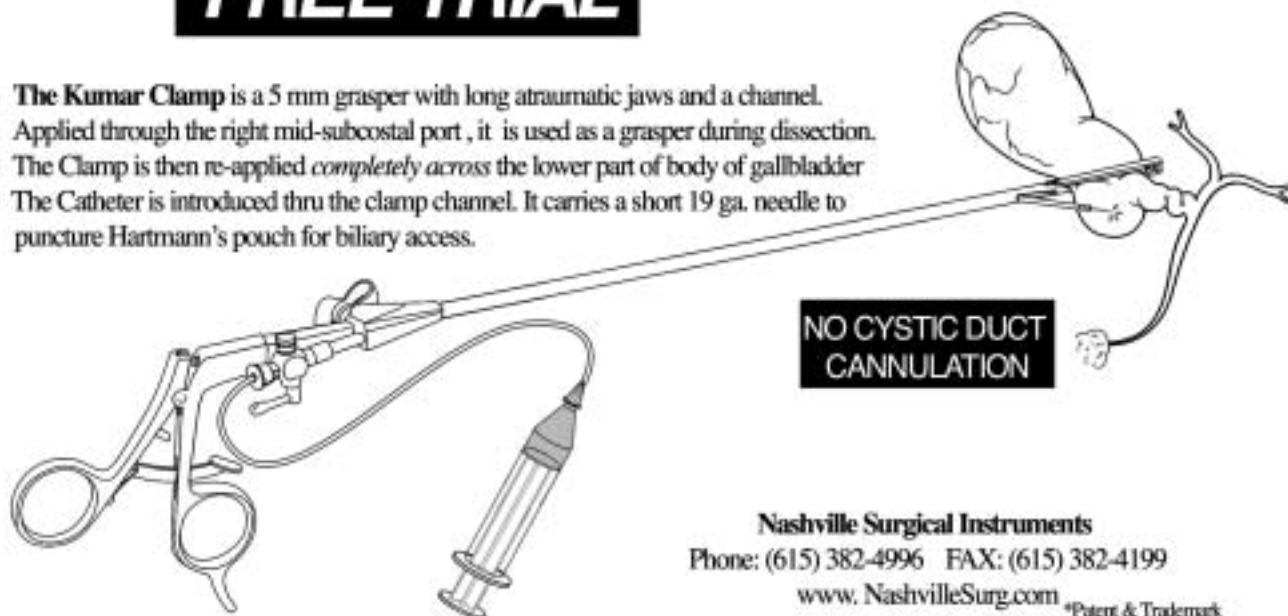
The task force called for requirements to maintain privacy in monitoring and enforcement, and for consumer protection that would allow patients to remove their data if certification is revoked. The group also recommended that standards-based criteria be developed that would require PHRs to send and receive data from as many potential data sources as possible, including ambulatory EHRs, hospital EHRs, labs, and networks.

In July, the task force made its recommendations and handed over responsibility for PHR certification to a CCHIT work group. That work group will develop the actual certification criteria that will be used to test PHR products starting next July, according to Dr. Jody Pettit, strategic leader for CCHIT's PHR work group. ■

The Kumar PRE-VIEW* Cholangiography

FREE TRIAL

- The Kumar Clamp is a 5 mm grasper with long atraumatic jaws and a channel.
- Applied through the right mid-subcostal port, it is used as a grasper during dissection.
- The Clamp is then re-applied *completely across* the lower part of body of gallbladder
- The Catheter is introduced thru the clamp channel. It carries a short 19 ga. needle to puncture Hartmann's pouch for biliary access.



Nashville Surgical Instruments

Phone: (615) 382-4996 FAX: (615) 382-4199

www.NashvilleSurg.com *Patent & Trademark

- After Cholangiography, clamp jaws are opened and gallbladder is aspirated. This makes it easier to separate the gallbladder from liver & to extract from the portsite.
- In Hydrops the catheter / needle is used to aspirate & decompress the gallbladder first, *without grasping*. This helps to dislodge the impacted stone. The gallbladder can then be grasped and dye injected thru the same biliary access.

U.S. Scores Low on Health Report Card

BY JANE ANDERSON
Elsevier Global Medical News

Access to care has declined significantly since 2003, with 42% of all working-age adults either uninsured or underinsured in 2007, according to a national health system scorecard from The Commonwealth Fund, which found that health care system performance in the United States has worsened slightly overall since 2006.

According to the scorecard report, U.S. scores are particularly low on efficiency, compared with top performers inside the country—states, regions, hospitals, health plans, or other providers—and internationally.

“These findings were very disturbing, considering the resources the U.S. spends on health care,” Dr. Karen Davis, president of The Commonwealth Fund, said in a briefing on the report, adding that the nation spends more on health care than any other in the industrialized world.

In the report, “Why Not the Best? Results From the National Scorecard on U.S. Health System Performance, 2008,” the United States scored an average of 65 out of a possible 100 across 37 key indicators of health outcomes, quality, access, efficiency, and equity.

“We need to change direction,” Dr. Davis said. “This latest scorecard demonstrates that we are in fact losing ground.”

The report found that the number of uninsured and underinsured Americans continues to rise: As of 2007, 42% of all working-age adults were either uninsured or underinsured—up from 35% in 2003.

In addition, the report said that the United States failed to keep up with improvements made in other countries, and fell from 15th place to dead last among 19 industrialized nations in premature deaths that could have been prevented by timely access to effective health care.

Rates for basic preventive care, such as cancer screening, failed to improve from 2005 to 2007, the report said.

In addition, “scores on efficiency are particularly low, pulled down by fragmented, poorly coordinated care,” along with lack of access to care and high administrative costs, said Cathy Schoen, senior vice president of The Commonwealth Fund.

In 2007, for example, as in 2005, patients in the United States were three to four times more likely than patients in other countries to report having had duplicate tests or to report that medical records or test results were not available at the time of their appointment. And, although primary care physicians in the United States used electronic medical records (EMRs) increasingly from

2001 to 2006—17% to 28%—the United States lags far behind leading countries, where EMRs now are used by nearly all physicians (98%) to improve care, the scorecard reported.

However, the report found evidence that focusing on specific areas through targeted initiatives can yield substantial improvement, Ms. Schoen said. For example, hospital standardized mortality ratios, a

key indicator of patient safety, improved by 19% over 5 years, following broad public and private efforts to assess and improve hospital safety. Also, chronic care and acute hospital care quality metrics also showed significant progress.

“We find that what gets attention gets improved,” Ms. Schoen said. “But to date we have focused too narrowly. Current initiatives often fail to encourage more ef-



fective or more efficient care.”

Dr. Davis pointed out that, with a new president and administration next year, the United States has a real opportunity to re-focus and rebuild its health care system.

“The most important thing is extending health insurance to all,” she said. ■

vision & ergonomics
at work

SurgiTel®

See Your Best, Feel Your Best



SurgiCam™
Digital Video Camera
(shown with SurgiTel Compact Prism Telescopes)

- USB plug-and-play connectivity
- Can be connected to any monitor
- Straight digital output - no conversion!
- Store video directly on your hard drive
- Extract digital pictures from video



Excellent Posture



Poor Posture
Neck Pain

“SurgiTel eliminated all of the neck pain that I previously endured with other telescopes.”
Raymond L. Singer, MD



SurgiTel®
Loupes



Laser & X-Ray Protection Filters



Xenon Lights

Call (800) 959-0153 or visit www.surgitel.com

THE 20/20 VISION

New Guidelines Update Strategies for Thrombosis Prevention, Management

BY BETSY BATES

Elsevier Global Medical News

Sweeping new clinical guidelines issued by the American College of Chest Physicians provide updated recommendations on how to prevent and

manage thrombosis in surgical patients and special risk groups, including pregnant women, children, obese patients, and patients with prosthetic heart valves or a history of cardiovascular disease or stroke.

