

The Federal Call for Accelerated Comparative Effectiveness Research in Health Care

The new economic stimulus bill, also known as the American Recovery and Reinvestment Act (ARRA), includes the allocation of \$1.1 billion to accelerate comparative effectiveness research (CER) in health care. The purpose of comparative effectiveness research is to provide critical, evidence-based information to physicians and patients so that they can engage in informed, shared, decision making when it comes to treatment options. While there is growing consensus among stakeholders that such information is critical, there remains some controversy over exactly how such research should occur.

Comparative effectiveness research is not new, but until now, most CER has been funded and performed by the private sector, primarily by health plans (to determine drug formularies and to set coverage policies for medical devices and services), and by pharmaceutical and medical device makers interested in marketing their products using clinical effectiveness research to show superiority over alternatives. Public sector CER was relatively limited until 2003 when the Medicare Modernization Act granted the federal Agency for Healthcare Research and Quality (AHRQ) a limited mandate to conduct CER to improve the quality, effectiveness and efficiency of health care delivered through Medicare, Medicaid and SCHIP. Since then, AHRQ has continued to play an important, yet relatively minor, role in conducting CER, mainly because of its very modest budget for CER (\$30 million in 2008).

What is Comparative Effectiveness Research (CER)?

Although CER is not explicitly defined in the bill, ARRA states that the money shall be used “to accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies, through efforts that: (1) conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions; and (2) encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data.”

For comparative purposes, other entities have previously defined comparative effectiveness as follows:

Agency for Healthcare Research and Quality (AHRQ):

A type of health care research that compares the results of one approach for managing a disease to the results of other approaches. Comparative effectiveness usually compares two or more types of treatment, such as different drugs, for the same disease. Comparative effectiveness also can compare types of surgery or other kinds of medical procedures and tests. The results often are summarized in a systematic review.

Congressional Budget Office (CBO):

A comparison of the impact of different options that are available for treating a given medical condition for a particular set of patients. Such studies may compare similar treatments, such as competing drugs, or they may analyze very different approaches, such as surgery and drug therapy. The analysis may focus only on the relative medical benefits and risks of each option, or it may go on to weigh both the costs and the benefits of those options.

Institute of Medicine (IOM):

Within the overall umbrella of clinical effectiveness research, the most practical need is for studies of comparative effectiveness, the comparison of one diagnostic or treatment option to one or more others. In this respect, primary comparative effectiveness research involves the direct generation of clinical information on the relative merits or outcomes of one intervention in comparison to one or more others. Secondary comparative effectiveness research involves the synthesis of primary studies (usually multiple) to allow conclusions to be drawn. Secondary comparisons of the relative merits of different diagnostic or treatment interventions can be done through collective analysis of the results of multiple head-to-head studies, or indirectly, in which the treatment options have not been directly compared to each other in a clinical evaluation but reside in larger databases. Conclusions utilize inferential adjustments based on the relative effect of each intervention to a specific comparison, often a placebo.

Center for Medical Technology Policy:

A set of analytic tools that allow for the comparison of one treatment – drug, device, or procedure - to another treatment on the basis of risks, benefits, and potentially, cost. The tools include: systematic reviews of evidence; modeling; retrospective analyses of databases (either electronic health records (EHRs) or administrative data used to process

claims); and prospective, but non-randomized controlled trials research (adaptive trials, practical trials, etc). The research setting is “real world” health care interactions, rather than randomized and controlled trials.

Note that a few of the definitions above leave open the possibility that CER includes consideration of cost-effectiveness when comparing treatments. It is important to note that any reference to “comparative cost effectiveness” or cost-based decisions is absent from ARRA. Furthermore, what little public sector CER is already underway at AHRQ specifically leaves out any provision to determine the cost-effectiveness of treatments. The matter is addressed further in the issues table that begins on page 4.

What is the international experience with CER?

