

Some discrepancies exist between outcomes indicated in trial registration and later publications

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Comparison of the primary outcomes of registered clinical trials with their subsequent publication appears to show some discrepancies, according to a study in the September 2 issue of *JAMA*.

In 2005, the International Committee of [Medical Journal](#) Editors (ICMJE) adopted a policy requiring researchers to deposit information about randomized controlled trials into a clinical trials registry before study participants enrolled as a precondition for publication of the study's findings in member journals. "One of the main objectives of trial registration is to help achieve transparency in results and make information about the existence and design of clinical trials publicly available," the authors provide as background information. "This policy should permit knowledge sharing about the key elements of clinical trials and help decrease the risk of selective reporting of outcomes that was previously identified in published results of RCTs [randomized controlled trials]."

Sylvain Mathieu, M.D., of Hopital Bichat-Claude Bernard, Paris and colleagues conducted a search of the MEDLINE via PubMed to identify randomized controlled trials in three areas: cardiology, rheumatology, and [gastroenterology](#), that were indexed in 2008 in the 10 general medical journals and specialty medical journals with the highest impact factors. The researchers sought to compare the primary outcomes specified in trial registries with those reported in the published articles

and to determine whether outcome reporting bias favored significant primary outcomes. Of the 323 included articles, 114 (35.3 percent) were published in general medical journals and 209 (64.7 percent) in specialty journals.

"A total of 147 trials (45.5 percent) were adequately registered (i.e., registered before the end of the trial, with the primary outcome clearly specified)," the authors write. "Trial registration was lacking for 89 published reports (27.6 percent), 45 trials (13.9 percent) were registered after the completion of the study, 39 (12.1 percent) were registered with no or an unclear description of the primary outcome, and 3 (0.9 percent) were registered after the completion of the study and had an unclear description of the primary outcome." The authors note that the proportion of registered trials was greater for the general medical journals than the specialty publications. "Among articles with trials adequately registered, 31 percent (46 of 147) showed some evidence of discrepancies between the outcomes registered and the outcomes published." Of those 46 articles, the authors report "19 of 23 (82.6 percent) had a discrepancy that favored statistically significant results (i.e., a new, statistically significant primary outcome was introduced in the published article or a nonsignificant primary outcome was omitted or not defined as the primary outcome in the published article)."

"Trial registration provides a good opportunity for editors, peer-reviewers, and policy makers to identify outcome reporting bias, and other deviations from the planned study to prevent such distortions from reaching publication," the authors write.

"In conclusion, although trial registration is now the rule, careful implementation of trial registration, with full involvement of authors, editors, and reviewers is necessary to ensure publication of quality, unbiased results."

More information: *JAMA*. 2009;302[9]:977-984.

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