Compiled by more than 90 experts, the 700 recommendations run more than

1,000 pages, although a 38-page executive summary is available (Chest 2008;133:71S-109 [doi:10.1378/chest.08-0693]).

Among the most noteworthy recommendations is a renewed call for venous thromboembolism (VTE) prophylaxis of most hospitalized patients. The new rec-

ommendations for VTE prophylaxis include bariatric and coronary artery bypass surgery.

The length of recommended postsurgical prophylaxis has been extended from the previously recommended 2-week period to 28 days (and in some cases to 35 days) for most general, gynecologic, and orthopedic procedures, noted Dr. Geno J. Merli, chief medical officer of Thomas Jefferson University Hospital, Philadelphia.

A new chapter expands evidence-based guidance for perioperative management of patients on antithrombotic therapy who need emergency or elective surgery. Detailed sections provide advice for circumstances ranging from minor dermatologic surgery to hip fracture.

"This [publication] is not meant to be read from cover to cover," said Dr. Jack Hirsh in an interview. "It is an encyclopedic reference to be used by physicians if the patient has had a stroke, is at risk of stroke, has had a heart attack, is at risk of heart attack, has atrial fibrillation, has an inherited thrombophilia, or is pregnant and on antithrombotic therapy," said Dr. Hirsch, professor emeritus of medicine at McMaster University and founding director of the Henderson Research Center, both in Hamilton, Ont.

The guidelines offer two options—one monitored and one unmonitored—for subcutaneous heparin administration for acute DVT, Dr. Merli said in an interview.

The first regimen calls for an initial dose of 17,500 U or a weight-adjusted dose of about 250 U/kg every 12 hours, with the dose adjusted to achieve and maintain an activated partial thromboplastin time (aPTT) prolongation that corresponds to plasma heparin levels of 0.3-0.7 IU/mL anti-Xa activity when measured 6 hours after injection (rather than beginning therapy with the smaller initial dose).

The second option is a fixed-dose, unmonitored regimen that calls for an initial dose of 333 U/kg followed by a twice-daily dose of 250 U/kg.

The guidelines also suggest the use of catheter-directed thrombolysis with thrombus fragmentation and/or aspiration in "selected patients with extensive acute proximal DVT who have a low risk of bleeding," but advocate this pharmacomechanical approach only if "appropriate expertise and resources are available."

The guidelines also say that INR monitoring during anticoagulation therapy may be reduced in very low risk patients with an unprovoked DVT, Dr. Merli noted. ■

3%
commodities allocation

NEW FUND ALLOCATION

A **3% commodities allocation** has been added to SDIF in an effort to further align its asset allocation with that of the ACS endowment. The commodities component allows SDIF shareholders to obtain exposure to various types of commodities, including industrial and precious metals, agriculture, livestock and energy. Commodities exposure adds an asset class to SDIF that provides further diversification, and one that historically has a negative correlation to stocks and bonds.

For more information about SDIF, please contact Tom Kiley at 312/202-5019, tkiley@facs.org, or Savi Pai at 312/202-5056, spai@facs.org.



Surgeons | **DIVERSIFIED INVESTMENT FUND**

An investor should consider the charges, risks, expenses and investment objective carefully before investing. For more information or for a free copy of the prospectus, please download a copy at www.surgeonsfund.com or call 1-800-208-6070 and a copy will be mailed to you. Read the prospectus carefully before you invest or send money.

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



Plastic Surgery Education Expands to Meet Demand for Greater Expertise

BY DOUG BRUNK
Elsevier Global Medical News

Changes in plastic surgery training that will take effect on July 1, 2009, mean that residents enrolled in independent programs will need to complete 3 years of concentrated plastic surgery education, while 6 years will be required for those in integrated programs sanctioned by the Accreditation Council for Graduate Medical Education (ACGME) following receipt of an MD or DO degree. That is the most common paradigm for integrated programs; only four programs require 5 years, according to the ACGME.

These changes reflect a shift to more uniform standards in light of the expanding knowledge and skills required of plastic surgeons.

“Plastic surgery continues to innovate, and these innovations drive the need for a greater knowledge base,” Dr. Robert Havlik, chair of the ACGME’s Residency Review Committee for Plastic Surgery (RRC-PS), said in an interview. The field has seen major refinements in reconstruction, including breast reconstruction, as well as in craniofacial, hand, and aesthetic surgery, and bariatric reconstruction.

Changes in training related to the adoption of the 80-hour work week and changes in general surgery training requirements over the past 2 years also “had implications for the plastic surgery candidate,” said Dr. Havlik, an ACS Fellow with the division of plastic surgery at Indiana University, Indianapolis.

The RRC-PS identified 21 main areas of expertise that were important for plastic surgery trainees, and defined the knowledge base and technical skills necessary within each area. After examining plastic surgery training paradigms from programs based in Canada and in the United Kingdom, the RRC-PS concluded that more than 2 years of training are required, Dr. Havlik explained.

Other changes mandate that sponsoring institutions support program directors “with a minimum of 15% protected time, which may take the form of direct or indirect salary support, such as release from clinical activities provided by the institution, for programs with one to six residents. Programs with more than six residents shall provide the program director with a minimum of 25% protected time.”

For program coordinators, the new requirements mandate 0.5 full-time equivalent for programs with up to six residents and 1.0 full-time

equivalent for programs with more than six residents.

“While we recognize that there are cost implications, our primary concern is the satisfactory education and the development of technical expertise of the plastic surgery trainee,” Dr. Havlik commented.

Dr. Linda G. Phillips, an ACS Fellow who directs the integrated residency program in plastic surgery at the University of Texas Medical Branch, Galveston, called the changes historic. In 2004 her program shifted from a 5-year integrated paradigm to a 6-year paradigm. “Some of our resi-

dents need that additional maturation and repeated exposure to plastic surgery that you only get with additional time.”

Go to www.acgme.org to view the changes. Click on “review committees,” then on “plastic surgery,” then on “program requirements.”

New InfoV.A.C.® Therapy System

Better by Design

The Next Generation of V.A.C.® Therapy



The InfoV.A.C.® Therapy System delivers the same positive outcomes you trust – but is now simpler and more efficient than ever.*

- Easier to Use.** Designed with busy clinicians in mind.
- Simpler Training.** Designed to be easier to learn, improving proficiency.
- Better Information.** Designed to provide consistent wound progress tracking.



www.InfoVACTherapy.com • 1-800-275-4524



*As compared to V.A.C. ATS® Therapy
Note: Specific indications, contraindications, warnings, precautions, and safety tips exist for this product and therapy. Please consult Product Instructions for Use prior to applications. ©2008 KCI Licensing, Inc. All rights reserved. KCI USA, 8023 Vantage Drive, San Antonio, TX 78230. All trademarks and service marks designated herein are the property of KCI and its affiliates and licensors. The V.A.C.® (Vacuum Assisted Closure®) System and most KCI products are subject to patents and/or pending patents.

NEWS FROM THE COLLEGE

Dr. Britt Becomes Chair of ACS Board of Regents

On August 5, 2008, L.D. Britt, M.D., MPH, FACS, assumed the position of chair of the ACS Board of Regents following the resignation of Josef E. Fischer, M.D., FACS, who stepped down because of time constraints and numerous personal commitments.

Dr. Britt, who was previously vice-chair of the board, will serve as chair until the Adjourned Meeting of the Board of Regents following the Clinical Congress in San Francisco, when the regents will elect officials for the 2008-2009 calendar year.

A Fellow of the College since 1989, Dr. Britt is the Brickhouse Professor and chairman, Department of Surgery, Eastern Virginia Medical School, Norfolk. He is the first African-American in the country to have an endowed chair in surgery.

