

'Attribute-Based' Medicine Better Than 'Race-Based'

BY JOYCE FRIEDEN
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BALTIMORE — Targeting medicines at particular racial categories “is a misguided approach, and what we should be pursuing is attribute-based medicine,” Sharona Hoffman said at the annual meeting of the American Society of Law, Medicine, and Ethics.

One example of a medicine targeted at racial categories is BiDil (fixed-dose isosorbide dinitrate and hydralazine), a heart failure drug that was approved specifically for use in blacks. Some experts have concluded that a good response to BiDil has more to do with attributes and genes than it does with racial identity.

Patient attributes that might be considered relevant for assessing disease vulnerability or treatment responses include genetic variations or alleles that might be more common for people who are of one ancestral origin rather than others but could still cross population lines. “Then there are other factors such as diet, exercise, stress level, and exposure to toxins” that play into treatment response, said Ms. Hoffman, a professor of law at Case Western Reserve University in Cleveland.

“The Human Genome Project showed us that race is not a biologically valid or genetically valid concept, and therefore the emergence of ‘race-based’ medicine is both perplexing and troubling,” she said at the meeting, which was cosponsored by the University of Maryland. “Race doesn’t mean much of anything” from a genetic perspective because “99.9% of genes are identical for all humans,” and in the remaining 0.1%, 90%-95% of genetic variations are found at equal rates in every population.

Society also has difficulty defining race, with legal definitions of race varying from one state to another, Ms. Hoffman said. The race categories listed in the U.S. Census also change every decade. Almost 7 million people checked off more than one race in the 2000 census, she noted. “If you ask people to self-identify, they may say they’re African American when they are really of mixed race. And visual observation is even more misleading.”

In addition to these problems, using “race-based” medicine may exacerbate health disparities, because “it’s possible doctors may try to specialize in treating blacks or whites,” said Ms. Hoffman. That may violate federal or state antidiscrimination laws.

Instead of pursuing race-based protocols, Ms. Hoffman recommended designing attribute-based trial protocols, and having institutional review boards and scientific review boards subject them to special scrutiny.

“Consider the genetic variations and the psychosocial, economic, cultural, environmental, and other factors, which you can measure or ask about—stress, diet, exercise, exposure to toxins, and cultural and religious barriers to treatment compliance,” she said. “Maybe people aren’t doing well because they are not following the protocol—because they either don’t understand it [due to] a language barrier, or they have religious beliefs that prevent them from doing some of the things you need them to do.”

Also, be aware of the limits of self-identification or identification through visual observation. “Don’t use skin color as a proxy. What questions do you need to ask? Do you need to do further genetic testing?” Ms. Hoffman said. “It’s very hard to tell what ancestry people have if you don’t ask specific questions.” ■

Performance Measures Can Boost Quality, Reduce Costs

BY MARY ELLEN SCHNEIDER
New York Bureau

Nationwide use of performance measures related to just two clinical areas—coronary artery bypass graft surgery and pneumonia—could have saved hospitals as much as \$1 billion in 2004.

That conclusion is part of an analysis from Premier Inc., an alliance of not-for-profit hospitals and health care systems. Officials at Premier also estimated that use of the same performance measures would have improved quality of care in hospitals resulting in about 3,000 fewer deaths, 6,000 fewer complications, 6,000 fewer readmissions, and 500,000 fewer days in the hospital nationwide over 1 year.

The analysis is an extrapolation of the first-year results of a Medicare pay-for-performance demonstration project that involved more than 250 Premier member hospitals in 38 states around the country. As part of the demonstration project, which began in October 2003, Premier collected data on the use of quality indicators for five clinical conditions—myocardial infarction, coronary artery bypass graft (CABG), pneumonia, heart failure, and hip and knee replacement.

The Centers for Medicare and Medicaid Services offered incentive payments to hospitals based on their performance on the quality indicators. The 3-year project is still ongoing but the first-year results showed improvements in all clinical categories.

As part of its national analysis, Premier concentrated on two high-volume diagnoses—pneumonia and CABG—and extrapolated outcomes for the use of seven pneumonia measures and four CABG measures. The predictions on cost savings and quality improvement are based on all pneumonia and CABG patients receiving 76% or more of the recommended performance measures.

“Improving patient care in these two clinical areas... can be proven statistically to reduce costs, save a noticeable number of lives, to reduce complications of care, to reduce readmissions, and to shorten length of stay,” Richard A. Norling, president and CEO of Premier, said during a teleconference to announce the results of the analysis.

