



AMA-RFS Issue Brief on Comparative Effectiveness Research - March 2009

Background information

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 medications to gain FDA approval, manufacturers conduct research to compare their drug to placebo, rather than comparing their drug to similar drugs. This lack of comparative research has translated into a lack of knowledge about whether new treatments outperform existing ones.

In September 2007, the Institute of Medicine defined comparative effectiveness research (CER) as “the direct generation of clinical information on the relative merits or outcomes of one intervention in comparison to one or more others, and secondary comparative effectiveness research involves the synthesis of primary studies to allow conclusions to be drawn.”

What is the current status of CER at the federal level?

Until recently, there was no single federal agency dedicated to CER. Of the few agencies that conduct comparative effectiveness research, their initiatives have been limited in scope and funding. To address this, the American Recovery and Reinvestment Act of 2009, signed into law 17 February 2009, will increase CER funding by \$1.1 billion. This law establishes the Federal Coordinating Council for CER, an advisory board that will be comprised of up to 15 representatives of federal agencies (at least half of whom will be clinicians). This board will coordinate CER but reportedly will not mandate coverage, reimbursement, or other policies of public or private payers.

Existing AMA Policy on CER

The AMA Council on Medical Service prepared a report on CER in 2008 as part of its ongoing efforts to further develop AMA policy related to value, costs, and improving health care decision-making. In their report, which was passed by the AMA House of Delegates, the Council asserted that AMA principles governing CER were needed to guide AMA advocacy on the implementation of CER (see box at right).

The report explained that one of the most critical issues of CER legislation is the membership of the governing board of the CER entity. Accordingly, the Council believes that physicians, medical researchers, and patients should have primary and substantial representation on the governing body. Although the Council believes that wide implementation of CER will lead to adoption of cost-effective care, the primary goal of CER should not be to contain costs. Rather, the goal should be to enhance physician clinical judgment and foster the delivery of quality patient-centered care. In certain cases, the most effective intervention could be the one that is the most costly. Once the clinical effectiveness of alternative services is compared, it may be appropriate to consider costs. However, CER should not be a tool for indiscriminately cutting costs by reducing physician payment and instituting coverage decisions based solely on cost.

AMA principles for creation of a centralized CER entity:

1. value
2. independence
3. stable funding
4. rigorous scientifically sound methodology
5. transparent process
6. significant patient and physician oversight role
7. conflicts of interest disclosed and minimized
8. scope of research
9. dissemination of research
10. coverage and payment
11. patient variation and physician discretion

References

H-460.909 Comparative Effectiveness Research. CMS Rep. 5, I-08.
American recovery and reinvestment act of 2009: summary of major health care provisions. <http://www.ama-assn.org/ama/pub/legislation-advocacy/current-topics-advocacy/hr1-stimulus-summary.shtml>. 2009.