Dr. Britt is a graduate of Harvard Medical School and Harvard School of Public Health, and a member of several national and international organizations, including Alpha Omega Alpha Honor Society, Society of University Surgeons, Southern Surgical Association, Société Internationale de Chirurgie, Halsted Society, and the American Surgical Association. He has served on the National Institutes of Health SOH Study Review Panel and has had many national and international leadership positions, including president of the Society of Surgical Chairs, past chairman of the ACGME Residency Review Committee for Surgery, secretary of the Southern Surgical Association, and

executive director of the Society of Black Academic Surgeons.

A member of the Executive and Finance Committees of the ACS Board of Regents, Dr. Britt also sits on the executive board of the National Board of Medical Examiners and is a former member of the Examination Committee of the American Board of Surgery. He was also a member of the Executive Council of the ACS National Committee on Trauma and was chair of all of the

COT's regional committees, which include all 50 states and the international community.

Previously, Dr. Britt was vice-president of the American Association for the Surgery of Trauma, and he is cur-

rently the recorder/program chair for the organization. He is the immediate past president of the Southeastern Surgical Congress, president of the Halsted Society, and director of the American Board of Surgery, and he was appointed to the Robert Wood Johnson Clinical Scholar Program National Advisory Committee.

Dr. Britt is well known as an outstanding educator and role model. He has been recognized with many national and institutional awards for his excellence in teaching. He has also been recognized for his dedicated community service and for his work related to combat trauma care.

As chair of the Board of Regents, Dr. Britt will work closely with Thomas R. Russell, M.D., FACS, Executive Director of the College, in conducting ACS business. ■



L.D. BRITT, M.D., MPH, FACS

Fellows To Be Honored for Volunteerism

Awards will be presented to the 2008 recipients of the ACS/Pfizer, Inc. Surgical Volunteerism Awards and the newly established Surgical Humanitarian Award at the Clinical Congress in October. The Governors' Committee on Socioeconomic Issues received nominations for many exceptional individuals, which demonstrates the substantial commitment of ACS Fellows to the care of the underserved.

Joseph A. Gurri, M.D., FACS, of Melbourne Beach, Fla., will be awarded the Surgical Volunteerism Award for domestic outreach in recognition of extensive work in his local community. Upon arriving in Brevard County, Fla., in 1981 as a young surgeon, Dr. Gurri, who is fluent in Spanish, began helping migrant workers with their health care needs. In 1992, when the local hospital launched a system of free clinics, Dr. Gurri stepped up as a surgical volunteer.

Assessing gaps in available care, Dr. Gurri created a program at the Brevard Health Alliance Breast Cancer Clinic for the identification, education, treatment, and follow-up of women with breast cancer, providing complete access to breast health services. Through this and similar programs over nearly three decades, Dr. Gurri

has proved to be a champion in providing surgical care to the uninsured and the less fortunate.

Bradley D. Wong, M.D., FACS, of Honolulu, Hawaii, will be awarded the Surgical Volunteerism Award for international outreach in recognition of his participation in numerous medical missions to the Philippines, Viet Nam, China, American Samoa, and Nepal. As a medical student, Dr. Wong volunteered at an outreach clinic in Philadelphia's Chinatown. Since 1988, he has been involved with the Honolulu-based Aloha Medical Mission's annual trips and has served on the mission's board of directors, helping to expand its services and acquire a clinic in Honolulu. By immersing himself in everything from patient care to education, Dr. Wong demonstrates a strong commitment to international surgical care.

Guy Theodore, M.D., FACS, of Pignon, Haiti, is the inaugural recipient of the 2008 American College of Surgeons/Pfizer, Inc. Surgical Humanitarian Award, which recognizes surgeons who have dedicated a substantial portion of their career to ensuring surgical care for underserved populations without expectation of commensurate reimbursement. A native of Haiti, Dr. Theodore received his graduate medical training in the United

States and later joined the U.S. Air Force. While away from his homeland, he developed a strategy to build the Hôpital de Bienfaisance de Pignon when he returned in 1983. Over the past 25 years, Dr. Theodore has also built public health services encompassing human immunodeficiency virus care, dental and eye clinics, midwifery, clean water and sanitation initiatives, and microfinance programs in Pignon and the surrounding communities.

With the assistance of expatriate surgeons who volunteer with the Christian Mission of Pignon, Community Coalition of Haiti, and Project Haiti, Dr. Theodore regularly holds courses for physicians from all areas of Haiti. His efforts have resulted in a modern hospital facility with a broad complement of medical and surgical services.

Dr. Gurri, Dr. Wong, and Dr. Theodore will speak at the plenary session on volunteerism (GS08) on Monday, Oct. 13, 9:45 a.m.–1:00 p.m., and will attend a volunteer networking reception that evening. Their exceptional contributions will be formally recognized at the annual Board of Governors dinner on Tuesday, Oct. 14.

For details, go to the ACS Web site at www.operationgivingback.facs.org or check the *Clinical Congress News*. ■

ACS Web Portal Logs Thousands Of Visitors

Usage statistics indicate that approximately 7,500 unique visitors visit e-FACS.org, the College's members-only Web portal, each quarter. Recently, the portal surpassed 1 million page views.

Below are some of the functions you can perform in the portal. To begin, go to <http://www.efacs.org> and log in with your ACS membership ID. For each function listed below, go to http://efacs.org/portal/page/portal/ACS_Content and then to the specific areas indicated for each.

- ▶ Track CME credits.
(Go to MYPAGE/myCME.)
- ▶ Update your College profile.
(Go to MYPAGE/MYPROFILE.)
- ▶ Log your cases.
(Go to MYPAGE/MYCASES.)
- ▶ List all of your favorite Web sites in one place.
(Go to MYPAGE/myBookmarks.)
- ▶ Check out the newly redesigned Women Surgeons community.
(Go to ACSCOMMUNITIESSPECIALITIES/WomenSurgeons.)
- ▶ View the Minimally Invasive Surgery "Image of the Month."
(Go to ACSCOMMUNITIESSPECIALITIES/GenSurg_SpA/MinInvCmty.)

A work in progress, the ACS Web Portal continues to grow and develop daily. Come and see for yourself why more and more members are taking advantage of this free tool.

The portal is being directed by George F. Sheldon, M.D., FACS, who is Editor-in-Chief, and Lazar J. Greenfield, M.D., FACS, the portal's Associate Editor. ■



Dr. Gurri studying films.



Dr. Theodore (right) with patient.



Dr. Wong examining a skin graft.

NEWS FROM THE COLLEGE

Dr. Collicott Chosen to Receive 2008 Distinguished Service Award

The ACS Board of Regents has named Paul E. Collicott, M.D., FACS, the recipient of its highest honor, the Distinguished Service Award for 2008. He will receive the award at the 2008 Clinical Congress.

Dr. Collicott is being recognized for his staunch and devoted service as an ACS Fellow. Among his achievements are his role in developing the Advanced Trauma Life Support (ATLS) course, acting as a national and international ATLS course director, serving as a member of the General Surgery and Coding Reimbursement Committee and the Committee on Trauma, and serving as an ACS regent.

Dr. Collicott is also being commended for his superb clinical activity as a peripheral vascular and trauma surgeon in Lincoln, Neb., work he conducted for nearly three decades, and as trauma director and chief of surgery at Lincoln General Hospital.

Previously, he was president of the Nebraska Medical Association and the Lancaster County Medical Society, an 8-year member of the Nebraska Medical Association's delegation to the American Medical Association (AMA) House of Delegates, and a special adviser to the AMA/Specialty Society Relative Value Update Committee.

Since 2001, Dr. Collicott has

been director of the ACS Division of Member Services, and has responsibility in numerous areas: the Board of Governors activities and committees, chapter activities and committees, membership recruitment and retention, the Resident



PAUL E. COLLICOTT,
M.D., FACS

and Associate Society, the Committee on Young Surgeons, 12 specialty Advisory Councils, the Central Judiciary Committee, Research Integrity Officer, Operation Giving Back, scholarships administration, seven additional committees, the online Job Bank, and affinity programs offering benefits to members.