For pneumonia patients, Premier officials estimated the impact of oxygenation assessment, pneumococcal vaccination, blood culture before first antibiotic, adult smoking cessation counseling, initial antibiotic selection, initial antibiotic within 4 hours of hospitalization, and influenza vaccination.

For CABG patients, Premier calculated the effect of aspirin prescribed at discharge, prophylactic antibiotic selection for surgical patients, prophylactic antibiotic within 1 hour prior to surgical incision, and prophylactic antibiotic discontinued within 24 hours after the end of surgery. ■

For more information on the Premier analysis of the impact of performance measures, go to www.premierinc.com/p4p/press.

Clinton, Obama Pitch Patient Safety Approach to Liability Crisis

BY MARY ELLEN SCHNEIDER
New York Bureau

Two Democratic senators are aiming to move patient safety to the center of the medical liability debate.

Sen. Hillary Rodham Clinton (D-N.Y.) and Sen. Barack Obama (D-Ill.) have introduced legislation that would provide grant funding for physicians, hospitals, and health systems to routinely report medical errors to a national database. In cases in which patients were harmed, the hospitals and physicians involved would disclose the error and offer to enter into confidential negotiations on compensation. Any disclosures and apologies from physicians would be considered confidential under the bill.

“For too long, our health care system has discouraged the kind of communication needed to find and correct the conditions that lead to medical errors,” Sen. Clinton said in a statement. “Our bill puts patient safety first and creates an avenue for doctors and patients to find solutions outside of the courtroom.”

The two senators recently touted the benefits of the bill, the National Medical Error Disclosure and Compensation Act

(S. 1784), in a perspective published in the *New England Journal of Medicine*.

In addition, medical liability insurers who participate in the program would be required to put a portion of any savings realized toward reducing physician premiums. For health care providers who participate, a portion of the savings must be used for activities that reduce medical errors and improve patient safety.

But some physician leaders are skeptical that the bill will gain any traction in an election year. The legislation was introduced last September and was referred to the Senate Committee on Health, Education, Labor, and Pensions. Dr. Joseph Flood, chairman of the government affairs committee for the American College of Rheumatology, said the focus on patient safety is important but that the approach outlined in the bill could have unintended consequences. The bill is unlikely to be effective as long as it requires the reporting of errors without providing an environment in which physicians will not be unduly punished, he said.

Dr. Larry S. Fields, president of the American Academy of Family Physicians, said that Sen. Clinton and Sen. Obama had their chance to vote for comprehensive li-

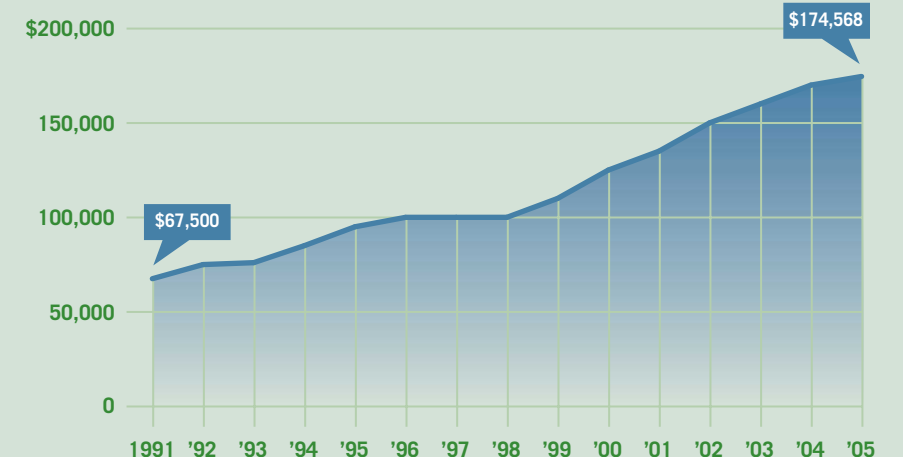
ability reform back in May when the Senate defeated a motion to consider S. 22. That bill would have capped noneconomic damages at \$250,000 and allowed courts to restrict the payment of attorney con-

tingency fees. Sen. Clinton voted against the motion, and Sen. Obama did not vote.

As long as medical liability reform remains a partisan issue, it will be difficult to pass meaningful reform, Dr. Fields said. ■

DATA WATCH

Median Malpractice Payments Made on Behalf of Physicians



Note: Based on a total of 221,485 payments reported to the National Practitioner Data Bank from 1991 to 2005.

Source: Health Resources and Services Administration