Medicare Panel Debates Genetic Test Coverage

BY JOYCE FRIEDEN

BALTIMORE — If Medicare pays for genetic tests, what criteria should it use to decide which to cover?

That was one of the questions tackled by a Medicare Evidence Development and Coverage Advisory Committee panel at a May meeting. The 17-member panel included an ethicist, a patient advocate, representatives from the insurance and genetic-testing industries, and experts in cancer, ophthalmology, and cardiology.

Panel members heard presentations on various aspects of genetic testing. Dr. W. Gregory Feero, senior adviser to the director of genomic medicine at the National Human Genome Research Institute, argued that a good family history was vital to deciding which patients should receive particular genetic tests. "Family history is still the cheapest, most time-tested way to get an idea of disease risk," he said. "It also helps you understand family relationships and understand patients' concerns."

Although several new practice guidelines call on physicians to collect family histories, "family history collection by primary care clinicians is actually quite poor," said Dr. Feero, a board-certified family physician. "I would argue that it's going to get worse with [the advent of] electronic health records, as most systems are not well set up to enable clinicians to collect family health information."

The Centers for Medicare and Medicaid Services seems to be conflicted on the genetic-testing issue, including its relationship to family history, he continued. On the one hand, at a meeting of the Secretary's Advisory Committee on Genetics, Health, and Society in March, Dr. Barry Straube, director of CMS's Office of Clinical Standards and Quality, said that Medicare does not cover genetic tests based on family history alone. "In the year 2009, [Medicare] may need to rethink this," Dr. Feero said.

On the other hand, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) allows Medicare to consider covering diagnostic tests, as long as the test is reasonable and necessary and has been given a grade A or B recommendation from the U.S. Preventive Services Task Force, Dr. Feero noted. Currently, the only genetic test addressed by the USPSTF is the test for the BRCA1 or BRCA2 genetic mutations that increase the risk of breast cancer; however, the task force's guidance recommends only counseling about the test, and does not address how to decide whether the test should be given.

A panel member asked Dr. Feero if using family history to determine whether a beneficiary needs a genetic test would mean that the family history itself becomes the screening test. "That is why I [support] the idea of having a [procedure] code for family history," Dr. Feero replied, adding that family history can mean different things in different contexts.

Panel members also heard from fellow panelist Dr. Steven Teutsch, chief science officer of the Los Angeles County Public Health Department. Dr. Teutsch is a member of the EGAPP (Evaluation of Genomic Applications in Practice and Prevention) working group, an independent body organized in 2004 by the Centers for Disease Control and Prevention to provide guidance on the appropriate use of genetic tests in clinical practice.

"At the end of the day, the question is whether genetic tests can modify outcomes," he said. Dr. Teutsch also urged panel members to consider the potential harm caused by some of these tests, including labeling, anxiety, additional testing, and false reassurance from negative tests.

"For preventive applications for genomic tests, the bar should be high" for their use, he said. "We want to screen for something important [and] common, and [something] that you can do something about."

During the public participation section of the meeting, Dr. Richard Wenstrup, chief medical officer of Myriad Genetics Inc., noted that guidelines on hereditary breast and ovarian cancer from the National Comprehensive Cancer Network recommend performing genetic testing on high-risk individuals.

He also said that an analysis of his company's own data for 2000-2009 showed that 5.6% of patients with deleterious mutations developed cancer after age 65. "It's presumable that if they had been identified and tested before developing the cancer, they could have taken preventive measures to reduce their risk," he said.

Panel member Dr. Neil Holtzman, professor of public health at Johns Hopkins University in Baltimore, said that there had been confusion among some speakers about the definition of screening. He noted that a panel convened by the National Academy of Sciences during the 1970s had defined genetic screening as "a search in the population."

"A number of speakers have concluded that [in] individuals who have been identified through family history but who are asymptomatic, availability or use of [genetic] tests is defined as screening," Dr. Holtzman said. "I don't think that kind of testing is screening. It would save a lot of confusion if we defined screening as a search in the population … and not in a high-risk situation where there's a family history."

Dr. Marcel Salive, director of the division of medical and surgical services within CMS's coverage and analysis group, said he agreed with Dr. Holtzman. "If we want to discuss how can we cover genetic tests for other than diagnostic purposes, we're going to have to discuss it here as a preventive service," he said. "Can we change things in the future and recognize things differently? Sure. Congress just gave us this authority last year, and they may change it in the future, but currently the only way to cover this type of testing is as a preventive service." ■

Leaders Meet With Obama

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and manage chronic disease more effectively.

► Implementing proven prevention strategies.

► Making common-sense improvements in care delivery, health information technology, workforce development, and regulatory reforms.

Dr. Joseph Flood, a member of the American College of Rheumatology's board of directors, said he agreed that liability reform would help cut health care costs. "There are a lot of tests people do because they don't want to miss that one-in-a-million chance of there being something more than their intuition and their skills in physical diagnosis and history taking would lead them to believe."

As to whether the meeting accomplished anything, "it's hard for us to say," added Dr. Flood of Ohio State University in Columbus. "I certainly trust the president; if he thinks it's a watershed event, I think he can make it be that. But you know, the $2 trillion reduction over 10 years, I don't know that we're going to get there."

The American Medical Association told the president that although evidence-based guidelines will help reduce costs, the reductions could be enhanced if physicians had more liability protection. "If everyone who walks into the emergency room gets an MRI for a headache, it's a costly procedure," AMA president-elect J. James Rohack said in an interview. "We know that in some areas of the country [the test has] been done, because people sued when they didn't get the test. If we create scientifically based guidelines that say not everyone needs to have the MRI for a headache, physicians have got to have liability protection so they don't get sued if they follow that guideline."

Dr. Rohack said he felt the president heard what the AMA was conveying. "Clearly, the message of [defensive medicine's] costing dollars in the health care system was received, as was the recognition that prior attempts at tort liability [reform] by just creating global caps hasn't been successful. We are going to have to work at other creative ways of achieving the goal."

The president called the White House meeting historic. "[This is] a watershed event in the long and elusive quest for health care reform," he said after the gathering. "And as these groups take the steps they are outlining, and as we work with Congress on health care reform legislation, my administration will continue working to reduce health care costs to achieve similar savings."

Reaction to the meeting varied.

"If the savings described today truly occur, this may be one of the most significant developments in promoting meaningful health care reform," Ron Pollack, executive director of Families USA, a liberal consumer health organization, said in a statement. "These savings would cut projected health care costs for families and businesses, and they would enable adequate subsidies to be offered so that everyone has access to high-quality, affordable health care."

Others were less impressed. "We are very cautious about the particulars of the voluntary effort that groups proposed to the White House," said a statement from the National Coalition on Health Care, a progressive advocacy group. "Most of the measures that they cited would help to make the health care system more efficient over time, but, as the Congressional Budget Office has indicated, should not be counted on to produce substantial savings soon. … We are heartened by the sector's growing acceptance of responsibility to engage constructively in a search for solutions, but we believe that those solutions will need to be embodied in law." ■

OFFICIAL WHITE HOUSE PHOTO BY PETE SOUZA

President Obama meets to discuss health care reform with stakeholders in the Roosevelt Room at the White House, May 11, 2009.