Several European nations have well-established CER efforts. In Britain, the publically-funded National Institute for Health and Clinical Excellence (NICE) conducts comparative effectiveness research and provides formal guidance on the use and coverage of drugs and services to Britain’s government-run, single-payer health care system known as the National Health Service (NHS). NICE has been a controversial body, as it has denied patients access to, and coverage for, certain necessary services that have been deemed too expensive. In March 2009, for example, NICE banned two drugs for advanced breast cancer and a rare form of stomach cancer because the drugs were found to be too expensive.

In Germany, a publically-funded, private foundation known as the Institute for Quality and Efficiency conducts CER to determine the quality and efficiency of drugs and health services. The Institute reports its findings to the Federal Joint Committee (FJC) — the entity responsible for designing the benefit package for 70 million Germans. It is then up to the FJC to decide which services to reimburse. In Australia, the Pharmaceuticals Benefits Advisory Committee (PBAC) uses CER to recommend coverage decisions to the health minister, who is responsible for making final decisions.

What are the arguments for and against CER?

Proponents of CER argue that it will reduce unwarranted variations in treatment among providers; reduce spending on inappropriate, unnecessary or harmful care; provide patients greater comfort in knowing more accurately what to expect from various treatment options and, ultimately, improve quality of care. According to Elliott Fischer of the Dartmouth Medical School, “[E]ffectiveness research is...the only way to protect ourselves from practices that are not beneficial and even dangerous, like so many treatments now in use are.” As such, CER is a necessary vehicle to improve both patient safety and health outcomes.

Critics of CER argue that it has the potential to stifle technological and pharmaceutical innovation and deny patients access and coverage for certain potentially life-saving treatments. According to Edward Abrahams, executive director of the Personalized Medicine Coalition, “If it’s done right, [comparative effectiveness] could propel us into better health care and lower

Stimulus funds

How can states and other entities apply for CER grants made available with stimulus dollars?

Of the \$1.1 billion allocated to CER by the ARRA, AHRQ will receive \$300 million. According to AHRQ’s Web site, it will be issuing CER grants as soon as it receives additional guidance from the Federal Coordinating Council, the IOM and other external sources as to what will be funded. Potential grantees may go to <http://effectivehealthcare.ahrq.gov/> to sign up for updates.

Additional ARRA funds for comparative effectiveness research are available through National Institutes of Health Challenge Grants. Entities may apply for these funds at http://grants.nih.gov/grants/funding/challenge_award/.

cost. But if it’s done wrong, it’s going to trap us into the old system of static ineffective care, of one-size-fits-all, and trial and error.”

How much money could be saved using CER?

Estimating the savings of CER is extremely difficult, given the uncertainty of what the research will find. However, several groups have weighed in with estimates:

- Consumer Reports Best Buy Drugs, using scientific evidence and research from the Drug Effectiveness Review Project (a public-private collaborative performing CER on the efficacy and safety of drugs), compares drugs used to treat 20 common ailments — such as diabetes, heart disease, high blood pressure and depression. Individual drugs are compared on how well they work, how safe they are and how much they cost. Researchers found that if Americans taking four medicines for high-blood pressure, heart disease and high cholesterol switched to lower-cost “Best Buys,” more than \$2.75 billion would be saved annually.
- Researchers at the Dartmouth Atlas Project have shown that per capita Medicare spending in some areas of the United States is much more than in other areas, but the additional spending does not generate better health outcomes, even when taking the population health into account. They estimate that if practice styles in the lowest-spending parts of the nation were utilized in the rest of the country, the U.S. could realize annual savings of up to 30 percent of our national health costs (approximately \$700 billion), with no net change in health outcomes.
- The Congressional Budget Office estimated that a 2007 legislative proposal to create a comparative effectiveness research center (costing \$2.9 billion over 10 years) would reduce total health care spending by nearly \$6 billion over the 2008 to 2017 time period, and much more in the years beyond.
- A Commonwealth Fund study released in December 2007 estimated that CER, by generating information and creating payment and cost-sharing incentives for providers and consumers to use it, could result in estimated health system savings of \$368 billion over 10 years, shared by all payers.

legislative language

Comparative Effectiveness: Excerpts from the American Recovery and Reinvestment Act of 2009 (ARRA)

SEC. 804. FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH. (a) ESTABLISHMENT.—There is hereby established a Federal Coordinating Council for Comparative Effectiveness Research (in this section referred to as the “Council”).

