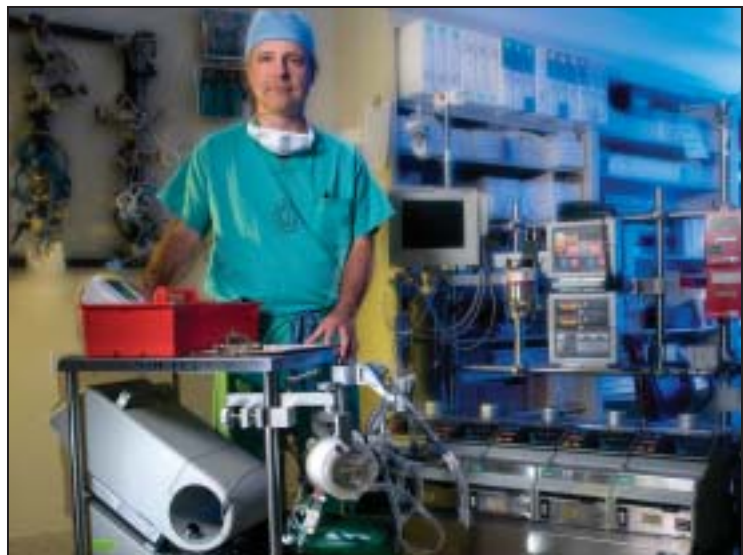




# AMERICAN COLLEGE OF SURGEONS

## SURGERY NEWS



PHOTOGRAPHY/WAKE FOREST UNIVERSITY SCHOOL OF MEDICINE

'Any hospital that does heart surgery' can use extracorporeally supported DCD protocols, said Dr. Michael H. Hines.

## Protocol Changes May Increase Donor Organs

BY JEFF EVANS  
Elsevier Global Medical News

Advances in the use of extracorporeal support technology could add a small but significant number of donor organs to the available pool, according to results obtained by two pioneering centers.

The technology might preserve organs such as the kidneys, liver, and pancreas after withdrawal of life support and cardiac death in people with unrecoverable neurologic impairment.

Kidneys procured under extracorporeally supported donation after cardiac death (DCD) protocols might have a lower rate of delayed graft function (DGF) than those obtained from tradi-

tional DCD or donation after brain death (DBD). Other preliminary results suggest that livers and pancreases from these donors also can be transplanted successfully.

And using extracorporeal support protocols in situations involving uncontrolled organ donation, such as in sudden cardiac death, might expand the number of donors, according to experts in the field.

"Any hospital that does heart surgery can do this," said Dr. Michael H. Hines, an ACS Fellow who is a cardiothoracic surgeon at Wake Forest University Baptist Medical Center, Winston-Salem, N.C., where he also directs the

See **Donor Organs** • page 10

## Call to Action Issued to Support DVT, PE Prevention

High incidence has prompted concern.

BY DENISE NAPOLI  
Elsevier Global Medical News

WASHINGTON — Although some progress has been made in preventing deep vein thrombosis and pulmonary embolism, the persistently high incidence of these conditions has prompted a Call to Action statement by Acting Surgeon General Steven K. Galson.

Among hospitalized spinal cord injury patients who do not receive venous thromboembolism prevention, the risk of developing a deep vein thrombosis (DVT) is 60%-80%. The risk is 40%-60% among similar hip or knee surgery patients, 20%-40% among patients undergoing major general surgery or gynecologic procedures, and 10%-20% for patients with acute illnesses like pneumonia, according to the Venous Disease Coalition, which is a collaborative network of organizations working to increase public and health professional

awareness of venous disease.

The Call to Action statement was released at the second annual meeting of the Venous Disease Coalition.

"There is now a public acknowledgment that this is a very significant health care issue that deserves attention from multiple facets of the medical community," Dr. Thomas Wakefield said in an interview. "Although we've known for a long time that this is a very significant problem, since it doesn't belong to one group or another and it spans so many specialties, it has been difficult to mobilize and raise awareness," said Dr. Wakefield, an ACS Fellow and head of vascular surgery at the University of Michigan, Ann Arbor.

Dr. Wakefield was one of the roughly 44 physicians and non-physicians who met with former Surgeon General Richard H. Carmona, an ACS Fellow, in May 2006 to urge the medical

See **Call to Action** • page 4

## CMS Targets 2011 for Switch to ICD-10

BY MARY ELLEN SCHNEIDER  
Elsevier Global Medical News

Officials at the Centers for Medicare and Medicaid Services plan to replace the ICD-9-CM diagnosis and procedure code set with a significantly expanded set of codes—the ICD-10—by Oct. 1, 2011.

Calling the agency's plan rushed and unworkable, physician groups are urging CMS to reconsider its compliance date.

In addition to the requirements for using the ICD-10 code sets, CMS also is proposing to require entities covered under HIPAA to implement updated versions of electronic transmission standards—the Accredited Standards Committee X12 Version 5010 and the National Council for Prescription Drug

Programs Version D.0. Both electronic standards have a compliance date of April 1, 2010. The X12 Version 5010 must be in place before the ICD-10 codes can be used, according to CMS.

The two proposed regulations were published in the Federal Register on Aug. 22. CMS will accept comments on the proposals until Oct. 21.

The switch to ICD-10 has been under consideration by the

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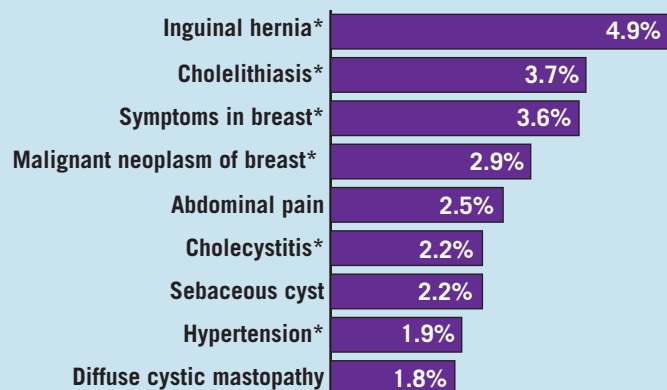
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### VITAL SIGNS

#### Top Diagnoses by General Surgeons in 2007



\*Not otherwise specified.

Note: Based on January-September 2007 data for 45,665 diagnoses.

Source: Verispan

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See **ICD-10** • page 14

BRIEF SUMMARY

# ENTEREG® (alvimopan) Capsules

The following is a brief summary only; see full prescribing information for complete product information.

**WARNING: FOR SHORT-TERM HOSPITAL USE ONLY**

ENTEREG is available only for short-term (15 doses) use in hospitalized patients. Only hospitals that have registered in and met all of the requirements for the ENTEREG Access Support and Education (E.A.S.E.) program may use ENTEREG. [See Warnings and Precautions (5.1 and 5.2)]

**4 CONTRAINDICATIONS**

ENTEREG is contraindicated in patients who have taken therapeutic doses of opioids for more than 7 consecutive days immediately prior to taking ENTEREG.

**5 WARNINGS AND PRECAUTIONS**

**5.1 Myocardial Infarction in a 12-Month Study in Patients treated with Opioids for Chronic Pain**

There were more reports of myocardial infarctions in patients treated with alvimopan 0.5 mg twice daily compared with placebo-treated patients in a 12-month study of patients treated with opioids for chronic pain. In this study, the majority of myocardial infarctions occurred between 1 and 4 months after initiation of treatment. This imbalance has not been observed in other studies of alvimopan, including studies in patients undergoing bowel resection surgery who received alvimopan 12 mg twice daily for up to 7 days. A causal relationship with alvimopan has not been established.

**5.2 Distribution Program for ENTEREG**

ENTEREG is available only to hospitals that enroll in the E.A.S.E. program. To enroll in the E.A.S.E. program, the hospital must acknowledge that: hospital staff who prescribe, dispense, or administer ENTEREG have been provided the educational materials on the need to limit use of ENTEREG to short-term, inpatient use; patients will not receive more than 15 doses of alvimopan; and ENTEREG will not be dispensed to patients after they have been discharged from the hospital. Contact the E.A.S.E. program at 1-866-4ADOLOR (1-866-423-6567).

**5.3 Opioid Tolerance and Gastrointestinal-Related Adverse Effects**

Patients recently exposed to opioids are expected to be more sensitive to the effects of  $\mu$ -opioid receptor antagonists. Since ENTEREG acts peripherally, clinical signs and symptoms of increased sensitivity would likely be limited to the gastrointestinal tract (e.g., abdominal pain, nausea and vomiting, diarrhea). Patients receiving more than 3 doses of an opioid within the week prior to surgery were not studied in the postoperative ileus clinical trials; therefore, ENTEREG 12 mg capsules should be administered with caution to these patients.

**5.4 Severe Hepatic Impairment**

In patients with severe hepatic impairment, there is a potential for 10-fold higher plasma levels of drug [see Clinical Pharmacology (12.3) of full prescribing information]. There are no studies of ENTEREG in patients with severe hepatic impairment undergoing bowel resection. Because of the limited data available, ENTEREG is not recommended for use in patients with severe hepatic impairment.

**5.5 End-Stage Renal Disease**

No studies have been conducted with end-stage renal disease. ENTEREG is not recommended for use in these patients.

**5.6 Bowel Obstruction**

Use of ENTEREG in patients undergoing surgery for correction of complete bowel obstruction is not recommended.

**6 ADVERSE REACTIONS**

**6.1 Clinical Trials Experience**

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

The data described below reflect exposure to ENTEREG in 1,650 patients in 9 placebo-controlled studies worldwide. The population was 19 to 97 years old, 68% were female, and 83% were Caucasian; 61% were undergoing bowel resection surgery. The first dose of ENTEREG was administered 30 minutes to 5 hours before the scheduled start of surgery and then twice daily until hospital discharge (or for a maximum of 7 days of postoperative treatment).

Table 1 presents treatment-emergent adverse reactions reported in  $\geq 3\%$  patients treated with ENTEREG and for which the rate for ENTEREG was  $\geq 1\%$  than placebo. Treatment-emergent adverse reactions are those events occurring after the first dose of study medication treatment and within 7 days of the last dose of study medication or those events present at baseline that increased in severity after the start of study medication treatment.

**Table 1. Treatment-Emergent Adverse Reactions That Were Reported in  $\geq 3\%$  of Either Bowel Resection Patients Treated With ENTEREG or All Surgical Patients Treated With ENTEREG and for Which the Rate for ENTEREG Was  $\geq 1\%$  Than Placebo**

System Organ Class	Bowel Resection Patients		All Surgical Patients	
	Placebo (n = 986) %	ENTEREG (n = 999) %	Placebo (n = 1,365) %	ENTEREG (n = 1,650) %
Blood and lymphatic system disorders				
Anemia	4.2	5.2	5.4	5.4
Gastrointestinal disorders				
Constipation	3.9	4.0	7.6	9.7
Dyspepsia	4.6	7.0	4.8	5.9
Flatulence	4.5	3.1	7.7	8.7
Metabolism and nutrition disorders				
Hypokalemia	8.5	9.5	7.5	6.9
Musculoskeletal and connective tissue disorders				
Back pain	1.7	3.3	2.6	3.4
Renal and urinary disorders				
Urinary retention	2.1	3.2	2.3	3.5

**7 DRUG INTERACTIONS**

**7.1 Potential for Drugs to Affect Alvimopan Pharmacokinetics**

Based on *in vitro* data, alvimopan is not a substrate of CYP enzymes. Therefore, concomitant administration of ENTEREG with inducers or inhibitors of CYP enzymes is unlikely to alter the metabolism of alvimopan. No clinical studies have been performed to assess the effect of concomitant administration of inducers or inhibitors of cytochrome P450 enzymes on alvimopan pharmacokinetics.

*In vitro* studies suggest that alvimopan and its 'metabolite' are substrates for p-glycoprotein. A population PK analysis did not reveal any evidence that alvimopan or 'metabolite' pharmacokinetics were influenced by concomitant medications that are mild-to-moderate p-glycoprotein inhibitors. No clinical studies of concomitant administration of alvimopan and strong inhibitors of p-glycoprotein (e.g., verapamil, cyclosporine, amiodorone, itraconazole, quinine, spirinolactone, quinidine, diltiazem, bepridil) have been conducted.

A population PK analysis suggests that the pharmacokinetics of alvimopan were not affected by concomitant administration of acid blockers or antibiotics. However, plasma concentrations of the 'metabolite' were lower in patients receiving acid blockers or preoperative oral antibiotics (49% and 81%, respectively). Because the 'metabolite' is not required for efficacy, no dosage adjustments are necessary in these patients.

**7.2 Potential for Alvimopan to Affect the Pharmacokinetics of Other Drugs**

Alvimopan and its 'metabolite' are not inhibitors of CYP 1A2, 2C9, 2C19, 3A4, 2D6, and 2E1 *in vitro* at concentrations far in excess of those observed clinically. Alvimopan and its 'metabolite' are not inducers of CYP 1A2, 2B6, 2C9, 2C19 and 3A4. *In vitro* studies also suggest that alvimopan and its 'metabolite' are not inhibitors of p-glycoprotein. These *in vitro* findings suggest that ENTEREG is unlikely to alter the pharmacokinetics of coadministered drugs through inhibition or induction of CYP enzymes or inhibition of p-glycoprotein.

Coadministration of alvimopan does not appear to alter the pharmacokinetics of morphine and its metabolite, morphine-6-glucuronide, to a clinically significant degree when morphine is administered intravenously. Dosage adjustment for intravenously administered morphine is not necessary when it is coadministered with alvimopan.

