

# Comparative Effectiveness: The Impact on Managed Care and Patient Outcomes

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## Summary

Although discussed and debated for several years, comparative effectiveness research is coming to the forefront as health care reform again becomes a federal government focus. There is significant debate ongoing about how to best fund, implement, and apply comparative effectiveness research. The recent economic stimulus bill has postponed some of the debate by providing a significant amount of money for this type of research.

## Key Points

- Comparative effectiveness aims to assess how various procedures or interventions for a given ailment compare with each other.
- Different models for conducting comparative effectiveness research include a private entity doing the research, a public only entity, or a private/public partnership.
- Funding for this type of research may be public, private, or a combination.
- There is an ongoing debate on many aspects of this type of research.
- Key players in the debate include various federal agencies, managed care organizations, other health care payers, health care professional organizations, and trade associations.

COMPARATIVE EFFECTIVENESS (CE) research aims to assess how various procedures or interventions for a given ailment compare with each other. Traditionally, this has been a comparison of two or more health care interventions. It can also be an examination of how a particular health care product and various health care practices work together. CE can also be even broader to encompass assessment of any aspect of health care delivery.

Several things are driving the CE discussion. This is an important part of the current health care reform debate. Another driver is increased costs of providing health care, particularly pharmaceuticals and medical technology. There is a belief that CE will save money—the Congressional Budget Office says this will not occur any time soon, but perhaps over the long term. Other attempts to reduce health care costs have failed. Additionally, CE could improve the quality of health care and appears to work elsewhere in the world. Lastly, there is hope that CE is an opportunity to get under-served populations better access to health care.

Parallel issues related to the CE discussion and debate include implementation of Medicare Part D, electronic prescribing and hand held formularies, and the follow-on biologicals debate. The creation of value based purchasing programs and other quality-based payment incentives are also impacting the issue of CE.

There are many concerns about the design, conduct, and application of CE research. There are arguments for a separation of determining what works (comparative clinical effectiveness) versus the costs (cost-effectiveness). There are concerns about cost restricting access to treatment. Many groups are worried that CE will ultimately be used as a cost-cutting tool only. American consumers do not like the idea of rationing; when ill, they want everything that is available. Each group in the debate has a different opinion on the role of cost. Beyond costs, there are other issues—who collects the data, who interprets the data, how results are disseminated to various groups, and how payments should be affected. There is also the impact on physicians—there is concern that this type of research will be used to further limit the power of physicians. Vari-

ous physician groups want practicing physicians as part of the planning process.

There are different models for doing CE research, including a private entity doing the research, a public-only entity, or a private/public partnership. The entity controlling the research is very much at the center of the debate over this type of research. Whatever the format for conducting CE research, the process needs to be open and transparent.

The funding debate for CE research has focused on both private and public funds. Private funding sources may include private payers or investors with rights to “own” the research entity. Privately funded CE research efforts are already occurring. The Blue Cross/Blue Shield Association has had a Technology Evaluation Center since 1985. The Technology Evaluation Center conducts reviews of existing clinical evidence to determine the effectiveness and appropriateness of a given procedure, medication, or device.

Public funds for CE research may come from tax dollars or a payment from Medicare beneficiaries and other taxes. Public funding already goes to the Agency for Healthcare Research and Quality (AHRQ) but they need more money. AHRQ has been given the mandate and money to do CE research through legislation. Currently, they do not have enough money to complete all their mandates. The agency has an Effective Healthcare Program that contracts with 14 Evidence-based Practice Centers to synthesize existing knowledge. Five conduct technology assessments for CMS. Some people are concerned that AHRQ is too political. Some groups would like the National Institutes of Health (NIH) to have more funding for CE research rather than AHRQ.

Another option is the creation of a new independent entity that is governed by a separate body that sets research priorities. Health plans and pharmaceutical companies have supported the development of a new agency for this purpose. The Institute of Medicine (IOM), a private entity, recommends a new national program to prioritize, fund and manage reviews of clinical effectiveness. MedPAC, a group that makes recommendations on Medicare payment issues, supports a private-public mix option with an independent board to oversee the development of unbiased research.

The Centers for Medicare and Medicaid Services (CMS) has an interest in the development and direction of CE research as the agency moves from a role as payer alone to a role of consumer of clinical information. Their coverage groups are making decisions based on evidence and costs. CMS does not have money to fund CE research, but does have an interest in it to better manage their patients.

Trade associations for health plans, pharmaceuti-

cal companies, and pharmacy benefit managers also have an interest in this debate. These groups are looking for financial support for what they are already financing and political validation of their current CE research. The trade associations for the pharmaceutical and biotech companies are concerned about how cost will be factored into CE. They think research should not be narrowly defined as two medication head-to-head trials. They would like a broader definition of health care costs.

Legislation to advance CE research has been building during the past few years. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) became law July 15, 2008. This legislation funded an IOM study to identify the methodological standards for conducting systematic reviews of clinical effectiveness research on health and health care in order to ensure that organizations conducting such reviews have information on methods that are objective, scientifically valid, and consistent.

The Comparative Effectiveness Research Act of 2008, better known as the Conrad/Baucus bill, sought to establish a Health Care Comparative Effectiveness Research Institute to identify national CE priorities, establish a research agenda, consider systematic reviews of existing research before providing for new research, and enter into contracts to conduct research preferably with federal agencies such as AHRQ. The Institute would also have advisory panels, peer-review, widely disseminated findings, and public meetings. The funding would be a mixture of general funds, a tax on self-insured and other health plans, and \$1 per Medicare beneficiary. The recent economic stimulus package displaced this bill but it will probably be reintroduced.

The economic stimulus package has preempted public funding discussions for now by providing a significant amount of money for CE research. The stimulus package provided \$1.1 billion for CE research to the existing entities that are already conducting research—AHRQ and NIH. Within the \$1.1 billion, \$300 million will be administered by AHRQ, \$400 million went to NIH, and \$400 million will be allocated at the discretion of the Secretary of Health and Human Services. Both NIH and AHRQ will use their current infrastructure to conduct the research. The Congressional intent of this package was for the groups to use the money “to conduct or support research to evaluate and compare the clinical outcomes, effectiveness, risk, and benefits of two or more medical treatments and services that address a particular medical condition.” The money cannot be used to mandate coverage for a particular product.

The Federal Coordinating Council for Comparative Effectiveness Research was set up to coordinate

comparative effectiveness and other related health services research and advise where evidence is lacking. The council is made up of 15 members, including one senior official from AHRQ, CMS, NIH, the Office of the National Coordinator for Health Information Technology, FDA, the Veterans Health Administration, and the Department of Defense. The council is to report by June 30, 2009 describing current federal comparative effectiveness research and recommendations for further research.

### **Conclusion**

The next steps in moving CE research forward include the reintroduction of Conrad/Baucus bill and continuing the cost versus clinical efficacy debate. The long-term implications of CE research need to be determined. **JMCM**

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