

Effectiveness Research Federal Panel Hears Public Concerns About Comparative Effectiveness Research

By Nathaniel Weixel

At the first public meeting of a new federal council on comparative effectiveness research, representatives of the medical devices industry emphasized April 14 that federally funded research should look at effectiveness of health care treatments and not at their costs.

The 15-member Federal Coordinating Council for Comparative Effectiveness Research held its first “listening session” as it works to prepare a report, due June 30, on how the health and human services secretary should use \$400 million in comparative effectiveness funding authorized by the recent economic stimulus law. The panel, which is made up of federal officials, heard from a wide variety of public stakeholders on how to best focus the research efforts.

Comparative effectiveness research, or CER, looks at the effectiveness of different medical treatments—such as drugs or medical devices—for diseases or conditions. While some industry representatives at the April 14 meeting cited concerns about making sure that cost is not a factor, other speakers said that cost is a valid and inevitable factor to consider in such comparisons.

The council is authorized by the American Recovery and Reinvestment Act or ARRA (Pub. L. No. 111-5), the \$787 billion economic stimulus package signed into law Feb. 17 by President Obama. According to the law, the council will help coordinate research and guide investments in CER funded by ARRA. The law authorized \$300 million for the Department of Health and Human Services' Agency for Healthcare Research and Quality, \$400 million for the National Institutes of Health, and \$400 million for the HHS secretary to support comparative effectiveness research.

Carolyn Clancy, director of AHRQ and a panel member, said there will be at least two more public listening sessions before the June 30 deadline. The council members were named recently by HHS (3 MELR 191, 3/25/09).

More than 30 individuals spoke at the listening session, representing an array of provider, patient, research, industry, and other health care organizations. They urged the panel to continue its mission of aiding federal agencies with CER in a transparent manner, and to consider all funding options, including collaborating with state agencies and analyzing the cost effectiveness of certain treatments.

Concern From Device Companies.

Representatives from the medical devices industry, speaking during the listening session, said the council, and by extension HHS, should direct its research focus to matters other than the cost of health care treatments. Teresa Lee, vice president of payment and policy the Advanced Medical

Technology Association (AdvaMed), said HHS should focus on developing methods of turning clinical research into practice.

Lee said CER “should be used to help patients and physicians make informed medical decisions, not hinder physicians” in their ability to practice medicine. She said using cost as an outcome measure would end up denying patients important treatment.

Thomas Novelli, director of federal affairs at the Medical Device Manufacturers Association, said the council and HHS should look at reforming the health care delivery system as a method to control costs. He said the department should attempt to fix disparities in the health care system among minorities, women, and people with disabilities, instead of looking at cost effectiveness.

He also said the council should not just focus on comparing medical technologies and treatments. Novelli said the council should look at investing CER money in methods of prevention and overall wellness programs.

Dissemination, Research.

Winifred Hayes, president and chief executive officer of Hayes Inc., an independent health technology research and consulting company in Lansdale, Pa., said that cost has to be discussed.

“At one point or another we're going to have to talk about cost,” Hayes said at the listening session.

Hayes also said the current health care system has failed to “effectively and efficiently integrate scientific evidence” into the decisionmaking process. Hayes said the majority of the CER funding should be allocated to primary research, like human clinical trials. While they may be costly, Hayes said they will have the greatest impact in the long run, especially outside the clinical setting.

Hayes also urged the council to explore the best ways to disseminate the research to the public. The research conducted on different treatments would not matter, she said, if the information could not be accurately disseminated to the public.

According to the statute, the council is to create a process of funding and disseminating comparative effectiveness research that is transparent, professional, and free from conflicts of interest. In an interview with BNA Feb. 11, after Congress passed ARRA, Hayes said the only way a truly transparent process could happen is if the government funded organizations in the private sector to synthesize the effectiveness data and then disseminate it to the public (3 MELR 117, 2/25/09).

John Martin, director of Premier Research Services, a clinical research group owned by nearly 200 nonprofit hospitals and health care organizations, said the council needs to ensure the CER funding goes to “true” patient-focused research, and not administrative activities.

Martin said the results of CER should be used only as a guide and should not be used as a substitute for health care provider judgment. He said CER should examine not just the results from clinical trials, but should also focus on whether a treatment provides the greatest benefit to the patient “in a real-world health care environment.”

In discussing the actual format for CER trials, Martin said the quality, safety, and efficiency of particular treatments should each be considered separately. He also urged the council not to discount cost data.

By Nathaniel Weixel

Contact Information:

Nathaniel Weixel
Reporter
BNA
1801 S. Bell Street
Arlington, VA 22202
703-341-5727
nweixel@bna.com