**8 USE IN SPECIFIC POPULATIONS**

**8.1 Pregnancy**

**Teratogenic Effects: Pregnancy Category B:** Reproduction studies have been performed in pregnant rats at about 68 to 136 times the recommended human oral dose based on the body surface area and intravenous doses of about 3.4 to 6.8 times the recommended human oral dose based on the body surface area and in pregnant rabbits at intravenous doses at about 5 to 10 times the recommended human oral dose based on the body surface area and have revealed no evidence of impaired fertility or harm to the fetus due to alvimopan. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

**8.2 Nursing Mothers**

Alvimopan and its 'metabolite' are detected in the milk of lactating rats. It is not known whether alvimopan is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ENTEREG is administered to a nursing woman.

**8.3 Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

**8.4 Geriatric Use**

Of the total number of patients in 5 clinical efficacy studies treated with ENTEREG or placebo, 45% were 65 years of age and over, while 18% were 75 years of age and over. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. No dosage adjustment based on increased age is required [see Clinical Pharmacology (12.3) of full prescribing information].

**8.5 Hepatic Impairment**

Although there is a potential for higher plasma levels of drug in patients with mild-to-moderate hepatic impairment [see Clinical Pharmacology (12.3)], dosage adjustment in these patients is not required. Patients with mild-to-moderate hepatic impairment should be closely monitored for possible adverse effects (e.g., diarrhea, gastrointestinal pain, cramping) that could indicate high drug or 'metabolite' levels, and ENTEREG should be discontinued if adverse events occur. ENTEREG is not recommended for use in patients with severe hepatic impairment. [See Warnings and Precautions (5.4) and Dosage and Administration (2.2) and Clinical Pharmacology (12.3) of full prescribing information]

**8.6 Renal Impairment**

Alvimopan has not been studied in patients with end-stage renal disease and ENTEREG is not recommended for use in these patients. Patients with mild-to-severe renal impairment do not require dosage adjustment, but they should be monitored for adverse effects. [see Dosage and Administration (2.2) and Clinical Pharmacology (12.3) of full prescribing information]. Patients with severe impairment should be closely monitored for possible adverse effects (e.g., diarrhea, gastrointestinal pain, cramping) that could indicate high drug or 'metabolite' levels, and ENTEREG should be discontinued if adverse events occur.

**9 DRUG ABUSE AND DEPENDENCE**

ENTEREG has no known potential for abuse or dependence.

**10 OVERDOSAGE**

There is no specific antidote for overdosage with ENTEREG. Patients should be managed with appropriate supportive therapy. Single doses up to 120 mg and multiple doses up to 48 mg for 7 days have been administered to normal, healthy subjects in clinical studies and were well tolerated.

**13 NONCLINICAL TOXICOLOGY**

**13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

Two year carcinogenicity studies have been conducted with alvimopan in CD-1 mice at oral doses up to 4000 mg/kg/day and in Sprague Dawley rats at oral doses up to 500 mg/kg/day. Oral administration of alvimopan for 104 weeks produced significant increases in the incidences of fibroma, fibrosarcoma and sarcoma in the skin/subcutis, and osteoma/osteosarcoma in bones of female mice at 4000 mg/kg/day (about 674 times the recommended human dose based on body surface area). In rats, oral administration of alvimopan for 104 weeks did not produce any tumor up to 500 mg/kg/day (about 166 times the recommended human dose based on body surface area).

Alvimopan was not genotoxic in the Ames test, the mouse lymphoma cell (L5178Y/TK<sup>+</sup>) forward mutation test, the Chinese Hamster Ovary (CHO) cell chromosome aberration test or the mouse micronucleus test. The pharmacologically active 'metabolite' ADL 08-0011 was negative in the Ames test, chromosome aberration test in CHO cells and mouse micronucleus test.

Alvimopan at intravenous doses up to 10 mg/kg/day (about 3.4 to 6.8 times the recommended human oral dose based on the body surface area) was found to have no adverse effect on fertility and reproductive performance of male and female rats.

**13.2 Animal Toxicology and/or Pharmacology**

A single oral dose of 500 mg/kg of alvimopan was not lethal to mice and rats.

Reproduction studies have been performed in pregnant rats at oral doses up to 200 mg/kg/day (about 68 to 136 times the recommended human oral dose based on the body surface area) and intravenous doses up to 10 mg/kg/day (about 3.4 to 6.8 times the recommended human oral dose based on the body surface area) and in pregnant rabbits at intravenous doses up to 15 mg/kg/day (about 5 to 10 times the recommended human oral dose based on the body surface area) and have revealed no evidence of impaired fertility or harm to the fetus due to alvimopan.

**17 PATIENT COUNSELING INFORMATION**

**17.1 Recent Use of Opioids**

Patients should be informed that they must disclose long-term or intermittent opioid pain therapy, including any use of opioids in the week prior to receiving ENTEREG. They should understand that recent use of opioids may make them more susceptible to adverse reactions to ENTEREG, primarily those limited to the gastrointestinal tract (e.g., abdominal pain, nausea and vomiting, diarrhea).

**17.2 Hospital Use Only**

Patients should be informed that ENTEREG is for hospital use only for no more than 7 days after their bowel resection surgery.

**17.3 Most Common Side Effects**

Patients should be informed that the most common side effects with ENTEREG in patients undergoing bowel resection are constipation, dyspepsia, and flatulence.



Manufactured for Adolor Corporation  
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*(alvimopan)*

**The first and only FDA-approved agent indicated to accelerate the time to upper and lower GI recovery following partial large or small bowel resection surgery with primary anastomosis**

### Important Safety Information

#### **WARNING: FOR SHORT-TERM HOSPITAL USE ONLY**

ENTEREG is available only for short-term (15 doses) use in hospitalized patients.

Only hospitals that have registered in and met all of the requirements for the ENTEREG Access Support & Education (E.A.S.E.<sup>™</sup>) Program may use ENTEREG.

- ENTEREG is contraindicated in patients who have taken therapeutic doses of opioids for more than 7 consecutive days immediately prior to taking ENTEREG
- There were more reports of myocardial infarctions in patients treated with alvimopan 0.5 mg twice daily compared with placebo-treated patients in a 12-month study of patients treated with opioids for chronic pain. In this study, the majority of myocardial infarctions occurred between 1 and 4 months after initiation of treatment. This imbalance has not been observed in other studies of alvimopan, including studies of patients undergoing bowel resection surgery who received alvimopan 12 mg twice daily for up to 7 days. A causal relationship with alvimopan has not been established
- ENTEREG should be administered with caution to patients receiving more than 3 doses of an opioid within the week prior to surgery. These patients may be more sensitive to ENTEREG and may experience GI side effects (eg, abdominal pain, nausea and vomiting, diarrhea)
- ENTEREG is not recommended for use in patients with severe hepatic impairment, end-stage renal disease, or in patients undergoing surgery for correction of complete bowel obstruction
- ENTEREG is available only to hospitals that enroll in the E.A.S.E. Program.  
To enroll in the E.A.S.E. Program, the hospital must acknowledge that:
  - Hospital staff who prescribe, dispense, or administer ENTEREG have been provided the educational materials on the need to limit use of ENTEREG to short-term, inpatient use
  - Patients will not receive more than 15 doses of ENTEREG
  - ENTEREG will not be dispensed to patients after they have been discharged from the hospital

For more information on the E.A.S.E. Program, contact Adolor Corporation at 1-866-4ADOLOR (1-866-423-6567) or visit [www.entereg.com](http://www.entereg.com).

Please see Brief Summary of Prescribing Information on next page.

ENTEREG is a registered trademark and E.A.S.E. is a trademark of Adolor Corporation.

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## Raising Awareness

Call to Action • from page 1

establishment to help raise awareness of DVT and pulmonary embolism (PE), and to increase research funding.

Dr. Galson's Call to Action will "mean great things for the prophylaxis and treatment of this disease," according to Dr. Wakefield.

Along with the Call to Action, the National Heart, Lung, and Blood Institute has awarded 5 years' worth of funding to eight different research groups who will investigate venous thromboembolism treatments and prevention—among them, a group to be co-led by Dr. Wakefield.

Other ongoing studies include a multicenter, randomized clinical trial of genotype-guided dosing of warfarin therapy, which is currently the most commonly used treatment for prophylaxis of recurrent venous thromboembolism, according to Dr. Elizabeth Nabel, director of clinical research at the NHLBI.

However, Dr. Wakefield pointed out, more studies are needed, including studies of newer drugs and pharmacologic therapies that have less-adverse effects and interactions, and less need for monitoring than has warfarin. Studies of short- and long-term outcomes associated with more aggressive interventions for DVT and PE should also be considered, he said. One such study, which has been funded by the National Institutes of Health and is slated to start soon, will compare pharmacomechanical thrombolysis plus standard anticoagulation versus standard anticoagulation alone for the treatment of significant proximal venous thrombosis.

Dr. Frank Michota, director of academic affairs in the department of hospital medicine at the Cleveland Clinic and founder of the clinic's hospital medicine program, said that hospitalists also were represented at the May 2006 meeting with the Surgeon General. As a member of the Coalition to Prevent DVT, Dr. Michota spoke on public advocacy at that meeting. He advocated the development of "reminder systems, preprinted order sheets, and multidisciplinary protocols so that no patient falls through the cracks in regards to DVT prevention."

As of Oct. 1, 2008, any DVT or PE associated with total knee and hip replacement procedures acquired during an inpatient stay will have "payment implications," according to the Centers for Medicare and Medicaid Services (SURGERY NEWS, September 2008, p. 1).

Just how many patients are affected annually by venous thromboembolism is debated among different groups. Without an autopsy, many cases—perhaps as many as 50%—are misclassified as heart attack, said Dr. Wakefield. Dr. Galson put PE- or DVT-related deaths at 100,000 annually, with 350,000-600,000 Americans contracting DVT or PE each year. The American Heart Association estimated the incidence of venous thromboembolism to be 250,000-2 million cases per year (Circulation 2002;106:1436). Upcoming studies put the number somewhere in between.

In any case, said Dr. Galson, "We know that as the U.S. population ages, these numbers are only going to increase." ■

## Clot Prevention Guides Offered by AHRQ

Two new publications aim to help educate patients and physicians alike on preventing blood clots.

"Your Guide to Preventing and Treating Blood Clots" is a 12-page consumer booklet summarizing the causes and symptoms of clots, ways to avoid them, and what to expect from treatment.

"Preventing Hospital-Acquired Venous Thromboembolism: A Guide for Effective Quality Improvement" is a 60-page "tool to help hospitals and clinicians implement processes to prevent dangerous blood clots," including case studies, according to Dr. Carolyn Clancy, director of the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality, which published the reports.

Free copies are available by calling 800-358-9295 or by e-mailing HRQpubs@ahrq.hhs.gov.

## Clinical Congress Sites To Include Wash., D.C.

BY DOUG BRUNK

Elsevier Global Medical News

The American College of Surgeons' annual Clinical Congress will not meet in New Orleans for the foreseeable future, but the District of Columbia has been added to the list of meeting sites.

"We've always been looking for an urban East Coast destination that fulfills our needs the best," Felix P. Niespodziewanski, director of the ACS's convention and meetings division, said in an interview.

That need was met when D.C.'s Walter E. Washington Convention Center opened in 2003. After ACS officials visited the property, they determined "that it could accommodate the needs of the congress from an exhibit standpoint as well as for the number of meeting rooms they have."

Mr. Niespodziewanski, who has worked for the ACS for 18 years, emphasized that the decision to drop New Orleans from the list of rotating meeting sites was made well before Hurricane Katrina hit that city in September 2005.

"The ACS has been seeking an East Coast destination for the Clinical Congress ever since the days of Atlantic City not being able to accommo-

date most conventions. That goes back a long time."

New Orleans had been a rotating site since 1992 and last hosted the Clinical Congress in 2007.

Advantages of Washington, D.C., he said, include a large East Coast population base, access to three major airports and public transportation, and major cultural events and tourist attractions.

Traveling to New Orleans by air for previous clinical congresses "was a problem due to the limited number of direct flights," Mr. Niespodziewanski said. "It is not in the center of a large population. Our attendance always suffered."

Future dates and sites for the Clinical Congress are as follows:

- ▶ Oct. 11-15, 2009: Chicago
- ▶ Oct. 3-7, 2010: Washington, D.C.
- ▶ Oct. 23-27, 2011: San Francisco
- ▶ Sept. 30-Oct. 4, 2012: Chicago
- ▶ Oct. 6-10, 2013: Washington, D.C.
- ▶ Oct. 26-30, 2014: San Francisco
- ▶ Oct. 4-8, 2015: Chicago
- ▶ Oct. 16-20, 2016: Washington, D.C.
- ▶ Oct. 21-16, 2017: San Diego (tentative)
- ▶ Oct. 20-25, 2018: Boston (tentative)



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# New ACS Institute Looks Into Future of Surgery

BY JANE ANDERSON  
Elsevier Global Medical News

Workforce issues head the list of research projects planned for the American College of Surgeons' new Health Policy and Research Institute, along with the evolution of surgical practice over time, according to the institute's leaders, Dr. George F. Sheldon and Thomas J. Ricketts, Ph.D.

The institute, housed at the University of North Carolina's Cecil G. Sheps Center for Health Policy Research, was established earlier this year in an effort to provide solid data on which to base ACS policy, said Dr. Sheldon, an ACS Fellow and director of the institute.

