

Myths and Facts: Comparative Effectiveness Research

FACT SHEET

Patients and health care providers make better medical decisions when they have access to the latest research comparing the effectiveness and safety of different treatment options. Armed with better information, patients and their doctors can choose the course of action that is *right for them and their situation*. This can improve care and save time and money by preventing unnecessary tests and wasted days or weeks, on less effective (or even ineffective) treatments and drugs.

Unfortunately, misinformation continues to circulate about what Comparative Effectiveness Research (CER) is and how it will be used. This fact sheet seeks to dispel some of the more common myths so that consumers have clear and accurate information about CER.

Some Definitions

What is CER?

Comparative effectiveness research compares different drugs, devices, and surgical interventions to determine the most effective approach to a given illness or condition. To provide this information, comparative effectiveness research must examine how different people, with varying backgrounds and needs, respond to different treatment options.

Why is it used?

The purpose of CER is to make information based on medical science and evidence available to patients, clinicians, and other decision-makers. When combined with other sources of information and your doctor's judgments, and taking your unique health circumstances into account, CER can help steer you to the treatments which have the best chance of making you better.

What does it include?

CER is conducted on all sorts of treatments, including prescription medicines, diagnostic and surgical procedures, devices and technologies, behavioral changes, and delivery system strategies.

Myth

- **CER will result in the rationing of health care. People, and especially older and disabled patients, may be denied care that is deemed too expensive.**

The Facts

- Coverage decisions are being made today without the benefit of good clinical evidence. CER will provide the robust, objective, and transparent scientific support necessary to ensure that coverage decisions are based on a patient's medical needs.
- CER will provide patients and their doctors with more information, not less, to make informed choices about the best treatment options.
- With clear comparative information patients will no longer have to waste their time and money or risk their health on less effective and potentially harmful

treatments. Instead, they can be sure that they are receiving the right care, at the right time, for the right reason.

- CER will be especially useful to the most vulnerable patients, such as older people and underserved individuals, whose lives are dependent on knowing which treatment is the best for them.
- CER will reveal when different treatment options provide the same benefits – meaning that patients can choose the least invasive option without worry that they are compromising their health.
- CER will help ensure that Americans get the best care possible for their health care dollar.
- CER may demonstrate that a costlier treatment is, in fact, most effective and worth the expense.

Consider - A 2009 study published in Lancet showed that, on the whole, patients with coronary disease had similar mortality rates when treated with coronary-artery bypass surgery or with percutaneous coronary intervention (PCI). Yet, when the results are divided by age a significant difference appears. For patients age 65 and up, mortality was considerably lower with surgery. For patients age 55 and younger, mortality was lower with PCI.¹

Myth

- **CER will lead to “one-size-fits all” medicine. Patients will be forced into treatments that research says is best for the population as a whole, rather than what their doctors believe is best for them individually.**

The Facts

- CER can actually enhance more personalized medicine by generating research that is more relevant to individual patients.
- CER will give doctors more information about what treatments and services are most appropriate for an individual patient, in a particular situation, given their patient’s history and individual needs. Such information isn’t always available today.
- CER can also help to show when treatments might be more appropriate for a particular group of patients. For instance, some cancer treatments show little to no effect on the overall survival of the “average” patient, but have huge effects for particular patients.

Consider - A 2004 comparative effectiveness study published in the Journal of the American Medical Association found that magnetic resonance imaging (MRI) is more sensitive for detecting breast cancers than mammography, clinical breast examination or ultrasound in women who carry the BRCA1 and BRCA2 mutation.²

Myth

- **CER will exclude minority and disabled populations, and consequently increase inequalities in the quality of and access to health care.**

The Facts

- CER will allow us to look at how different populations respond to treatments and services, helping to remedy the historical exclusions of certain populations, including minorities, women, children, and the disabled from research.
- CER funded through the stimulus legislation passed in February 2009 is required to include these populations. Specifically, minority health issues will be the focus of a new Citizen's Forum, to be launched with \$10 million from the stimulus package that will involve a cross-section of patients in CER discussions.

Consider - CER priority study identified by the Institute of Medicine: "Compare the effectiveness of clinical interventions (e.g. prenatal care, nutritional counseling, smoking cessation, substance abuse treatment, combinations of these interventions) to reduce incidences of infant mortality, pre-term births, and low birth rates among African American women."³

Myth

- **Government bureaucrats will interfere with the doctor-patient relationship by making decisions about who gets what care. Doctors already have all the information they need to help their patients and know what is best for their patients.**

The Facts

- Doctors and patients want and need better information to make the best decisions. CER will help strengthen the doctor-patient relationship because they will have better tools and information to select the best treatment option.
- The Federal Coordinating Council for Comparative Effectiveness Research – created by the February 2009 stimulus package – will NOT interfere with the doctor-patient relationship or decide who gets what care. It will coordinate the research being conducted by various federal agencies to ensure that their work is complimentary and not duplicative, and make recommendations to Congress and the President on priority areas so that research topics can be selected that best meet the needs of Americans.

