Studies that compare effectiveness of medications often do not include nonpharmacologic therapies

March 9 2010

An analysis of comparative effectiveness studies finds that few compare medications with nonpharmacologic interventions, and few examine safety or cost-effectiveness, according to a study in the March 10 issue of *JAMA*.

Comparative effectiveness (CE) research refers to studies that compare "the benefits and harms of different interventions and strategies to prevent, diagnose, treat, and monitor health conditions," according to background information in the article. In contrast to research on new interventions and strategies, CE studies help physicians use existing treatments and treatment strategies more effectively and help determine which interventions and strategies are most effective, safest, or least costly when multiple options are available.

The U.S. Congress recently passed legislation that will provide more than $1 billion to support CE studies because of concerns that insufficient research is currently devoted to improving the use of existing therapies. "Despite the recent interest in CE research, only limited information is available about existing CE studies," the authors write. "Additional information about existing CE research could help guide policy makers as they determine the amount and types of CE research that are most needed."

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Angeles, and Danny McCormick, M.D., M.P.H., of Harvard Medical School, Boston, examined the characteristics and prevalence of CE research concerning medications published between June 2008 and September 2009 in the six general medicine and internal medicine journals with the highest impact factors. The researchers identified 328 studies evaluating medications, 104 of which were CE studies.

Of the 104 CE studies, 43 percent compared 2 or more medications with each other, 11 percent compared medications with non-pharmacologic interventions, 31 percent compared different pharmacologic strategies, and 15 percent compared different medication doses, durations or frequencies of treatment, or different medication formulations. Nineteen percent of the CE studies focused on safety and 2 percent included cost-effectiveness analyses. Comparative effectiveness studies were less likely than non-CE studies to have been exclusively commercially funded: 13 percent vs. 45 percent. In total, noncommercial entities jointly or exclusively funded 87 percent of the CE studies, including 10 of the I1 CE studies comparing medications with nonpharmacologic interventions. Government entities at least partially funded 63 percent of the 104 CE studies.

The authors add that of 212 randomized trials, 46 percent used an active comparator (active therapy); the rest used an inactive control (such as placebo). Active-comparator trials were less likely (44 percent) than trials with inactive controls (66 percent) to report positive results.

"Overall, this study of CE research involving medications underscores the importance of the recent legislation passed in the United States to expand public funding for CE studies. In particular, our findings suggest government and noncommercial 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. In addition, our findings highlight the

need for regulatory agencies like the FDA to require active-comparator trials for medication approval whenever feasible," the authors conclude.

More information: *JAMA*. 2010;303[10]:951-958.

Provided by JAMA and Archives Journals

Citation: Studies that compare effectiveness of medications often do not include nonpharmacologic therapies (2010, March 9) retrieved 17 July 2024 from https://medicalxpress.com/news/2010-03-effectiveness-medications-nonpharmacologic-therapies.html

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