"One of the key questions in health care today is, What services do people provide?" Dr. Sheldon said. "Certainly in surgery, interchangeability is much less—you can't have a brain surgeon and a urologist covering for each other."

The institute's initial work involves "getting a grasp on how many surgeons there are, how many are in training, and what we're doing and what we need to be doing in terms of payment and disease burden," said Dr. Ricketts, deputy director of the UNC health policy research center and administrative director for the ACS institute.

"We're looking through our existing files to make sure we have a sense of who really is doing surgery. It's a lot harder than you'd think to actually follow these folks as their practice careers change. We're interested in seeing how their careers change over the long haul," he explained.

Refinement of the available national databases is the first task, he said. Next, the ACS institute intends to investigate how, exactly, surgeons are practicing.

"In North Carolina, we have data on all physicians in the state. We can merge that into data on inpatient and ambulatory procedures," Dr. Ricketts said. The data then can be used to determine what general surgeons actually are doing, and information also can be teased out on differences that arise between surgeons of different sexes and ages, groups vs. solo practitioners, and small vs. large hospitals, he said.

"We'll get a sense of what they're doing and how that changes over time," Dr. Ricketts said. This type of baseline work—which is expected to take about 2 years to complete—will allow ACS policy makers to make educated guesses about future workforce levels, he said.

In addition, "as we go along, we'll be able to answer some specific questions that arise," Dr. Ricketts said. For example, there has been a rapid rise in orthopedic procedures, and "we're looking at procedures trying to see if this is a real dramatic uptick or if it has moved up steadily with the population," he said. "We hope to get some preliminary answers soon."

Another project for the new institute is developing an index of surgical underservice, Dr. Sheldon said. The institute also will be looking at progressive subspecialization in surgery. "Seventy-nine percent of every 1,000 people who finish general surgical training take additional training," he said.

In addition, the ACS institute intends to

be very involved in crafting health care reforms on a national level—an endeavor Dr. Sheldon hopes will move to the forefront in the spring of 2009.

The ACS decided to work with the UNC center after considering other ways to create the new institute, including building it in-house. By collaborating with UNC researchers, "we have access to an incredible amount of expertise," said Dr. Sheldon. In addition, the UNC center already has infrastructure in place: a data system that will allow research to proceed more quickly, he

said. The institute is working with two surgeons who are resident fellows at UNC, and three other fellows pursuing UNC doctoral degrees in public health.

As one of six federally designated regional workforce analysis centers in the United States, the UNC center is well-equipped to help tackle questions about the surgeon workforce, Dr. Sheldon noted. Although federal funding for the center's health workforce research was discontinued in 2006, UNC continues to be active in such work.

Over the next few years, the ACS institute hopes to develop a group of younger surgeon-researchers who can continue studying the key areas of interest, according to Dr. Ricketts.

The institute intends to move to the college's new headquarters in Washington once it is complete in 2010.

"Hopefully over the next 3 years, we will find some surgeons and clinical people who have the interest in and capacity to do these things who will populate that building in D.C.," said Dr. Ricketts. ■

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## EDITORIAL

## Salamander Secrets

Lee Spievack is a 69-year-old hobby shop worker in Ohio who loves model airplanes. Three years ago, he got a little too close to the propeller of one of them, and lost the end of his middle finger. The amputated tissue could not be found and in such cases, a flap or graft typically is used for wound cover. Instead, his brother, Dr. Alan Spievack, sent him a powdered extract of pig bladder containing extracellular matrix with instructions to apply it to the wound. Dr. Spievack was working at the University of Pittsburgh's regenerative medicine laboratory with Dr. Stephen F. Badylak, a research veterinarian who has reported successful tissue regeneration using this matrix in a variety of animal wound models (*J. Surg. Res.* 2008;147:61-7). Sure enough, the fingertip grew back in about 4 weeks.

Prof. Simon Kay, a hand surgeon at the

University of Leeds, (England), suggested that this injury most likely had little or no bone loss and sufficient nail bed to allow for normal regrowth (*BBC News*, May 2, 2008). But if a fingertip can regrow after injury, why can't we regenerate more proximal amputations? We know that frogs can replace developing limbs in the tadpole stage, but among vertebrates, only the salamander retains the ability as an adult to regenerate limbs over and over again (*Sci. Am.* 2008;298:56-63).



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

The salamander response to limb amputation differs significantly from that of mammals.

After vascular constriction to limit blood loss, the layer of wound epidermis transforms into a layer of signaling cells called the apical epithelial cap (AEC). Instead of forming scar tissue, the fibroblasts that migrate into the wound collect in the center of the AEC to form a blastema, an aggre-

gation of cells that are progenitors for the new limb. These blastema cells recapitulate embryonic limb development by running the same genetic program (*Nature* 1982;298:369-71). Since we humans can make limbs as embryos, we also should carry the necessary programming to regenerate limbs as adults. We just have to figure out how to form a blastema.

To learn about blastemas, researchers made a wound on the side of the limb, where simple healing would be expected to form a scar (*Semin. Cell Dev. Biol.* 1999;10:385-93). Since it was known that innervation was necessary for regeneration, they also deviated a nerve to the wound and found that wound fibroblasts did indeed convert into a blastema. Only, it didn't progress to form a limb until they grafted some skin from the opposite side of the limb. These essential elements of wound epidermis, nerves, and fibroblasts from the opposite side of the limb then required a lot of cellular crosstalk and signaling by growth factors to complete

the regeneration. In this process, the family of fibroblast growth factors (FGFs) is critical as well as the Hox gene family, which provides positional information about how much limb needs to be constructed.

Research that might be more applicable to man is taking place in a mouse model in which an amputation blastema also can be demonstrated. These proliferating cells express bone morphogenetic protein 4 (Bmp4) and appear to come from fibroblasts in connective tissue and bone marrow (*Dev. Biol.* 2008;315:125-35). Since so many wartime injuries result in amputation, the U.S. Department of Defense is funding these efforts at a level of about \$8 million as investigators strive to learn the secrets of regeneration. So if primitive behavior leads to amputation, perhaps a more primitive ancestor can teach us how to improve the outcome. ■

DR. GREENFIELD is editor in chief of SURGERY NEWS.

## POINT/COUNTERPOINT

## Is the Joint Commission's MS 1.20 a step in the right direction?

*It would let medical staff partner with the hospital.*

In the process of modernizing and streamlining the Joint Commission standards, it was decided that those pertaining to a medical staff would be listed in MS 1.20. This states that a medical staff should be self-governing, and that the bylaws should include a means for initiating, developing, and approving medical staff bylaws, rules, and regulations; for selecting and removing medical staff officers; for determining mechanisms used for establishing and maintaining patient care standards; for credentialing and delineating clinical privileges; and for engaging in performance improvement activities.

Medical staff play a crucial role in ensuring the quality and safety of the medical care that is provided in a hospital or other health care facility. Having a mechanism for agreement from all participants in an organization is key to its success, and medical staff can obtain such agreement through its bylaws.

Some procedural details may be delegated to a medical staff executive committee, but that committee cannot be charged with determining a medical staff's responsibilities and privileges. If that were to happen, the medical staff might not buy into all decisions regarding quality and patient safety.

The partnership between a hospital's governing body and its medical staff is crucial for forming a system committed to quality patient care and safety. To that end, the Joint Commission leadership standards and the medical staff standard must be taken as a whole. The governing body should

act in accordance with the medical staff bylaws, rules, and regulations, and with the policies adopted by the medical staff and approved by the governing body. The bylaws of the governing body should not conflict with those of the medical staff.



J. JAMES ROHACK, M.D., FACC, FACP

Being on a medical staff is a privilege with responsibilities. Some of the controversy surrounding MS 1.20 stems from a belief among some hospital leaders that certain medical staff members are obstructing quality care improvement and using their executive committees to speak and act on behalf of all the members. This becomes more challenging if the executive committee members on the medical staff are employees of the hospital and they do not address the concerns of all of their colleagues.

To improve quality and ensure patient safety, the whole medical staff, the hospital administration, and the governing body need to be aligned. I believe MS 1.20, along with the leadership standards, will provide the framework for that alignment.

To quote Dr. Arthur C. Scott Sr., a general surgeon, "What a patient desires most when they enter a hospital is safety, and it is the duty of every hospital board and scientific staff to see that no stone be left unturned to secure the greatest degree of safety known to the science and art of medicine." ■

DR. ROHACK is a member of the Joint Commission Board of Commissioners and the American Medical Association Board of Trustees.

*It would be disruptive and slow decision making.*

Historically, the Joint Commission has supported the principles of continuous quality improvement as a vital part of an accredited organization's culture. However, the revisions as originally proposed for MS 1.20 work against continuous quality improvement. The overly prescriptive nature of the revised hospital medical staff standard MS 1.20 discourages innovation and slows down administrative decision making.

Continuous quality improvement suggests that standards should describe the desired result, and those who are doing the work should come up with the process needed to achieve the desired result.

Accredited organizations had expected the review of MS 1.20 to produce greater flexibility around the relationship of the hospital board, hospital physicians, and the medical staff. Instead, the draft of the new MS 1.20 moved back to being more prescriptive. In fact, some physicians suggest it is more akin to the standards from the 1980s.

As proposed, the revised MS 1.20 dictates a process that would force hospitals and health systems to make changes at the pace of the slowest part of the organization, even as today's environment requires successful organizations to move quickly. For example, if the medical staff executive committee adopted an on-call policy for neurosurgeons, which would promote patient safety and benefit the majority of the medical staff, a small group could challenge the decision. In addition, the difficult task of recruiting staff members to serve

on the medical staff executive committee would be even tougher.

MS 1.20 also has the potential to stifle creativity. A hospital that is planning to reorganize its medical staff by disease status, such as cancer and diabetes, instead of the traditional delineation of surgery, obstetrics, and medicine, would likely not be allowed to implement this type of change under the revised standard.

These changes seem to be aimed at preventing abuses by the medical staff executive committee or the hospital management. While that is a worthy goal, this policy is a poor way to deal with a small number of misdeeds. The Joint Commission should develop a process that deals with those exceptional circumstances, not punish all accredited organizations by imposing the kind of rigor suggested in this standard.

The revised standard should focus on the desired outcome—providing high-quality care—not on how to achieve that goal. It should specify the need for accredited organizations to credential the professional working in the organization; a method to assess the credentialed professional's performance; and a plan for corrective action, if the expected levels of performance fall short. At the same time, accredited organizations need the flexibility to design these processes in a way that meets their unique needs and those of their employees. ■

MR. CASTLE is president and CEO of the Ohio Hospital Association in Columbus.



JAMES R. CASTLE

## ELECTION 2008: PHYSICIANS' PERSPECTIVES

## Obama: Keep What Works, Improve What Doesn't

As doctors, you know well what ails our health care system. Are there any among us who have not cared for a patient without health insurance? Who hasn't noticed that the cost of care has risen so high that many can no longer afford the care we provide? Who doesn't sometimes feel that we spend more time on paperwork than we do with our patients, as insurers create an onerous maze of rules and regulations?

Though America's doctors are healers of unrivaled skill, we increasingly practice in a system that strains our ability to practice our craft. That's why Sen. Barack Obama (D-Ill.) believes that we need health care reform now. His plan is simple: cover everyone, cut red tape, extract more value from our health care dollar, and put patient safety at the center of medical liability reform. All told, this will reduce the costs of health care by up to \$2,500 for every American family.

Here's how he'll do it: The Obama plan will guarantee coverage for every American through shared responsibility between employers, private insurers, and government. The plan builds on and improves our current system. Under his plan, if you like the insurance that you have, you keep it. But if you don't have insurance or if you're underinsured, you can choose from a range of public and private insurance options that offer the same benefits available to members of Congress.

His plan will expand Medicaid and the State Children's Health Insurance Program. If you don't qualify for these programs but still cannot afford insurance, you'll get a subsidy to purchase an insurance plan of your choice. Moreover, Obama's plan will make it easier for Americans to buy insurance by requiring that insurers charge fair premiums and by barring them from discriminating against people with preexisting conditions.

Sen. Obama's plan also will reduce the cost of care, not by shifting more of the cost onto individuals, as Sen. John McCain's plan would, but by making our system safer and more efficient. First, he will invest \$10 billion per year for the next 5 years to create a national, state-of-the-art health information system—an investment that will cut costs and improve the quality and safety of care. This program will make grants available to hospitals and physicians to help them acquire electronic medical records, if they wish to do so.

The Obama plan will also invest in comparative effectiveness research, so we can get more value for the dollars that we spend, increase the use of generic drugs, and allow drug reimportation

from other developed countries. Because the 5% of people who have the highest health care expenses spend half of our health care dollars, his plan would offer federal reinsurance to employers to make sure that catastrophic illnesses do not make employer plans unaffordable. And, because the best way to reduce costs and improve health is to prevent illness, the Obama plan will make major new investments in preventive and public health services.

On medical liability reform, the Obama plan stresses that our goal should be to reduce malpractice suits—that's why preventing patient injury is key. Investments in health information technology are a start. In addition, his plan would promote alternative models of dispute resolution that would allow doctors to learn from mistakes without penalty and report preventable medical errors while being protected from malpractice suits. Above all, the Obama plan focuses on improving systems of care so that the injuries that generate litigation are reduced. We need to let doctors focus on patient safety, not worry about being sued.