Before joining the staff of the College, he served on the ACS Board of Regents, the Board's Executive Committee, Nominating Committee, Member Services Liaison Committee, and Central Judiciary Committee. He was also a member of the Board of Governors and of the Governors' Committee on Physician Health and Competence.

Furthermore, Dr. Collicott has been chair of the Central Judiciary Committee, a member of the Advisory Council for Vascular Surgery, and a member of the General Surgery and Coding Reimbursement Committee. He also has served as a member of the Committee on Trauma and its Executive Committee, chair of the ATLS subcommittee, and National

and International ATLS course director, and he was instrumental in introducing ATLS in 1980. He has received numerous awards for his trauma endeavors and is known as the "father of ATLS."

Dr. Collicott received his medical degree from the University of Nebraska College of Medicine and served as a general rotating intern at Lincoln General Hospital. His training was interrupted while he served in the U.S. Air Force during the Viet Nam conflict, but he later completed his residency in general surgery and a peripheral vascular surgery fellowship at University of Washington Hospitals, Seattle.

After completing postgraduate training, Dr. Collicott was a community surgeon in Nebraska for 28 years, specializing in peripheral vascular and trauma surgery. In addition, he was the trauma director and chief of surgery at Lincoln General Hospital and held clinical faculty appointments at the University of Nebraska and Creighton University.

He has been a leader in numerous surgical and medical organizations, including the American Board of Surgery, American Surgical Association, Central Surgical Association, Western Surgical Association, Southwestern Surgical Congress, Society for Vascular Surgery, AMA, American Association for Vascular Surgery, International Society of Surgery, Society for Clinical Vascular Surgery, and American Association for the Surgery of Trauma. ■

Statement Issued On Cell Phone Usage in the OR

This statement was developed by the American College of Surgeons' Committee on Perioperative Care and was approved by the Board of Regents at its June 2008 meeting.

Cellular telephone technology has become ubiquitous. Whether for voice or for data, many surgeons have come to rely on cellular devices for communication outside the office. Nevertheless, the casual use of cellular devices in the operating room (OR) may be distracting. For these reasons, the use of cellular devices in the OR should be guided by the following considerations:

1. The undisciplined use of cellular devices in the OR—whether for telephone, e-mail, or data communication, and whether by the surgeon or by other members of the surgical team—may pose a distraction and may compromise patient care.

2. Surgeons should be considerate of the duties of personnel in the OR suite and refrain from engaging them unnecessarily in activities, including assistance in cellular communication, that might divert attention from the patient or the conduct of the procedure.

3. Cellular phones must not interfere with patient monitoring devices or with other technologies required for patient care.

4. Whenever possible, members of the OR team, including the operating surgeon, should only engage in urgent or emergent outside communication during surgery. Personal and routine calls should be minimized. Calls should be kept as brief as possible.

5. Whenever possible, incoming calls should be forwarded to the OR desk or to the hardwired telephone in the OR to minimize the potential distraction of cellular phones.

6. Whenever possible, cellular telephone calls and data transmissions should be forwarded to voice mail or to memory. The ring tone should be silenced. An inaudible signal may be employed.

7. Whenever possible, a distinct signal for urgent or emergent calls should be enabled. This signal may be implemented via a "page" option in most cellular telephones. Callers should be advised to use this function only for urgent and emergent calls if the phone is unanswered.

8. The use of cellular devices or their accessories (such as earphones or keyboards) must not compromise the integrity of the sterile field. Special care should be taken to avoid sensitive communication within the hearing of awake or sedated patients.

9. Communication using hardwired phones in the operating room is subject to the same discipline as communication using cellular technology.

10. The use of cellular devices to take and transmit photographs should be governed by hospital policy on photography of patients and by government regulations pertaining to patient privacy and confidentiality. ■

New Accreditation Program Begins for Breast Centers

The National Accreditation Program for Breast Centers (NAPBC) Board announced on July 24 that the developmental phase of the program is nearly complete, and that it would begin accepting applications for accreditation on Sept. 1.

Twenty-seven standards have been defined and are included in this multidisciplinary program. Of those, 18 can be evaluated through the password-protected Survey Application Record, and nine require on-site review by an NAPBC surveyor.

The standard categories include center leadership, clinical management, research, community outreach, professional education, and quality improvement. This program is amenable to all practice models and incorporates the concepts of provided and referred services in order to meet the NAPBC Standards.

For more information, contact the NAPBC office by e-mail at napbc@facs.org or call 312-202-5185. ■

Enhancements Make Surgical Reference Robust

The internationally renowned medical publisher BC Decker, Inc., is now publishing *ACS Surgery: Principles & Practice*. As the only continuously updated surgical reference endorsed by the College, *ACS Surgery* provides its subscribers with unrivaled content, cutting-edge information, and timely updates. In addition, a modernized Web site with new features, search tools, and increased functionality was launched during the summer.

Order your copy of the bound volume for just \$169 (previous price: \$219).

ACS Surgery: Principles & Practice is also available in CD-ROM and online-only subscription packages. Special pricing for multiple formats is available.

Call toll free at 1-800-568-7281 (U.S. and Canada) or 905-522-7017; send a fax to 905-522-7839; or e-mail customer@bcdecker.com. ■

Recommendations for using ultrasound guidance to place central venous catheters will be published in the October issue of *Surgery News*.

More Coverage Denial Planned

Never Events • from page 1

fective patient safety approach would be to encourage compliance with evidence-based guidelines by health care professionals.”

CMS officials estimate that the nonpayment for preventable errors policy will save Medicare about \$20 million a year. However, the policy is not about saving money, Kerry Weems, CMS acting administrator, said during a press conference.

“I would be perfectly happy if we never came to a point where we didn’t have

to pay because somebody got a hospital-acquired condition,” Mr. Weems said. “This is about changing hospitals and making them safer places.”

The CMS originally had proposed adding nine new conditions to the preventable conditions nonpayment list. Agency officials pared down the list after public comments raised questions about including the other conditions. Some conditions that were not included in the final rule are delirium, ventilator-associated

pneumonia, *Staphylococcus aureus* septicemia, *Clostridium difficile*-associated disease, legionnaires’ disease, and iatrogenic pneumothorax.

However, those conditions may appear in future proposals once the agency has refined them, according to Mr. Weems.

The CMS also is in talks with the National Quality Forum, the Agency for Healthcare Research and Quality, the Leapfrog Group for Patient Safety, and others about expanding the list of never events and considering how to expand the nonpayment policy to nonhospital settings such as nursing homes and home health agencies.

In addition to the expansion of the conditions on the preventable hospital-acquired conditions list, CMS is also beginning to develop three National Coverage Determinations to deny Medicare coverage for three never events—surgery on the wrong body part, surgery on the wrong patient, and wrong surgery performed on a patient.

“These national coverage decisions will mandate what seems obvious—never events should never occur,” Mr. Weems said. “They should not be reimbursed by the Medicare trust fund.”

A proposed decision memorandum on these surgical errors is scheduled to be issued by next February and is expected to be made final by the end of next April.

Including these events in Medicare’s coverage policy also would apply to Medicare Advantage plans. Medicare Advantage plans are required to follow all Medicare fee-for-service coverage policies, even when those policies differ from their commercial practices, according to the CMS.

The CMS also sent a letter to state Medicaid directors to encourage states to adopt similar policies on payment for preventable hospital-acquired conditions. The letter also provides information on how states can adopt the policies outlined in the final Medicare inpatient prospective payment system regulation. Nearly 20 states are considering methods to eliminate payment for certain never events, or already have them in place, according to the CMS.

Finally, as part of the Acute Care Inpatient Prospective Payment System final rule, the CMS is adding 13 new measures to the Reporting Hospital Quality Data for Annual Payment Update program. Under the program, hospitals are required to report quality data publicly on the Medicare Hospital Compare Web site in order to receive their full payment update. The payment implications for the new quality measures will take effect in fiscal year 2010.

