



Statement

of the

American Medical Association

to the

Institute of Medicine

**RE: National Comparative Effectiveness Research
Priorities**

**Presented by: Nancy H. Nielsen, MD, PhD
March 20, 2009**

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Presented by: Nancy H. Nielsen, MD, PhD

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Good morning. My name is Nancy H. Nielsen, MD, PhD. I am an internist and currently serve as the President of the American Medical Association (AMA). I am also a clinical professor of medicine and senior associate dean for medical education at the State University of New York at Buffalo School of Medicine and Biomedical Sciences. The AMA commends the Committee for convening this public meeting and reaching out to clinicians and medicine to solicit our input.

Physicians today have access to a wide array of medical information. However, there remains far too little rigorous evidence available about which treatments work best for which patients. The AMA strongly supports increased federal funding of comparative effectiveness research (CER). Though there are a broad array of areas where CER would bring benefits, **we must strategically target support for CER where it will significantly improve health care value**

by enhancing physician clinical judgment, foster the delivery of patient-centered care, and produce substantial benefit to the health care system as a whole.

All aspects of the CER process, including priority setting, must be transparent and include a central role for physicians in its oversight and governance. Given the nascent nature of this endeavor, the perception among physicians that the CER agenda is being driven by payers who only have cost containment as their goal will seriously undermine efforts to cement physician support as we continue forward on comprehensive health care system reform. It is imperative that physicians, including clinicians and their organizations, have an active, ongoing, and central role at all stages of the CER process. Let me be clear; the AMA strongly supports CER and looks forward to results that will guide shared decision-making by patients and their physicians.

The AMA supports the view that the priority areas of CER should focus on high volume, high cost diagnostic and treatment modalities, and other health services for which there is significant variation in practice.

The AMA supports a broad definition of CER that involves a comparison of different modalities to manage a specific health problem, condition, or disease. Besides the more typical areas of research such as pharmaceuticals and medical devices, CER should also focus on implementation and dissemination issues that would shed light on the most effective strategies that promote a learning health care system and improved clinical outcomes.

In terms of methodology and study design, CER should include long-term and short-term assessments. CER should not be limited to new treatments. In addition, the findings should be re-evaluated periodically, as needed, based on the development of new alternatives and the emergence of new safety or efficacy data.

Much of the expertise for setting CER priorities focusing on specific diseases and interventions lies within the medical specialty societies. The AMA has urged them to submit comments through the process established by this IOM Committee. In addition, we have recommended that the specialties send representatives to today's public meeting.

That said, the AMA also would like to put forth its own recommendations for CER priorities and identify two mechanisms that would help build the necessary infrastructure to sustain work in this area.

The AMA strongly believes that the national CER priorities should address the prevention, management, and treatment of **preventable disease** which collectively represent 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). For example, in the area of wellness, prevention, nutrition, and obesity there is a paucity of CER findings. It is an area with a wide range of available interventions with little clarity about which is most effective .

CER usually considers technology and pharmaceuticals, but behavioral interventions potentially could have the greatest impact for individual patients and system-wide.

Prioritizing interventions designed to change physician behavior and to effect behavioral change in patients, in addition to other clinical interventions, technologies, and pharmaceutical remedies, is necessary. Because prevalence rates and the most effective interventions for many diseases vary greatly by race, ethnicity, gender, age, geography, and economic status, the AMA strongly supports the inclusion of **racial and ethnic health disparities**—and health disparities more generally—as a CER priority area.

In addition to the foregoing, the National Priorities and Goals identified by the National Priorities Partnership (NPP) convened by the National Quality Forum (NQF) provides a rich source of information for the IOM to consider. The NPP, comprised of 28 national organizations, focused on achievable goals that would, if implemented broadly, reduce harm, improve patient-centered care, eliminate health care disparities, and remove waste from the system. In preparing the report, the NPP solicited extensive input from broad array of individuals and organizations. Utilizing the NPP National Priorities and Goals as a reference point will help the Committee to identify national CER priorities that will build the evidence-base in a targeted fashion in the areas that are likely to produce substantial system-wide improvements.

In addition to the NPP report, the AMA–convened Physician Consortium for Performance Improvement (PCPI) has developed a valuable survey mechanism that can be utilized by the

Committee to gather additional detailed information concerning national CER priorities. In order to obtain timely, quality responses from the more than 100 national medical specialty and state medical societies, experts in methodology and data collection, and many others involved in quality improvement and performance measurement, the PCPI constructed a survey mechanism. It is a powerful new tool to identify variations in practice, to assess the evidence base in a wide array of areas, and to identify areas where there are gaps in knowledge. The PCPI plans a significant expansion of these efforts. **This provides much needed capacity and infrastructure for priority setting.** We would welcome the opportunity to have the Committee work with the PCPI to utilize this survey mechanism as it develops the recommendations concerning national CER priorities.

We urge the Committee to consider two powerful infrastructure mechanisms, registries and clinical data networks. These have been used by specialty societies such as the Society of Thoracic Surgeons and the American College of Cardiology, and have markedly improved quality and patient safety. The National Surgical Quality Improvement Program (NSQIP) and the Northern New England Cardiovascular Collaborative are examples of utilizing these two mechanisms to advance quality and obtain research data at the point of care, and create what our country needs, a learning network. Expansion of existing clinical registries and databases would provide a strong foundation when conducting CER and at the same time these registries would also provide an excellent beginning point for CER. Utilizing, replicating, expanding, or integrating existing clinical registries would constitute an invaluable investment in the much needed infrastructure for accurately comparing clinical outcomes based on “real life” conditions

where delivery of care settings vary, patients may have numerous co-morbidities, and the patient population is diverse. In turn the clinical registries are not identical and may to greater or lesser extent be able to promote a learning health care environment; thus, evaluating the comparative clinical effectiveness of various clinical registry models and alternatives to them remains a vital priority. Building CER infrastructure and capacity in part upon registries and clinical data networks will leverage CER resources and boost the capacity of the system as a whole to learn and adapt in real time.

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 and with care, will address escalating health care costs. We look forward to working closely with the Committee to ensure that physicians remained engaged, enthusiastic, and involved stakeholders in this process.

There is a final cautionary tale. In the February 12, 2009, issue of JAMA there is a description of what can happen when science and politics collide. The Infectious Disease Society of America (IDSA) studied the evidence base for the treatment of Lyme disease and in 2006 issued new guidelines advising against the long-term use of antibiotics. The IDSA was promptly sued by the Connecticut Attorney General alleging violations of antitrust laws and restraint of trade. The case was settled without IDSA admitting any fault and assenting to an ombudsmen-reviewed panel to assess the 2006 guidelines. If we cannot separate science and politics in a case such as

this, how will we ever manage to deal with the really hard issues? We hope the Committee will elucidate a thoughtful and deliberative approach that can guide our country.