

There is no evidence that the high-risk feature of node positivity after chemotherapy should be used to deviate from completing perioperative chemotherapy. Although the fact that less than 50% of patients in the MAGIC study received all six cycles of chemotherapy suggests that a benefit may be obtained without receiving all doses of chemotherapy, there is no analysis to justify abandoning the perioperative strategy that we initiated in the treatment of our patient.

Furthermore, although node positivity increases the risk of locoregional recurrence, distant metastasis probably remains the dominant pattern of treatment failure.<sup>3,4</sup> Thus, we were hesitant to abandon a level 1 recommendation with demonstrated metastatic benefit<sup>1</sup> for an approach with no metastatic effect.<sup>2,4</sup> The role of chemoradiation remains unclear, in terms of both necessity and timing, and we look forward to the results

of the Adjuvant Chemotherapy or Chemoradiotherapy in Resectable Gastric Cancer (CRITICS) study (ClinicalTrials.gov number, NCT00407186) to clarify this issue.

Theodore S. Hong, M.D.  
Eunice L. Kwak, M.D., Ph.D.

Massachusetts General Hospital  
Boston, MA

1. Cunningham D, Allum WH, Stenning SP, et al. Perioperative chemotherapy versus surgery alone for resectable gastroesophageal cancer. *N Engl J Med* 2006;355:11-20.
2. Macdonald JS, Smalley SR, Benedetti J, et al. Chemoradiotherapy after surgery compared with surgery alone for adenocarcinoma of the stomach or gastroesophageal junction. *N Engl J Med* 2001;345:725-30.
3. Yoo CH, Noh SH, Shin DW, Choi SH, Min JS. Recurrence following curative resection for gastric carcinoma. *Br J Surg* 2000;87:236-42.
4. Kim S, Lim DH, Lee J, et al. An observational study suggesting clinical benefit for adjuvant postoperative chemoradiation in a population of over 500 cases after gastric resection with D2 nodal dissection for adenocarcinoma of the stomach. *Int J Radiat Oncol Biol Phys* 2005;63:1279-85.

## CMS's Landmark Decision on CT Colonography

**TO THE EDITOR:** Although evidence-based, cost-effective medicine is an important concept and a goal to strive for, these concepts must be applied in a way that is cognizant of the needs of real-world patients. The decision by the Centers for Medicare and Medicaid Services (CMS) to deny Medicare beneficiaries access to computed tomographic (CT) colonography, as discussed in the Perspective article by Dhruva et al. (June 25 issue),<sup>1</sup> will adversely affect tens of thousands of America's seniors. Contrary to statements made by the CMS, data that are specific to a population over the age of 65 years exist and show that CT colonography is clinically effective and cost-effective for this population subgroup.<sup>2</sup> These data were presented to the CMS before its recent ruling. The CMS also argues that access to CT colonography does not guarantee increased screening rates, yet the National Naval Medical Center has seen a 70% increase in colon screening since CT colonography was offered as an option. Respected medical professionals and associations, including the American Cancer Society, stand behind the value of CT colonography for the Medicare population,<sup>3</sup> and 97% of the public comments on this decision favored coverage.<sup>4</sup> Beyond this CMS decision, there are potentially serious repercussions associated with the authors' proposed rigid and unre-

alistic data requirements. Placing such requirements on all coverage decisions would severely curtail patients' access to lifesaving technologies.

Brooks D. Cash, M.D.

Walter Reed National Military Medical Center  
Bethesda, MD

The views expressed in this letter are those of the author and do not necessarily reflect the official policy or position of the Department of the Navy, the Department of Defense, or the U.S. government.

Dr. Cash reports having served as the director of a continuing-medical-education course sponsored by the American Gastroenterological Association to introduce gastroenterologists to the use of CT colonography and having served as an uncompensated consultant to Colon Health Centers of America. No other potential conflict of interest relevant to this letter was reported.

1. Dhruva SS, Phurrough SE, Salive ME, Redberg RF. CMS's landmark decision on CT colonography — examining the relevant data. *N Engl J Med* 2009;360:2699-701.
2. Pickhardt PJ, Hassan C, Laghi A, Kim DH. CT colonography to screen for colorectal cancer and the aortic aneurysm in the Medicare population: cost-effectiveness analysis. *AJR Am J Roentgenol* 2009;192:1332-40.
3. Levin B, Lieberman DA, McFarland B, et al. Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008: a joint guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. *CA Cancer J Clin* 2008;58:130-60.
4. Public comments for screening computed tomography colonography (CTC) for colorectal cancer (CAG-00396N). (Accessed September 3, 2009, at [http://www.cms.hhs.gov/mcd/viewpubliccomments.asp?nca\\_id=220&rangebegin=02%5F11%5F2009&rangeend=03%5F13%5F2009](http://www.cms.hhs.gov/mcd/viewpubliccomments.asp?nca_id=220&rangebegin=02%5F11%5F2009&rangeend=03%5F13%5F2009).)