“Not only will the measures promote quality improvements by hospitals and their staff, they will also allow patients to compare different hospitals, to [help them] decide where they will receive the best care,” Mr. Weems said. ■

AMERICAN COLLEGE OF SURGEONS 94th annual Clinical Congress

October 12–16, 2008:
San Francisco, CA
Moscone Convention Center
SAVE THE DATE!

Join us in San Francisco for the 94th annual Clinical Congress. As always, it will be an educational opportunity you won’t want to miss!

Please be sure to visit WWW.FACS.ORG in the coming months for more details regarding the educational program, registration, housing, and transportation.



Eight Preventable Conditions Cited

Medicare currently lists eight preventable health care-acquired conditions under its nonpayment policy and will not reimburse hospitals for secondary diagnoses associated with these conditions if acquired after hospital admission:

- ▶ Foreign object retained after surgery.
- ▶ Air embolism.
- ▶ Blood incompatibility.
- ▶ Pressure ulcer at stages III and IV.
- ▶ Falls and trauma.
- ▶ Catheter-associated urinary tract infection.
- ▶ Vascular catheter-associated infection.
- ▶ Mediastinitis after coronary artery bypass graft.

Preventable Surgical Errors Cost \$1.5 Billion Annually

BY ALICIA AULT
Elsevier Global Medical News

Preventable surgical errors are likely costing insurers more than \$1 billion a year, according to a new study by the Agency for Healthcare Research and Quality.

The report is a fuller accounting of the true cost of potentially preventable errors than had been previously published, according to the authors, William E. Encinosa, Ph.D., and Fred J. Hellinger, Ph.D., both with AHRQ's Center for Delivery, Organization, and Markets.

They looked at the comprehensive, per-episode cost of medical errors, including payments to hospitals for the initial admission and readmission; and payments for physicians, for outpatient services, and for prescription drugs. All cost data were included for 90 days after surgical admission. The authors drew their analysis from the 2001-2002 MarketScan Commercial Claims and Encounter Database, which covers 5.6 million enrollees in private, employer-sponsored plans (Health Serv. Res. [doi: 10.1111/j.1475-6773.2008.00882.x]).

"Most papers that estimate the cost of medical errors only examine the initial hospitalization in which the medical error occurred," they wrote. But, they added, "We find that the death rate increases by 50% over 90 days once the patient leaves the hospital." Postdischarge costs also are often higher than those for the initial admission, they noted.

By looking at an entire episode of care over 90 days, the researchers make a strong argument in favor of spending money on quality, Dr. Darrell A. Campbell, an ACS Fellow and professor of surgery at the University of Michigan, Ann Arbor, said in an interview.

The case-control study examined 14 potentially preventable adverse medical events, defined by AHRQ as patient safety indicators. A total of 161,004 adult, nonelderly, major operations were analyzed; 2.6% (4,140) of cases had at least one of the 14 preventable events, and 5.6% of those cases had additional errors.

Acute respiratory failure was the most common preventable event, which occurred in 0.9% (1,392) of all surgical procedures. That also was the most expensive event, at \$106,000 per instance, and patients who had respiratory failure also had the highest death rate, at about 12% over the 90-day period tracked.

For all patients who had at least one preventable event, the 90-day death rate was 6%, versus 0.6% for those without a preventable event. The 90-day readmission rate was 15% for patients with an event, versus 5.5% for those without.

In all, 23% of patients who had potentially preventable events were readmitted, versus 10% of those without an event. The 90-day cost for an operation that included a potentially preventable event was \$66,800, compared with \$18,200 for a procedure that did not involve such an event. Lengths of stay were longer, at 22 days for patients with events, versus 5 days for those without.

By extrapolating the results to the entire population of insured nonelderly adults in the United States, the authors report that 11% of 90-day postdischarge deaths and 2% of 90-day readmissions are due to the 14 potentially preventable adverse events, and 2% (\$1.5 billion) of all 90-day expenses after surgery.

Going forward, it will be possible to collect stronger data on errors because hospitals are now recording whether certain preventable conditions are present on admission, Dr. Campbell said.

Additional Surgery Costs for Patients Resulting From Medical Errors

Acute respiratory failure	\$28,218
Infections	\$19,480
Nursing-sensitive events	\$12,196
Metabolic problems	\$11,797
Pulmonary and vascular problems	\$7,838
Wound problems	\$1,426
Technical problems	\$646

Note: Based on 2001-2002 data for 161,004 observations from MarketScan Commercial Claims and Encounters Database.
Source: Health Services Research

ELSEVIER GLOBAL MEDICAL NEWS

AMERICAN COLLEGE OF SURGEONS • DIVISION OF EDUCATION

Announcing

THE BASIC ULTRASOUND COURSE on CD-ROM

The American College of Surgeons and the National Ultrasound Faculty have developed "Ultrasound for Surgeons: The Basic Course" for surgeons and surgical residents on CD-ROM.

The objective of the course is to provide the practicing surgeon and surgical resident with a basic core of education and training in ultrasound imaging as a foundation for specific clinical applications.

- ^ Replaces the basic course offered by the American College of Surgeons.
- ^ A printable CME certificate is available upon successful completion.
- ^ CD will install the necessary software (PC or Mac).
- ^ The learner is offered two attempts to pass a multiple-choice exam with a minimum score of 80% at the completion of the program.
- ^ Residents must submit a letter from their director/chair to document residency status.
- ^ Only one user per CD is allowed. Online access is needed to register the CD and to take the exam.
- ^ \$300 for nonmembers
- ^ \$225 for Fellows of the College
- ^ \$125 for residents with letter proving status*
- ^ \$90 for Resident and Associate Society (RAS) members
(Additional \$16 for shipping and handling of international orders)

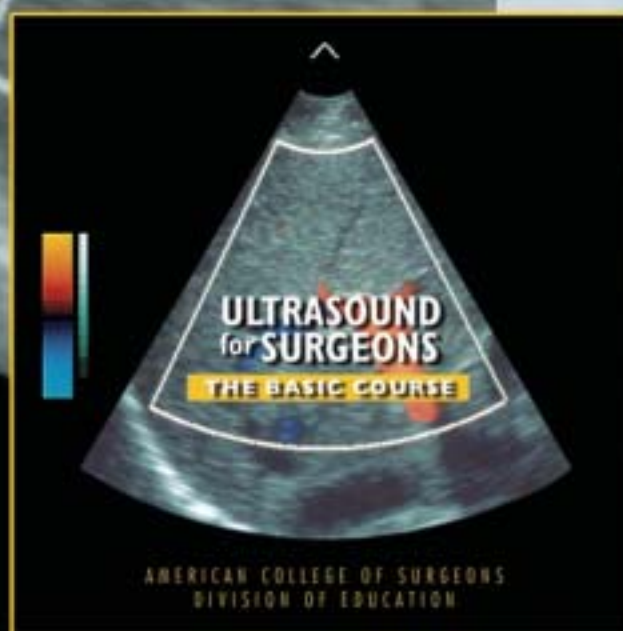
*Non-RAS residents must supply a letter confirming status as a resident from a program director or administrator and are limited to one CD-ROM.

The CD can be purchased online at <http://www.acs-resource.org> or by calling Customer Service at 312/202-5474.

For additional information, contact Olivier Petinaux, MS, tel. 866/475-4696, e-mail elarning@facs.org

The American College of Surgeons (ACS) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. The ACS designates this educational activity for a maximum of four AMA PRA Category 1 Credits™ toward the AMA Physician's Recognition Award.

Each physician should claim only those credits that he/she actually spent in the activity. The American Medical Association has determined that physicians not licensed in the U.S. who participate in this CME activity are also eligible for AMA PRA Category 1 Credits™.