(b) PURPOSE.—The Council shall foster optimum coordination of comparative effectiveness and related health services research conducted or supported by relevant Federal departments and agencies, with the goal of reducing duplicative efforts and encouraging coordinated and complementary use of resources.

(c) DUTIES.—The Council shall—

(1) assist the offices and agencies of the Federal Government, including the Departments of Health and Human Services, Veterans Affairs, and Defense, and other Federal departments or agencies, to coordinate the conduct or support of comparative effectiveness and related health services research; and

(2) advise the President and Congress on—

(A) strategies with respect to the infrastructure needs of comparative effectiveness research within the Federal Government; and

(B) organizational expenditures for comparative effectiveness research by relevant Federal departments and agencies.

(d) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Council shall be composed of not more than 15 members, all of whom are senior Federal officers or employees with responsibility for health-related programs, appointed by the President, acting through the Secretary of Health and Human Services (in this section referred to as the “Secretary”). Members shall first be appointed to the Council not later than 30 days after the date of the enactment of this Act.

(2) MEMBERS.—

(A) IN GENERAL.—The members of the Council shall include one senior officer or employee from each of the following agencies:

(i) The Agency for Healthcare Research and Quality.

(ii) The Centers for Medicare and Medicaid Services.

(iii) The National Institutes of Health.

(iv) The Office of the National Coordinator for Health Information Technology.

(v) The Food and Drug Administration.

(vi) The Veterans Health Administration within the Department of Veterans Affairs.

(vii) The office within the Department of Defense responsible for management of the Department of Defense Military Health Care System.

(B) QUALIFICATIONS.—At least half of the members of the Council shall be physicians or other experts with clinical expertise.

(3) CHAIRMAN; VICE CHAIRMAN.—The Secretary shall serve as Chairman of the Council and shall designate a member to serve as Vice Chairman.

(e) REPORTS.—

(1) INITIAL REPORT.—Not later than June 30, 2009, the Council shall submit to the President and the Congress a report containing information describing current Federal activities on comparative effectiveness research and recommendations for such research conducted or supported from funds made available for allotment by the Secretary for comparative effectiveness research in this Act.

(2) ANNUAL REPORT.—The Council shall submit to the President and Congress an annual report regarding its activities and recommendations

concerning the infrastructure needs, organizational expenditures and opportunities for better coordination of comparative effectiveness research by relevant Federal departments and agencies.

(f) STAFFING; SUPPORT.—From funds made available for allotment by the Secretary for comparative effectiveness research in this Act, the Secretary shall make available not more than 1 percent to the Council for staff and administrative support.

(g) RULES OF CONSTRUCTION.—

(1) COVERAGE.—Nothing in this section shall be construed to permit the Council to mandate coverage, reimbursement, or other policies for any public or private payer.

(2) REPORTS AND RECOMMENDATIONS.—None of the reports submitted under this section or recommendations made by the Council shall be construed as mandates or clinical guidelines for payment, coverage, or treatment.

Agency for Healthcare Research and Quality Healthcare Research and Quality (including transfer of funds)

For an additional amount for “Healthcare Research and Quality” to carry out titles III and IX of the Public Health Service Act, part A of title XI of the Social Security Act, and section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, \$700,000,000 for comparative effectiveness research: Provided, That of the amount appropriated in this paragraph, \$400,000,000 shall be transferred to the Office of the Director of the National Institutes of Health (“Office of the Director”) to conduct or support comparative effectiveness research under section 301 and title IV of the Public Health Service Act: Provided further, That funds transferred to the Office of the Director may be transferred to the Institutes and Centers of the National Institutes of Health and to the Common Fund established under section 402A(c)(1) of the Public Health Service Act: Provided further, That this transfer authority is in addition to any other transfer authority available to the National Institutes of Health: Provided further, That within the amount available in this paragraph for the Agency for Healthcare Research and Quality, not more than 1 percent shall be made available for additional full-time equivalents.

