



National Business
Coalition on Health

Comparative Effectiveness Research (CER)

NBCH Issue Brief- April 2009

The term comparative effectiveness research refers to a rigorous evaluation of two or more alternatives available for treating a given medical condition for a particular set of patients. (Congressional Budget Office, Key Issues in Analyzing Major Health Insurance Proposals, December 2008)

The Political Landscape: Heralded for the past several years as a cornerstone for reducing health care costs and increasing the quality of care, many lawmakers and health care experts say more research should be done to study which medicines, devices, and procedures work best at treating different diseases. As a nation, if we can better align treatment with medical best practices, it is probable or use likely that we could improve the quality of care patients receive and lower the costs of health care.

To that end, a small, safe step toward health care reform and a modest proposal to accelerate comparative effectiveness research was signed into law on February 17, 2009 by President Obama as part of the \$787 billion spending bill intended to stimulate the economy. But the vocal and written opposition to the provision took Democrats somewhat by surprise and probably foretells difficult fights ahead when President Obama seeks to make broader changes to the health care system, including an expected expansion of the comparison studies. Compared to the overall size of the stimulus, the \$1.1 billion dedicated to comparative effectiveness research, while far more than the \$50 million the government spent in fiscal 2009 on such research, is small relative to the cost of the work that needs to be done.

One of the major CER “line in the sand” issues is that the public seemingly will not support the use of comparative effectiveness research to deny treatment that patients need. The conference report language made clear that the comparative effectiveness research is not intended to be used to mandate coverage, reimbursement, or other policies for any public or private payer. Ultimately, the goal is to **provide patients and physicians with good, patient-centered information on cost and clinical effectiveness of treatments. Without good information “right care” is too easily defined by industry agendas.**

Another major CER issue has been its linkage to payment. CER provisions in the stimulus package provide coverage for clinical-effectiveness but no linkage to cost-effectiveness due to concern that too much emphasis would be placed on support for treatments that cost less but are not necessarily the most effective treatment for patients. This issue is so divisive that it was left

out of the final version of the stimulus bill. However, there now is concern about how to bring value to the system through CER. At this point, the hope is that doctors will read the research and results, and will be encouraged to alter their practice patterns accordingly. At this point, CER data will be made public to consumers and providers, so that they can use the information to do their own cost comparisons.

ARGUMENTS FOR CER:

We need to overhaul how we pay for and deliver health care so that doctors can focus on providing high quality care to patients so they have the best information necessary to manage their own health and focus more on prevention. The health care system should provide the right information and incentives for doctors not just to provide more health care, but the most effective high quality health care based on scientific evidence. This will make the health care system more responsive to patient needs, and more convenient.

- **CENTRALIZED POLICY-MAKING:** CER provides an organized, centralized health policy decision-making process, whether in the public or private sector, that is patient-centered and supportive of quality and value. In this respect, it would foster scientific advances, health information technology, and the emerging science of personalized medicine.
- **REDUCE MEDICAL ERRORS/MEDICAL MALPRACTICE:** Advances in health care occur so fast we need to provide doctors with constantly updated information based on the most current scientific evidence available. The best information should be available to doctors. This would help doctors do what is right for patients and give patients the best quality care while reducing medical errors and physician risk of medical malpractice. CER helps **doctors do a better job by providing clinical and cost-effectiveness information, as well as supplements doctors' clinical knowledge.**
- **NOT USED FOR COVERAGE DECISIONS:** To address the concerns that CER would be another big government bureaucracy that dictates patient treatment and infringes on physician experience and judgment, the final stimulus bill language says that the law does not intend for Medicare or other "public or private payers" to use the research to make coverage decisions. Medicare might adopt similar practices, using comparative effectiveness research to support its decisions.
 - Insurers are strong supporters of comparative effectiveness research, but the insurance industry's support for the research is not reassuring to people suspicious of the new policy.
 - Advocates for the research say the concerns are overstated, and opponents are simply trying to protect the interests of health care industry groups worried that their products could be deemed less effective.
- **CONTROLS OVER-USE/SUPPORTS PREVENTION:** The U.S. produces the most advances in medical technology in the world, but that doesn't mean that this technology has to be utilized with every episode of care. Over-use of the health care system contributes to the high cost of tests and treatments for everyone, and often does nothing to improve our health and can actually harm it. We need to support doctors with the best information about prevention, and the treatments that actually work the best for patients.
- **SUPPORTS MODERNIZATION:** CER can help provide a basic infrastructure by which to modernize our health care system in order to control costs and ensure high quality health care. If we continue with our outdated system of using paper records, rewarding doctors for providing tests and treatments without regards to quality, and not supporting healthy living, doctors will keep spending more time on paperwork and less time on their patients.

- **LESSENS GEOGRAPHIC VARIATION:** Researchers at Dartmouth University found that some evidence suggests that geographic variation in treatment patterns is greater when less evidence is available on the best course of treatment to use.
- **PAYMENT REFORM/BENEFIT DESIGN:** Link both new and existing evidence to payment rules or cost-sharing requirements in Medicare or Medicaid so as to provide incentives for providers and/or enrollees for using more clinically effective or cost-effective services or discourage the use of other services.
- **EMPLOYEE HEALTH EDUCATION TOOL:** Maximize CER value and information by integrating into broader strategies of patient engagement, health care literacy, and employee health care support.