This is what Sen. Obama's plan will do. But just as important is what his plan will not do. It will not result in "socialized medicine." It will not eliminate private insurance or result in the government's telling doctors how to practice medicine. Unlike Sen. McCain's plan, which would eliminate the tax exemption for employer-sponsored health insurance and cause millions of Americans to lose their coverage, the Obama plan does not seek a radical overhaul. It aims to preserve parts of our health care system that work and to improve the parts that don't.

And unlike Sen. McCain's plan, which would reward insurance companies that rely on high deductibles and copayments—shifting the cost of health care onto the shoulders of American families—Sen. Obama's plan would ensure that American workers are protected against the financial ruin that can result from serious illness.

Our nation deserves a health care system that does justice to the tremendous skill and dedication of its physicians. Sen. Obama's health plan is a huge leap toward this goal. ■

DR. RAJKUMAR is a physician at Brigham and Women's Hospital in Boston. DR. BLUMENTHAL is director of the Institute for Health Policy at Massachusetts General Hospital, also in Boston. Both are health care advisers to Obama for America.

## McCain: Control Costs, Ensure Access

For the past several months I have closely followed the health care policies of Sen. John McCain (R-Ariz.). I am impressed how the senator places the individual—patient and physician—at the center of this policy. The McCain plan is not simply about insurance or government programs. It is about opening more doors to more Americans when they find themselves in need of health care. Those with insurance, and those without, will see new choices and new options.

The single biggest threat to our health care system is rising costs. Sen. McCain's plan has a set of comprehensive policies that will bring these costs under control and ensure access to affordable care for all Americans. He will accomplish this by promoting research and development of new treatment models, encouraging wellness and prevention initiatives, rewarding quality and coordinated care, investing in technology, and empowering Americans with better information.

Sen. McCain recognizes the discriminatory aspects of our tax code, and proposes changes that level the playing field. Everyone would be treated equally. A refundable tax credit of \$5,000 for families and \$2,500 for individuals would create more choices, including keeping one's current coverage. Nothing changes as to the tax treatment for the employer. If there was value in providing insurance coverage to employees in the current system, there would be no reason not to continue. On the individual side, the tax break simply moves from being an invisible exclusion to a visible, direct, and portable credit.

So most families with employer-sponsored coverage would see little to no change under the McCain plan. In fact, this generous credit will give additional help to millions of middle-class American families for medical expenses. However, for the first time, those without employer-based coverage, or those with no coverage at all, will have a refundable tax credit to help purchase the insurance coverage of their choice.

Going from a world that discriminates to a world that works is important to Sen. McCain. In addition to retaining the benefit for employer-sponsored insurance, Sen. McCain believes that no American should be denied access to quality and affordable coverage simply because of a preexisting condition like cancer. This is a very important priority in his health care plan. And to make sure people get the high-quality coverage they need, Sen. McCain has proposed a Guaranteed Access Plan that will combine industry, state, and federal resources to help in the purchase of coverage for those hardest to

insure, including those with preexisting conditions. There would be limits on premiums, and lower-income Americans would get additional financial assistance.

Cooperation among states in the purchase of insurance would also be a crucial step in ridding the market of both needless and costly regulations, and the dominance in the market of only a few insurance companies. Sen. McCain will break down these barriers to competition, creativity, and excellence with the goal of establishing a national market to make innovative policies and lowest prices available to every person in every state. It makes no sense that an individual in Maryland must pay a higher premium than an individual who lives in the District of Columbia. This type of discriminatory practice must change, and there would be concentrated interest from Sen. McCain to see these changes occur.

If we continue to cling to the ideas of the past, the only opportunity for savings comes in the form of cuts in provider reimbursement. Jonathan Oberlander, Ph.D., writing on the cost of Sen. Barack Obama's national plan, said "its effectiveness in slowing spending would depend on... the political willingness to restrain provider payments" (N. Engl. J. Med. 2008;359:781-4).

I hear from my physician friends: "I just want to see patients, and yes, I do need to be paid like anyone else operating a small business." Most don't care what the source of payment is, whether it's a government entity, private insurance, or the patients themselves. Doctors operate in a high-stress environment, and as a consequence ask that the "hassle factor" be kept to a minimum. And continued cuts definitely constitute a hassle.

Patients generally want to have care when it's needed, and most are willing to pay for some portion of their care, or some amount each month to have the availability of the service. But what they are disinclined to do is to pay and pay and pay, and then be denied coverage when they need it the most. And they are concerned about continued cuts in reimbursement limiting their access to their doctors.

Frequently I hear policy makers quote doctors in saying "first, do no harm." This is a reasonable philosophy which has carried many of us through our medical careers. But there is another phrase, one used by Alpha Omega Alpha, the medical honor society, which designates someone as "worthy to serve the suffering." In my opinion, the plan proposed by Sen. McCain provides for both of these lofty ideals. ■

REP. BURGESS (R-Tex.) is an ob.gyn. and a volunteer adviser to McCain-Palin 2008.

Election  
2008



BY RAHUL  
RAJKUMAR, M.D.



BY DAVID  
BLUMENTHAL, M.D.



BY REP. MICHAEL C.  
BURGESS, M.D.

# THE 20/20 VISION

## Evolutionary Changes in Surgical Practice

# Uninsured Rate Dipped Lower in 2007, to 15.3%

BY MARY ELLEN SCHNEIDER  
*Elsevier Global Medical News*

The number of Americans without health insurance coverage dropped to 45.7 million in 2007, down from 47 million in 2006, mainly because of increased enrollment in government-funded health insurance programs, according to new data from the U.S. Census Bureau.

The percentage of uninsured Americans fell from 15.8% in 2006 to 15.3% in 2007.

The Census data also showed that fewer U.S. children went without health insurance in 2007. The number of uninsured children fell from 8.7 million in 2006 (11.7%) to 8.1 million in 2007 (11%).

The new figures come from the Annual Social and Economic Supplement to the Current Population Survey.

Census officials are still researching why

the number of uninsured Americans has decreased, but the data points toward increased enrollment in government-funded health insurance programs. For example, the number of Americans covered by private health insurance stayed about the same at 202 million, but the number covered by government health insurance programs rose to 83 million from 80.3 million in 2006.

There were statistically significant increases in the percentage of people covered by both Medicare and Medicaid. The number of people with Medicare coverage increased from 40.3 million (13.6%) in 2006 to 41.4 million (13.8%) in 2007, and the number enrolled in Medicaid increased from 38.3 million (12.9%) in 2006 to 39.6 million (13.2%) in 2007.

"The expansion in public coverage is really what's driving this reduction," said Len Nichols, Ph.D., an economist and

director of the health policy program at the New America Foundation, a nonpartisan public policy institute.

As the economy has weakened, more people who previously could not afford private coverage became eligible for public programs. The public programs safety net has caught these individuals, Dr. Nichols said, but more and more people will drift into government-sponsored coverage if health care reform remains stalled.

A careful analysis of the Census figures shows that the private health insurance system in the United States is "hanging on by its fingernails," Dr. Nichols said, and is in need of reform.

Worrisome trends in the Census data could cause the number of uninsured Americans to go back up in the near future, said Mark A. Goldberg, senior vice president for policy and strategy at the National Coalition on Health Care.

The organization is a nonpartisan coalition focused on achieving coverage for all Americans.

Even though the number of uninsured Americans declined in 2007, the percentage of individuals who were able to obtain either employer-based or individual coverage also dropped. If the current economic downturn continues, safety net programs like Medicaid will be vulnerable to state-level budget cuts, he said, and could be unable to keep up with demand.

The latest uninsured figures highlight the need to shore up the employer-based health insurance system, said Karen Davis,

Ph.D., president of the Commonwealth Fund. Policy makers need to find ways to make coverage more affordable for employers who want to offer it to their workers and for individuals purchasing their own, she said. ■



'The expansion in public coverage is really what's driving this reduction' in the uninsured rate.  
DR. NICHOLS

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## Medical Bills: More Than 40% Of Adults Struggle to Pay

A growing number of working-age Americans are struggling to pay their medical bills or have gone into debt because of high medical expenses, according to a new report from the Commonwealth Fund.

In 2007, 41% of U.S. adults aged younger than 65 years reported having medical bill problems or medical debt, compared with 34% in 2005. The problem is growing across all income groups but is most common among low- and moderate-income individuals, where more than half reported being unable to pay their medical bills, being contacted by a collection agency about an unpaid medical bill, significantly changing their way of life to pay a medical bill, or paying off medical debt over time.

As health care costs have risen, employers have struggled to provide employee health insurance, leading some to drop coverage or increase employee cost sharing, said Sara R. Collins, Ph.D., lead author of the report and assistant vice president at the Commonwealth Fund. At the same time, most Americans are facing relatively stagnant wages and rising prices for other necessities such as food and gas, Dr. Collins said during a press briefing to release the report.

The findings are based on the Com-

monwealth Fund Biennial Health Insurance Survey, a nationally representative telephone survey conducted in 2001, 2003, 2005, and 2007. The 2007 data come from an analysis of survey responses from 2,616 adults aged under 65 obtained between June and October 2007.

Of the 28% of working-age adults who were paying off medical debt over time in 2007, nearly a quarter of them owed \$4,000 or more. The debt burden was higher among uninsured individuals. About 34% of adults who were uninsured at the time of the survey reported owing \$4,000 or more in medical bills, compared with 20% of those who were insured.

Part of the problem is that both insured and uninsured Americans are spending more out of pocket for their care, according to the report. For example, in 2007, 48% of Americans aged 19-64 years spent 5% or more of their income annually on out-of-pocket costs and premiums, up from 41% in 2001. And 33% of working-age Americans spent 10% or more annually on these out-of-pocket medical expenses, compared with 21% in 2001.

—Mary Ellen Schneider

The report is available at [www.commonwealthfund.org](http://www.commonwealthfund.org).

# States Try to Fill Gaps in SCHIP Coverage

BY ALICIA AULT  
Elsevier Global Medical News

Even though the Bush administration has made it nearly impossible to expand the State Children's Health Insurance Program, and the economic downturn has put a squeeze on Medicaid budgets, many states are keeping children covered and some are even expanding eligibility, according to two new studies by Families USA, a Washington, D.C.-based advocacy organization.

In August 2007, the Bush administration issued a directive limiting SCHIP eligibility, going forward, to families with incomes at or below 250% of the federal poverty level. That directive has remained essentially unchanged, although the Centers for Medicare and Medicaid Services announced in May that it would look at expansion programs on a case-by-case basis.

However, CMS rejected expansion plans by New York and Ohio. New York used state funds to expand coverage to children living in families with incomes up to 400% of the poverty level. Ohio is using state money to cover children who can't get private health coverage, but the expansion is not through Medicaid or SCHIP, according to the Families USA report, "Detour on the Road to Kids Coverage: Administration Creates Roadblocks, So States Seek Alternative Routes."

Ohio also raised eligibility to the federal ceiling (250% of the poverty level).

Indiana, Louisiana, Oklahoma, and Wisconsin had planned to raise eligibility for their programs to 300% of the poverty level, but have now scaled that back to 250%, according to the Detour report. Other states—including Colorado, Florida, Iowa, and Kansas—are planning to expand coverage next year. The expansions in Iowa and Kansas, however, depend on a reauthorization of the SCHIP program, according to the Detour report.

California is wrangling over its budget, which includes an increase in cost sharing for SCHIP and reduced Medicaid coverage for parents. Rhode Island is also looking at paring back its SCHIP coverage in fiscal 2009 and increasing cost sharing for families.

"States are committed to covering kids, but they are clearly hampered by the roadblocks the administration has put up," said Families USA senior policy analyst Jenny Sullivan in a briefing with reporters.

Most states are also feeling the pinch as tax revenues recede while Medicaid costs—increasingly a larger proportion of most state budgets—continue to rise, accord-

ing to the second Families USA report, "Precarious Position: States Must Balance Declining Revenues With a Growing Need for Medicaid." The report found that 16 states and Puerto Rico are looking at budget deficits in fiscal year 2008, and 29 states and the District of Columbia are looking at shortfalls in fiscal 2009.

As unemployment rises, more American

families will turn to Medicaid for health coverage, said the organization. The Medicaid report cited a study by the Kaiser Family Foundation showing that each 1% rise in unemployment increased Medicaid and SCHIP enrollment by 1 million, leaving states with an additional \$1.4 billion obligation.

Families USA is pushing for federal relief, such as a temporary increase in the

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matching rate given to states for Medicaid. Congress passed such a temporary fix in 2003, and several bills have been introduced in this congressional session. But it is unclear whether a proposed fix could make it out of Congress this year, said a Families USA staffer in the briefing. ■

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## Adding to Pool

Donor Organs • from page 1

extracorporeal membrane oxygenation (ECMO) service. Only Wake Forest and the University of Michigan, Ann Arbor, have substantial experience in using extracorporeally supported DCD protocols after the withdrawal of life support, but Dr. Hines noted that similar services are getting underway at other hospitals.

After consent for donation has been granted, the common protocol for extracorporeally supported DCD in severely neurologically impaired patients begins with preparatory cannulation of the femoral artery and vein in the ICU. Organ procurement does not proceed unless cardiac death occurs within 60 minutes of withdrawal of life support. Once the primary medical team declares death, another 5 minutes must pass to ensure that cardiac reanimation does not occur. The primary medical team is separated from the organ procurement service at all steps.

