

they try to plan for a shortage of primary care doctors that will probably get worse before it gets better. Kaiser Permanente Colorado is trying to make its EMR system easier to use, and it recently began testing Sinsky's pre-appointment planning strategy. Said internist Michael Chase, the organization's associate medical

director for quality, "We're all wrestling with the same issues and looking for solutions."

No potential conflict of interest relevant to this article was reported.

Dr. Okie is a national correspondent for the *Journal*.

1. Sinsky CA. Improving office practice: working smarter, not harder. In: Family practice management. Leawood, KS: American

Academy of Family Physicians, November/December 2006;28-34. (Accessed November 6, 2008, at <http://www.aafp.org/fpm/20061100/28impr.html>.)

2. Scott JC, Conner DA, Venohr I, et al. Effectiveness of a group outpatient visit model for chronically ill older health maintenance organization members: a 2-year randomized trial of the cooperative health care clinic. *J Am Geriatr Soc* 2004;52:1463-70.

Copyright © 2008 Massachusetts Medical Society.

## Pay Now, Benefits May Follow — The Case of Cardiac Computed Tomographic Angiography

Rita F. Redberg, M.D., and Judith Walsh, M.D., M.P.H.

Related article, p. 2324

The average American might assume that new medical procedures are proved beneficial before insurers pay for them. In reality, many new procedures are paid for even with no persuasive evidence of benefit. One consequence is health care expenditures that are growing substantially faster than the economy and a Medicare program projected to become insolvent in the next decade. Increased use of technology is the largest driver of this growth; its effect dwarfs that of the aging of our population. We should be able to curb these costs and increase value in health care by taking an evidence-based approach to insurance coverage — but our political environment and medical culture undermine efforts to do so.

Medicare, under current law, covers treatments that are "reasonable and necessary." About 10 to 18 times per year, the Centers for Medicare and Medicaid Services (CMS) issues a national determination for coverage of a new procedure or device, through

a process that includes an evidence review. Most Medicare coverage decisions, however, are made by regional carriers, through local coverage determinations, with little or no formal review of the evidence. Moreover, even a formal technology assessment is no guarantee of an evidence-based coverage decision, since review findings are not always followed. Cardiac computed tomographic (CT) angiography is a recent example. Cardiac CT angiography is performed with the use of a multidetector or multislice CT scanner. During scanning, patients receive a contrast agent intravenously, often along with beta-blockers that slow the heart rate to facilitate data acquisition. The scan lasts about 10 minutes and produces high-resolution, three-dimensional color pictures of the heart and coronary arteries (see image).

In May 2006, the CMS convened a meeting of the Medicare Coverage Advisory Committee (now called the Medicare Evidence Development and Coverage

Advisory Committee [MedCAC]) to review cardiac CT angiography. MedCAC found that the relevant data were limited to small, single-center studies of selected populations and did not demonstrate a benefit with regard to outcomes. But after a day's worth of enthusiastic testimony from radiologists, cardiologists, and representatives of professional societies, the CMS declined to issue a national coverage decision. Proponents then vigorously lobbied the regional insurers, advocating adoption of a favorable local coverage determination. Within months, Medicare was covering cardiac CT angiography in all 50 states.

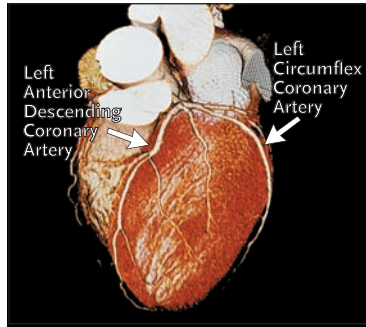
A year later, alarmed at the costs of exploding use of cardiac CT angiography, CMS announced a proposed national coverage analysis, stating that the "evidence is inadequate to conclude that cardiac computed tomographic angiography (CTA) is reasonable and necessary . . . for the diagnosis of . . . coronary artery disease . . . ; however, the agen-

cy believes the evidence is promising for two clinical indications and that coverage with evidence development . . . would be appropriate for these indications.”<sup>21</sup> The CMS received 670 comments on this proposed analysis, 200 of which were identical form letters. The comments overwhelmingly opposed the use of “coverage with evidence development,” often arguing that “CT scanning of every body part (except for the heart) is already approved for funding, without ever going through a [coverage with evidence development] process.”

Once again, enthusiasm for unfettered use of new technology prevailed: in March 2008, the CMS withdrew its proposal for developing evidence. It found that “there is uncertainty regarding any potential health benefits or patient management alterations from including coronary CTA in the diagnostic workup of patients who may have [coronary artery disease]. No adequately powered study has established that improved health outcomes can be causally attributed to coronary CTA for any well-defined clinical indication, and the body of evidence is of overall limited quality and limited applicability to Medicare patients with typical comorbidities in community practice.” Nevertheless, because of the commenters’ overwhelming opposition to its proposal, the CMS decided that coverage of cardiac CT angiography “shall remain at local [Medicare] contractor discretion, and no national coverage determination . . . is appropriate at this time.”<sup>22</sup>

Ironically, a key argument by coverage proponents is that Medicare covers other imaging procedures with even less evidence of benefit. In other words, justifi-

cation for covering this unproven technology lies mainly in Medicare’s history of covering unproven technologies. Such is the legacy of “reasonable and necessary.”



