

More Comparative Effectiveness Studies Needed

BY MARY ANN MOON

A review of the recent literature confirms that comparative effectiveness research—studies designed to help physicians use existing treatments and treatment strategies more effectively—is severely lacking.

Fewer than a third of the studies published in the six top journals covering general and internal medicine qualified as comparative effectiveness research.

This finding “supports concerns that only limited clinical research is currently devoted to helping physicians” improve the use of existing therapies and determine which interventions and strategies are the most effective and safe, and the least costly, said Dr. Michael Hochman and Dr. Danny McCormick of Cambridge (Mass.) Health Alliance and Harvard Medical School, Boston.

Congress recently passed legislation to provide more than \$1 billion to support comparative effectiveness studies, and President Obama’s budget for 2011 recommends further funding of comparative effectiveness research.

Noting that few data are available on the current status of comparative effectiveness research, Dr. Hochman and Dr. McCormick reviewed all clinical studies

assessing medications that were published between June 2008 and October 2009 in the six “highest impact” medical journals: New England Journal of Medicine, Lancet, JAMA, Annals of Internal Medicine, British Medical Journal, and Archives of Internal Medicine.

These publications “are the most widely read, quoted, and covered by the media, and thus are disproportionately likely to influence clinicians,” the investigators said (JAMA 2010;303:951-8).

Of the 328 randomized trials, observational studies, or meta-analyses involving medications included in the analysis, 104 (32%) were comparative effectiveness studies.

Of those, just 11% compared medications with nonpharmacologic treatments, confirming that there is a relative lack of such research.

Comparative effectiveness studies that compare medications with nonpharmacologic interventions are particularly important because they help clinicians “make fundamental therapeutic decisions,” Dr. Hochman and Dr. McCormick said.

Nearly 90% of the comparative effectiveness studies relied on noncommercial funding, primarily from government sources, a finding that

highlights how essential such funding is.

“Commercial entities presumably devote much of their research to the development of novel therapies and to funding inactive-comparator studies aimed at expanding indications for their products,” they noted.

More than half of the randomized trials in this analysis used an “inactive com-

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parator” such as placebo, rather than comparing a medication against existing treatments. Such trials were disproportionately funded by commercial sources and were disproportionately likely to show that a medication produced positive results.

In addition, 24% of the randomized trials that did use an active comparator sought to show only the noninferiority of a medication to that comparator; there was no effort to clarify the optimal therapy, only to test equivalency. Such

trials were exclusively funded by commercial sources.

Patient safety was the focus of 19% of the comparative effectiveness studies, implying that safety concerns are not adequately measured in medication studies.

Only 2% of the comparative effectiveness studies and 1% of all studies in the analysis included formal cost-effectiveness analyses, which are critical to promoting efficient health care. This absence “may reflect policies or editorial priorities of journal editors favoring publication of clinical outcome reports rather than a true dearth of cost-effectiveness studies,” the investigators said.

Overall, the findings “underscore the importance of the recent legislation passed in the United States to expand public funding for comparative effectiveness studies. In particular, our findings suggest government and non-commercial support should be increased for studies involving nonpharmacologic therapies, for studies comparing different therapeutic strategies, and for studies focusing on the comparative safety and cost of different therapies,” Dr. Hochman and Dr. McCormick said.

The investigators reported no financial conflicts of interest. ■

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