Dr. Robert H. Bartlett, the inventor of ECMO, and his colleagues at the University of Michigan have refined their extracorporeal support protocol to include the use of an aortic occlusion balloon catheter to block blood from returning to the heart.

Dr. Bartlett, an ACS Fellow, and Dr. Hines said in interviews that thus far, all of the families given the option of the extracorporeal technique for organ donation "have been cooperative, supportive, very positive about it [and] frequently bring it up when discussing the withdrawal of care," Dr. Hines said.

Michigan researchers, who were the first to perform extracorporeal support of DCD donors, reported delayed graft function in 2 (11%) of 19 transplanted kidneys (Ann. Transplant. 2004;9:57-8). Later, they found that kidneys taken from extracorporeally supported DCD donors had a

lower DGF rate (2 [8%] of 24) than did kidneys from DBD donors (24 [24%] of 100). The protocol resulted in a 24% increase in the overall number of deceased donor kidneys (J. Trauma 2005;58:1095-1102). Dr. Bartlett and his colleagues are switching from perfusing the donor at body temperature to room temperature.

Dr. Hines and his colleagues are submitting a paper that describes their experience with a series of patients with severe and unrecoverable neurologic injury (but without brain death) who underwent the center's extracorporeal interval support for organ retrieval (EISOR) protocol. The group has now transplanted kidneys, pancreases, and livers from these DCD donors by using the EISOR circuit and protocol, designed by Dr. Hines and Dave Charles, chief perfusionist at Wake Forest.

In this protocol, organs are slowly cooled in situ to 20°-25° C to ensure that their metabolic processes are inactive when they are procured and flushed with a cold saline solution. This mimics the process of deep hypothermic circulatory arrest that is achieved when cardiopulmonary bypass machines cool a patient's blood until the oxygen demand of organs and tissue is nearly zero. The cooling process might account for why kidneys from EISOR donors have a lower DGF rate than do organs from DBD donors, which are rapidly cooled from normothermic to hypothermic temperatures during procurement, Dr. Hines said.

The technique also may have the effect of mimicking ischemic preconditioning, in which the arterial blood supply to an organ such as the liver is cut off briefly in order to prepare the organ to withstand the stress of a longer period of ischemia that will follow, he explained.

All the pancreases procured by the Wake Forest team with the EISOR protocol have functioned immediately and survived in the recipient.

"That's a pretty good sign that this technique works," Dr. Hines said.

The setup for the procedure involves the percutaneous insertion of cannulae into a femoral artery and vein of the donor. These cannulae are attached to a "simplified and very portable heart-lung machine" with a single centrifugal pump, an oxygenator, and a heat exchanger, he said.

With greater understanding of organ preservation techniques, Dr. Hines suspects that the arbitrary 1-hour window in which the heart must stop beating in order for organ procurement to proceed could change to a system in which the potential donor is monitored for as long as stable physiologic signs are present.

"To be ultraconservative [in pronouncing death], we wait for 5 minutes after electrical silence of the heart rather than for 5 minutes after pulselessness," Dr. Hines said. After that, lidocaine is mixed into the perfused blood to prevent reanimation of the heart during the process.

At both centers, the local organ procurement organizations have paid the extra costs entailed by extracorporeal support, but providing better-functioning donor organs could offset those costs by reducing the number of days donor organ recipients spend in the ICU. Both groups have used their protocols only on patients with severe, irreversible neurologic injury. But a much larger organ donor pool exists for "uncontrolled" organ donation from people who have sudden cardiac death.



Well-perfused organs are shown in this procedure using the extracorporeal interval support for organ retrieval protocol.

DR. MICHAEL H. HINES

The Department of Health and Human Services has funded a pilot project at New York's Bellevue Hospital that seeks to determine the feasibility of procuring organs from people who die from sudden cardiac death. The protocol, which is not yet established, would allow paramedics who work around the hospital to call a second group of paramedics with a specially outfitted ambulance to begin extracorporeal support in people who are unsuccessfully resuscitated.

The process for consent and the possibility of placing cannulae prior to consent are issues that are still under debate. But no organs would be procured without consent of family, according to Dr. Bartlett, who has consulted with Bellevue on the project.

The unknown, yet unlikely, potential to resuscitate the brain of these potential DCD donors with extracorporeal support would be prevented with an aortic occlusion balloon, Dr. Bartlett said.

Already at some centers, cardiac arrest patients who are unsuccessfully resuscitated on ECMO can become DCD donors with their family's consent. ■

## Trial Supports Early Steroid Withdrawal After Renal Transplant

BY BRUCE JANCIN  
Elsevier Global Medical News

NEW YORK — Withdrawal of corticosteroids 7 days after kidney transplantation results in patient and allograft survival rates comparable to those achieved with chronic steroid maintenance therapy, while avoiding the myriad adverse cardiovascular, bone, and metabolic consequences of long-term steroids, according to a 5-year, double-blind, placebo-controlled, randomized trial.

These results counter those of a 25-year-old Canadian randomized trial that concluded that early steroid withdrawal significantly increased the risk of graft failure. That study has served as a major obstacle to widespread adoption of early removal of steroids, Dr. E. Steve Woodle, an ACS Fellow, reported at the annual meeting of the American Surgical Association.

"We believe that the primary difference with the Canadian trial is their patients were on Sandimmune (cyclosporine) monotherapy with inadequate trough levels. This is very different from being on tacrolimus and mycophenolate mofetil, modern potent immunosuppression," said Dr. Woodle, professor of surgery and director of the division of transplantation at the University of Cincinnati.

He presented the final results of the 34-center trial, in which the 386 participating adult kidney transplant

recipients and their physicians remained blinded as to assigned treatment for the full 5-year study duration.

The primary composite end point in the trial was death, graft loss, or severe acute rejection. The rate for this end point was similar—roughly 15%—in the early steroid withdrawal and chronic steroid maintenance arms.



The composite end point of death, graft loss, or severe acute rejection was roughly 15% in both trial arms.

DR. WOODLE

Fracture or avascular necrosis occurred in 5.2% of the early withdrawal patients, versus 11.3% of those on chronic steroids. There were no deaths due to infection in the early withdrawal group, versus 3.1% in the chronic maintenance group. Serum triglyceride levels were a mean of 50 mg/dL lower in the early withdrawal group for the first 4 years of follow-up.

There was also less new-onset diabetes in the early withdrawal group: Insulin therapy for 30 days or more was required in only 3.7% of the early withdrawal group but in 11.6% of patients on chronic steroids.

On the other hand, the early withdrawal group had a higher rate of chronic allograft nephropathy: 9.9%, versus 4.1% in the chronic steroid group. But this was not associated with any differences in renal function.

Of note, the average prednisone dose in the control group was only 5 mg/day after 6 months. Had higher maintenance doses of prednisone been used, as often occurs in clinical practice, the advantages of early steroid withdrawal would have been even greater, Dr. Woodle said.

A key procedural point was that steroid withdrawal at 1 week post transplant was always carried out with T-cell depleting antibody induction using Thymoglobulin (rabbit antithymocyte globulin) or interleukin-2R antibody. Dr. Woodle said he believes this is the right way to go, citing a University of Cincinnati study that showed a 40% reduction in the risk of acute rejection with the use of T-cell depleting antibody induction.

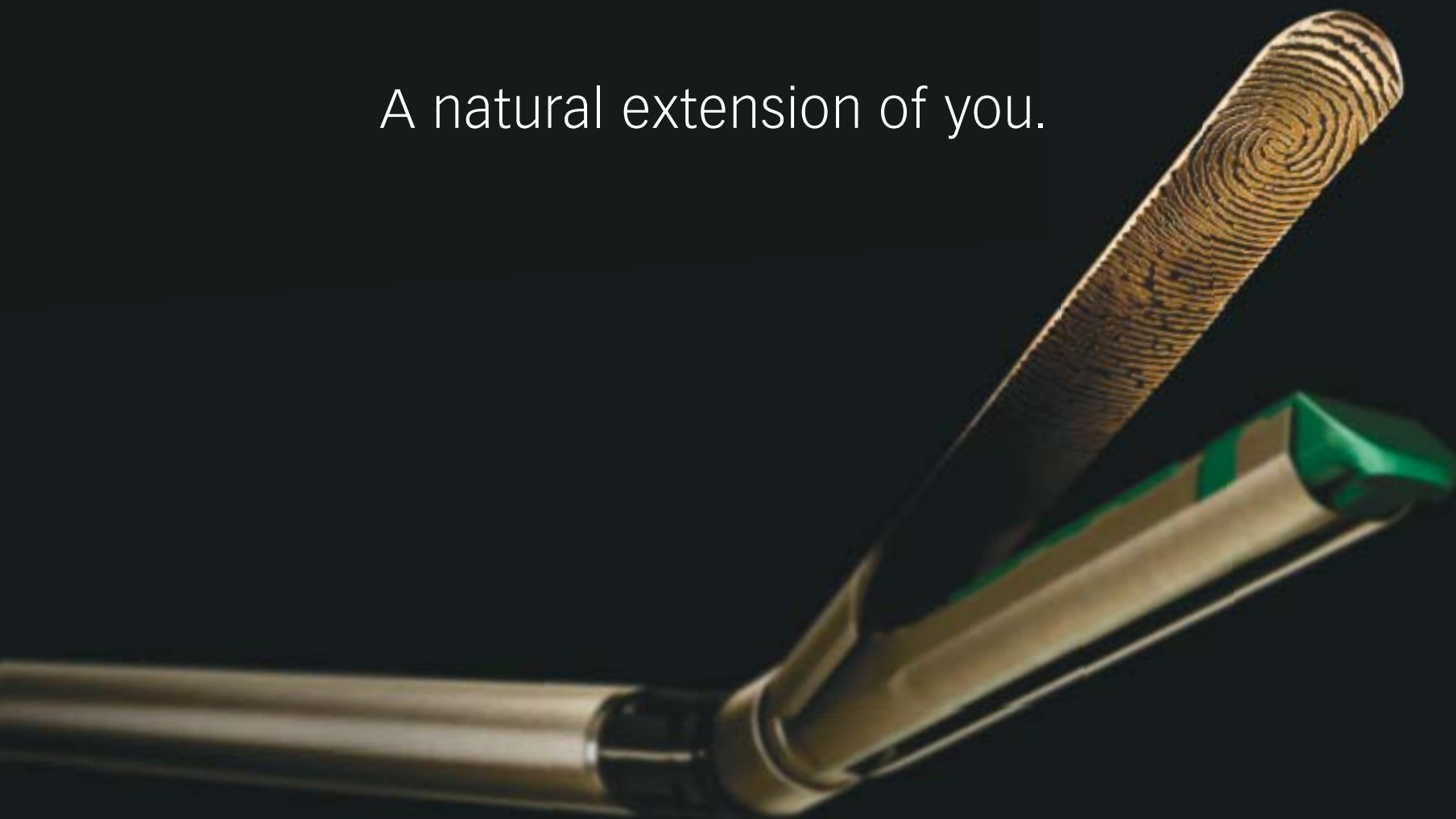
Overall, 20% of the study participants were African American, a group known to be at high risk for graft rejection. They had no increase in graft failure with early steroid withdrawal, and experienced greater cardiovascular risk reduction with early withdrawal than other groups. Mortality in African Americans with a functioning graft was only 4% in those withdrawn from steroids early, versus 16% in those with chronic steroids.

Discussant Dr. Ron Shapiro, an ACS Fellow, called this "a landmark trial." "This study will be cited for many years to come," predicted Dr. Shapiro, professor of surgery and director of kidney, pancreas, and islet transplantation at the University of Pittsburgh.

Dr. Marshall Z. Schwartz commented that early steroid withdrawal also can be accomplished safely in pediatric patients. Steroid-induced acne often causes adolescents to stop taking their medications, noted Dr. Schwartz, an ACS Fellow and professor of surgery and pediatrics at Drexel University, Philadelphia.

Dr. Woodle disclosed receipt of research grant support from Astellas Pharma Inc., sponsor of the trial. ■

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## NEWS FROM THE COLLEGE

# NCDB Study Shows Usefulness of Quality Measures

**M**ore cancer deaths could be avoided by focusing national quality initiatives on factors affecting long-term survival, according to a study comparing patient mortality in the days and weeks following cancer operations with 5-year survival outcomes. The study, published in the August 1 issue of the *Journal of Clinical Oncology*, was conducted by researchers from the National Cancer Data Base (NCDB) of the American College of Surgeons.

"We were surprised by the number of deaths that could be avoided long term if care at lower-volume hospitals could be improved," reported lead author Karl Y. Bilimoria, M.D., a general surgery resident at Northwestern University's department of surgery in Chicago and a former ACS research fellow. He and his colleagues compared these outcomes in the highest-volume hospitals with those in the lowest-volume hospitals across the country.

This study is "not just another article on cancer surgery and patient outcomes," Nicholas J. Petrilli, M.D., wrote in the commentary accompanying the article. "Dr. Bilimoria and associates look at this issue from a different perspective. [Their] objective was to determine whether differences in hospital surgical volume have a larger ef-

fect on perioperative mortality or on long-term survival."

The study team monitored 243,103 NCDB records for patients who had surgery for non-metastatic colon, esophageal, gastric, liver, lung, pancreatic, or rectal cancer from 1994 through 1999. They compared survival during the perioperative period within 60 days of death and 5-year survival, excluding perioperative deaths. "First, we compared the magnitude of the relative differences between hospitals in both time frames, perioperative and long term. Second, we calculated the number of potentially avoidable deaths if outcomes could be improved at lower-volume hospitals to those seen at highest-volume hospitals," Dr. Bilimoria said.

