

Most research on the effectiveness of medical treatments has compared the effects of a given treatment to no treatment. To improve clinical outcomes while getting more for our health care dollars, there is a need for comparative effectiveness research (CER) that compares the benefits of various treatment and diagnostic modalities to each other. The primary goal of CER should not be to contain costs. In fact, in certain cases, the most effective intervention could be the one that is most costly. The goal of CER should be to enhance physician clinical judgment to provide the right treatment at the right time.

The AMA supports the central physician representation on any CER entity, adequate funding of CER, appropriate implementation of CER findings and development of priorities for CER.

The American Medical Association (AMA) strongly supports comparative effectiveness research (CER) as a way to provide physicians and patients with information about which treatment or intervention works best. There is widespread consensus that physicians and patients would benefit from research that compares the benefits of various treatment and diagnostic modalities. CER has the potential to have a profoundly positive impact on the quality of the information available to physicians and patients and, when used appropriately, will improve value and may address escalating health care costs. CER should improve health care value by enhancing physician clinical decision-making—not dictating it—and fostering the delivery of patient-centered care.

Background

“There is not enough credible, empirically based information for health care providers and patients to make informed decisions about alternative services for diagnosing and treating most common clinical conditions.”

—June 2007 report of the Medicare Payment Advisory Commission (MedPAC)

Most research on medical treatments to date has focused on comparing the effects of a given treatment to no treatment, rather than comparing alternative treatments to each other. For example, for prescription drugs to gain Food and Drug Administration (FDA) approval, prescription drug manufacturers conduct research that compares their drugs to a placebo in the majority of cases, versus comparing their drugs to similar drugs. The lack of comparative research on the effects of alternative services and treatments has led to a lack of knowledge about whether new treatments outperform existing treatments.

Current state of affairs

- The Patient Protection and Affordable Care Act, the health system reform legislation enacted into law in March 2010 (Public Law 111-148), provides for the creation of the Patient-Centered Outcomes Research Institute (Institute), an independent, not-for-profit entity that is tasked with supporting research on comparative clinical effectiveness. The Institute model is highly consistent with AMA policy calling for the creation of an objective, independent CER authority.
- The Institute will be governed by an independent Board of Governors that is required by law to include individuals representing practicing clinicians.

- The Institute is prohibited by law from issuing mandates or recommendations concerning practice guidelines, coverage recommendations or policy. It is vital to maintain the separation between entities that conduct and support CER and those entities and agencies that make coverage and payment determinations.
- The Institute is charged with using rigorous evidence standards and methodologies.
- The Federal Coordinating Council for Comparative Effectiveness Research (FCC-CER), established as part of the American Recovery and Reinvestment Act (ARRA) of 2009 (Public Law 111-5), was therefore terminated in the Patient Protection and Affordable Care Act. The purpose of the FCC-CER was to coordinate CER and related health services research among federal agencies in order to reduce “duplicative efforts,” and encourage “coordinated and complementary use of resources.”
- ARRA also included \$1.1 billion to fund additional CER administered by the Agency for Healthcare Research and Quality, National Institutes of Health, and Secretary of the Department of Health and Human Services (HHS).
- In the private sector, health plans often conduct their own reviews of existing evidence and treatments, but can treat such findings as proprietary and keep their findings confidential. In addition, private sector investment in CER to date has been limited, as health plans investing in CER will likely not reap all of the benefits resulting from the findings, and instead only capture those that affect their beneficiary populations.

How to get the most for our health care dollars

Ensure physician representation on any CER entity

To ensure that science and the well-being of patients are prioritized in any CER entity, physicians, researchers and patients should have substantial and central representation on the governing body and subsidiary units. As key decision-makers, physicians and patients are uniquely motivated to promote the delivery of quality care while maximizing the opportunity to get the most for our health care dollars. Therefore, it is vital that representatives of actively practicing physicians, who currently have strong relationships with their patients, have substantial representation on any governing body or subsidiary group within an entity or agency that conducts CER.

Adequately fund CER

The AMA supports the secure and sufficient funding necessary to produce high-quality CER through the Patient-Centered Outcomes Research Trust Fund, which was established in the Patient Protection and Affordable Care Act. This funding for CER will build the clinical evidence base and address knowledge gaps that cannot be undertaken by physicians in isolation. Consistent with AMA policy, the funding stream is not subject to the political process, thereby safeguarding the independence of the CER entity.

Appropriately implement CER findings

CER findings alone will not transform health care quality and value without a concerted set of strategies to ensure physicians and other health care providers are able to readily access findings, synthesize them into clinical guidelines and decision support systems, and utilize them. Without these components, which are designed to engage physicians in the process and support their decision-making, the true promise of CER will not be realized.

- Information and evidence resulting from CER should be easily available to physicians in a useable format, and be incorporated into the latest communications vehicles and technologies, such as health information technology. Also, the AMA supports expanding CER capacity, including expansion of clinical registries and engagement of medical specialties, to facilitate rapid dissemination of CER findings for use by clinicians and specialties for their development of practice guidelines.
- CER implementation must respect the individuality of and differences among patients, and the physician-patient relationship. Physician discretion in the treatment of individual patients, the core of the practice of medicine, must be upheld.
- Physicians have a key role and responsibility to disseminate comparative effectiveness information to patients.
- The AMA opposes conferring the CER entity with authority to issue recommendations or mandates concerning practice guidelines, coverage, payment or policy.

Develop priorities for CER

- Defining CER: The AMA believes that CER should be broadly defined to include a comparison of how to manage a specific health problem, condition, or disease. CER should include long- and short-term assessments of diagnostic and treatment modalities for a given disease or condition in a defined population of patients. Diagnostic and treatment modalities should include drugs, biologics, imaging and laboratory tests, medical devices, and health services. It should not be limited to new treatments.

■ Priority areas for research:

- Prevention, management and treatment of high-volume, high-cost treatments for which there are significant practice variations.
- Prevention, management and treatment of preventable disease, which is a major cost driver in today's health care system. Key areas in need of further study and research include cardiovascular, endocrinology and metabolism disorders (including diabetes) and nutrition (including obesity).
- Effectiveness of treatments in racially and ethnically diverse populations where health disparities exist.

SPOTLIGHT: AMA-convened Physician Consortium for Performance Improvement

The AMA-convened Physician Consortium for Performance Improvement® (PCPI) is a national physician-led initiative dedicated to improving health care quality through:

- Identifying and developing evidence-based clinical performance measures and measurement resources that enhance quality of patient care and foster accountability;
- Promoting the implementation of effective and relevant clinical performance improvement activities; and
- Advancing the science of clinical performance measurement and improvement.

In an effort to obtain timely, quality responses from the more than 170 national medical specialty and state medical society PCPI stakeholders, experts in methodology and data collection, and many others involved in quality improvement and performance measurement, the PCPI surveys its members periodically to identify variations in practice, assess the evidence base in a wide array of areas, and identify areas where there are gaps in knowledge. These surveys provide an ongoing opportunity to identify clinical conditions and treatments in need of study by the CER entity.