

Many NIH-funded clinical trials go unpublished over two years after completion

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In a study that investigates the challenges of disseminating clinical research findings in peer-reviewed biomedical journals, Yale School of Medicine researchers have found that fewer than half of a sample of trials primarily or partially funded by the National Institutes of Health (NIH) were published within 30 months of completing the clinical trial.

These findings appear in the January issue of the <u>British Medical Journal</u>, which focuses on the topic of unpublished evidence.

"When research findings are not disseminated, the scientific process is disrupted and leads to redundant efforts and misconceptions about clinical evidence," said Joseph Ross, M.D., first author of the study and a Yale assistant professor of medicine. "Such inaction undermines both the trial in question and the evidence available in peer-reviewed medical literature. This has far-reaching implications for policy decisions, and even institutional review board assessments of risks and benefits associated with future research studies."

Ross and co-authors performed a cross-sectional analysis of NIH-funded clinical trials registered within ClinicalTrials.gov, a trial registry and results database maintained by the U.S. National Library of Medicine. All trials in the study sample were registered after September 30, 2005 and completed by December 31, 2008, allowing at least 30 months for publication following completion of the trial.

They found that overall fewer than half of NIH-funded trials in the sample were published in a peer-reviewed, MEDLINE-indexed biomedical journal within 30 months of trial completion. They also found that one-third of trials remained unpublished 51 months after completion.

Ross said that there may be many reasons for lack of publication, such as not getting accepted by a journal or not prioritizing the dissemination of research findings. Still, he said, there are alternative methods for providing timely public access to study results, including the results database at ClinicalTrials.gov that was created in response to Federal law.

"Steps must be taken to ensure the timely dissemination of publicly funded research so that data from all those who volunteer are available to inform future research and practice," Ross said.

While this study was focused on trials funded by NIH, Ross said that similar problems with non-publication and delayed publication of research findings have been described among trials funded by the pharmaceutical and medical device industries, as well as by non-profit organizations.

"This suggests that the current culture of research needs to prioritize the timely public dissemination of research findings, ideally via peer-reviewed journals, for research funded by both public and private sources," said Ross. "More work needs to be done to better understand impediments to publication."

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