In addition, \$400,000,000 shall be available for comparative effectiveness research to be allocated at the discretion of the Secretary of Health and Human Services (“Secretary”): Provided, That the funding appropriated in this paragraph shall be used to accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies, through efforts that: (1) conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions; and (2) encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data: Provided further, That the Secretary shall enter into a contract with the Institute of Medicine, for which not more than \$1,500,000 shall be made available from funds provided in this paragraph, to produce and submit a report to the Congress and the Secretary by not later than June 30, 2009, that includes recommendations on the national priorities for comparative effectiveness research to be conducted or supported with the funds provided in this paragraph and that considers input from stakeholders.

The Federal Call for Accelerated Comparative Effectiveness Research in Health Care

Issue	ARRA
Governance	The new CER initiatives will be administered by a Federal Coordinating Council consisting of a group of 15 federal employees, half of whom "must be physicians or other experts with clinical expertise." There is no representation of other stakeholder groups.
Placement of a CER Governing Body	ARRA establishes a Federal Coordinating Council to recommend and coordinate CER efforts, but does not go so far as to call for the creation of a Federal Health Board (as championed by former Senator Tom Daschle) that would have much greater authority over coverage decisions. Nonetheless, the bill raises the question, "Will the Federal Coordinating Council eventually morph into a Federal Health Board?"
Long-Term Funding of a CER Governing Body	Silent
Research Mechanics & Methodologies	Not specified
One Size Fits All Medicine	The ARRA notes that, consistent with existing federal HHS policy, CER research design must look at differences in clinical outcomes among patient subgroups, such as racial/ethnic minorities and women, because their response to medical treatments may vary.
Setting Priorities for CER	The IOM (under a \$1.5 million contract) is charged with developing a set of recommendations on the national priorities for CER. IOM is to submit such recommendations to Congress and the Secretary of HHS in a report, no later than June 30, 2009.
Effect on Technological Innovation (medical devices) & Pharmaceutical R&D	Silent