**THE AUTHORS REPLY:** The analysis of CT colonography that Cash cites used a model that was validated in younger adult populations,<sup>1</sup> and the CMS's final decision memo noted that this model had been neither well tested nor previously used.<sup>2</sup> Furthermore, the memo acknowledged that this analysis combined outcomes from screening for colorectal cancer and abdominal aortic aneurysm. The Preventive Services Task Force recommends performing such screening only once in men who are 65 to 75 years of age and who have a history of smoking; the task force does not recommend such screening in women.<sup>3</sup> Thus, less than one sixth of Medicare beneficiaries would be expected to have any benefit. Although the CMS reviewed other data showing that CT colonography is cost-effective only at reimbursement levels that are much lower than current rates,<sup>4</sup> its decision was based primarily on the inadequacy of the evidence of benefit for this test and not its cost-effectiveness.<sup>2</sup>

The CMS covers what is "reasonable and necessary."<sup>5</sup> It would be irresponsible to cover services for which there are no clinical data show-

ing benefits among its beneficiaries, since such services may be associated with harm — from additional unnecessary testing and procedures, anxiety about "incidentalomas," and additional diagnoses of uncertain clinical implications. It is essential that the CMS make decisions on the basis of high-quality clinical trials that reflect the effects on its elderly population.

Sanket S. Dhruva, M.D.

Rita F. Redberg, M.D.

University of California, San Francisco  
San Francisco, CA

1. Pickhardt PJ, Hassan C, Laghi A, Kim DH. CT colonography to screen for colorectal cancer and aortic aneurysm in the Medicare population: cost-effectiveness analysis. *AJR Am J Roentgenol* 2009;192:1332-40.
2. Centers for Medicare & Medicaid Services. Decision memo for screening computed tomography colonography (CTC) for colorectal cancer (CAG-00396N). (Accessed September 3, 2009, at <https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=220>.)
3. Fleming C, Whitlock EP, Beil TL, Lederle FA. Screening for abdominal aortic aneurysm: a best-evidence systematic review for the U.S. Preventive Services Task Force. *Ann Intern Med* 2005; 142:203-11.
4. Vijan S, Hwang I, Inadomi J, et al. The cost-effectiveness of CT colonography in screening for colorectal neoplasia. *Am J Gastroenterol* 2007;102:380-90.
5. Social Security Act, § 1862, 42 U.S.C. 1395y(a)(1)(A)(1965).

## Hypersensitivity to Generic Drugs with Soybean Oil

**TO THE EDITOR:** The use of generic drugs has increased in the European Union in recent years. The main regulatory requirement for these products is that they be bioequivalent to the branded drug. However excipients such as soybean oil can be a cause of hypersensitivity reactions<sup>1,2</sup>; the protein content of fully refined seed oils should be suspected in the case of allergic reactions.<sup>3</sup>

We report on two women (58 and 81 years of age) who presented with anaphylaxis a few minutes after ingesting a generic omeprazole capsule.<sup>4,5</sup> In both women the systolic blood pressure fell to less than 90, and both had sudden onset of difficulty breathing. Both women had previously taken nongeneric omeprazole and had not had a reaction. The generic drug that each of the women took contained approved soybean oil as an excipient. After the women provided written informed consent, skin-prick tests and soybean-specific IgE assays (ImmunoCAP assay, Phadia) were performed. Patient 1 had a wheal diameter of 20 mm after the injection of soybean extract (ALK-Abelló) and a wheal diameter of 14 mm after the injection of the powder contained in a

capsule of generic omeprazole diluted 1:10 in 0.9% saline solution; her soybean-specific IgE level was 9.01 kU per liter. Patient 2 had a wheal diameter of 14 mm after the injection of soybean extract and of 12 mm after the injection of the powder contained in generic omeprazole; her soybean-specific IgE level was 23 kU per liter.

The skin-prick tests for nongeneric omeprazole were negative in the 2 patients and in 10 controls without atopy. The skin-prick tests for generic omeprazole extract were positive in five patients who were sensitized to soybean (wheal diameter, 10 mm).

An IgE dot blot (Bio-Rad) was performed on the powder contained in generic omeprazole capsules from two manufacturers, on the powder in nongeneric omeprazole capsules reconstituted in 20% ethanol and 80% water, on soybean extract, and on soybean oil. The serum from the two patients showed a positive response to the generic omeprazole produced by each of the two manufacturers, to soybean oil, and to soybean extract but a negative reaction to diluent control wells and to nongeneric omeprazole. The serum