# Evidence Base Is Lacking for Medicare Coverage Decisions

BY LEANNE SULLIVAN
*Associate Editor*

Data reviewed by the Centers for Medicaid and Medicare Services to inform Medicare treatment coverage decisions reflect populations that are significantly different from the Medicare beneficiary population, a recent analysis has shown.

In 1998, the CMS established a panel of physicians and other professionals to review the evidence base before the agency makes national Medicare coverage decisions. The independent panel, now called the Medicare Evidence Development and Coverage Advisory Committee (MedCAC), reviews the literature described in a technology assessment and votes on the evidence to determine the health benefit of the medical procedure or device, wrote Sanket S. Dhruva and Dr. Rita F. Redberg, both of the University of California, San Francisco, which, along with the Robert Wood Johnson Foundation, provided support for the study. Dr. Redberg is a member of MedCAC, but had no financial conflicts of interest to disclose.

To examine whether the data used by MedCAC was generalizable to the Medicare population, Mr. Dhruva and Dr. Redberg looked at all six MedCAC decisions involving a cardiovascular product or service and analyzed the sample size, participant demographics, inclusion criteria, study location, and outcome stratification of the relevant technology assessments. The data in the technology assessments used for these six decisions included 141 peer-reviewed reports and 40,009 patients (Arch. Intern. Med. 2008;168:136-40).

The researchers concluded that the data used by MedCAC as evidence on which to base national treatment coverage decisions "are derived from populations that differ significantly from the Medicare beneficiary population in terms of age, sex, country of residence, and comorbid conditions." The trial populations are "younger, healthier, male, non-U.S. populations," reflecting a "persistent underrepresentation of women and elderly people" in clinical trials in general, the authors noted.

"Closer linkage of evidence to coverage would promote better value and improved outcomes" for Medicare patients, the researchers concluded. ■



## POLICY & PRACTICE

### CVS Clinics to Open in Mass.

Immediately after Massachusetts regulators approved store-based medical clinics last month, CVS Corp. said it would open as many as 30 in-store MinuteClinics in the state over the next year. CVS said that it plans to have 100-120 clinics in stores across the state within 3-5 years. The nurse practitioners staffing the clinics will treat minor problems such as sore throats and ear infections, but will refer patients with more serious conditions to a physician or an emergency department. The Massachusetts Medical Society, along with organizations representing family physicians, pediatricians, hospitals, and community health centers, raised concerns about retail medical clinics as the state's Department of Public Health considered whether to allow them, according to the medical society. Dr. Bruce Auerbach, MMS president, said in a statement that the department's final regulations seemed to address many of the medical community's biggest concerns about the clinics, including sanitation and infection control, fragmentation of care, and physician oversight.

### ED Waits Increase

Waits for emergency care are getting longer each year, with waits for patients who have acute myocardial infarction rising by 150%, according to a study by the Cambridge Health Alliance and Harvard Medical School. The study, which analyzed the time between a patient's arrival in the emergency department and when that patient was first were seen by a physician, found that the increasing delays affected patients from all racial and ethnic groups, regardless of health insurance status. Between 1997 and 2004, waits increased 36% for all patients (from 22 to 30 minutes, on average). But for those classified by a triage nurse as needing immediate attention, waits increased by 40% (from 10 to 14 minutes). Patients with acute myocardial infarction waited only 8 minutes in 1997, but waited 20 minutes on average in 2004, and one-quarter of these patients waited 50 minutes or more in 2004 before seeing a physician. The study, published online last month in Health Affairs, analyzed more than 90,000 emergency department visits.

### Pandemic Preparation Not Enough

The United States, its international partners, and the pharmaceutical industry are investing substantial resources to address the availability and efficacy of antivirals and vaccines in the case of an influenza pandemic, the U.S. Government Accountability Office said in a report. But antivirals and vaccines might not be very effective in the case of such a pandemic, the GAO said. For effective antiviral use, health authorities must be able to detect a pandemic influenza strain quickly; effectiveness could be limited if antivirals are used more than 48 hours after the onset of symptoms, or by the emergence of strains resistant to antivirals. And, it could take up to 23 weeks to manufacture a pandemic vaccine, so such vaccines are likely to play "little or no role" in efforts to forestall a pandemic in its initial phases, the GAO said in its report, "Influenza Pandemic."

### Blues Launch Campaign

The Blue Cross and Blue Shield Association last month unveiled a 5-point plan for building on the current employer-based health insurance system to improve quality, rein in costs, and provide universal coverage. The plan would create an independent institute to support research comparing the relative effectiveness of different medical treatments; change incentives so that providers are rewarded for delivering high-quality, coordinated care, especially for those with chronic illnesses; empower consumers and providers with personal health records and cost data on medical services; promote healthy lifestyles to prevent and manage chronic illness; and foster public-private solutions to cover the uninsured. For each of the five action steps, the proposal outlines what Blues plans are doing in their local communities, and lists the necessary stages for implementing the steps nationwide. The BCBSA said that it and its 39 member plans will promote the plan in a multifaceted campaign this year.

### Docs Mistrust Error Report Systems

U.S. physicians are willing to report medical errors but don't trust the current error reporting systems, according to a study in the January/February issue of Health Affairs. Between July 2003 and March 2004, researchers surveyed more than 1,000 physicians in rural and urban areas of Missouri and Washington state. They found that because of their mistrust of current systems, most physicians rely on informal discussion with colleagues as a way to report and share information about errors. Most of the physicians also reported that they had been involved in an error—56% with a serious error, 74% with a minor error, and 66% with a "near miss." When asked what would increase their willingness to formally report errors, 88% of the respondents said they wanted information to be kept confidential and nondiscoverable, 85% wanted evidence that error information would be used for system improvements, and 53% said they wanted review activities confined to their department. "These findings shed light on an important question—how to create error-reporting programs that will encourage clinician participation," said Dr. Carolyn M. Clancy, director of the Agency for Healthcare Research and Quality, which funded the study. "Physicians say they want to learn from errors that take place in their institution. We need to build on that willingness with error-reporting programs that encourage their participation."

—Jane Anderson