Claudication Compromises Success of Cardiac Rehab

BY DOUG BRUNK
Elsevier Global Medical News

SAN DIEGO — The prevalence of peripheral arterial disease and intermittent claudication in a group of patients referred for cardiac rehabilitation ranged from 24% to 29%, results from a year-long study showed.

"We are all familiar with the fact that patients with peripheral arterial disease and intermittent claudication are at high risk for cardiac death," Dr. John V. White said at the Vascular Annual Meeting. "These patients would benefit from participation in a supervised cardiac rehabilitation program. Unfortunately, the exercise demands of cardiac rehabilitation may exceed the walking capabilities of the body. A policy of selective invasive treatment [of peripheral arterial disease] is warranted for those patients who cannot successfully complete cardiac rehabilitation."

Dr. White, an ACS Fellow with Advocate Lutheran General Hospital, Park Ridge, Ill., and his associates reviewed the records of 126 patients who were referred by

their cardiologists to attend a cardiac rehabilitation program in 2004. Cardiac rehabilitation failure was defined as termination of participation prior to the completion of 32 sessions, or failure to reach a target heart rate within the last 3 sessions.

Study participants completed a Walking Impairment Questionnaire (WIQ) after termination or completion of their cardiac rehabilitation program. A subset of 39 patients also presented for the recording of an ankle brachial index. Cardiac rehabilitation performance was then correlated with WIQ-reported symptoms, WIQ-reported walking distance, and the ankle-brachial index (ABI).

Patients with significant walking impairment—such as that resulting from severe claudication, critical limb ischemia, severe arthritis, or stroke—were excluded from the study.

The patients' mean age was 65 years, and nearly three-quarters (74%) were male. Dr. White reported that the prevalence of peripheral arterial disease was 29% based on WIQ claudication symptoms, 24% based on WIQ walking distance score, and 26% based on ABI.

Intermittent claudication symptoms had a significantly negative effect on the successful completion of cardiac rehabilitation. Of 37 patients who reported claudication symptoms on the WIQ, 28 (76%) failed cardiac rehabilitation, whereas only 23 of the 89 patients (26%) who reported no symptoms of claudication failed the program.

Of 23 patients who reported joint pain only on ambulation, 9 (39%) failed the cardiac rehabilitation program. "This was similar to the 41% failure rate noted in patients who reported no joint pain," Dr. White said. "Therefore, joint pain did not interfere with the successful completion of the exercise program."

He also reported that 17 of the 30 patients (57%) with peripheral arterial disease based on their walking distance score failed cardiac rehabilitation, compared with 34 of the 96 patients (35%) who had no peripheral arterial disease based on their walking distance score.

A higher percentage of patients with an ABI less than 0.90 failed cardiac rehabilitation than did those with an ABI of 0.90 or greater (70% vs. 38%, respectively).

Dr. White had no relevant conflicts to disclose. ■

Drug-Eluting Stent Proves Durable at 6- and 12-Month Follow-Up

BY DOUG BRUNK
Elsevier Global Medical News

SAN DIEGO — The Zilver PTX Drug-Eluting Peripheral Stent appears to have excellent durability in the superficial femoral artery at 6- and 12-month follow-up, interim results from a large registry study showed.

Manufactured by Cook Inc., the Zilver PTX is an investigational self-expanding nitinol stent coated with paclitaxel. "It does not use a polymer or binder," Dr. Michael D. Dake said at the Vascular Annual Meeting. "This differentiates it from most of the drug-eluting stents in practice today."

He reported on interim results from the registry arm of the study, which included 790 patients treated at 30 sites in Europe, Russia, Canada, and Korea. A randomized study that intends to enroll 400 patients is currently underway in the

United States, Japan, and Germany.

The registry trial involved treatment of the above-the-knee femoropopliteal artery from a point 1 cm below the bifurcation to a point above the medial femoral epicondyle. The reference vessel diameters were 4-9 mm.

"The trial included all comers," Dr. Dake, chairman of the department of radiology at the University of Virginia Health System, Charlottesville, and the study's principal investigator. "There was no lesion length limitation. Up to four stents per patient could be placed."

The mean age of patients was 67 years, and most (73%) were men. More than one-third (36%) had diabetes, 55% had high cholesterol, 80% had hypertension, and 79% were past or current smokers.

The mean lesion length was 9.6 cm, the reference vessel diameter was 5.4 mm, and the mean diameter of stenosis was 85%.



Prestenting (I) and poststenting of long lesions show effect of Zilver stent.



Occluded lesions are shown before (I) and after Zilver stent placement.



"Roughly one-third of the patients were total occlusions."

He reported 6-month follow-up data on 435 patients and 12-month follow-up data on 200 patients. In terms of stent in-

tegrity, the fracture rate was 1% at 6 months (8 of 825 stents) and 2% at 12 months (11 of 547 stents). "Actually these are fractures pending confirmation, so the rate may actually be less than that, but at least it's in the low single digits," he said.

Event-free survival was defined as freedom from death, amputation, revascularization, or worsening of Rutherford classification by two classes or to a class 5 or 6. The event-free survival was 94% at 6 months and 84% at 12 months.

Stent effectiveness as measured by the clinical end point of freedom from target lesion revascularization, defined as clinically driven reintervention or greater than a 50% stenosis within the treated segment, was 96% at 6 months and 88% at 12 months.

Clinical outcomes, as measured by ankle brachial index, Rutherford score, and walking distance and speed scores, improved significantly at 6 and 12 months, compared with preprocedure values.

"There are no safety concerns apparent at this time with the Zilver PTX stent," Dr. Dake concluded. "In terms of effectiveness, this appears favorable, with the initial results appearing better than expected for complex TASC C and D lesions, occlusions, in-stent restenosis, and lesions longer than 7 cm."

Dr. Dake disclosed that he receives research support from Cook Inc., which sponsored the trial. ■

Strive to be the best. Seek accreditation from the Commission on Cancer (CoC) of the American College of Surgeons.

Has your facility's cancer program reached its full potential?

When your facility's cancer program is accredited by the CoC, it demonstrates its commitment to offering cancer patients the highest standard in quality treatment and care. Plus, the Commission on Cancer helps you strengthen your cancer program through its standard-setting, educational, and research initiatives.

Even more, CoC accreditation offers a model for managing your facility's cancer program by:

- Setting Standards to promote high-quality, multidisciplinary patient care
- Facilitating ongoing assessment of your program's activities
- Providing real-time access to National Cancer Data Base data to evaluate and improve your delivery of care

Take the challenge, build a better cancer program for your facility and for your patients, and become accredited by the Commission on Cancer.

Visit the Commission's Web site at: www.facs.org/cancerprograms/mh08
Or send an E-mail query to: CoC@facs.org



Heart Transplant Waiting-List Risks Quantified

New results may help physicians decide when to use a bridge-to-transplant device.

BY MITCHEL L. ZOLER
Elsevier Global Medical News

BOSTON — Patients with three or more risk factors who were listed with the highest urgency for a heart transplant—status 1A—on the U.S. waiting list had at least a 30% risk of dying before a donor heart was available, based on actual experience during 2000-2006.

Records from the United Network for Organ Sharing (UNOS) for this period showed that when high-risk patients (defined as those with more than three risk factors for death) received a mechanical circulatory support device, their 90-day survival rate jumped



When high-risk patients received a circulatory support device, 90-day survival rates rose from 50% to 89%.

DR. LIETZ

from 50% to 89%, said Dr. Katherine Lietz, who presented an analysis of UNOS data at the annual meeting of the International Society for Heart and Lung Transplantation. A ventricular assist implant used this way is often called a “bridge-to-transplant” device.