Considerations

- | |
|--|
| <ul style="list-style-type: none"> Should CER be administered by a governmental, quasi-governmental, independent or public-private entity? Could centralized government control lead to manipulation of the CER scientific and decision-making processes, in order to support political ideologies and budgetary constraints at the expense of patient access to medical treatments? Will existing private-sector CER efforts be crowded out under the structure created by ARRA? How can we be sure that the decision-makers on the Federal Coordinating Council do not have conflicts of interests (e.g., revolving door of doctors working for industry and government)? Why did the legislation specifically exclude private sector and consumer representation on the Federal Coordinating Board? If the government is involved in oversight of CER, should it be subject to regular reviews by the Government Accountability Office (GAO) to ensure accountability? |
| <ul style="list-style-type: none"> Should the entity be free-standing like the Federal Reserve Board or should it be housed within a government agency like AHRQ? Should it be structured as a Federally Funded Research and Development Center (e.g., Lawrence Livermore Labs) that is primarily funded by government (minimum of 70%) and sponsored by an executive branch agency which monitors its use of funds? |
| <ul style="list-style-type: none"> Should the funding be from a direct Congressional appropriation? Or should any public funding for a CER entity be insulated from the annual Congressional appropriations process to ensure its revenue over a longer period? Should there be mandatory financing from a combination of public and private sources (e.g., combination of Medicare Trust Fund monies, direct appropriations and a small assessment on all privately-covered lives)? |
| <ul style="list-style-type: none"> Who will conduct the studies? Who will synthesize the data? What constitutes adequate evidence? In other words, what type of studies will be considered in the evidence base (claims data, randomized controlled trials, “real-world” clinical trials, observational data, meta-analyses, registries, etc)? How will we know when we have “enough” evidence? Will there be a common outcome measure by which to measure effectiveness? (e.g., increase in life expectancy or an increase in quality-adjusted life years, or QALYs) How will CER take into account patient behaviors/preferences and the impact on treatment outcomes? How will CER take into account whether treatment is administered correctly by the physician? What will it take to ensure a transparent process and transparent results? Will CER include the evaluation of alternative and complimentary medicine options? Should it? |
| <ul style="list-style-type: none"> CER relies on population-based study results that may not be applicable to the needs of the individual patient. How will CER take into account patient genetics, co-morbidities, income levels, ethnicity, etc., all of which can affect treatment? |
| <ul style="list-style-type: none"> What might the criteria for prioritization be? <ul style="list-style-type: none"> Areas of high need for better evidence Conditions with the highest disease burden Conditions/treatments for which large practice variations exist Areas of greatest potential for improved care Health conditions or treatments with the highest associated expenditures Will CER address purely medical treatments, or will some priority be given to comparing public health interventions, health care delivery systems, and alternative medicines/therapies? How will IOM's recommendations fit with those currently in place at AHRQ? |
| <ul style="list-style-type: none"> Will CER stifle innovation? CER takes a snapshot of available competing treatments but does not take into account developing technologies and the incremental manner in which medical devices and drugs evolve and improve based on predecessor experience. How can CER account for the fact that new products take time to earn market confidence before widespread adoption can occur? Likewise, it takes physicians time to become familiar with operating new medical devices correctly. CER evaluations done too early in a product's life-cycle might unfairly penalize the product and stifle innovation. Will CER squelch the notion of “break-through” drugs? If an early drug is found to be only marginally better than the existing standard of care, an unfavorable CER rating might inhibit the drug's sales. With no sales income to recoup R&D losses and to reinvest in the next generation of the drug, the pharmaceutical company is likely to halt production. If private CER shows that an emerging practice or technology is effective, should there be a probationary period during which the treatment may be used until further CER is able to be conducted? How will CER of pharmaceuticals take into account patient compliance or non-compliance that can affect treatment outcomes? |

The Federal Call for Accelerated Comparative Effectiveness Research in Health Care

Issue	ARRA
Impact on Access to Care & Coverage	According to ARRA, the Federal Coordinating Council is charged with recommending and coordinating research but will not be able to establish clinical guidelines or to “mandate coverage, reimbursement, or other policies for any public or private payer.” Likewise, “none of the reports submitted under this section or recommendations made by the Council shall be construed as mandates or clinical guidelines for payment, coverage, or treatment.”
Changing Practice Patterns	Silent
Privacy Concerns	Under ARRA, one member of the Federal Coordinating Council is a senior employee of the Office of the National Coordinator of Health Information Technology which is charged with using health information exchange to, among other things, “facilitate health and clinical research and health care quality.”
Consideration of Cost-Effectiveness	<p>ARRA makes no mention of incorporating cost-effectiveness into CER. However, there is no explicit policy in place to prevent that from happening.</p> <p>Interestingly, previous legislative proposals have suggested incorporating cost. The Baucus/Conrad Proposed Comparative Effectiveness Research Act of 2008 stated, “The methodology committee is also charged with examining whether scientifically valid methods exist for including cost and health plan design in comparative effectiveness research. Cost and health plan design factors will not be used by the Institute, but a future Congress may decide to incorporate these factors into the Institute’s research down the road.</p> <p>In addition, the draft report on the recent stimulus bill issued by the House Appropriations Committee stated: “By knowing what works best and presenting this information more broadly to patients and healthcare professionals, those items, procedures, and interventions that are most effective to prevent, control, and treat health conditions will be utilized, <u>while those that are found to be less effective and in some cases, more expensive, will no longer be prescribed.</u>”</p>
Slippery Slope	The ARRA contains no language indicative of governmental interference in the patient-doctor relationship and treatment decisions on the basis of CER.