The researchers discovered that hospital surgical volume was a factor for both time periods studied for all cancer sites except for liver resection surgery, where no survival rate differences were noted. Outcomes during the 60-day perioperative period showed that overall, patients treated at highest-volume

hospitals had significantly lower mortality rates than those treated at the lowest-volume centers. Likewise, over a 5-year period, patients treated at the highest-volume centers had significantly higher survival rates than those treated at lowest-volume centers. For the seven cancer sites combined, the total number of potentially avoidable deaths in the U.S. each year was 2,207 during the 60-day perioperative period and 7,245 for long-term survival under these adjusted circumstances. "We found that the magnitude of the risk of dying is greater early on, but the number of lives affected long term is considerably greater," he said.

"Our results indicate that quality initiatives should move beyond measuring factors affecting perioperative outcomes," he noted. Dr. Bilimoria believes the key is to improve the quality of surgical treatment at all hospitals to potentially affect long-term outcomes: "We can achieve this goal by making sure we remove all of the cancer, take out the right number of lymph nodes, give all appropriate individuals

chemotherapy and other treatments as necessary, and aggressively follow patients for recurrences. We may also encourage some patients to participate in clinical trials."

Quality measures already developed for treatment of pancreatic cancer and melanomas will soon be attached to practical guidelines for low-volume hospitals to follow, Dr. Bilimoria said. "Most patients in the U.S. undergo cancer resection at low-volume hospitals. Moving all patients to high-volume centers is an impractical policy initiative at the national level. Rather, we would like to find what those highest-volume hospitals do to get their better outcomes and transfer those treatment strategies to the lowest-volume hospitals."

His co-investigators were David J. Bentrem, M.D., FACS; Mark S. Talamonti, M.D., FACS; James S. Tomlinson, M.D.; Andrew K. Stewart, M.A.; David P. Winchester, M.D., FACS, Medical Director, Cancer Programs, ACS Division of Research and Optimal Patient Care; and Clifford Y. Ko, M.D., M.S., MSHS, FACS, Director, ACS Division of Research and Optimal Patient Care. The study was supported by the ACS Clinical Scholars in Residence program and Feinberg School of Medicine at Northwestern University. ■



**We were surprised by the number of deaths that could be avoided at lower-volume hospitals.**

**DR. BILIMORIA**

## CoC Announces Paper Competition Winners

**T**hree winners of the 2008 Commission on Cancer (CoC) Paper Competition have been selected from among 80 abstracts that were submitted describing cancer care in basic laboratory research, clinical investigation, or quality of care/health services research. Reviewed by members of the CoC's Committee on Cancer Liaison, the abstracts were scored on the basis of originality, scientific merit, research quality, relevance, and importance. Selecting the winners was not easy; all papers showed promise and progress in the fight against cancer.

The first-place winner was Jocelyn Logan-Collins, M.D., University of Cincinnati (Ohio) College of Medicine, for *Silencing of the RON Tyrosine Kinase Receptor Results in Decreased Cell Survival and Increased Sensitivity to Gemcitabine in vivo*. She received a \$1,000 award and was invited to speak at the CoC meeting on Sunday, Oct. 12, during the Clinical Congress.

The second- and third-place winners received a \$500 award and were asked to present their work at the Cancer Liaison physician breakfast on Monday, Oct. 13.

Second place went to Karl Y. Bilimoria, M.D., M.S., Evanston Northwestern Healthcare, Evanston, Ill., for *Sentinel Lymph Node Biopsy Alone vs. Completion Axillary Lymph Node Dissection for Node-Positive Breast Cancer*.

Third place went to J. Robert Newman, M.D., University of Alabama at Birmingham, for *Blocking Anti-CD147 Antibody Suppresses Growth of Head and Neck Cancer Xenografts and Sensitizes Tumors to Radiation Therapy*.

The competition was open to U.S. general surgery residents, surgical specialty residents, subspecialty residents, and oncology fellows. It is funded by the CoC and a memorial gift from Mrs. A. Lee Campione, in honor of her late husband, Matthew P. Campione, M.D., FACS.

Individuals who submitted an abstract and were not selected have been encouraged to work with their CoC state chair and chapters of the ACS to explore opportunities to present their work at an upcoming meeting.

The call for abstracts for the 2009 CoC Paper Competition will be issued in November. ■

## Revamped Web Site Steers Users To Volunteerism Resources

**A**restructured Operation Giving Back Web site makes it easier for surgeons interested in volunteerism to find the resources and information they seek.

On the OGB homepage, located at [www.operationgivingback.org](http://www.operationgivingback.org), is a menu tab entitled Resource Centers. Click on this tab for links to information organized by subject matter and relevance to different groups. For instance, under Resources for Surgeons in Practice, you'll find general information useful to all actively practicing surgeons exploring volunteerism, as well as information specific to the needs of military and international surgeons.

Resources for Surgeons in Training includes sections for surgical residents and medical students with links to programs that allow participation from surgeons-in-training and information on funding and education. Resources for retired surgeons contains information related to retiree licensure, liability, and other issues unique to these volunteers.

Resources for the Surgical Team directs you to surgical safety and quality initiatives applicable to all volunteers and volunteerism programs instituted by surgical colleagues in the anesthesia, nursing, physician assistant, and surgical technologist communities. The new Resources by Specialty category has infor-

mation related to your particular training and skills. There is also a new section called Resources for Volunteering in the U.S., and a separate section on disaster response.

The newly organized Reading Room section offers links to scientific articles of interest on volunteerism, books, news stories, and articles in the *Bulletin* that have featured the humanitarian outreach activities of ACS members.

Links to several dozen organizations that specialize in the exchange of medical equipment, supplies, or texts are provided under the heading Donations of Medical Goods. Although each volunteer opportunity listed in OGB includes a country-specific toolkit with information on the culture, customs, political climate, and other factors relevant to that opportunity, the Resource Center also contains links to these same travel resources in generic form, allowing you to search by country of interest.

Contact OGB if you have suggestions for other resources that might enhance this section of the Web site. As a reminder, the site's links and references are provided as a service to surgical volunteers and other interested parties; as such, the content and policy of any outside link do not necessarily reflect ACS policies. ■

## NEWS FROM THE COLLEGE

## Breast Cancer Trial Explores Cryoablation

BY DAVID M. OTA, M.D., FACS,  
AND HEIDI NELSON, M.D., FACS

The American College of Surgeons Oncology Group (ACOSOG) is conducting a cryoablation trial of T1 breast cancers to determine if early cancers can be completely ablated.

The primary objective of the study—Exploring the Success of Cryoablation Therapy in the Treatment of Invasive Breast Carcinoma (ACOSOG Z1072)—is to determine the rate of complete tumor ablation (defined as no remaining invasive or in situ carcinoma present upon pathological examination of the targeted lesion) in patients treated with cryoablation.

Led by Rache Simmons, M.D., FACS, the study has the following secondary objectives:

- ▶ Evaluate the negative predictive value of MRI in the post-ablation setting to determine residual in situ or invasive breast carcinoma.

- ▶ Describe the adverse events associated with cryoablation.

- ▶ Prospectively gather pain assessment data on cryoablation and surgical resection.

- ▶ Explore technical variables that may affect success of cryoablation.

The target accrual is 99 patients. Magnetic resonance imaging (MRI) for the breast has increased surgeons' ability to better identify localized early disease, which is suitable for in situ ablation. Post-ablation MRI will also be used to see if residual disease remains. In this trial design (see chart), all patients will undergo resection of the ablation site so that microscopic evaluation for residual disease can be done. There is also an optional correlative science component to investigate the immune response to cryoablation, which includes three blood samples.

Patient eligibility criteria include the following:

- ▶ Unifocal primary invasive ductal breast carcinoma diagnosed by core needle biopsy. Patients with multifocal

- and/or multicentric ipsilateral breast cancer, multifocal calcifications, or ductal carcinoma in situ with microinvasion are not eligible. Patients with contralateral disease will remain eligible.

- ▶ No history of rotational vacuum-assisted core biopsies, en bloc open surgical biopsy, and/or lumpectomy for diagnosis/treatment of the index breast cancer.

- ▶ Tumor size is <2.0 cm in greatest diameter. Specifically, the tumor must measure <2.0 cm in the axis parallel to the treatment probe and <1.5 cm in the axis antiparallel to the treatment probe. Largest size measured by mammogram, ultrasound, or MRI will be used to determine eligibility.

- ▶ Tumor enhancement is present in prestudy MRI.

- ▶ Tumor biopsy has <25% intraductal components in the aggregate.

- ▶ There is no prior or planned neoadjuvant chemotherapy for breast cancer.

- ▶ Patient is not pregnant or lactating.

- ▶ Adequate breast size for safe cryoablation.

Surgeons or radiologists wishing to participate must initially meet at least one of the following criteria:

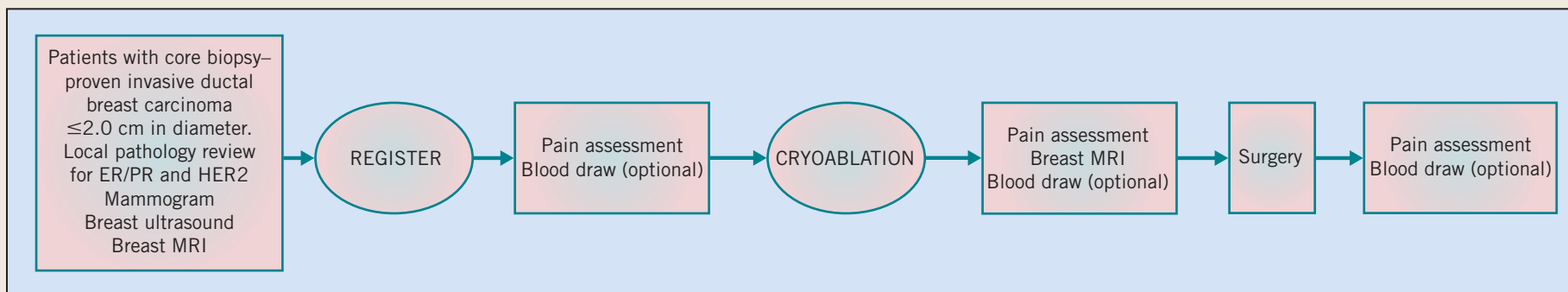
1. Surgeon is certified in ultrasound by the American Society of Breast Surgeons and has completed at least five ultrasound-guided cryoablations for breast fibroadenoma/cancer.

2. Surgeon is partnering with a radiologist certified by the American College of Radiology in breast ultrasound and has completed at least five ultrasound-guided cryoablations for breast fibroadenoma/cancer.

3. Surgeon can provide case list documentation of the last 20 breast interventional ultrasounds within the past 6 months and has completed at least five ultrasound-guided cryoablations for breast fibroadenoma/cancer.

The trial will be conducted in up to 20 clinical sites. Contact Dr. Simmons at [rms2002@med.cornell.edu](mailto:rms2002@med.cornell.edu).

DR. OTA, of Durham, N.C., and DR. NELSON, of Rochester, Minn., are ACOSOG co-chairs.



## Joint Commission Sets Conduct Standards

A new Sentinel Event Alert issued by The Joint Commission warns that rude language and hostile behavior among health care professionals go beyond being unpleasant and pose a serious threat to patient safety and the overall quality of care.

Intimidating and disruptive behaviors are so concerning that, in addition to the Sentinel Event Alert, The Joint Commission is introducing new standards requiring more than 15,000 accredited health care organizations to create a code of conduct that defines acceptable and unacceptable behaviors and to establish a formal process for managing unacceptable behavior. The new standards take effect January 1, 2009, for hospitals, nursing homes, home health agencies, laboratories, ambulatory care facilities, and behavioral health care facilities across the U.S.

Verbal outbursts, condescending attitudes, refusal to take part in assigned duties, and physical threats all create breakdowns in the teamwork, communication, and collaboration necessary to deliver patient care. The Institute for Safe Medication Practices found that

40% of clinicians have kept quiet or remained passive during disruptive events occurring during patient care rather than question a known intimidator.

"Most health care workers do their jobs with care, compassion, and professionalism," said Mark R. Chassin, M.D., MPP, MPH, and president of The Joint Commission. "But sometimes professionalism breaks down, and caregivers engage in behaviors that threaten patient safety. It is important for organizations to take a stand by clearly identifying such behaviors and refusing to tolerate them."

To help stop intimidating and disruptive behaviors among physicians, nurses, pharmacists, therapists, support staff, and administrators, the Sentinel Event Alert recommends that health care organizations take 11 specific steps, including the following:

- ▶ Educate all health care team members about professional behavior, including training in basics such as courteousness during telephone interactions, business etiquette, and general people skills.
- ▶ Hold all team members accountable

for modeling desirable behaviors, and enforce the code of conduct consistently and equitably.

- ▶ Establish a comprehensive approach to addressing intimidating and disruptive behaviors that includes a zero-tolerance policy, obtaining strong involvement and support from physician leadership, reducing fears of retribution against those who report intimidating and disruptive behaviors, and empathizing with and apologizing to patients and families who are involved in or witness intimidating or disruptive behaviors.

- ▶ Determine how and when disciplinary actions should begin.

- ▶ Develop a system to detect and receive reports of unprofessional behavior, and use nonconfrontational interaction strategies to address intimidating and disruptive behaviors within the context of an organizational commitment to the health and well-being of all staff and patients.

