



LENS

Treatment and Clinical Perspectives: Failure to Publish the Results of All Clinical Trials Is Hurting Medical Science

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Why do so many clinical studies go unpublished?

Imagine that you have just set up a new program for treating an eating disorder. How do you know the new treatment you developed works? The gold standard is to perform a randomized control trial involving the treatment. In this case, you would randomly select individuals with a particular eating disorder who would either receive your treatment or an alternative, usually a placebo. Once the study is complete and your treatment works, what do you do next?

If you are like most scientists, you write up the results and publish them. However, if your treatment did not show a significant difference in comparison to the alternative, what do you do then? The ideal response is to publish the results so that the world knows not only what works, but also what does not work. However, publication of negative results does not always happen. Sometimes, scientists move on to more

productive projects. This failure to publish negative results has come to be called the *file drawer problem*. This phenomenon is a significant complication if you do a literature search. Typically, your literature search shows you the treatment studies in which the treatment made changes in the disorder. However, what you do not see are those studies that did not find a significant change, as they remain unpublished in the researcher's file drawer or computer.

Why would so many studies go unpublished? Researchers, based on their own treatment preferences, might not like the results of a study that didn't verify certain treatment effectiveness. Large drug companies encourage the publication of studies whose results supported their own interests. Journals choose to publish research articles that found positive results. All of these factors contributed to the so-called file drawer problem.

To help deal with this problem, in 2007 the U.S. government passed an amendment to the Food and Drug Administration Act. This requires clinical trials of drugs, medical devices, or biologics to be registered at the website ClinicalTrials.gov. Further, a basic summary of the results is required to be submitted through the website within 1 year following the completion of the data collection. This was considered to be an ethical obligation to human participants to present results in an understandable fashion.

In order to determine the rate of compliance with the law, Monique Anderson and her colleagues (2015)