Sources

1. Alliance for Health Reform. Comparative Effectiveness: Better Value for the Money? August 2008. http://www.allhealth.org/Publications/Quality_of_care/Comparative_Effectiveness_Better_Value_for_the_Money_84.pdf.
2. The American Recovery and Reinvestment Act of 2009. 11th Congress. United States Government Printing Office. http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1enr.pdf
3. The ACP Advocate Blog by Bob Doherty. American College of Physicians. Will comparative effectiveness research lead to government-run health care? February 11, 2009. <http://blogs.acponline.org/advocacy/2009/02/will-comparative-effectiveness-research.html>
4. Baucus-Conrad Proposal Can Improve Quality, Lower Costs Throughout American Health Care System. Committee on Finance News Release. August 1, 2008. <http://finance.senate.gov/press/Bpress/2008press/prb080108.pdf>
5. Bending the Curve: Options for Achieving Savings and Improving Value in U.S. Health Spending. The Commonwealth Fund Commission on a High Performing Health Care System. December 2007. http://www.commonwealthfund.org/~media/Files/Publications/Fund%20Report/2007/Dec/Bending%20the%20Curve%20%20Options%20for%20Achieving%20Savings%20and%20Improving%20Value%20in%20U%20S%20%20Health%20Spending/Schoen_bendingthecurve_1080%20pdf.pdf
6. Begley, Sharon. Why Doctors Hate Science. Newsweek, March 9, 2009.
7. Buckley, Ted. The Complexities of Comparative Effectiveness. Biotechnology Industry Organization <http://www.allhealth.org/BriefingMaterials/BIO-Buckley-1149.pdf>
8. Cannon, Micheal. Daschle Care. National Review Online. January 30, 2009. <http://article.nationalreview.com/?q=MTE1YWYwZTgzOTIyOWQwNTEzZTg4N2U1MTc2NTE4YTI=>
9. Carey, Mary and Wayne, Alex. Comparative Effectiveness Research Sparks Concerns over Access to Health Care. Washington Health Policy Week in Review, The Commonwealth Fund, February 23, 2009. <http://www.commonwealthfund.org/Content/Newsletters/Washington-Health-Policy-in-Review/2009/Feb/Washington-Health-Policy-Week-in-Review-February-23-2009/Comparative-Effectiveness-Research-Sparks-Concerns-Over-Access-To-Health-Care.aspx>

Considerations

- Will insurers use the CER results to deny coverage for certain treatments, justify coverage preferences, and/or deny treatment altogether? Is it prudent to make non-coverage decisions based on what treatment works, on average, within a population?
 - Currently, coverage decisions by insurers are done in a widely inconsistent manner, lack transparency and do not always rely on the best available evidence. Will CER bring better clarity and predictability to insurer's coverage decisions?
 - Would patients, particularly those in a life-threatening situation for whom no other options exist, be precluded from accessing treatment that is still in the experimental phases if it has not already been evaluated by the CER process?
 - What impact will greater patient/consumer access to CER have on the availability and use of consumer-directed health plans?
- According to a recent RAND study, patients receive the recommended care only about 55% of the time. Even with CER, how can we change practice patterns to adhere to guidelines more closely? Will financial incentives be put in place to encourage doctors and patients to choose the higher-value care identified by comparative effectiveness research?
 - How will the evidence be communicated to consumers and patients in a way that earns their trust and adoption?
- With potential access to individual electronic medical records and comparative effectiveness research, is it possible that the Federal Coordinating Council could make decisions about what an individual's doctor or insurance company can do about their treatment?
 - With so many patients currently concerned with health privacy rights and many of them opting to forgo care or pay for care out of pocket, how will comparative effectiveness studies have complete data on which to make accurate decisions?
 - How can consumers be assured of their privacy in a way that will make CER the most effective it can be?
- Should the governing body of CER also govern comparative cost-effectiveness research or should it be completely separate?
 - Will incorporating cost lead to rationing of care based on cost alone?
 - Should coverage and reimbursement decisions be made on relative cost or value-for-money considerations?
 - Should coverage and reimbursement decisions be made exclusively on the basis of cost?
 - Medicare is effectively precluded from taking costs into account when making decisions about coverage and would need new legal authority to adjust payments to providers or cost-sharing requirements for enrollees to encourage the use of more cost-effective care.
 - Private insurers might be reluctant to alter payments to physicians based on cost-effectiveness if Medicare did not alter its own policies regarding coverage and payment.
 - Since good economic evaluations depend on the scientific robustness of the comparative effectiveness research, does it make sense to "table" this discussion until such time as CER achieves greater buy-in and comfort among stakeholders?
- Could this be the first step toward the government making clinical judgments, controlling clinical practice, interfering with the doctor-patient relationship and potentially denying treatments and rationing care?

