

RESEARCH ARTICLE

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

Christopher W. Jones¹*, Lukas G. Keil², Wesley C. Holland³, Melissa C. Caughey⁴ and Timothy F. Platts-Mills³

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 subsets 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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Comparison of Registered and Published Outcomes in Randomized Controlled Trials: a Systematic Review Warren Warren Press,2015-12-20 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 The British Journal of Psychiatry ,1994-04 **Journal of Health, Population, and Nutrition** ,2008 **Canadian Journal of Psychiatry** ,2005 **Effective Care in Pregnancy and Childbirth: Pregnancy** Iain Chalmers,Murray Enkin,Marc J. N. C. Keirse,1989 This landmark two volume treatise draws on the work of clinicians and researchers throughout the world to provide a unique new approach to clinical obstetrics Its aim is to determine the most effective methods of care during pregnancy and childbirth To this end the authors provide overviews of data taken from the available controlled trials in which alternative forms of obstetric care have been formally evaluated Evidence on the effectiveness of these methods both pro and con is presented along with information about implications for clinical practice and future research The result is the most systematic study available on the effectiveness and safety of the full range of clinical procedures regardless of the particular emphasis or medical context of treatment *Annual Meeting Proceedings American Society of Clinical Oncology*. Meeting,2007 **The International Journal of Oral & Maxillofacial Implants** ,2001 *New Zealand Medical Journal* ,1996 **BMJ** ,1993 *Sixteenth Annual Symposium on Computer Applications in Medical Care* Mark E. Frisse,1993 *Journal of the American Medical Association* ,1913 Includes proceedings of the association papers read at the annual sessions and lists of current medical literature **Cardiac Surgery in the Adult, Third Edition** Lawrence H. Cohn,2007-08-28 The classic leading edge guide to heart surgery in adults completely updated by leaders in the field In this trusted reference renowned cardiac surgeon and Harvard professor Dr Lawrence H Cohn takes you through all aspects of heart surgery in adults The text s acclaimed coverage begins with a solid review of cardiac surgery fundamentals then progresses to optimal perioperative and interoperative care before covering the full range of individual procedures Inside you ll find over 1 000 step by step illustrations that clarify each procedure along with important guidance on all of the discipline s fundamental operations and operative techniques With updated and revised content the new edition of this forward thinking landmark text is undoubtedly the most up to date resource of its kind available anywhere Features All the latest surgical perspectives and techniques in ischemic and valvular heart disease disease of great vessels cardiac arrhythmias and more Expert authorship by one of the world s most respected cardiac surgeons with contributions from an internationally recognized group of authors Cutting edge overview of cardiothoracic transplantations circulatory support and nontransplant options for heart failure Brand new timely chapters on cardiac imaging minimally invasive procedures and stem cell therapy Reworked illustration program featuring newly commissioned two color drawings with classic artwork from the previous editions colorized Two color format throughout the text which helps you efficiently navigate chapter material providing quick access to key information **Principles and Practice of Hospital Medicine, Second Edition** Sylvia C. McKean,John J. Ross,Daniel D. Dressler,Danielle Scheurer,2016-10-22 The leading textbook of hospital medicine completely updated to reflect today s challenges A Doody s Core Title for 2021 Since its publication in 2012 Principles and Practice of

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Annals of Saudi Medicine, 2006 **Surgical Management of Low Back Pain** Jeffrey C. Wang, 2009 The second edition presents the current diagnostic and surgical treatments for low back pain as well as the anatomic and physiologic rationale for their application. New sections cover the evidence based assessment of emerging biological strategies for the treatment of degenerative disk disease and more. *Early Acute Management in Adults with Spinal Cord Injury* Paralyzed Veterans of America, Consortium for Spinal Cord Medicine, 2008 After a spinal cord injury, people often have questions about their attractiveness, relationships and their ability to conceive and have children. Life does not end after a spinal cord injury and neither does the ability to have fulfilling intimate relationships and a satisfying sexual life. It is important that people with SCI and their partners are able to have open dialogue regarding sexuality with a knowledgeable and supportive health care provider. This guideline addresses a wide range of topics related to sexuality. It includes recommendations that address physical, interpersonal, emotional and medical concerns. It also addresses the importance of privacy and individuality as well as the practical needs of individuals with spinal cord injuries.

Comparison Registered Published Randomized Controlled Book Review: Unveiling the Power of Words

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