Stakeholders For CER: Most consumer/patient advocacy groups support CER but are cautious about the inclusion of cost information. Their position is that doctors need to have access to the latest research that compares the effectiveness of different types of treatments, such as comparing which drugs work best. This will help doctors and patients choose the best treatment for a specific medical situation and make more informed choices, rather than risk receiving less effective treatments. Interestingly, **the CER message tests better with seniors and Republicans when it explicitly cites cost-effectiveness. It does better with Democrats, women and independents when cost is not mentioned.** (Lake Research Partners)

The following is a list of groups that support CER and references supporting their position:

AARP: http://www.aarp.org/research/health/carequality/i17_comparative.html

America's Health Insurance Plans:

<http://www.ahip.org/content/pressrelease.aspx?docid=24134&textsize=small>

American College of Physicians:

http://www.acponline.org/advocacy/where_we_stand/policy/healthcare_system.pdf

American Medical Association: <http://www.ama-assn.org/ama1/pub/upload/mm/399/hsr-comparative-effectiveness.pdf>

Consumers Union:

http://www.prescriptionforchange.org/2009/02/comparative_effectiveness_comm_1.html

National Business Group on Health:

<http://www.businessgrouphhealth.org/pressrelease.cfm?ID=119>

US Chamber:

http://www.uschamber.com/publications/reports/0901_comparativeeffectiveness.htm

ARGUMENTS AGAINST CER:

America has high quality health care because we allow doctors and patients the freedom to choose the treatments and medicines that are right for them, not faceless government bureaucrats. The CER aspect of health care reform is about putting the government in charge of our personal health care decisions, tying the hands of your own doctor and creating a one-size fits all health care system run by a huge, costly new bureaucracy that we can't afford in these tough economic times.

- **NATIONALIZED HEALTH CARE MENTALITY:** There is concern that the U.S. could become like current national organizations that conduct CER, such as the National Institute for Health and Clinical Excellence in the United Kingdom or the Institute for Quality and Efficiency in Health Care in Germany, who seemingly ration health care technologies so that they mesh with the politically fixed budgetary allocations of the national government.
- **MISUSE OF INFORMATION:** CER information could be used, through Medicare and Medicaid, to control prices to deny coverage for treatments deemed less clinically effective or less cost-effective leading to rationing of care. Many Americans could be denied access to their choice of health treatment.
- **INTERFERENCE IN DOCTOR-PATIENT RELATIONSHIP:** Consumers do not want scientific and cost-effectiveness data to replace or interfere with their physician's judgment and forcing them to accept government mandates and guidelines about treatments and thusly putting government bureaucrats in charge of health care.
- **CLINICAL EFFECTIVENESS VS. COST EFFECTIVENESS:** There is value in doing research to see what is the best clinical approach, taking into consideration cost and quality, but there is concern about cost alone being a factor in making clinical or for non-coverage decisions to be based on what treatment works best on average. Devoid of a market and the language of price, this top-down system ironically ignores many of the societal costs associated with failure to treat severe illness, such as illness-related unemployment. Moreover, the fact that preventing access to more costly medicines may save money in the short term overlooks the costs for the future. If older medicines lead to more rapid deterioration of a condition, the effect could be a more expensive hospital or nursing home episode later.
- **WILL INVESTMENT BE REALIZED?** There is no actual timeline for savings to be realized from CER efforts and the funding level in the stimulus bill is not appropriate to fund the quality of research that is expected from costly clinical studies (currently being funded by the private sector). The Congressional Budget Office (CBO) estimates that although CER research would yield findings that reduce federal spending for certain types of health care; it would not be by enough to offset the costs of conducting that research over a 10-year budget time frame.
- **STEP TOWARD ONE-PAYOR SYSTEM:** CER provisions in the stimulus bill are another step in the direction of a government run, single-payer healthcare system.
- **EXCESSIVE INDUSTRY INFLUENCE:** There is concern that CER is not information that the private sector, in particular, will generate on its own, and that certain sectors of the health care industry does not want to share information with the public and will work to "defund" it as soon as it presents a threat.
- **STIFLES INNOVATION:** In a potential incentive structure that encourages providers to trade off the costs and benefits of health care technologies gives providers little incentive to use expensive but appropriate technologies, and gives researchers little incentive to continue to create it

Stakeholders Against CER: Officially, drug and device makers don't object to CER, but they are concerned about the slippery slope created when the government ends up cutting-out useful treatments just because it may be determined that they cost too much. These groups are engaging patient advocacy organizations to lobby Capitol Hill. A major goal is to give industry a seat at the table when federal officials decide what to research with the \$1.1 billion provided for in the stimulus package.

The following is a list of groups that have objections to CER:

Advanced Medical Technology Association:

<http://waysandmeans.house.gov/hearings.asp?formmode=printfriendly&id=6336>

PhRMA: Supportive of CER but believes research must focus on medical outcomes, rather than cost-effectiveness analysis that could be used to deny patients needed care.

http://www.phrma.org/news_room/press_releases/comparative_clinical_effectiveness_research_provision_an_important_step_forward_for_patient_care/

Varying Perspectives in Congress:

*Suspicion of the policy runs even deeper among some conservatives, who see a slow conspiracy unfolding to eventually ration health care. *The Washington Times* published an inflammatory editorial Feb. 11 comparing some of the stimulus bill's health policy provisions, including the comparative effectiveness language, with the euthanasia programs of Nazi Germany.

*But other Democrats, as well as members of the Congressional Black Caucus, have expressed concerns that comparative effectiveness research could hurt patients' access to medical treatments they need.