10. Congressional Budget Office. Research on the Comparative Effectiveness of Medical Treatments. Publication No. 2975, December 2007. <http://mail.hpio.net/exchweb/bin/redirect.asp?URL=http://www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf>
11. Daily Mail Reporter Online. Life prolonging cancer drugs to be banned because they cost too much. March 6, 2009. <http://www.dailymail.co.uk/health/article-1159506/Life-prolonging-cancer-drugs-banned-cost-much.html>
12. Evans, Helen. Comparative Effectiveness in Health Care Reform: Lessons from Abroad. The Heritage Foundation Backgrounder, No. 2239, February 4, 2009. <http://www.heritage.org/research/healthcare/bg2239.cfm>
13. GOP.gov Policy News. Question and Answer: Government-rationed Health Care. February 10, 2009. <http://www.gop.gov/policy-news/09/02/10/question-and-answer-government-rationed>
14. Jones, Val. Comparative Clinical Effectiveness Research: Good News In Shades Of Gray. Science-Based Medicine Online, February 19, 2009. <http://www.sciencebasedmedicine.org/?p=381>
15. McGlynn EA, et al., The Quality of Health Care Delivered to Adults in the United States, New England Journal of Medicine, Vol. 348, No. 26, June 26, 2003, pp. 2635-2645
16. National Health Policy Audioconference: The Implications of Comparative Effectiveness to Pharma, Device and Life Sciences Enterprises and Medical Practice, February 23, 2009.
17. Peel, Deborah. A Plea for Using Smart Consent Tools. Government HealthIT. August 13, 2008. <http://mail.hpio.net/exchweb/bin/redirect.asp?URL=http://govhealthit.com/articles/2008/08/a-plea-for-using-smart-consent-tools.aspx>
18. Prescription for Change. Comparative effectiveness: Common-sense research that saves money, lives. February 2009. http://www.prescriptionforchange.org/2009/02/comparative_effectiveness_comm_1.html
19. Slocum, Kim and Morrison, Ian. Consumer Directed Health Care: a 360 Degree View. CRC Press, 2009.
20. Wilensky, Gail. Comparative Clinical Effectiveness: Leveraging Innovation to Improve Health Care Quality for All Americans. Testimony before the U.S. Senate Committee on Finance. July 17, 2008. <http://finance.senate.gov/hearings/testimony/2008test/071708gwtest.pdf>
21. Turna, Ray. Healthcare Stakeholders Pushing for Pharmacogenomics to Guide Comparative Effectiveness Reviews, Pharmacogenomics Reporter, March 11, 2009.

The Health Policy Institute of Ohio is a nonpartisan, 501(c)(3) nonprofit organization that forecasts health trends, analyzes key health issues and communicates current research to policymakers, legislators and other decision makers.

Additional copies of this policy brief are available by calling the Health Policy Institute of Ohio at **614-224-4950** or by visiting the Institute's Web site at **<http://www.healthpolicyohio.org>**.



37 W. Broad St., Suite 350
Columbus, OH 43215-4198
614-224-4950
<http://www.healthpolicyohio.org>