Visit The Joint Commission's Web site at [www.jointcommission.org/SentinelEvents/SentinelEventAlert/](http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/) for more information.

## Apply Now for ACS Traveling Fellowship

The ACS International Relations Committee announces the availability of the Australia and New Zealand (ANZ) Chapter of the ACS Traveling Fellowship: a \$12,000 scholarship for a U.S. or Canadian Fellow of the ACS. This fellowship is intended to encourage international exchange of information concerning surgical science, practice, and education, and to establish professional and academic collaborations and friendships.

The ANZ Traveling Fellow will attend the annual Scientific Congress of the Royal Australasian College of Surgeons, in Perth, Australia, May 4-8, 2010. The Fellow will also visit surgical centers in Australia and New Zealand.

The closing date for receipt of completed applications is Nov. 17, 2008. For more information, contact [kearly@facs.org](mailto:kearly@facs.org), or visit [www.facs.org/memberservices/traveling.html](http://www.facs.org/memberservices/traveling.html).

## Code Switch

ICD-10 • from page 1

The ICD-9-CM also fails to provide adequate clinical details, according to CMS. For example, the ICD-9-CM has a single procedure code that describes endovascular repair or occlusion of the head and neck vessels. But the code leaves out details such as a description of the artery or vein on which the repair was performed, the precise nature of the repair, or whether it was a percutaneous procedure or was transluminal with a catheter.

“Because of the new and changing med-

ical advancements during the past 20-plus years, the functionality of the ICD-9-CM code set has been exhausted,” CMS officials wrote in the proposed regulation. “This code set is no longer able to respond to additional classification specificity, newly identified disease entities, and other advances.”

CMS also is urging a switch to the ICD-10 code sets in an effort to keep in step with other countries. As of October 2002, 99 countries had adopted ICD-10 or a clinical modification for coding and reporting morbidity data. And CMS contends that because it continues to use ICD-9-CM it has problems identifying

emerging recent global health threats such as anthrax, Severe Acute Respiratory Syndrome (SARS), and monkeypox.

Under the proposal, physicians, hospitals, health plans, and other covered health care entities would be required to use the ICD-10-CM for reporting diagnoses and the ICD-10-PCS for reporting procedures. The ICD-10 code sets offer about 155,000 codes across the two sets, compared with about 17,000 for diagnosis and procedure codes within the ICD-9-CM.

In addition to size, the ICD-10 code sets also provide greater specificity, such as being able to reflect the side of the body that is related to the diagnosis or proce-

dures. The more detailed information available through the ICD-10 codes also will aid in the implementation of electronic health records and transmission of data for bio-surveillance or pay-for-performance programs, according to CMS.

But physician groups say CMS is asking physicians and other health care providers to do too much too fast.

The American Medical Association balked at the idea of implementation of both the updated X12 Version 5010 electronic transaction standard and the ICD-10 coding system in just 3 years. The X12 Version 5010 standard should first be pilot tested before physicians and others are asked to implement it, AMA said.

“This is a massive administrative undertaking for physicians and must be implemented in a time frame that allows for physician education, software vendor updates, coder training, and testing with payers—steps that cannot be rushed and are needed for a smooth transition,” Dr. Joseph Heyman, AMA board chair, said in a statement.

The Medical Group Management Association also objected. While MGMA supports the switch to the ICD-10 code sets, they said that 3 years is not enough time for the industry to implement the new system.

Instead of a simultaneous implementation of the X12 Version 5010 standard and the ICD-10 code sets, MGMA is asking CMS to wait at least 3 years after the switch to X12 Version 5010 before implementing the ICD-10.

The switch to ICD-10 needs to be done separately because it will require significant changes from medical groups, according to MGMA.

Recent MGMA research indicates that most medical practices will have to purchase software upgrades for their practice management systems or buy all new software in order to implement the transition to ICD-10.

“Moving to these new code sets has the potential to be the most complex change for the U.S. health care system in decades,” Dr. William F. Jessee, president and CEO of MGMA, said in a statement. ■

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# FDA Spells Out Conflict-of-Interest Rules for Advisers

BY ALICIA AULT  
Elsevier Global Medical News

Experts serving on the Food and Drug Administration's advisory committees are now subject to new rules aimed at ensuring that they do not have conflicts of interest that could bias their decisions.

In early August, the FDA issued four final guidance documents and a draft guidance outlining how it plans to handle conflicts of interest among members of advisory committees, which review the safety and efficacy of drugs, medical devices, diagnostic tests, and other products and ingredients that the agency regulates.

In a separate move, the agency said that it plans to make it easier to find documents before and after advisory committee meetings by improving how it posts meeting information on its Web site.

Guidance documents represent the agency's current thinking on a topic, but carry less weight than does a regulation. The FDA has no power to enforce guidance documents, which manufacturers and the agency generally use as rules of thumb.

The newest guidance documents will help ensure that the FDA "is getting the highest quality scientific advice, while at the same time preserving public trust in our decisions," Randall Lutter, Ph.D., the FDA's deputy commissioner for policy, said in a teleconference briefing with reporters.

In the past, the agency has asked advisers to disclose potential conflicts of interest, but there was no monetary limit. Each potential conflict was weighed individually, and waivers were granted based on whether the adviser's expertise was considered necessary for a particular meeting.

With the new guidance, the agency sets a dollar limit on advisers' financial interests. If an adviser—or his or her spouse or minor child—has interests of at least \$50,000 in an entity that would be directly or indirectly affected by the outcome of a particular meeting, the adviser would be barred from participating. Advisers with interests less than \$50,000 will be allowed to participate and vote, unless they are found to have a significant conflict of interest.

An advocate who has been critical of the FDA's conflict of interest policy for advisers said that the \$50,000 cap is too high.

"The FDA wants us to believe that an advisory committee member can receive \$49,999 from a company and still make an unbiased decision. I don't buy it and the research doesn't support it," said Diana Zuckerman, Ph.D., president of the National Research Center for Women and Families, an advocacy organization in Washington, D.C.

She and another agency critic, Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, both expressed concern that the new guidance would still allow advisers with conflicts to vote. Those advisers will be granted waivers if they are determined to provide essential expertise.

This is not much of a change from cur-

rent policy, according to Dr. Wolfe and Dr. Zuckerman.

"The FDA has consistently used a very low standard for granting waivers, and there is no evidence that this will change," Dr. Zuckerman said.

But the FDA said that the Food and Drug Administration Amendments Act of 2007, which was signed into law last year, limits the number of waivers it is allowed to grant. The agency also has vowed to make the circumstances of the waivers public.

In another guidance, the agency said that it will require simultaneous voting by all committee members. Advisers at some meetings have begun using an electronic voting system to ensure that panel members don't influence the votes of those who succeed them in voting; the votes are conducted privately, and then broadcast immediately afterward on a screen.

Dr. Wolfe said that when he has seen the voting system in action, "it worked well and served the stated purpose."

He also praised the agency's proposed

guidance to set out a more definitive policy on when a product should be referred to an advisory committee for review. The basis for referral "has been less than clear," Dr. Wolfe said.

The FDA also is changing the administrative process for meetings of the advisory committees. The agency will formally notify a sponsoring company 55 days in advance that a meeting has been scheduled. Also, the FDA will post materials relating to the meeting on its Web site no later than 2 full days in advance of the meeting. ■

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# Data Show Rise in Postoperative Sepsis Rates

BY ELIZABETH MEHCATIE  
Elsevier Global Medical News

The rate of postoperative sepsis among adult patients increased significantly over a 17-year period, as did the proportion of cases that were considered severe, according to an analysis of a state inpatient database.

Although hospital mortality from postoperative sepsis dropped in patients undergoing nonelective surgery, the proportion of patients who developed severe

sepsis following elective surgery increased significantly, and mortality from sepsis after elective surgery did not improve, according to Dr. Todd Vogel. He presented results of the study at the annual meeting of the Surgical Infection Society.

“What’s concerning from the data is that elective cases did not show a significant decreased trend at all; in fact, we have not made any headway in mortality secondary to sepsis” after elective surgery, said Dr. Vogel of the Robert Wood Johnson Medical School, New Brunswick.

Dr. Vogel and his associates analyzed data from the State Inpatient Database for New Jersey from 1990 to 2006 for patients aged 18 and older who developed sepsis after elective or nonelective surgery, using diagnosis codes defined by the Agency for Healthcare Research and Quality.

There were 1,276,451 surgery discharges during that time, of which 42% were elective and 58% were nonelective. Sepsis was a complication in 3% of all surgical procedures.

Of the patients having elective surgery,

about 1% developed postoperative sepsis and 0.5% developed severe sepsis (defined as sepsis complicated by organ dysfunction). The rate of sepsis after elective surgery rose from 0.67% to 1.74%, and the rate of severe sepsis increased from 0.22% to 1.12%. Both were highly statistically significant increases. The proportion of sepsis cases that were severe after elective surgery nearly doubled from 33% to 65%, also a highly significant increase.

The rates of postoperative sepsis and severe sepsis were significantly higher among the patients who had nonelective surgery (about 4% for sepsis and about 2% for severe sepsis). The rate of sepsis after nonelective surgical procedures increased from 3.7% to 4.5%, and the rate of severe sepsis increased from 1.8% to about 3%. The proportion of sepsis cases after nonelective surgery that were severe increased

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**THE RATE OF SEPSIS AFTER  
NONELECTIVE SURGERY ROSE  
FROM 3.7% TO 4.5%, AND THE  
RATE OF SEVERE SEPSIS GREW  
FROM 1.8% TO ABOUT 3%.**

significantly from almost 48% to nearly 70%. However, in-hospital mortality among these patients dropped from 38% to 30% for sepsis and from 55% to 38% for severe sepsis, a highly significant decrease.

The pattern of pathogens also changed during the period studied, with a significant drop in rates of septicemia caused by staphylococci, anaerobes, pseudomonas, and *Escherichia coli* among the nonelective surgery cohort.

There was also a significant increase in the rates of streptococcal septicemia and staphylococcal septicemia in a subgroup of patients undergoing elective surgery, but the rates of septicemia caused by *E. coli*, pseudomonas, and anaerobes remained unchanged in this cohort.

The findings may be explained by changes in the types of patients who are admitted to the hospital for elective surgery, Dr. Vogel said in an interview. The trend toward minimally invasive procedures may mean that elderly or sicker patients are more likely to be admitted to the hospital for elective surgery, he speculated. The improved mortality among nonelective cases could be attributable to advances in critical care and antibiotics, and greater awareness of sepsis, he added, noting that this was not clear from the data and will be the focus of a future study.

The investigators also found a significant disparity based on ethnicity, sex, and age of patients, which Dr. Vogel said needs to be studied further. The rates of postoperative sepsis and mortality after nonelective and elective surgery were highest among black patients, compared with white patients (who had the lowest rates) and Hispanic patients. Men were more likely to have postoperative sepsis than were women, and there was a significant increase in the rates of postoperative sepsis with age. ■

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# Innovations Offer New Options for General Surgeons

BY JEFF EVANS

Elsevier Global Medical News

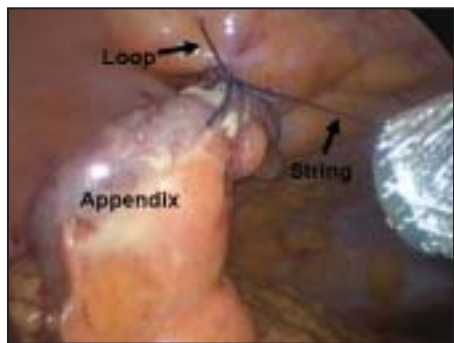
New devices and techniques that are either in development or on the market attest to the innovation at work in general surgery. SURGERY NEWS looks at an intra-abdominal loop suture, a duodenal-jejunal bypass sleeve, and a radiofrequency coagulating device that were presented at the Academic Surgical Congress.

## One- and Two-Port Laparoscopic Appendectomy

The third trocar port that is usually reserved for retraction during a laparoscopic appendectomy can be safely replaced with a simple intra-abdominal suture-pulley system, according to Dr. Kurt E. Roberts of the section of surgical gastroenterology in the surgery department at Yale University, New Haven, Conn.

Most surgeons use three standard ports for a laparoscopic appendectomy: one 12-mm port in the umbilicus, one 5-mm port in the left lower quadrant, and one 5-mm port placed superpubically or in the right upper quadrant. His two-port procedure, or "puppeteer technique," creates a 12-mm infraumbilical port, a pneumoperitoneum, and a 5-mm port in the lower left quadrant for the camera.

Instead of creating a 5-mm trocar port for retraction, he places a loop suture tied



COURTESY DR. KURT E. ROBERTS

The string-loop pulley system retracts the appendix without a third trocar port.

as an air knot to the anterior abdominal wall in the right upper quadrant. A pretied suture is placed around the appendix, through the pulley loop, and then through the 12-mm umbilicus port to the outside of the body, so that pulling on the string on the outside of the body acts like a pulley to adjust the amount of retraction. The technique allows a surgeon to elevate the appendix enough to view its base and the mesoappendix. (See photo.)

In his eight-case series, Dr. Roberts averaged 64 minutes of operative time per patient and did not require additional trocar placement or conversion to open appendectomy. There were no intraoperative complications, and only one patient developed periumbilical cellulitis, which resolved with oral antibiotics by 1 week after surgery. The patients had a mean body mass index (BMI) of 25 kg/m<sup>2</sup>.

