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

Christopher W. Jones^{1*}, Lukas G. Keil², Wesley C. Holland³, Melissa C. Caughey⁴ and Timothy F. Platts-Mills⁵

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

* Correspondence: jones-christopher@cooperhealth.edu
¹Department of Emergency Medicine, Cooper Medical School of Rowan University, One Cooper Plaza, Suite 152, Camden, NJ 08103, USA
Full list of author information is available at the end of the article

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**Michael G. Newman, Henry Takei, Perry
R. Klokkevold, Fermin A. Carranza**

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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 Neuro-Oncology Compendium for the Boards and Clinical Practice

Maciej M. Mrugala, Na Tosha Gatson, Sylvia C. Kurz, Jennifer L. Clarke, Kathryn S. Nevel, 2023 This essential text includes supplementary figures and tables succinct review flashcards end of chapter questions and answers as well as end of volume exams so readers can review and test their own comprehension Each chapter has been reviewed by the editors to ensure cohesive board level verbiage emphasizing practical clinical knowledge Neuro Oncology Compendium for the Boards and Clinical Practice is up to date and comprehensive eliminating the need for multiple sources of study Women in Cardiovascular Epidemiology and Prevention Liesl Joanna Zühlke, Amanda Henry, Stefania Triunfo, 2023-05-17 We are delighted to present the inaugural Frontiers in Cardiovascular Medicine Women in Cardiovascular Epidemiology and Prevention series of article collections At present less than 30% of researchers worldwide are women Long standing biases and gender stereotypes are discouraging girls and women away from science related fields and STEM research in particular Science and gender equality are however essential to ensure sustainable development as highlighted by UNESCO In order to change traditional mindsets gender equality must be promoted stereotypes defeated and girls and women should be encouraged to pursue STEM careers Therefore Frontiers in Cardiovascular Medicine is proud to offer this platform to promote the work of women scientists across all fields of basic and clinical cardiovascular medicine The work presented here highlights the diversity of research performed across the entire breadth of cardiovascular epidemiology and prevention research and presents advances in theory experiment and methodology with applications to compelling problems

Systematic Reviews in Health Research Matthias Egger, Julian P. T. Higgins, George Davey Smith, 2022-05-11 Systematic Reviews in Health Research Explore the cutting edge of systematic reviews in healthcare In this Third Edition of the classic

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Opportunities for Organ Donor Intervention Research National Academies of Sciences, Engineering, and Medicine, Health and Medicine Division, Board on Health Sciences Policy, Committee on Issues in Organ Donor Intervention Research, 2018-01-21 The organ donation and transplantation system strives to honor the gift of donated organs by fully using those organs to save and improve the quality of the lives of their recipients However there are not enough donated organs to meet the demand and some donated organs may not be recovered some recovered organs may not be transplanted and some transplanted organs may not function adequately Organ donor intervention research can test and assess interventions e.g. medications devices and donor management protocols to maintain or improve organ quality prior to during and following transplantation The intervention is administered either while the organ is still in the deceased donor or after it is recovered from the donor but before it is transplanted into a recipient Organ donor intervention research presents new challenges to the organ donation and transplantation community because of ethical questions about who should be considered a human subject in a research study whose permission and oversight are needed and how to ensure that such research does not threaten the equitable distribution of a scarce and valuable resource Opportunities for Organ Donor Intervention Research focuses on the ethical legal regulatory policy and organizational issues relevant to the conduct of research in the United States involving deceased organ donors This report provides recommendations for how to conduct organ donor intervention research in a manner that maintains high ethical standards that ensures dignity and respect for deceased organ donors and their families that provides transparency and information for transplant candidates who might receive a research organ and that supports and sustains the public's trust in the process of organ donation and transplantation

Newman and Carranza's Clinical Periodontology E-Book Michael G. Newman, Henry Takei, Perry R. Klokkevold, Fermin A. Carranza, 2018-05-29 From basic science and fundamental procedures to the latest advanced techniques in reconstructive esthetic and implant therapy Newman and Carranza's Clinical Periodontology 13th Edition is the resource you can count on to help master the most current information and techniques in

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Federal Register ,2013-05 **Methods and Biostatistics in Oncology** Raphael. L.C Araújo,Rachel P. Riechelmann,2018-04-16 This book introduces and discusses the most important aspects of clinical research methods and biostatistics for oncologists pursuing a tailor made and practical approach Evidence based medicine EBM has been in vogue in the last few decades particularly in rapidly advancing fields such as oncology This approach has been used to support decision making processes worldwide sparking new clinical research and guidelines on clinical and surgical oncology Clinical oncology research has many peculiarities including specific study endpoints a special focus on survival analyses and a unique perspective on EBM However during medical studies and in general practice these topics are barely taught Moreover even when EBM and clinical cancer research are discussed they are presented in a theoretical fashion mostly focused on formulas and numbers rather than on clinical application for a proper literature appraisal Addressing that gap this book discusses more practical aspects of clinical research and biostatistics in oncology instead of relying only on mathematical formulas and theoretical considerations Methods and Biostatistics in Oncology will help readers develop the skills they need to understand the use of research on everyday oncology clinical practice for study design and interpretation as well to demystify the use of EBM in oncology

Clinical Trials, Practice and Design in Gastrointestinal Cancers Alberto Puccini,Edouard Auclin,Jorg Kleeff,2023-11-07 *Comparative Effectiveness Research* Carol M. Ashton,Nelda P. Wray,2013-06-03 For all its costs flaws and inequities American health care is fundamentally rooted in a belief that treatment should be based on solid scientific research To this end between 2003 and 2010 three different federal laws were enacted the most recent being the Affordable Care Act of 2010 that mandated new federal investments in a type of clinical research called comparative effectiveness research CER research into what works best in medical care Comparative Effectiveness Research Evidence Medicine and Policy provides the first complete account of how and why the federal government decided to make CER an important feature of health reform Despite earlier legislative

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