

## New clinical programs launched

### *Minimally invasive surgery patients heal faster, use fewer pain killers, pay less*

The Minimally Invasive Surgical Center at Froedtert Hospital — one of the first in the U.S. — was recently initiated to increase alternatives to traditional surgery.

#### **Techniques pioneered at MCW**

Many minimally invasive surgical techniques have been pioneered at the College, such as the laparoscopic highly selective vagotomy — an extremely precise ulcer operation. “Minimally invasive surgery is truly the phenomenon of the century in general surgery,” said Constantine Frantzides, MD,

PhD, FACS, Minimally Invasive Surgical Center Director.

#### **Study shows benefits**

In a recent College study of 65 patients with severe heartburn, indigestion and other gastroesophageal reflux disease symptoms, laparoscopic techniques were compared to conventional abdominal surgery. Conventional surgery patients were hospitalized for an average of nine days, compared to two days for those who had minimally invasive surgery. Laparoscopic patients also used a

minimal amount of post-surgery pain killers — evidence of less pain.

Complication rates were 2.7 percent for laparoscopic patients and 17.2 percent for conventional surgery patients.

A recent cost analysis for minimally invasive surgeries and conventional surgeries showed an average \$4,000 savings per surgery. Patients who had minimally invasive surgery paid an average of \$17,492 per surgery compared to \$21,514 for conventional surgery.

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### *Comprehensive Stroke Center is first of its kind in Southeastern Wisconsin*

The Medical College and Froedtert Hospital have developed a Stroke Center — the first of its kind in Southeastern Wisconsin to offer an integrated approach to stroke prevention, diagnosis, treatment and research.

The Stroke Center includes physicians from Neurology, Neurosurgery, Emergency Medicine, Vascular Surgery, Radiology, Internal Medicine, Family and Community

Medicine, and Physical Medicine and Rehabilitation. A dedicated Stroke Coordinator will serve as a liaison with patients and the physician team.

A team approach will be used to provide cost-effective, improved patient care and improve the CPG's position in the health care marketplace.

Both the Medical College and Froedtert have been leaders in the neurosciences. The Stroke Center

will further demonstrate the expertise available.

The Stroke Center will serve as a regional referral center for physicians and patients.

Key aspects of the Stroke Center include:

#### **Prevention**

The Stroke Coordinator will develop programming for

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## HCFA liberalizes investigational devices rules

A new regulation that changes Medicare payment for some investigational devices and associated services went into effect Nov. 1. Comments can be registered until Dec. 6.

Under the regulation, the FDA will assign all devices granted an investigational device exemption (IDE) into Category A (experimental/investigational devices) or Category B (non-experimental/investigational). A Category A device "is an innovative device ... for which the 'absolute risk' of the device" has not been established (initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device can be safe and effective. All devices in Category A (and services related to the devices) are considered non-covered. No carrier in any state will be allowed to pay for the device or services related to it.

Category B devices are those "for which the incremental risk is the primary risk in question" (underlying questions of safety and effectiveness of that device are resolved). Category B is also used for devices that are considered safe and effective because other manufacturers have obtained FDA approval for that type of device. HCFA estimates that the "great majority" of FDA-approved clinical trials of devices will fall into Category B.

There will be coverage and reimbursement for devices in Category B, provided that other requirements are met. HCFA states that "to the extent Medicare covers a non-experimental/investigational (Category B) device, coverage is limited to beneficiaries meeting the protocol requirements." Further, coverage continues only as long as the device meets the criteria that led to its designation of Category B. Coverage for Category B devices also depends on the medical necessity and appropriateness of the device for a particular patient. Payment will be limited to the amount that would have

been paid for another FDA approved device currently used for the same medical purpose.

Once the FDA has categorized a device, it will notify HCFA and the device's sponsor of the decision. If the sponsor objects to a device being placed in Category A, the sponsor may request that the FDA re-evaluate its decision. If the FDA does not change its decision, the sponsor may request review by HCFA. Following HCFA review, no further reviews will be available to the sponsor.

By now the FDA expected to have categorized the 1200 devices currently in clinical trials under IDEs. As subsequent IDE applications are approved, devices will automatically be categorized. HCFA will publish quarterly lists of Category A and Category B devices in the Federal Register.

If you have any questions, please contact Quin Buechner at 456-4544.

## Minimally invasive surgery

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The Center will integrate all specialties providing minimally invasive surgery:

### General Surgery

Alonzo Walker, MD, FACS  
William Schulte, MD, FACS

### Cardiothoracic Surgery

George Haasler, MD  
Michael Bousamra, MD

### Obstetrics/Gynecology

Julianne Newcomer, MD  
James Aiman, MD

### Orthopaedic Surgery

Lee Riley, III, MD  
William Raasch, MD  
Howard An, MD

### Urology

Frank Begun, MD  
Mark Rozen, MD

The Center's goals are to:

- Provide patients with surgical options performed by multidisciplinary experts.
- Heighten patient awareness of minimally invasive options.

- Improve effectiveness of operating rooms, specifically with equipment and instruments needed for minimally invasive surgery.
- Promote the advantages of this service to patients, referring physicians and payors.
- Attract external research funds.

For a list of procedures performed at the Center or other information call Dr. Frantzides or Laura Haas, Administrative Assistant, at 454-5745.