Consider – "In 1993 the results of a large, well-conducted randomized controlled trial comparing two different treatments for a common condition, deep vein thrombosis, were published in the New England Journal of Medicine. The results demonstrated that a short series of injections of a new drug, enoxaparin, which could be done in an outpatient setting or at home, was just as effective as the traditional treatment of intravenous heparin which required a 5-7 day hospital stay. In addition, patients treated with the injection required many fewer blood tests and reported higher satisfaction with their care. There being no

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authoritative body to evaluate the results of this study, synthesize it with other evidence, and present judgments on the comparative effectiveness of the two treatment options, enoxaparin took years to become widely used in practice. [...] [And], without a recognized entity to present an authoritative assessment, insurance coverage for outpatient treatment remained uneven, causing many patients in the mid-to-late 1990s to undergo unnecessary hospitalization.”⁴

Myth

→ **CER is a slippery slope to putting price controls on treatments.**

The Facts

- Effectiveness research is about making sure that patients receive the right care, at the right time, in the right setting.
- Sometimes comparative effectiveness research will show that the least costly option is the best treatment. But other times the research may show that a more expensive treatment is best.
- At least one-third of medical procedures have questionable benefits, according to the RAND Corporation.⁵ Therefore CER will help us save money in the long run by getting patients and doctors the information they need to choose effective care.

Consider - Many cancer treatments show little to no effect on the overall survival of the “average” patient, but have huge effects for particular patients. One example is epidermal growth factor receptor (EGFR) inhibitors which are significantly more effective when used to treat lung cancer patients with certain mutations in the EGFR rather than all patients. Another example is Erbitux® (cetuximab) and Vectibix® (panitumumab) which is used to treat patients with metastatic colorectal cancer. When given to patients who have the normal KRAS gene, their survival outcomes improves. When given to patients who have a mutant form of the KRAS gene, there was no benefit.⁶

Myth

→ **CER will discourage innovation – drug and device makers will not have an incentive to develop new treatments.**

The Facts

- To receive FDA approval, drug and medical device companies only have to show that their products are better than a placebo. As a result, the market is flooded with new drugs and devices which are no better than those already in existence. CER will create incentives for companies to develop products that are more effective than existing alternatives.
- CER will shed light on areas where existing treatments and services are not meeting the needs of specific populations and could stimulate innovation in those areas.

The National Partnership for Women & Families is a non-profit, non-partisan advocacy group dedicated to promoting fairness in the workplace, access to quality health care and policies that help women and men meet the dual demands of work and family. More information is available at www.nationalpartnership.org.

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¹ Alan Garber, MD, PhD and Sean Tunis, MD, "Does Comparative-Effectiveness Research Threaten Personalized Medicine," *New England Journal of Medicine*, 2009;360: 1925-1927.

² Ellen Warner, MD et al, "Surveillance of BRCA1 and BRCA2 Mutation Carriers With Magnetic Resonance Imaging, Ultrasound, Mammography, and Clinical Breast Examination," *Journal of the American Medical Association*, 2004;292:1317-1325.

³ Report Brief: Initial National Priorities for Comparative Effectiveness Research, Institute of Medicine, June 2009: 5. Accessed at: <http://www.iom.edu/Object.File/Master/71/107/CER%20report%20brief%2008-13-09.pdf>.

⁴ Steve Pearson, MD, "From Better Evidence to Better Care: Using Comparative Effectiveness Research to Guide Practice and Policy" *Implementing Comparative Effectiveness Research: Priorities, Methods, and Impact*, The Brookings Institution, June 2009. Accessed at http://www.brookings.edu/events/2009/~media/Files/events/2009/0609_health_care_cer/0609_health_care_cer.pdf

⁵ The Rand Corporation. "Assessing the Appropriateness of Care: How Much Is Too Much?" 1998. Available at: http://www.rand.org/pubs/research_briefs/RB4522/index1.html Access April 22, 2009.

⁶ Alan Benson III, MD, FCAP, and Kim Lyerly, MD, "Improving Medical Decisions Through Comparative Effectiveness Research," *Friends of Cancer Research*, May 2009. Accessed at: http://focr.org/files/CER_REPORT_FINAL.pdf.