



Position Statement on Comparative Effectiveness Research (CER)

The North American Spine Society (NASS) is a multidisciplinary medical organization dedicated to fostering the highest quality, evidence-based, and ethical spine care by promoting education, research, and advocacy. NASS is comprised of more than 6,200 members from several disciplines including orthopedic surgery, neurosurgery, physiatry, neurology, radiology, anesthesiology, research, physical therapy and other spine care professionals.

Background/Introduction:

Comparative Effectiveness Research (CER) is a method of determining the effectiveness of a drug, device, or medical procedure in relation to another treatment option. The June 2009 Institute of Medicine Report-Initial National Priorities for Comparative Effectiveness Research¹ defines 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 success of the item being studied can be measured by clinical outcomes derived from the course of action taken to remedy a patient’s condition, which can range from no treatment to medical interventions to highly invasive surgical procedures. CER provides the consumer/society with the information necessary to determine what health care options provide the highest quality of care to patients, given their specific needs.

On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act of 2009 (ARRA). Within this bill, the President approved appropriation of \$1.1 billion for comparative effectiveness research. The money will be distributed to three agencies/institutes for research on CER: the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ) and the Department of Health and Human Services (HHS). By appropriating this significant amount of money, the President and Congress have highlighted the importance of improving quality through CER analysis. On June 30, 2009, the Federal Coordinating Council for Comparative Effectiveness Research released their report to the President and Congress. The Council held three listening sessions whereby various stakeholders were given an opportunity to discuss the various definitions and implementation strategies of CER. In their report the Council defined CER as “conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings.”²

The Importance of Comparative Effectiveness Research:

As the rising costs of health care take up a larger share of the US economy, it is becoming imperative that health care outcomes are in line with the dollars being spent within the health care system. Currently, the United States spends 16 percent of its gross domestic product (GDP) on health care services—ranking it 2nd in the World in health care spending by the World Health Organization (WHO). Despite spending more than almost every other industrialized nation, the WHO ranks the United States 37 out of 191 countries on the organization’s Health Care Ranking System. Analysts predict that the percentage of GDP dollars spent on health care will continue to increase over the coming decades. Some of the rising cost of health care is due to the increasing adoption of new and more expensive technologies which have the potential to improve the quality of care. Increased utilization also adds to the overall cost of care and may not necessarily provide an equal increase in quality improvement. It is believed that CER can further define quality care through research, advancing patient care and providing practitioners and patients with the tools necessary to make informed decisions. The impetus to create a center for comparative effectiveness research has been driven by the need to improve quality of care, with the hope that this will lead to decreased costs as well through:

- Providing better outcomes;
- Assistance to consumers, clinicians, purchasers and policy makers in making informed decisions;
- Reductions in disparities in care;
- Reductions in geographic variation in care;
- Reductions in use of ineffective care;
- Maximization of the benefit received for each health care dollar spent and allowing physicians and patients to reach an informed decision on the relative merits and risks of a particular procedure or diagnostic test.

¹ Institute of Medicine. Initial National Priorities for Comparative Effectiveness Research. June 2009. Available at: www.iom.edu/cerpriorities. Accessed: 06/30/09.

² Federal Coordinating Council for Comparative Effectiveness Research. Report to the President and Congress June 2009. (<http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>).

Comparative Effectiveness Research Coordination:

ARRA established a 15 member federal council whose task is to coordinate CER within the federal government. There are essentially three approaches that are currently being considered:

- (1) An agency within the Centers for Medicare and Medicaid Services (CMS), funded completely by federal funds;
- (2) An independent government institute that receives funding from both private and federal funds;
- (3) A private enterprise funded by insurance companies as well as CMS.

The fact that many stakeholders will benefit from studies published by a CER institute will likely prevent any institute from being funded solely by private dollars, as this would introduce an element of bias. Likewise, since nearly 50 percent of all health care dollars are spent by the federal government, it makes sense that the government should have a major financial stake in a CER institute, and it is clear that any research funded by the government will be available for all stakeholders to utilize in health policy and patient care decisions.

Organizations Currently Conducting Comparative Effectiveness Research:

AHRQ (<http://www.ahrq.gov/>) was created initially in 1989 as the Agency for Health Care Policy and Research (AHCPR) and reauthorized as the AHRQ in 1999 as an agency within the Department of Health and Human Services. With a budget of nearly \$330 million, its primary mission is to design research to improve the quality, safety and effectiveness of the United States health care system. Since its inception, AHRQ has expanded to include Evidence Based Practice Centers whose mission is to critically evaluate the evidence for various procedures, devices and drugs. AHRQ currently devotes \$30 million per year to CER and has produced many reports on the comparison of currently available therapies (<http://www.effectivehealthcare.ahrq.gov/index.cfm>). This budget will expand substantially with the additional \$300 million in CER funding provided by ARRA, as will the scope and amount of work done in this area.

The Veterans Administration (VA) and NIH also conduct studies on the effectiveness of various treatments, although CER studies represent only a small portion of the budget of these programs. Private insurance companies have also established their own programs to evaluate new technologies. The Blue Cross and Blue Shield Association Technology Evaluation Center (TEC), for example, has produced 20 – 25 evidence based reviews of new technology since its creation in 1985. These reports are publically available (<http://www.bcbs.com/blueresources/tec/tec-assessments.html>); however, many do not directly compare the effectiveness of alternative therapies.

