

Technology Set to Alter Colonoscopy Practices

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In response to new technologies and expected decreases in reimbursement for “traditional” procedures, gastroenterologists “will need to change what they do, where they practice, and how they practice,” according to a report issued by the American Gastroenterological Association Institute’s Future Trends Committee.

Above all, computed tomographic colonography (CTC) “is likely to become an accepted colorectal cancer screening option within 3 years,” said the report, which was based on expert presentations at a conference convened last spring.

To maintain their practices, gastroenterologists will need to consider new services, which could include providing and interpreting CTC, obesity care, gastroenterological cancer treatment, and natural orifice transluminal endoscopic surgery.

Chronic or difficult-to-treat conditions, like hepatitis and motility and functional disorders, might also assume a bigger role in practice. Nurse-practitioners and physician assistants will likely play larger roles as gastroenterologists “embrace and act on the philosophy that the gastroenterologist is the leader and manager, and not necessarily the direct provider” of digestive disease care, according to the report (*Gastroenterology* 2006;131:1287-312).

Dr. Timothy C. Wang, who chaired the 10-member consensus development panel, said that CTC will likely be the first technology to take a share of colorectal cancer screening, but that members found it “difficult to predict what percentage of the screening market will shift to CTC.

“Further studies will likely show that CTC is comparable to optical colonoscopy in terms of sensitivity and specificity; however, other advances also may prove to detect polyps.” Also, gastroenterologists “should not completely cede colon imaging to radiologists,” said Dr. Wang, chief of the division of digestive and liver diseases at Columbia University, New York. Some gastroenterology groups have expressed interest in purchasing CT scanners, and the committee recommended that the American Gastroenterological Association (AGA) Institute develop training programs for CTC interpretation.

Gastroenterologists contacted for their perspectives on the report called the conclusions provocative but differed about whether the report is realistic or alarmist.

The report “is thorough and thought provoking ... and anything that the AGA Institute can do to raise the level of thought and discussion is laudable,” said Dr. Ronald Vender, professor of medicine at Yale University, New Haven, Conn. “I think the impact [of CTC and other changes] will be much less than they’re predicting,” he said, especially when considered from a cost-benefit perspective.

“Colonoscopy rates will probably go up rather than down,” commented Dr. James T. Frakes, professor of medicine at the University of Illinois, Rockford. “But even

it that’s not the case, gastroenterologists should always be looking for ways to improve and broaden their services,” he said.

“Colonoscopy has become the tail that’s wagged the dog,” Dr. John L. Petrini of Sansum Clinic in Santa Barbara, Calif., said. “It’s become a huge part of what we do, and I’m not sure it’s going to stay that way. ... But I don’t think that CTC is going to be the one that’s a keeper.”

Optical colonoscopy also is getting better, and lesions can be removed immediately in patients who are found to have adenomatous polyps during screening. Avoiding the need for a second procedure makes optical colonoscopy a cost-effective, attractive screening option, he said.

Many patients, said Dr. Douglas K. Rex, professor of medicine at Indiana University, Indianapolis, “will be disillusioned if they have a polyp and have to go on to have another test. ... Americans like effectiveness. There will be other effective devices, but it’s going to be hard for them to be as effective as colonoscopy.”

There also “hasn’t been adequate discussion or education of the public regarding the potential risks of radiation” associated with screening CTC, he added.

Technologies ranging from wireless capsule endoscopy to simplified endoscopes will allow generalists and even non-physician providers to perform colon surveillance. And over the long term, it will become possible to stratify cancer risk through serum-based proteomics, for example, and genetic or epigenetic markers, eliminating “unnecessary” colonoscopies, the committee said in its report.

One major challenge in CTC interpretation, however, is the presence of significant extracolonic findings in 4.5%-12% of procedures. Direct costs would rise rapidly if all CTCs must be reviewed by radiologists for extracolonic findings after a CTC-trained gastroenterologist has reviewed the colon, the report stated.

Gastroenterologists overall may modify their scope of practice by offering services that don’t require extensive retraining. Obesity care may already be too competitive a niche for gastroenterologists to claim, according to those interviewed for this article, but they largely agreed with the committee’s conclusion that obesity treatment is a “natural opportunity” for gastroenterologists, especially those who are willing to be part of a multidisciplinary team.

The demand for physicians to treat functional and motility disorders is likely to increase as the population ages. New tools on the horizon should expand and improve the evaluation and management of these disorders.

The same holds true for hepatitis C therapy. “We’re only at the tip of the iceberg in taking care of patients with hepatitis C and chronic liver disease,” Dr. Frakes said.

