

Interim publications of randomized trials make news but may not be ready for prime time

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Dartmouth Institute researchers Lisa Schwartz and Steven Woloshin compared the consistency and prominence of interim publications with the final publications. They found that 21% of the time, results changed importantly. Credit: The Dartmouth Institute

Early results from randomized trials are sometimes published before the trial is completed. The results of such interim publications may generate a great deal of interest in the medical community because the findings often hold a great deal of promise for new and effective therapies. However, in an article recently published in *JAMA*, Dartmouth researchers compared the consistency and prominence of interim publications with the final publications. They found that 21% of the time, results changed significantly.

"Changes between interim and final publication matter because clinicians and the [public](#) could have been misled about whether an intervention was beneficial, harmful, or ineffective," says Lisa Schwartz, MD, a professor at The Dartmouth Institute for Health Policy, and who led the study, along with research partner Steven Woloshin, MD.

The research team searched PubMed for randomized trials from 2006-2015 with "interim," "not mature," or "immature" in the title or abstract. To identify final publications, they searched PubMed, ClinicalTrials.gov, and Web of Science through 2016. They emailed authors of interim reports when no final publication was identified. For interim and final publications reporting the same efficacy and or safety outcome, they compared trial characteristics and prominence. They also categorized abstract conclusions (not different, beneficial, or harmful) and compared changes between interim and final publications.

Among their findings:

- Interim results were reported in 613 of 1,267 screened publications.
- Of those, 72% reported on trials stopped early (for benefit, harm, futility, or other problems).
- The remaining 171 ongoing [trials](#) (mostly in oncology, surgery, or cardiology) reported interim efficacy or safety results.

- Forty-one percent of the publications stated that the interim analysis was specified in the protocol, but half provided no reason for the interim publication.
- Interim and final publications had similar journal and media prominence, and while most (79%) did not change, 21% did.

The researchers conclude that while most interim and final publications reached similar conclusions, frequent non-publication of final results can lead to confusion or unfounded assumptions with true treatment effects remaining unknown. To safeguard against any such confusion, the study authors recommend routinely adding the word "interim" in the title and justifying the reason in the publication. (Many interim publications reported analyses without any justification.)

"Most importantly", Woloshin says, "journals, authors, and funders should commit to making final results accessible by linking interim publications to final reports whenever available".

More information: Steven Woloshin et al, Characteristics of Interim Publications of Randomized Clinical Trials and Comparison With Final Publications, *JAMA* (2018). [DOI: 10.1001/jama.2017.20653](https://doi.org/10.1001/jama.2017.20653)

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