Congress, in ARRA, tasked the Institute of Medicine (IOM) with recommending a set of national priorities for research questions to be addressed by CER. Approximately 100 priorities were listed by the IOM, divided by level of importance into four quartiles. Priorities that directly involved the study of diseases of the spine include:³

- Establish a prospective registry to compare the effectiveness of treatment strategies for low back pain without neurological deficit or spinal deformity. (First Quartile)
- Compare the effectiveness of treatment strategies (eg, artificial cervical discs, spinal fusion, pharmacologic treatment with physical therapy) for cervical disc and neck pain. (Second Quartile)
- Compare the long-term effectiveness of weight-bearing exercise and bisphosphonates in preventing hip and vertebral fractures in older women with osteopenia and/or osteoporosis. (Second Quartile)
- Establish a prospective registry to compare the effectiveness of surgical and nonsurgical strategies for treating cervical spondylotic myelopathy (CSM) in patients with different characteristics to delineate predictors of improved outcomes. (Third Quartile)
- Compare the effectiveness of traditional and newer imaging modalities (e.g., routine imaging, magnetic resonance imaging [MRI], computed tomography [CT], positron emission tomography [PET] when ordered for neurological and orthopedic indications by primary care practitioners, emergency department physicians and specialists. (Third Quartile)
- Compare the effectiveness (e.g., pain relief, functional outcomes) of different surgical strategies for symptomatic cervical disc herniation in patients for whom appropriate nonsurgical care has failed. (Fourth Quartile)

Concerns About CER:

It is universally accepted by the health care community that more research must be conducted to maximize the value of health care spending on the entire system and improve outcomes for patients. With the costs of health care rising at a rate faster than inflation, there is a general consensus that costs need to be contained. A June 2007 report from the Medicare Payment Advisory Commission (MedPAC), the independent body that advises Congress on the Medicare program, stated that “there is not enough credible,

³ <http://www.iom.edu/CMS/3809/63608/71025.aspx>

empirically based information for health care providers and patients to make informed decisions about alternative services for diagnosing and treating most common clinical conditions.”

Much of the concern surrounding CER involves anxiety that “comparative effectiveness” is equivalent with or will eventually be substituted by “cost containment.” This raises issues related to limiting access to medical care based solely on financial considerations, rationing of care and intrusion of a governmental agency between the patient and physician.

Additional concerns surrounding CER pertain to the application of research findings to coverage decisions and the fear of increased regulation by the government in health care decision-making. While some medical conditions may follow predictable patterns, respond to evidence-based treatments and be generalized to a population, there are numerous other conditions and therapies that need to be individualized by the physician, based on the patient’s individual characteristics (e.g., co-morbidity, age, gender, race, potential for noncompliance with treatment and access to care). Atypical and unusual circumstances may require unique and creative solutions. Strict government policies based solely upon CER will inappropriately limit this decision-making process, and CER recommendations may occur without adequate representation and input from actively practicing physicians, who are responsible for patients’ well-being. In addition, inappropriate use of CER in coverage decisions could lead to health care triaging and blanket coverage policies to inappropriate populations.

NASS Position:

Based on the June 2009 Institute of Medicine Report - Initial National Priorities for Comparative Effectiveness Research⁴, CER is defined 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 objective 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.” NASS agrees with these statements.

Transparency. NASS supports CER that promotes the goal of achieving improved quality of health care. This research should be conducted in a transparent process that allows all stakeholders the opportunity to provide input. Dissemination of information should be wide and frequent. Any group or organization that will be affected by a CER review should have the opportunity to actively participate in the development process. Physicians and members of the health care work force should be allowed to participate in all panels that evaluate this research.

Agency. The agency which has the responsibility to conduct CER research should be a public entity with substantial representation by stakeholders within the medical community, including professional medical associations. This agency should have a steady source of funding. By doing so, NASS believes that the agency will have an unbiased opinion on the effectiveness of various procedures. A steady source of funding will allow the agency to be unaffected by changes in the political climate. The need to obtain funding on an annual basis incurs the risk of development of recommendations for publicity in order to procure funding from governmental bodies through public pressure.

Individualized Treatment. Policies based upon comparative effectiveness research should permit the physician, when necessary, to individualize treatment for any patient. Physicians and the public should be given sufficient information on the limitations and exceptions of CER research to better inform decision-making. One of the goals of CER is minimize disparities in care. One way to do this is to allow individualized treatment of patients and populations.

Application of Research Findings. CER is aimed at assisting consumers, clinicians, purchasers, and policy makers in making informed decisions that will improve health care at both the individual and population levels⁴. NASS agrees with the bipartisan legislative initiatives introduced in Congress that restrict recommendations of any CER agency from being used to influence insurance or other financial coverage decisions for any particular medical condition.

Liability Protection. Following CER recommendations and clinical treatment guidelines in the care of patients may in some circumstances place the physician at an increased risk of medical liability claims. NASS believes that compliance with recommendations based upon CER and clinical guidelines should impart a provider with protection from medical liability claims resulting from the use of these guidelines.

Approved by NASS Board of Directors, October 2009.

⁴ Institute of Medicine. Initial National Priorities for Comparative Effectiveness Research. June 2009. Available at: www.iom.edu/cerpriorities. Accessed: 6.30.09.