“To bridge or not to bridge is one of the most challenging decisions for medically managed, high-urgency, status 1A patients” who are awaiting a heart transplant, said Dr. Lietz, a transplant cardiologist at Columbia University in New York. Three key factors enter into this decision: the patient’s risk of dying while awaiting a donor heart, the chances of successfully receiving a transplanted heart, and the risk of complications from implantation with a mechanical support device.

To better document the first two factors, Dr. Lietz and her associates analyzed data collected on 1,755 patients who were listed with UNOS as status 1A candidates for a heart transplant during January 2000–December 2006. During their first 30 days on the UNOS list, 14% of the patients died, 49% received a transplanted heart, 33% remained active on the list, and the remaining 4%

were removed from the list because their status had improved.

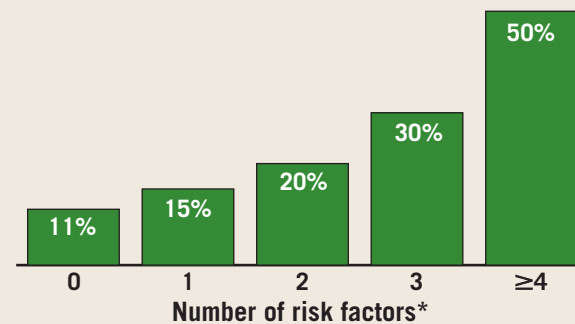
The investigators identified the following six features that were significantly associated with an elevated risk for death during the first 30 days on the list:

- ▶ Blood type O.
- ▶ Age older than 60 years.
- ▶ Ventilator support.
- ▶ Intra-aortic balloon pump.
- ▶ Serum creatinine greater than 1.5 mg/dL.
- ▶ Serum albumin less than 3.0 g/dL.

Analysis showed that the risk of death increased in patients who had more of these risk factors. Patients with none of the risk factors had an 11% risk of dying while they were maintained on medical treatment during their first 30 days on the list. Mortality risk increased as the number of risk factors rose (15% for patients with any single risk factor, 20% for two factors, 30% for three factors, and 50% for four or more factors).

A second analysis identified a non-O blood type and a body weight of 89 kg or less as the most important determinants of receiving a heart transplant during the first 30 days on the list. Patients who met both of these criteria had a 66% chance of receiving a heart during this period, those with either one of these

30-Day Mortality Risk Rates of Heart Transplant Patients Increase With Number of Risk Factors



*Risk factors are blood type O, age >60 years, ventilator support, intra-aortic balloon pump, serum creatinine >1.5 mg/dL, and serum albumin <3.0 g/dL.
Note: Based on data for 1,755 patients listed as status 1A candidates.
Source: Dr. Lietz

ELSEVIER GLOBAL MEDICAL NEWS

two factors had about a 50% chance, and patients without either factor had about a 23% chance, Dr. Lietz said.

Physicians need to determine how these findings can be used to help guide individual decisions about whether to rely on medical treatment alone or opt for implantation of a mechanical support device while a patient is awaiting a heart. A reasonable cutoff might be a risk for dying of 30% or greater while listed, which corresponds to a patient’s having three or more mortality risk factors, Dr. Lietz suggested.

Dr. Fred A. Crawford, Jr., an ACS Fellow who was asked to comment on the study, said that it does not really clarify the indication for implanting mechanical support, but contributes to it. Greater use of support devices in stable status 1A patients with multiple risk factors would hopefully prolong their overall survival, he said. “At the same time, careful follow-up of this group would be necessary to confirm the hypothesis,” said Dr. Crawford, surgery department chairman at the Medical University of South Carolina, Charleston. ■

Esophagectomy Database Patients Showed Lower Mortality

BY DOUG BRUNK
Elsevier Global Medical News

SAN DIEGO — Thoracic surgeons who participated in the Society of Thoracic Surgery’s general thoracic surgery database over a 5-year period performed esophagectomy for esophageal cancer with a mortality rate of 2.5%, which is significantly lower than published mortality rates ranging from 8% to 23%.

In addition, induction therapy was not associated with increased major morbidity.

Those are two key findings from an evaluation of 1,986 esophagectomies performed for esophageal cancer from January 2002 to June 2007 by 68 centers that participated in the STS’s general thoracic surgery database.

“While there are many single-institution reports on morbidity and mortality after esophagectomy, there is a paucity of multi-institutional reports,” Dr. Cameron D. Wright said at the annual meeting of the American Association for Thoracic Surgery. “The [Veterans Affairs] National Surgery Quality Improvement Program reported on 1,777 patients, but the VA patient population is not representative of the entire U.S. population, and the mortality was on the high side at 9.8%.”

He also pointed out that many parties—including government, insurance companies, and industry—“have decided that volume alone is an adequate proxy to

measure the quality of care in our esophagectomy patients due to the cost, difficulty of data collection, and lack of risk adjustment models,” said Dr. Wright, a thoracic surgeon at Massachusetts General Hospital, Boston, who also chairs the STS General Thoracic Surgery Database Task Force. “Clearly we need risk-adjusted models to assess and compare results after esophagectomy.”

He and his associates evaluated the standard risk factors, outcome measures, and adverse events from the 1,986 cases in the database, and constructed a multivariate risk model for mortality and major morbidity, which was defined as reoperation for bleeding, anastomotic leak, pneumonia, reintubation, initial ventilation beyond 48 hours, or death.

Forced expiratory volume in 1 second as a percentage of forced vital capacity and other pulmonary function data were excluded from the final multivariate model because of missing data in more than half of cases.

The mean age of patients was 63 years, and most (82%) were male. More than half (57%) had an American Society of Anesthesiologists (ASA) score greater than 3, indicating multiple serious comorbidities; 10% had a body mass index (BMI) greater

than 35 kg/m²; 24% had diabetes; and 44% had induction therapy.

Major morbidity occurred in 23% of patients. Only 7% of patients with no major morbidity returned to the operating room for another procedure during the same hospitalization, but 55% of patients who had major morbidity returned to the OR.

Overall mortality was 2.5%, but the incidence was significantly higher (11%) in those with major morbidity.

The mean hospital length of stay for patients without major morbidity was 11 days compared with 25 days for patients with major morbidity, a significant difference.

Univariate risk factors for major morbidity were age older than 75 years, African American race, a Zubrod performance status score greater than 3, an ASA score greater than 3,

a BMI greater than 35, heart failure, coronary artery disease, peripheral vascular disease, diabetes, hypertension, smoking, chronic obstructive pulmonary disease, and excessive intraoperative blood loss that required transfusion.

Postoperative events were more common in patients with major morbidity compared with those who did not have major morbidity, including deep vein



‘The STS database participants are very select. . . . I think that’s why the results are so good.’

DR. WRIGHT

thrombosis (3.4% vs. 1.4%); a need for tracheostomy (15% vs. 3%); atrial fibrillation (26% vs. 15%); sepsis (12% vs. 7%); a need for blood transfusions (7.4% vs. 4.6%); recurrent laryngeal nerve injury (4.6% vs. 1.4%); and renal failure (8.5% vs. 1%).

Multivariate analysis revealed the following risk factors for major morbidity after esophagectomy: age older than 75 years (odds ratio, 1.50); African American race (OR, 1.84), heart failure (OR, 2.68), peripheral vascular disease (OR, 1.70), diabetes (OR, 1.99), cigarette smoking (OR, 1.31), ASA score greater than 3 (OR, 1.45), and a BMI greater than 35 (OR, 1.67).

Important factors not associated with increased risk for major morbidity on multivariate analysis included induction therapy, gender, and a Zubrod score greater than 3.

“We also looked at the major morbidity by volume after esophagectomy, and there was not a striking relationship,” Dr. Wright said. “In fact, when we examined volume performance relationship in our model by adding volume as a linear covariate, there was no significant association.”

