

“Comparative Effectiveness”, two words that have created a lot of questions, uncertainty, and anxiety in healthcare and in the pharmaceutical and device industry. But, is Comparative Effectiveness a new term, for an old concept?

In June 2009, the National Priorities for Comparative Effectiveness Research, Institute of Medicine (IOM) Report Brief, defined Comparative Effectiveness Research (CER) as the generation and synthesis of evidence that compares the benefits and harms of alternative methods to PREVENT, DIAGNOSE, TREAT, and MONITOR a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels. The American Recovery and Reinvestment Act of 2009 included \$1.1 billion for Comparative Effectiveness Research (CER). The money was distributed accordingly, AHRQ \$300 million, NIH \$400 million and Office of the Secretary \$400 million.

Comparative Effectiveness Research (CER) is designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options. The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care.

True to form, AHRQ has undertaken a large scale effort to collect information and measure Comparative Effectiveness and is constantly asking for input. AHRQ has an Effective Health Care (EHC) Program Website. The Effective Health Care Program funds individual researchers, research centers, and academic organizations to work together with the Agency

for Healthcare Research and Quality (AHRQ) to produce effectiveness and comparative effectiveness research for clinicians, consumers, and policymakers. AHRQ is the lead Federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. As one of 12 agencies within the Department of Health and Human Services, AHRQ supports health services research that will improve the quality of health care and promote evidence-based decision making. The Effective Health Care Program produces three primary products:

**Research reviews:**

**Comparative effectiveness and effectiveness reviews**

**Technical**

**Original research reports**

**Summary guides**

How is the work being conducted by AHRQ and other organizations applicable in practice in the REAL WORLD? Some hospitals, clinicians and Pharmacy and Therapeutics Committees, in their own way have been practicing Comparative Effectiveness Research for years and developed Evidence Based Guidelines or Disease Specific Pathways. The term Comparative Effectiveness is new, but we may have called it Pharmacoeconomics or Thereconomics. Thereconomics measures both the financial and clinical quality outcomes associated with various treatment and prevention options, including drugs, devices, radiation, surgical and interventional procedures. It applies to diagnostics also, which can include radiology, lab, and genomics used to diagnose or prevent disease. It maintains a balanced scorecard approach which

many hospitals use. CE will be a challenge for hospitals that operate in the silos of department budgets/cost centers or even health plan budget based, where health plans do not coordinate inpatient care with outpatient care (preventative or treatment) from a quality and cost perspective. These are some of the challenges for industry, healthcare executives, clinicians, payers and patients.

Cancer is a CE disease model, where patients may get various treatments, including drugs, radiation, surgery, or a combination of each. The Tumor Board acts as a CE Committee, reviewing a patient's Tumor Type and what type of treatment/protocol is best. Some payers are conducting CER and may even be using cancer guidelines from organizations like NCCN (National Comprehensive Cancer Network). Certain diagnostic tests are evaluated to track effectiveness of treatment and even prevention of disease for cancer. Drug companies are developing Companion Genetic/Bio-markers for cancer drugs they are developing which may demonstrate CE for their drugs for certain tumors.

The move in some hospitals and Accountable Care Organizations (ACOs) maybe to create a Comparative Effectiveness Committee (CEC) and also to create a Comparative Effectiveness Pharmacist (CEP) to coordinate activities which historically would have went separate ways to a P and T and Value Analysis Committee. The movement to reimbursement models such as Value Based Purchasing, Bundled Payments, Shared Success Payments, is going to foster more of a move to Comparative Effectiveness. Value Based Insurance (VBI) programs have already been moving down this path to lower cost, improve efficiencies, and improve patient care.

As many pharmaceutical companies are finding out, Comparative Effectiveness studies may be part of the process in receiving approval for new drugs from the FDA. It may no longer be sufficient, to just compare your product to a placebo, but also to a gold standard. One example is new MRSA (methicillin resistance Staph aureus) drugs compared to the gold standard, vancomycin. Comparative Effectiveness is here to stay. Everyone needs to embrace the model in each of our businesses, with the ultimate goal, to demonstrate improvement in patient care, value (clinical and financial) for our products, and take cost out of the healthcare system in prevention, treatment, or diagnostic. We need to participate in CER, work with AHRQ and other organizations, such as ACOs, and help change the model if appropriate. CER should not deter research for drugs, devices, and diagnostics.

Written by:

Fred J. Pane R.Ph, FASHP  
Sr. Director  
The Medicines Company

(Comments and article do not reflect the views of The Medicines Company)