As the committee points out in its report, however, limited reimbursement for such labor-intensive cognitive services means that midlevel providers increasingly will need to be utilized to make services effective and financially viable. ■

POLICY & PRACTICE

Part D Battle Begins

As promised during the midterm elections, House Democrats began work immediately on tweaking Medicare’s Part D drug coverage. Rep. John Dingell (D-Mich.), with 189 colleagues, introduced H.R. 4, the Medicare Prescription Drug Price Negotiation Act of 2007. It would require the Health and Human Services department to negotiate prices with drug makers. The legislation was passed by the House in January by a vote of 255-170. Two Senators have taken up the cause—Harry Reid (D-Nev.) and Benjamin Cardin (D-Md.)—but it appears the Senate will take a more measured approach. The Senate Finance Committee held hearings Jan. 11 to investigate the impact of price negotiations. If enacted as initially written, the bill will have new prices go into effect for the plan year starting Jan. 1, 2008.

2007 Advocacy Agenda

Finding a permanent solution to how Medicare pays physicians is at the top of the agenda for both the American Medical Association and the American Academy of Family Physicians. Congress acted at the end of last year to stop a 5% Medicare pay cut from going into effect, but that was only a stopgap, according to the AMA. “This year we will work with Congress, the administration, and seniors to stop the 2008 Medicare cut and enact a more permanent solution to the flawed Medicare physician payment formula,” Dr. Cecil Wilson, AMA board chair, said in a statement. Both groups also plan to push this year for an expansion of health insurance coverage for the uninsured. Other top AMA priorities include reforming the medical liability system, closing health care gaps for minority patients, and preparing for and responding to public health emergencies.

Unique New Drugs on Decline

The Food and Drug Administration approved 18 new molecular entities last year, on par with the previous year, but close to a historic low. Throughout the 1980s and 1990s, the agency approved at least 20-30 NMEs annually. Among the 18 were 4 biologic therapies and 4 new vaccines. The paltry number of approvals and a Government Accountability Office report issued in December may point to a decline in new drug development, according to Rep. Henry Waxman (D-Calif.), Sen. Richard Durbin (D-Ill.), and Sen. Edward Kennedy (D-Mass.). The legislators requested the GAO report, which found that huge increases in drug industry research and development from 1993-2004 were not accompanied by a similar rise in new drug applications—especially for NMEs—to the FDA. From 1993-2004, research and development spending rose 147%; NME applications increased by only 7%. NME applications have declined especially since 1995. “These submission trends indicate that the productivity of research and development investments has declined,” the GAO report said. Over the same period, FDA has continued to approve most submissions, but the num-

ber approved overall has declined, GAO said.

FDA Panels Held Less Often

An advocacy group is charging that the FDA is holding outside advisory panel meetings less often than it did a decade ago. Public Citizen’s Health Research Group analyzed the 275 advisory committee meetings held from 1997 to 2006. In 1998 and 1999, almost half of approved NMEs were preceded by panel meetings; from 2000 to 2006, only 24% (35) of the 147 NMEs approved had a committee meeting first, according to Public Citizen’s letter in the Dec. 23 issue of *The Lancet*. The group also found that the FDA did not present its scientific opinion as a counterbalance to the drug maker’s presentation at 18%, or 49 of the 275 meetings. The FDA overruled the panel conclusions 28% of the time, “a figure higher than is generally assumed,” according to Public Citizen.

Cancer Care Time Costs Add Up

The cost of the time spent by cancer patients in fighting their illness amounted to about \$2.3 billion in 2005, according to a study in the January issue of the *Journal of the National Cancer Institute*. Researchers analyzed the time that cancer patients spent getting to and from appointments, waiting for care, consulting with physicians, and undergoing treatments. They valued that time at \$15.23 per hour, the median U.S. wage rate in 2002. The researchers used data from the Surveillance, Epidemiology, and End Results-Medicare database to find the net patient time costs associated with cancer care for 11 common tumors. They analyzed records for 767,010 patients who were initially diagnosed during 1973-1999 and were 65 years or older during the study observation period of 1995-2001, and included 1,145,159 matched controls. The net patient time costs associated with medical care during the first 12 months after diagnosis were lowest for melanoma (\$271) and prostate cancers (\$842) and highest for gastric (\$5,348) and ovarian (\$5,605) cancers. In most cases, hospital stays accounted for the greatest net time costs.

New Osteoporosis Health Claims

FDA officials are proposing to allow a new health claim stating that foods and dietary supplements containing both calcium and vitamin D have the potential to reduce the risk of osteoporosis. Currently, only calcium supplements may claim they have the potential to do so. The new proposal also would broaden the health claim that can be made for products containing calcium by dropping references to sex, race, and age since the benefits apply to both sexes and all ages and races. The change is being proposed based on an FDA review of the scientific evidence, including the 2004 Surgeon General’s report on bone health and osteoporosis.

—From staff reports