RESOLUTION 203 - 2011

Subject: Clinical Effectiveness Research

Introduced by: Paul Wertsch, MD

Referred to: Quality and Clinical Outcomes

Whereas, There is a tremendous variability in the treatment of common medical problems with a large variation in the cost of treatments; and

Whereas, New drugs and procedures are being continually produced which are frequently not tested against the current drugs or procedures so that clinicians are often faced with deciding on a course of action without good data to help with selecting the best, most cost-effective treatments; and

Whereas, Physicians and other clinicians desire to treat their patients with the best, safest and most cost-effective drugs or procedures but often lack good comparative data to make the proper decisions; and

Whereas, The Patient Protection and Affordable Care Act provides for the establishment of a Center for Clinical Effectiveness Research which can provide some of the answers to these questions but will have budget limitations and will have to set priorities in their work; and

Whereas, There should be a way for practicing clinicians to submit topics they feel are important to study for clinical effectiveness; therefore be it

RESOLVED, That the Wisconsin Medical Society request that a specific interactive webpage or an interactive site within www.ama-assn.org be established to allow members and others to submit articles or postings about current clinical topics where clinical effectiveness research should be conducted; and be it further

RESOLVED, That the Wisconsin Medical Society request that the AMA promote the use of such a webpage or site by all practicing physicians and other clinicians; and be it further

RESOLVED, That our AMA use such an interactive webpage or site to periodically invite AMA members to rank topics where the need for clinical effectiveness research is most pressing, and that the results of such rankings be forwarded to the Center for Clinical Effectiveness Research once it is established, or to another relevant federal agency.

Fiscal note: Within current budget unless Society would have to develop content for the website or develop and disseminate material to rank the priorities.

Relevant Policies

Society:
DRU-010

Increased Standards For Pharmaceutical Approval: The Wisconsin Medical Society supports increased standards for FDA approval of new pharmaceuticals, requiring clinical trials that demonstrate the effectiveness and safety of these drugs in comparison to standard therapy, active controls and placebos. (BOD, 0610)
REQ-008
Comparative Effectiveness Research: The Wisconsin Medical Society believes that Physicians must play an active part in the governing Comparative Effectiveness Research entity to ensure that the effect does not disrupt the trust between a physician and her/his patient. The Wisconsin Medical Society supports using Comparative Effectiveness Research as a tool for determining what is the best evidentiary value-based approach based on quality over cost. The Wisconsin Medical Society supports policy makers using Comparative Effectiveness Research as long as the benefits from such use are not diverted to non-health care funds, and that decisions on coverage are not based solely on cost. (HOD, 0410)

REQ-009
Comparative Effectiveness Research
The following Principles for Creating a Centralized Comparative Effectiveness Research Entity are the official policy of our AMA:
PRINCIPLES FOR CREATING A CENTRALIZED COMPARATIVE EFFECTIVENESS RESEARCH ENTITY:
A. Value. Value can be thought of as the best balance between benefits and costs, and better value as improved clinical outcomes, quality, and/or patient satisfaction per dollar spent. Improving value in the US health care system will require both clinical and cost information. Quality comparative clinical effectiveness research (CER) will improve health care value by enhancing physician clinical judgment and fostering the delivery of patient-centered care.
B. Independence. A federally sponsored CER entity should be an objective, independent authority that produces valid, scientifically rigorous research.
C. Stable Funding. The entity should have secure and sufficient funding in order to maintain the necessary infrastructure and resources to produce quality CER. Funding source(s) must safeguard the independence of a federally sponsored CER entity.
D. Rigorous Scientifically Sound Methodology. CER should be conducted using rigorous scientific methods to ensure that conclusions from such research are evidence-based and valid for the population studied. The primary responsibility for the conduct of CER and selection of CER methodologies must rest with physicians and researchers.
E. Transparent Process. The processes for setting research priorities, establishing accepted methodologies, selecting researchers or research organizations, and disseminating findings must be transparent and provide physicians and researchers a central and significant role.
F. Significant Patient and Physician Oversight Role. The oversight body of the CER entity must provide patients, physicians (MD, DO), including clinical practice physicians, and independent scientific researchers with substantial representation and a central decision-making role(s). Both physicians and patients are uniquely motivated to provide/receive quality care while maximizing value.
G. Conflicts of Interest Disclosed and Minimized. All conflicts of interest must be disclosed and safeguards developed to minimize actual, potential and perceived conflicts of interest to ensure that stakeholders with such conflicts of interest do not undermine the integrity and legitimacy of the research findings and conclusions.
H. Scope of Research. CER should include long term 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, health services, or combinations. It 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. The priority areas of CER should be on high volume, high cost diagnosis, treatment, and health services for which there is significant variation in practice. Research priorities and methodology should factor in any systematic variations in disease prevalence or response across groups by race, ethnicity, gender, age, geography, and economic status.
I. Dissemination of Research. The CER entity must work with health care professionals and health care professional organizations to effectively disseminate the results in a timely manner by
significantly expanding dissemination capacity and intensifying efforts to communicate to physicians utilizing a variety of strategies and methods. All research findings must be readily and easily accessible to physicians as well as the public without limits imposed by the federally supported CER entity. The highest priority should be placed on targeting health care professionals and their organizations to ensure rapid dissemination to those who develop diagnostic and treatment plans.

