Helping to DEcIDE

David B. Nash, MD, MBA

Buried inside the Medicare Modernization Act (MMA) of 2003 is a very important plank, Section 1013, entitled “Research on Outcomes of Healthcare Items and Services.” This program is significant because it covers the quality and efficiency of health care delivery and improved outcomes in health care.

Section 1013 is designed to adjust for the lack of comparative data on prescription drugs. It instructs the Secretary of the Department of Health and Human Services (DHHS), acting through the Agency for Healthcare Research and Quality (AHRQ), to conduct and support research with a focus on outcomes; comparative clinical effectiveness; and appropriateness of medical devices, pharmaceuticals, and services in order to meet priorities and to request scientific evidence in certain fields.

The AHRQ’s mission is to improve the safety and efficiency of health care for all Americans. Its Effective Health Care Program has three basic components:

1. Reviewing and synthesizing existing knowledge through Evidence-Based Practice Centers (EPCs).
2. Promoting and generating new knowledge through a research network called DEcIDE (Developing Evidence to Inform Decisions about Effectiveness).
3. Compiling data from both the EPCs and the DEcIDE Research Network and disseminating these findings.

The mission of Section 1013 is clear—to help “DEcIDE” which drugs should be covered and which drugs should be on which tier of the formulary.

A group of experts at the John M. Eisenberg Clinical Decisions and Communications Science Center was chosen to disseminate this knowledge. The center is a collaboration of the Oregon Health and Science University in Portland, Oregon; the Portland Veterans Affairs Medical Center; and the Kaiser Permanente Center for Health Services Research. The task of this experienced triumvirate is to combine the data compiled by the EPCs and the DEcIDE Research Network and to make this federally funded activity relevant to the design and construction of the formulary of the future.

Created by the AHRQ in 2005 in partial fulfillment of MMA requirements, the DEcIDE network of research centers is conducting accelerated practical studies on health care services, as charged under Section 1013. This network comprises research-based health organizations that have electronic health information databases and a capacity to conduct rapid turn-around research (in less than two years).

The official position of Section 1013 is that coverage of a prescription drug, based on the results of future studies, should not be withheld. I believe, however, that Section 1013 and the DEcIDE Research Network may have far-reaching implications for every P&T committee.

As our readers probably know, no pharmaceutical company or government agency has taken the initiative to conduct head-to-head trials to determine whether one treatment is superior to another for a given disease state. Instead, with most trials that are submitted to the Food and Drug Administration (FDA), a new drug must be superior only to a placebo to gain the agency’s approval. Under Section 1013, one of the highest priorities of the MMA will be to study pharmaceuticals in such a way so that previously omitted key questions on economics can be answered.2

Another arm of this research—the Comparative Effectiveness Review (CER)—is being conducted by the EPCs. A CER identifies research gaps and recommendations for assignment of drugs to various formulary tiers. CERS are performed primarily because of their epidemiological impact and because of high-cost therapies being used in the field. For example, a CER might evaluate a current therapy for rheumatoid arthritis involving multiple drug regimens and drug classes such as oral agents, biologics, and other categories.

When we examine Section 1013, the EPCs, the DEcIDE Network, and CERS, I think the ramifications are clear: Medicare is slowly heading toward the creation of a national formulary to be supported by solid head-to-head comparative evidence and with supporting work relating to cost-effectiveness and quality of life. Indeed, the DEcIDE Network’s initial research will most likely focus on outcomes of prescription drug use and other interventions for which randomized controlled trials would not be feasible or timely or would raise difficult-to-address ethical concerns. Other DEcIDE projects might center on electronic registries, methods of analyzing health databases, and prospective observational or interventional studies.

In my view, helping to DEcIDE how to organize and create a formulary will become a major research cornerstone of the MMA as we move forward. It would be prudent for all P&T committee members to follow the work of the DEcIDE Research Network and the CER apparatus.

Astute readers will probably recognize that aspects of all of the programs mentioned in this article are eerily familiar to the work already under way in the United Kingdom through the National Institute for Health and Clinical Excellence (NICE).3 The MMA and Section 1013 appear to be laying the groundwork for introducing a comparable program in the U.S. in the next three to five years. I hope that your P&T committee is ready to adopt this methodology in helping to DEcIDE the future formulary design.

I am interested in your views. Please contact me at david.nash@jefferson.edu.

REFERENCES