

RESEARCH ARTICLE

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Comparison of registered and published outcomes in randomized controlled trials: a systematic review

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Abstract

Background: Clinical trial registries can improve the validity of trial results by facilitating comparisons between prospectively planned and reported outcomes. Previous reports on the frequency of planned and reported outcome inconsistencies have reported widely discrepant results. It is unknown whether these discrepancies are due to differences between the included trials, or to methodological differences between studies. We aimed to systematically review the prevalence and nature of discrepancies between registered and published outcomes among clinical trials.

Methods: We searched MEDLINE via PubMed, EMBASE, and CINAHL, and checked references of included publications to identify studies that compared trial outcomes as documented in a publicly accessible clinical trials registry with published trial outcomes. Two authors independently selected eligible studies and performed data extraction. We present summary data rather than pooled analyses owing to methodological heterogeneity among the included studies.

Results: Twenty-seven studies were eligible for inclusion. The overall risk of bias among included studies was moderate to high. These studies assessed outcome agreement for a median of 65 individual trials (interquartile range [IQR] 25–110). The median proportion of trials with an identified discrepancy between the registered and published primary outcome was 31 %; substantial variability in the prevalence of these primary outcome discrepancies was observed among the included studies (range 0 % (0/66) to 100 % (1/1), IQR 17–45 %). We found less variability within the subset of studies that assessed the agreement between prospectively registered outcomes and published outcomes, among which the median observed discrepancy rate was 41 % (range 30 % (13/43) to 100 % (1/1), IQR 33–48 %). The nature of observed primary outcome discrepancies also varied substantially between included studies. Among the studies providing detailed descriptions of these outcome discrepancies, a median of 13 % of trials introduced a new, unregistered outcome in the published manuscript (IQR 5–16 %).

Conclusions: Discrepancies between registered and published outcomes of clinical trials are common regardless of funding mechanism or the journals in which they are published. Consistent reporting of prospectively defined outcomes and consistent utilization of registry data during the peer review process may improve the validity of clinical trial publications.

Keywords: Clinicaltrials.gov, Primary outcome, Publication bias, Reporting bias, Selection bias, Trial registration

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Guidelines for Reporting Health Research David Moher, Douglas Altman, Kenneth Schulz, Iveta Simera, Elizabeth Wager, 2014-08-06 Guidelines for Reporting Health Research is a practical guide to choosing and correctly applying the appropriate guidelines when reporting health research to ensure clear transparent and useful reports This new title begins with an introduction to reporting guidelines and an overview of the importance of transparent reporting the characteristics of good guidelines and how to use reporting guidelines effectively in reporting health research This hands on manual also describes over a dozen internationally recognised published guidelines such as CONSORT STROBE PRISMA and STARD in a clear and easy to understand format It aims to help researchers choose and use the correct guidelines for reporting their research and to produce more completely and transparently reported papers which will help to ensure reports are more useful and are not misleading Written by the authors of health research reporting guidelines in association with the EQUATOR Enhancing the QUALity and Transparency Of health Research Network Guidelines for Reporting Health Research is a helpful guide to producing publishable research It will be a valuable resource for researchers in their role as authors and also an important reference for editors and peer reviewers

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