J. Coverage and Payment. The CER entity must not have a role in making or recommending coverage or payment decisions for payers.

K. Patient Variation and Physician Discretion. Physician discretion in the treatment of individual patients remains central to the practice of medicine. CER evidence cannot adequately address the wide array of patients with their unique clinical characteristics, co-morbidities and certain genetic characteristics. In addition, patient autonomy and choice may play a significant role in both CER findings and diagnostic/treatment planning in the clinical setting. As a result, sufficient information should be made available on the limitations and exceptions of CER studies so that physicians who are making individualized treatment plans will be able to differentiate patients to whom the study findings apply from those for whom the study is not representative (HOD, 0410).

AMA:

H-155.960 Strategies to Address Rising Health Care Costs

Our AMA: (1) recognizes that successful cost-containment and quality-improvement initiatives must involve physician leadership, as well as collaboration among physicians, patients, insurers, employers, unions, and government; (2) supports the following broad strategies for addressing rising health care costs: (a) reduce the burden of preventable disease; (b) make health care delivery more efficient; (c) reduce non-clinical health system costs that do not contribute value to patient care; and (d) promote "value-based decision-making" at all levels; (3) will continue to advocate that physicians be supported in routinely providing lifestyle counseling to patients through: adequate third-party reimbursement; inclusion of lifestyle counseling in quality measurement and pay-for-performance incentives; and medical education and training; (4) will continue to advocate that sources of medical research funding give priority to studies that collect both clinical and cost data; use evaluation criteria that take into account cost impacts as well as clinical outcomes; translate research findings into useable information on the relative cost-effectiveness of alternative diagnostic services and treatments; and widely disseminate cost-effectiveness information to physicians and other health care decision-makers; (5) will continue to advocate that health information systems be designed to provide physicians and other health care decision-makers with relevant, timely, actionable information, automatically at the point of care and without imposing undue administrative burden, including: clinical guidelines and protocols; relative cost-effectiveness of alternative diagnostic services and treatments; quality measurement and pay-for-performance criteria; patient-specific clinical and insurance information; prompts and other functionality to support lifestyle counseling, disease management, and case management; and alerts to flag and avert potential medical errors; (6) encourages the development and adoption of clinical performance and quality measures aimed at reducing overuse of clinically unwarranted services and increasing the use of recommended services known to yield cost savings; (7) encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are reduced for maintenance medications used to treat chronic medical conditions, particularly when non-compliance poses a high risk of adverse clinical outcome and/or high medical costs. Consideration should be given to tailoring cost-sharing requirements to patient income and other factors known to impact compliance; and (8) supports ongoing investigation and cost-effectiveness analysis of non-clinical health system spending, to reduce costs that do not add value to patient care. (CMS Rep. 8, A-07; Reaffirmed: CMS Rep. 7, A-08; Reaffirmed in lieu of Res. 828, I-08; Reaffirmation A-09; Reaffirmation I-09)