

Clinical trial results inconsistently reported among journals, government website

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Medical researchers often presented the findings of their clinical trials in a different way on a federal government website than they did in the medical journals where their studies were ultimately published, according to an Oregon Health & Science University analysis published April 1 in the *Annals of Internal Medicine*.

Researchers' reports in peer-reviewed [medical journals](#) often were more favorable to the drug or intervention being studied than the reports on the government website—ClinicalTrials.gov—which required data for specific categories, according to the analysis.

One of the most notable discrepancies: Of the 84 clinical trials the researchers looked at where a "serious adverse event" was reported on ClinicalTrials.gov, 33 of those trials reported fewer adverse events in the medical journals than they had reported to the government website. In 16 of those cases, no adverse events were reported in the journals.

OHSU researchers said their analysis demonstrated the ongoing problem with inaccurate and sometimes biased reporting in medical journals. But it also showed that the [government website](#) could be another viable source for objective medical information.

"There's a general recognition that [adverse events](#) historically haven't been reported consistently in the medical literature. And underreporting of these events is a major concern because it can distort how health care providers balance the benefits and harms of drugs and other medical

interventions for their patients," said Daniel Hartung, Pharm.D., M.P.H., associate professor in the Oregon State University/OHSU College of Pharmacy and lead author of the study. "But our analysis also seemed to show that ClinicalTrials.gov could be a good alternative for consumers and health care providers to get comprehensive information about a drug or medical intervention."

The OHSU researchers looked at 110 medical trials that had been completed by Jan. 1, 2009, and that had been reported on ClinicalTrials.gov. Congress required that after September 2008, many clinical trials of drugs and medical interventions report their results at the website. The move was intended to give consumers and health care providers better information about the results of clinical trials.

Researchers looked only at trials completed by 2009 to allow for the clinical trial results to be later published in medical journals.

Of the 110 trials the OHSU analysis looked at, most were industry-sponsored studies—paid for by the pharmaceutical industry or medical companies. The analysis found that discrepancies between information on the same trial at ClinicalTrials.gov and in the medical journals were common. Twenty percent of the trials were inconsistent between the website and medical journals in how they reported the primary outcomes of the trial. Still, in most cases, these discrepancies were small and did not affect the statistical significance of the result.

Another discrepancy between the two areas of reporting came in how deaths that were part of the clinical trials were reported. In that circumstance, deaths seemed to be underreported or inconsistently report on ClinicalTrials.gov. For instance, in 17 percent of the trials that did not reported deaths on ClinicalTrials.gov, deaths were reported in the journal article on the trial. Prior studies have indicated ClinicalTrials.gov does not have a uniform way of reporting deaths and that may lead to

inconsistencies.

"This is the most comprehensive study of ClinicalTrials.gov to date," said Mark Helfand, M.D., M.S., M.P.H., professor of medicine and medical informatics and clinical epidemiology, OHSU School of Medicine, and a study co-author. "It shows that patients and clinicians could use it to find information that is not available in the published literature, particularly to get more complete information about the harms of various treatment options. It also shows that, to best serve the public, death rates and some other items in ClinicalTrials.gov should be audited to keep them up to date."

Provided by Oregon Health & Science University

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