**A Cardiac Computed Tomographic Angiogram.**

Some proponents argue that diagnostic cardiac CT angiography should not be held to the same outcome standard as therapeutic procedures, since diagnostic procedures are not directly responsible for improved outcomes. However, the value of diagnostic tests lies in whether, by leading to a more appropriate choice of therapy, they ultimately result in better outcomes. To date, the explosive growth of imaging has not been associated with any improvement in patients’ outcomes, and it is difficult to justify imaging scans without knowing how the additional information they provide will improve the care patients receive.

The article on 64-row cardiac CT angiography by Miller et al. in this issue of the *Journal* (pages 2324–2336) exemplifies current research in the field. Although this study was carefully done and provides more data on diagnostic accuracy, it does not advance our knowledge of the appropriate use and possible benefits of the technology. Miller et al. sought to identify “patients with suspected coronary artery disease who

should be referred for conventional coronary angiography.” However, because all patients received both cardiac CT angiography and conventional coronary angiography and no data on outcomes are reported, the study does not answer this important question. With respect to risks, moreover, the authors state that the new technology compares favorably to conventional coronary angiography, even though in their study the radiation exposure with cardiac CT angiography was significantly greater than that with conventional coronary angiography. In any event, the authors conclude that cardiac CT angiography is not accurate enough to replace the older technology for patients with chest pain, adding to the body of research failing to prove a benefit of the new procedure.

The use of cardiac imaging has been increasing by 26% per year, despite a lack of evidence of outcome benefit. Without such evidence, a high-resolution cardiac CT angiographic image of the heart is just another pretty picture. In fact, there is some evidence that cardiac imaging leads to additional unnecessary procedures, such as additional diagnostic testing, revascularizations, or biopsies for “incidental findings.” Worse, cardiac CT angiographic equipment bombards patients with radiation many orders of magnitude greater than that of traditional radiographs — posing a risk that has never been studied in depth. Brenner and Hall<sup>3</sup> estimated that 1.5 to 2.0% of all cases of cancers in the United States may be attributable to CT radiation.

Obstacles to implementing an evidence-based approach include our faith in technology, the mistaken belief that tests can pre-

vent heart attacks, the influence of lobbying on CMS policy, a fee-for-service system that often pays for procedures without sufficient oversight regarding their appropriateness, and the lack of consensus that evidence of a benefit of a technique should be a prerequisite to its widespread use. Of these obstacles, perhaps the most detrimental is the last: the failure of providers to recognize the advantages of, and advocate for, an evidence-based approach to determining coverage.

The \$2.1 trillion the United States spends annually on health care yields a poor return on its investment. The 2008 National Scorecard on U.S. Health System Performance evaluated 37 performance indicators and gave the United States a near-failing score of 65%.<sup>4</sup> Rapidly increasing health care costs, which have affected

all aspects of the economy, have become a top domestic-policy concern. Yet our fee-for-service system encourages the use of expensive but unproven medical devices by generously reimbursing for new procedures without regard to their benefit. Although randomized clinical trials are expensive and time-consuming, these costs must be weighed against those of procedures (and downstream tests) that may have little or no benefit or, worse, harmful consequences. The continued unrestrained use of new technology, in the absence of evidence-based criteria, portends a bleak future for Medicare and our health care system.

Dr. Redberg reports receiving grant support from the Blue Shield of California Foundation. No other potential conflict of interest relevant to this article was reported.

Dr. Redberg is a professor of medicine at the University of California, San Francisco (UCSF), School of Medicine and director of

women's cardiovascular services at the UCSF Medical Center — both in San Francisco. Dr. Walsh is a professor of clinical medicine and epidemiology at the UCSF School of Medicine.

1. Proposed decision memo for computed tomographic angiography (CAG-00385N). Baltimore: Centers for Medicare & Medicaid Services, 2007. (Accessed November 6, 2008, at <http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?from2=viewdraftdecisionmemo.asp&id=206&>.)

2. Decision memo for computed tomographic angiography (CAG-00385N). In: Medicare national coverage determinations manual. Sect. 220.1F. Baltimore: Centers for Medicare & Medicaid Services, March 12, 2008. (CMS publication 100-03.) (Accessed November 6, 2008, at <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=206>.)

3. Brenner DJ, Hall EJ. Computed tomography — an increasing source of radiation exposure. *N Engl J Med* 2007;357:2277-84.

4. Why not the best? Results from the National Scorecard on U.S. Health System Performance. New York: Commonwealth Fund Commission on a High Performance Health System, 2008. (Publication no. 1150.) (Accessed November 6, 2008, at [http://www.commonwealthfund.org/publications/publications\\_show.htm?doc\\_id=692682](http://www.commonwealthfund.org/publications/publications_show.htm?doc_id=692682).)

Copyright © 2008 Massachusetts Medical Society.