

Comparative Effectiveness Research

Faced with an ever-increasing number of scientific advances and treatment options, physicians, patients, payers, and others within the health care system have a need to know more about how different treatments and approaches compare with each other. Scientific research evidence, the evaluation of different treatments and interventions, will better equip patients and their physicians to make informed health decisions. Better care decisions help improve the quality of patient outcomes and lead to the more efficient use of resources across the health care system. However, the evidence from this comparative effectiveness research should not be used to deny coverage or reimbursement for care deemed most appropriate for each patient.

Background

The number of available interventions (such as diet, exercise, counseling, and over-the-counter products, among others) and treatment options has risen. As a result, physicians, payers, patients, and policy-makers want to understand more about how different health care treatments and approaches compare. To address this need, the federal government has dedicated funding to increase the generation of comparative effectiveness research in the United States. The Institute of Medicine (IOM) defines comparative effectiveness research as “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor clinical conditions, or to improve the delivery of care. The purpose of **comparative effectiveness research** is to assist consumers, physicians, purchasers and policy-makers to make informed decisions that will improve health care at both the individual and population levels.”¹ Many organizations are involved in efforts to understand how different treatments compare.

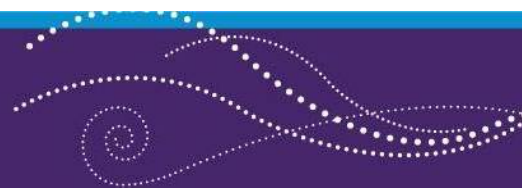
The government expanded its funding of comparative effectiveness research in 2009 under the American Recovery and Reinvestment Act of 2009² (ARRA, sometimes called the “stimulus package”). Beyond increasing the government’s role in prioritizing topics for conducting comparative effectiveness research, the funding is being used to:

- Develop new data sources and research infrastructure (such as registries);
- Develop and standardize research methodologies;
- Train a workforce to do research and translate findings; and
- Conduct research on a variety of health care interventions and in underrepresented populations.

The Affordable Care Act³ (ACA) passed in March 2010 calls for the creation of a non-profit, non-governmental public-private entity to conduct comparative effectiveness research, known as the Patient-Centered Outcomes Research Institute. The Institute’s charge is to:

- Identify research priorities to inform its research project agenda;
- Conduct research in-house; and/or
- Contract with other entities to conduct research, giving preference the Agency for Health care Research and Quality (AHRQ) and the National Institutes of Health (NIH).

The Institute’s mandate covers a broad range of research topics and study methodologies, including medications, devices, procedures, and health care delivery systems. It focuses on clinical effectiveness rather than cost effectiveness, and requires research to account for patient differences in response to similar treatments. The law prohibits the Secretary of Health and Human Services (HHS) from using findings from comparative effectiveness research as the sole basis for coverage decisions, although it may inform them.



Key Facts and Figures

- ARRA allocated \$1.1 billion to the Department of Health and Human Services (HHS), AHRQ, and the NIH to support comparative effectiveness research over two years.
- ACA authorized the creation of a Trust Fund with appropriations beginning in 2010 and increasing through 2019.
 - FY 2010-2012: Appropriations of \$10M, \$50M, and \$150M respectively.
 - FY 2013-2019: Mix of public and private funds, reaching as much as \$600M per year.

Pfizer's Position

The effectiveness of Pfizer medicines is evaluated every day by health care professionals, health plans, regulators, and patients. More research will help facilitate good decision-making, but should not be used to deny coverage or reimbursement for care to all patients. Pfizer encourages rigorous research to inform health care decisions for individual patients, and toward that end supports the creation of an independent entity to oversee comparative effectiveness research studying treatments, health care system infrastructure, and health insurance plan benefit design.

How Patients and Health Care Professionals Benefit

Rigorous research comparing treatments and interventions can help patients and their physicians choose the correct treatment. Evidence focusing on how different patients respond to the same treatments may also help improve patient outcomes and quality of care.

How the Health Care System Benefits

More information about different treatments can help better direct health care resources and spending so that the right patients receive the right treatments or interventions at the right time; this makes the healthcare system more efficient and a better value for the investment.

What it Means for Pfizer

Greater sources of information help ensure Pfizer products are used appropriately through the sharing of evidence about how different treatments work, and by better equipping patients and their physicians to make informed care decisions. Evidence from comparative effectiveness research should not be used to limit patients' access to Pfizer medications and other products when deemed the appropriate treatment.

¹ IOM. <http://iom.edu/Reports/2009/ComparativeEffectivenessResearchPriorities.aspx>

² American Recovery and Reinvestment Act. Pub. L. 111-5.

³ The Patient Protection and Affordable Care Act (PPACA, P.L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA, P.L. 111-152), is collectively referred to in this paper as the Affordable Care Act of 2010 (ACA).