He cautioned that this volume performance relationship may not be true of all surgery centers in America. “The STS database participants are very select: They belong to the STS, they’re board certified, and they’re very interested in quality improvement,” Dr. Wright said. “I think that’s why the results are so good.” ■

CLASSIFIEDS

Also available at www.elsevierhealthcareers.com

PROFESSIONAL OPPORTUNITIES

HCA PHYSICIAN RECRUITMENT

Robert Goldwire,
Physician Recruiter specializing in General Surgery,
is focusing efforts on connecting well-trained, highly
qualified Surgeons to their ideal practice.

Whether you are just starting out or looking for a change,
HCA is committed to helping you live and practice
where you want!



*HCA owns and operates over 170 facilities nationwide,
with more than 60 opportunities for Surgeons.*

For more information on open
General Surgery opportunities, visit:
<http://HCAgeneral2.recruital.org>

Robert Goldwire
615.517.0567 Cell
866.451.0752 Fax
800.661.3365 ext.5164 Toll Free
Robert.Goldwire@HCAHealthcare.com

PITTSBURGH AREA SURGICAL POSITIONS

Modern and financially stable 238 bed hospital in family oriented community 30 minutes from downtown Pittsburgh seeks General Surgery 1-2 call, ENT either hospital employed or join well established practice with 1-3 call and hospital employed Plastic Surgery position. Excellent salary (\$250-350) range, bonus and benefits. SURGICAL SEARCH 800-831-5475 F: 314-984-8246 E/M: surgicalsrch@aol.com

NW OHIO

Hospital employed General Surgery position in family oriented community 30 minutes to Ft. Wayne and 45 minutes to Lima, Ohio associated with a modern and profitable 100 bed hospital. 1-2 call. Excellent \$250K negotiable salary, bonus and benefits including malpractice insurance. SURGICAL SEARCH 800-831-5475 F: 314-984-8246 E/M: surgicalsrch@aol.com

South Central Pennsylvania

Join well established and respected General Surgeon in private practice in historic family community 2 hrs. to Pittsburgh, Baltimore and Washington, D.C. associated with UPMC Hospital facility. 1-3 call. Attractive salary, bonus, benefits and future partnership. Surgical Search 800-831-5475 fax: 314-984-8246 email: surgicalsrch@aol.com

METRO SOUTH CAROLINA

Hospital employed General Surgery and Colon/Rectal Surgery positions in desirable South Carolina metro area two hours to Atlanta and nestled in the Blue Ridge Mountains associated with a growing 450 bed three campus health system. 1-12 ER call. Excellent salary, bonus and benefit package. SURGICAL SEARCH 800-831-5475 F: 314-984-8246 E/M: surgicalsrch@aol.com

Disclaimer

SURGERY NEWS assumes the statements made in classified advertisements are accurate, but cannot investigate the statements and assumes no responsibility or liability concerning their content. The Publisher reserves the right to decline, withdraw, or edit advertisements. Every effort will be made to avoid mistakes, but responsibility cannot be accepted for clerical or printer errors.

INSURANCE COMPANIES

Are you paying too much for your Medical Malpractice Insurance?



CALL US IF YOU NEED:

- To get out of the non standard market
- Rates for part time practice
- Coverage for cosmetics procedures
- **A Premium reduction on your next renewal**

*Special discount programs for Non Standard Physicians
and Medical Groups.*

Call HCP National at 1-888-478-6756 (Toll Free)
Or visit our web site: WWW.HCPNATIONAL.COM

License #OC97525

FOR CLASSIFIED RATES AND INFORMATION:

Danny Wang
Elsevier-Surgery News
360 Park Avenue South
New York, NY 10010
(212) 633-3158
FAX: (212) 633-3820
Email ad to: d.wang@elsevier.com

Help Fight Leukemia Donate Blood and Platelets

For information on donating blood,
Call 1-800-GIVE-LIFE
Or contact your
local Red Cross

Gastric Bypass Improves Sexual Function in Men

BY DAMIAN McNAMARA
Elsevier Global Medical News

ORLANDO — Gastric bypass surgery leads to significant improvement in the sexual dysfunction experienced by many morbidly obese men, according to a recent study.

The effects of surgical weight loss on sexual function are not well studied, although dramatic improvements in diabetes, hypertension, and cardiovascular disease risk have been associated with gastric bypass surgery in previous studies.

“The reason this is newsworthy is we have an increasing problem with obesity worldwide,” said Dr. Ira Sharlip, moderator of a press briefing at the annual meeting of the American Urological Association. “One of the problems that arise[s] with morbid obesity is sexual dysfunction.” Dr. Sharlip, an ACS Fellow, practices internal medicine and urology in San Francisco.

The decrease in sexual function can be considerable. “A male—obese or morbidly obese—has the same amount of sexual dysfunction as a male 20 years older than him,” study coauthor Dr. Jason A. Smith said during the briefing.

Participants had substantially lower sexual function scores before surgery than did normal-weight men, said Dr. Smith, a urology resident at Albert Einstein Medical Center in Philadelphia. The researchers used sexual function scores from a reference group of normal-weight men who participated in a previous study (J. Urol. 2007;177:1438-42).

“We believe sex life is important to men, so this will be an incentive for men to seek gastric bypass,” Dr. Smith said.

Dr. Smith, with lead author Dr. Ramsey M. Dallal, an ACS Fellow and bariatric surgeon in Elkins Park, Pa., and their associates assessed sexual function among 95 morbidly obese men before and after Roux-en-Y gastric bypass surgery. Their mean body mass index was 51 kg/m² and the mean age was 48 years. No participant was taking a phosphodiesterase type 5 (PDE5) inhibitor.

Participants rated their preoperative and postoperative sexual function using the 11-question Brief Sexual Inventory.

Postoperative assessment was conducted at a mean of 19 months after surgery. “Overall, in all sexual domains, all improved. This is what we expected to find,” Dr. Smith said. But “the degree to which they improved exceeded our expectations.”

Sexual drive scores, for example, improved from 3.9 to 5.4 (scale of 0-8) in a

bivariate analysis. Erectile dysfunction scores improved from 6.3 to 8.9 (scale of 0-12), ejaculatory function improved from 4.9 to 6.3 (scale of 0-8), problem assessment improved from 7.4 to 9.5 (scale of 0-12), and sexual satisfaction improved from 1.6 to 2.2 (scale of 0-4). All of these changes were statistically significant.

The amount of weight loss predicted the enhancement in all sexual function domains in a multivariate analysis that controlled for age, diabetes, hypertension, and cigarette smoking.

On average, participants’ mean weight fell from 155 kg (342 pounds) to 102 kg (225 pounds) after 1 year. Because the researchers controlled for confounders, “weight alone was responsible for sexual dysfunction [preoperatively], and weight loss alone was responsible for improvement in scores,” Dr. Smith said.

Sexual dysfunction “should be considered one of the numerous reversible conditions in the morbidly obese,” Dr. Smith said, adding that this is the first study to look at sexual function in men following

Roux-en-Y gastric bypass.

Not stratifying patients according to prior use of PDE5 inhibitors is a potential limitation of the study, said Dr. Harkaway, a urologist who practices in Philadelphia. Also, the researchers did not account for psychogenic impotence, “which is supposed to be about 20% in all [impotent] men, but could be higher in obese men because body image plays a role.”

The researchers plan to assess the impact of gastric bypass surgery on sexual dysfunction in females as well. ■

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.

Glycylglycine 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.

Glycylglycine 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 including 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 therapy 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.

INDEX OF ADVERTISERS

Ethicon Endo-Surgery, Inc.	
Echelon Flex	3
General Scientific Corporation	
SurgiTel Surgi-Cam	5
KCI	
InfoV.A.C.	7
Nashville Surgical Instruments	
Kumar PRE-VIEW	4
Wyeth Pharmaceuticals Inc.	
Tygacil	15-16

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.

© 2008, Wyeth Pharmaceuticals Inc., Philadelphia, PA 19101 August 2008 234909-01

Tygacil[®]
tigecycline IV

Expanded coverage for resistant pathogens