Dr. Roberts recently completed another 13 laparoscopic appendectomies using only one port through the umbilicus, which contains a 10-mm camera with a 5-mm working channel for an instrument. He still uses his suture-pulley method for obtaining retraction. One of his single-port patients had a BMI of 39 kg/m<sup>2</sup>. The

single-port appendectomy takes longer to complete because the camera's visualization of the operative field is reduced in comparison with the offset visualization provided by the camera in the two-port method.

## Endoscopic Duodenal-Jejunal Bypass Sleeve

Early results from a U.S. randomized, patient-blinded clinical trial for short-term weight loss prior to bariatric surgery show promise for the EndoBarrier, an endoscopic duodenal-jejunal bypass sleeve.

The first U.S. patient in the trial to receive the EndoBarrier was a 263-pound, 36-year-old woman with a BMI of 45 kg/m<sup>2</sup> (Surg. Innov. 2007;14:275-8). She had lost 9.2 pounds at week 4, 15 pounds at week 8, and 20 pounds at week 12. Two other patients who had undergone the procedure lost 12.8 pounds and 8.4 pounds by week 4.

Most U.S. patients have lost about 8%-10% of their total body weight so far, said Dr. Keith S. Gersin, chief of bariatric surgery at the Carolinas Medical Center, Charlotte, N.C., and an ACS Fellow.

Two control patients who underwent a sham procedure (esophagogastroduodenoscopy) lost 4 pounds and 13.8 pounds by week 4.

"Most of our patients require preoperative endoscopy anyway," said Dr. Gersin, who is a paid consultant and member of the advisory board for GI Dynamics, the developer of the EndoBarrier.

After an esophagogastroduodenoscopy, an over-the-wire catheter system brings the EndoBarrier to the duodenum. Under fluoroscopic guidance, an inner catheter deploys the 2-foot sleeve from the capsule as it moves through the intestine, guided



GI DYNAMICS INC.

The EndoBarrier includes a self-expanding anchor at its proximal end that utilizes barbs to prevent movement of the device.

by an atraumatic ball. A self-expanding anchor uses barbs to prevent movement of the device. (See photo.)

The device is designed to prevent contact between chyme and the intestinal wall but to allow bile and pancreatic secretions to travel on the outside of the sleeve and later mix with the chyme at the sleeve's end. On removal, drawstrings that are attached to the anchor struts collapse the anchor and retract the barbs from the intestinal wall.

The collapsed anchor is then drawn into a protective hood and the whole system is endoscopically removed from the GI tract.

"There are those who would make the argument, and rightfully so, that 2 feet

may not be long enough to create malabsorption," Dr. Gersin said. But the mechanism of the device likely involves more than malabsorption. It may involve some hormonal changes that are yet to be elucidated [and/or] some delays in gastric emptying, giving patients a sense of fullness, and therefore satiety," he said.

Initial implantations and removals of the device have all been performed under general anesthesia within about 30 minutes each, but Dr. Gersin said that in the future the device will probably be placed and removed while patients are under conscious sedation.

Some patients have experienced non-life-threatening GI bleeding, most likely because of an early barb design that has since been changed. The bleeding stopped when the device was removed endoscopically, Dr. Gersin said.

About 40-60 patients in the United States are currently being enrolled in the trial. The device is also being evaluated in clinical trials in Europe and in South American countries.

Early indicators suggest that the device improves or resolves diabetes, so "it's probably not just a weight-loss device," Dr. Gersin said, citing clinical experience with 12 patients in Chile who received the EndoBarrier to lose weight prior to undergoing bariatric surgery. The device remained in 10 of the 12 patients for a full 3 months; the other two patients had to have the devices explanted 9 days after implantation because of excessive abdominal pain and discomfort. Type 2 diabetes resolved in three of four patients who had the condition prior to the procedure. Other patients also had different comorbidities that resolved. The average total weight loss in the 10 patients who completed the study was about 22 pounds (Surg. Obes. Relat. Dis. 2008;4:55-9).

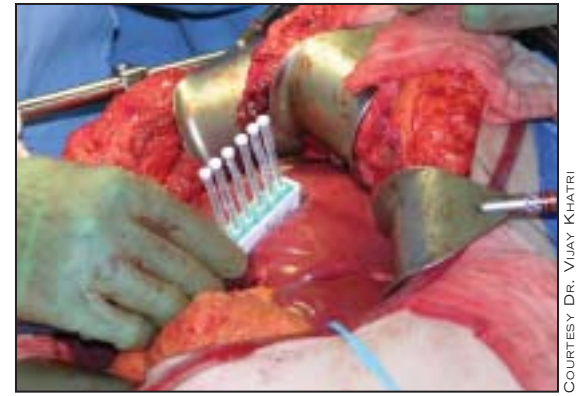
A total of 55 adverse events were linked to the device, including abdominal pain, nausea, and vomiting. One patient experienced an oral-pharyngeal mucosal tear and another had an esophageal mucosal tear during explantation, but these were not considered serious, according to the investigators.

"The plan would be in the next 9 months to a year to begin a pivotal trial in the United States with over 200 patients," Dr. Gersin said.

## Hepatic Resection With Multichannel Radiofrequency Device

The amount of blood lost during a hepatic resection might be significantly reduced by using a multichannel bipolar radiofrequency device to ablate a long, deep, and narrow plane where the liver will be transected, according to Dr. Vijay Khatri, an ACS Fellow.

Portal triad clamping (the Pringle maneuver) has been the traditional way to reduce blood loss during hepatic resection,



COURTESY DR. VIJAY KHATRI

The radiofrequency device ablates a plane of the liver that is 1 cm wide, 5 cm long, and 6 cm deep.

but large amounts of blood can still be lost. Attempts to ablate transection planes of the liver with multiple uses of a single monopolar device prior to using more traditional dissection methods has been associated with more complications than has the InLine bipolar RF linear coagulator device (Br. J. Surg. 2007;94:287-91; World J. Surg. 2007;31:2208-12). The In-Line device uses six bipolar electrodes to coagulate a plane of tissue up to 1 cm wide by 5 cm long by 6 cm deep. Each ablation takes 3-5 minutes. (See photo.)

The InLine device, which is manufactured by Resect Medical Inc., Fremont, Calif., is approved by the Food and Drug Administration for coagulating tissue during laparoscopic and intraoperative surgical procedures. Dr. Khatri of the division of surgical oncology at the University of California, Davis, said that he has no conflicts of interest with Resect Medical.

In a study conducted by Dr. Khatri and his associates, the first 24 consecutive patients who underwent hepatic ablation prior to liver transection lost an average of 240 mL blood and only 2 patients needed a transfusion. The investigators used intraoperative ultrasound to guide the placement of the device in the patients, who were undergoing resection for focal nodular hyperplasia (1), hepatoma (5), or metastases to the liver (18).

The investigators improved from using a median of 16 minutes of portal triad clamping in the first 7 cases to a median of 0 in the remaining 17 cases. The last 17 cases had a median blood loss of 100 mL, compared with 500 mL in the first 7 cases. Eleven of these 24 patients had taken multiagent chemotherapy, which can lead to postchemotherapy steatohepatitis. Eight patients developed complications, but none died and no bile duct injuries or abscess formations occurred.

At the American Hepato-Pancreato-Biliary Association meeting, Dr. Khatri and his associates compared these patients with the prior 24 patients who had undergone hepatic resection without the device. The first group lost a mean of 804 mL blood, but this fell to a mean of 240 mL with the InLine device. Clamping time also significantly declined from a mean of 30 minutes before the device was used to a mean of about 8 minutes after it was introduced.

When the device is used in conjunction with portal triad clamping, the width of the device's ablation increases from 1 cm to 2 cm because of the lack of rapid blood flow next to it that normally acts as a heat sink, Dr. Khatri said in an interview. ■

# Bariatric Surgery: Risky but Beneficial for Disabled

BY JEFF EVANS  
Elsevier Global Medical News

NATIONAL HARBOR, MD. — Disabled Medicare patients who undergo bariatric surgery may have higher operative mortality and a greater rate of complications than those outside of the federal program, but these risks appear to be counterbalanced by a substantial improvement in health, according to a single-center, retrospective study.

Perceptions of the risks and benefits of bariatric surgery in Medicare patients (or older patients in general) have tipped back and forth in various studies since 2004, when a report found that patients older than 55 years had elevated 30-day mortality from the procedures, especially at low-volume centers (Ann. Surg. 2004;240:586-

**HYPERTENSION WAS RESOLVED IN 56% OF MEN WITH MEDICARE COVERAGE, VERSUS 30% OF MEN NOT COVERED BY MEDICARE, A SIGNIFICANT DIFFERENCE.**

93), said Dr. James W. Maher of the division of general surgery at Virginia Commonwealth University (VCU), Richmond.

At the annual meeting of the American Society for Metabolic and Bariatric Surgery, Dr. Maher reviewed the results of bariatric procedures performed at VCU during 1981-2006. Prior to 1999, most bariatric procedures at VCU consisted of open Roux-en-Y gastric bypass (RYGB) or vertical banded gastroplasty. Since then, the university's surgeons have performed mostly laparoscopic RYGB and a small number of laparoscopic adjustable gastric banding procedures.

Dr. Maher and his coinvestigators compared the outcomes of 282 Medicare patients with those of 3,169 non-Medicare patients. All but 27 of 282 Medicare patients were on disability. Of the 282 Medicare patients, 175 had received open RYGB and 107 had received laparoscopic RYGB.

Compared with non-Medicare patients at baseline, Medicare patients had a significantly higher mean age and mean body mass index, as well as significantly higher rates of hypertension, diabetes, obstructive sleep apnea, and obesity-hypoventilation

(pickwickian) syndrome. Differences in the prevalence of comorbidities were even more pronounced in 72 men with Medicare coverage than in 576 men not covered by Medicare, according to Dr. Maher.

Among all patients, those with Medicare coverage lost a significantly lower percentage of excess weight than did those who were not covered by Medicare (60% vs. 66%). While hypertension resolved more often among non-Medicare patients than among Medicare patients (65% vs. 49%, respectively), diabetes resolved at

similar rates between the groups (77% vs. 65%, respectively).

Men in both groups lost a similar percentage of excess weight, and diabetes resolved at similar rates (30% for Medicare vs. 23% for non-Medicare). But hypertension was resolved in 56% of men with Medicare coverage, compared with 30% of men not covered by Medicare, a significant difference.

Mortality at 30 days was significantly higher among Medicare patients than among non-Medicare patients (2.5% vs.

0.8%). There was an even greater disparity in mortality between male Medicare patients and male non-Medicare patients (5.6% vs. 1.5%). Of the 27 Medicare patients not on disability, no one older than 65 years died.

Compared with non-Medicare patients, those who were covered had a slightly higher rate of anastomotic leak but a lower rate of pulmonary embolism, possibly because they had a higher rate of preoperative insertion of inferior vena cava filters, Dr. Maher said. ■

## TYGACIL® (tigecycline) Brief Summary

See package insert for full Prescribing Information. For further product information and current package insert, please visit [www.wyeth.com](http://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, <sup>14</sup>C-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 <sup>14</sup>C-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 <sup>a</sup> (N=1415)	Comparators <sup>b</sup> (N=1382)
<b>Body as a Whole</b>		
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
<b>Cardiovascular System</b>		
Hypertension	4.9	5.6
Hypotension	2.3	1.7
Phlebitis	1.8	3.8
<b>Digestive System</b>		
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
<b>Hemic and Lymphatic System</b>		
Anemia	4.2	4.8
Leukocytosis	3.7	2.5
Thrombocytopenia	6.1	6.2
<b>Metabolic and Nutritional</b>		
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	2.5
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 <sup>c</sup>	4.3	4.4
SGPT Increased <sup>c</sup>	5.6	4.7
<b>Nervous System</b>		
Dizziness	3.5	2.7
Insomnia	2.3	3.3
<b>Respiratory System</b>		
Cough Increased	3.7	3.8
Dyspnea	2.9	2.7
Pulmonary Physical Finding	1.9	2.2
<b>Skin and Appendages</b>		
Pruritus	2.6	4.1
Rash	2.4	4.1
Sweating	2.3	1.6
<b>Other</b>		
Local Reaction to Procedure	9.0	9.1

<sup>a</sup> 100 mg initially, followed by 50 mg every 12 hours

<sup>b</sup> Vancomycin/Aztreonam, Imipenem/Cilastatin, Linezolid

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

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

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

Other events included nonsignificant differences in abscess (1.8% vs 1.6%) and infections, including wound infections (1.7% vs 1.1%) for TYGACIL vs comparators, respectively.

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

Discontinuation from 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 (LD<sub>50</sub>) was 124 mg/kg in males and 98 mg/kg in females. In rats, the estimated LD<sub>50</sub> was 106 mg/kg for both sexes. Tigecycline is not removed in significant quantities by hemodialysis.

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

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**Expanded broad-spectrum  
coverage is on your side<sup>1\*†</sup>**

**Gram positives**  
**Gram negatives**  
**Anaerobes**  
**Resistant gram positives**  
**Resistant gram negatives**



\* The clinical significance of in vitro activity is unknown.

† TYGACIL does not cover *Pseudomonas aeruginosa*.

### **TYGACIL is indicated for**

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

### **Important Safety Information**

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

Please see brief summary of Prescribing Information on adjacent page.

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

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**Tygacil**<sup>®</sup>  
tigecycline IV

**Expanded coverage for resistant pathogens**