

# Lack of transparent reporting of trial monitoring approaches in randomised controlled trials: A systematic review of contemporary protocol papers

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## Abstract

**Background:** Monitoring is essential to ensure patient safety and data integrity in clinical trials as per Good Clinical Practice. The Standard Protocol Items: Recommendations for Interventional Trials Statement and its checklist guides authors to include monitoring in their protocols. We investigated how well monitoring was reported in published ‘protocol papers’ for contemporary randomised controlled trials.

**Methods:** A systematic search was conducted in PubMed to identify eligible protocol papers published in selected journals between 1 January 2020 and 31 May 2020. Protocol papers were classified by whether they reported monitoring and, if so, by the details of monitoring. Data were summarised descriptively.

**Results:** Of 811 protocol papers for randomised controlled trials, 386 (48%; 95% CI: 44%–51%) explicitly reported some monitoring information. Of these, 20% (77/386) reported monitoring information consistent with an on-site monitoring approach, and 39% (152/386) with central monitoring, 26% (101/386) with a mixed approach, while 14% (54/386) did not provide sufficient information to specify an approach. Only 8% (30/386) of randomised controlled trials reported complete details about all of scope, frequency and organisation of monitoring; frequency of monitoring was the least reported. However, 6% (25/386) of papers used the term ‘audit’ to describe ‘monitoring’.

**Discussion:** Monitoring information was reported in only approximately half of the protocol papers. Suboptimal reporting of monitoring hinders the clinical community from having the full information on which to judge the validity of a trial and jeopardises the value of protocol papers and the credibility of the trial itself. Greater efforts are needed to promote the transparent reporting of monitoring to journal editors and authors.

## Keywords

Systematic review, trial monitoring, on-site monitoring, central monitoring, risk-based monitoring, reporting monitoring, protocol paper, randomised controlled trial

## Background

Clinical trial monitoring<sup>1</sup> plays a vital role in ensuring participants’ well-being is protected, trial data are accurate and complete, and the conduct of the trial complies with the protocol, regulatory requirements and Good Clinical Practice (GCP) guidelines.<sup>2</sup> ‘Monitoring’ here refers to the methods used by a sponsor to oversee the conduct of, and reporting of data from, clinical trials, including the ‘review of site processes, procedures and records, and verification of the accuracy of data submitted to the sponsor’.<sup>3</sup> In the past, clinical trials predominantly relied on on-site monitoring, in which trial monitors systematically and repeatedly visited sites

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# Methods Trial Papers

**Brendan G. Carr**



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*Papers on Sociological Methods* Francis Stuart Chapin, 1924

**The Advanced Handbook of Methods in Evidence Based Healthcare** Andrew Stevens, Keith Abrams, John Brazier, Ray Fitzpatrick, Richard Lilford, 2001-01-02 This handbook is an excellent reflection of the growing maturity and methodological sophistication of the field of Health Technology Assessment The Handbook covers a spectrum of issues from primary evidence clinical trials through reviews and meta analysis to identifying and filling gaps in the evidence Up to date clearly written and well edited the handbook is a needed addition to any personal or professional library dealing with Health Technology Assessment Professor David Banta TNO Prevention and Health The Netherlands This text presents the most advanced knowledge on methodology in health care research and will form the backbone of many future studies Paula Roberts Nurse Researcher The effectiveness revolution both in research and clinical practice has tested available methods for health services research to the extreme How far can observational methods routine data and qualitative methods be used in health care evaluation What cost and outcome measures are appropriate and how should data be gathered With the support of over two million pounds from the British Health Technology Assessment Research Programme the research project for this Handbook has led to both a synthesis of all of the existing knowledge in these areas and an agenda for future debate and research The chapters and their authors have been selected through a careful process of peer review and provide a coherent and complete approach to the field The handbook has been a unique collaboration between internationally regarded clinicians statisticians epidemiologists social scientists health economists and ethicists It provides the most advanced thinking and the most authoritative resource for a state of the art review of methods of evaluating health care and will be required reading for anyone involved in health services research and management

**The Mixed Methods Research Workbook** Michael D. Fetters, 2019-10-03 The Mixed Methods Research Workbook by Michael Fetters is the perfect tool for doctoral students and researchers who want support throughout their research project as well as a practical way to apply the knowledge they have learned With this text students can tackle their mixed methods research project with confidence [Parliamentary Papers](#) Great Britain. Parliament. House of Commons, 1903

*MEDINFO 2007* K.A. Kuhn, J.R. Warren, T.-Y. Leong, 2007-08-02 Contains papers which reflect the breadth and depth of the field of biomedical and health informatics covering topics such as health information systems education standards consumer health and human factors emerging technologies sustainability organizational and economic issues genomics and image and signal processing *Sessional Papers of the Dominion of Canada* Canada. Parliament, 1901 Report of the Dominion fishery commission on the fisheries of the province of Ontario 1893 issued as vol 26 no 7 supplement *Paper*, 1916 *Text Mining of the Scientific Literature to Identify Pharmacogenomic Interactions* Yael Garten, 2010 Pharmacogenomics is the study of how variation in the human genome impacts drug response in patients It is a major driving force of personalized medicine in which drug choice and dosing decisions are informed by

individual information such as DNA genotype The field of pharmacogenomics is in an era of explosive growth massive amounts of data are being collected and knowledge discovered which promises to push forward the reality of individualized clinical care However this large amount of data is dispersed in many journals in the scientific literature and pharmacogenomic findings are discussed in a variety of non standardized ways It is thus challenging to identify important associations between drugs and molecular entities particularly genes and gene variants Thus these critical connections are not easily available to investigators or clinicians who wish to survey the state of knowledge for any particular gene drug disease or variant Manual efforts have attempted to catalog this information however the rapid expansion of pharmacogenomic literature has made this approach infeasible Natural Language Processing and text mining techniques allow us to convert free style text to a computable searchable format in which pharmacogenomic concepts such as genes drugs polymorphisms and diseases are identified and important links between these concepts are recorded My dissertation describes novel computational methods to extract and predict pharmacogenomic relationships from text In one project we extract pharmacogenomic relationships from the primary literature using text mining We process information at the fine grained sentence level using full text when available In a second project we investigate the use of these extracted relationships in place of manually curated relationships as input into an algorithm that predicts pharmacogenes for a drug of interest We show that for this application we can perform as well with text mined relationships as with manually curated information This approach holds great promise as it is cheaper faster and more scalable than manual curation Our method provides us with interesting drug gene relationship predictions that warrant further experimental investigation In the third project we describe knowledge inference in the context of pharmacogenomic relationships Using cutting edge natural language processing tools and automated reasoning we create a rich semantic network of 40 000 pharmacogenomic relationships distilled from 17 million Medline abstracts This network connects over 200 entity types with clear semantics using more than 70 unique types of relationships We use this network to create collections of precise and specific types of knowledge and infer relationships not stated explicitly in the text but rather inferred from the large number of related sentences found in the literature This is exciting because it demonstrates that we are able to overcome the heterogeneity of written language and infer the correct semantics of the relationship described by authors Finally we can use this network to identify conflicting facts described in the literature to study change in language use over time and to predict drug drug interactions These achievements provide us with new ways of interacting with the literature and the knowledge embedded within it and help ensure that we do not bury the knowledge embodied in the publications but rather connect the often fragmented and disconnected pieces of knowledge spread across millions of articles in hundreds of journals We are thereby brought one step closer to the realization of personalized medicine and ensure that as scientists we continue to build on the knowledge discovered by past generations and truly to stand on the shoulders of giants

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