

How to Read a Clinical Trial Paper: A Lesson in Basic Trial Statistics

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Abstract: While the number of clinical trials performed yearly is increasing, the application of these results to individual patients is quite difficult. This article reviews key portions of the process of applying research results to clinical practice. The first step involves defining the study population and determining whether these patients are similar to the patients seen in clinical practice in terms of demographics, disease type, and disease severity. The dropout rate should be compared between the different study arms. Design aspects, including randomization and blinding, should be checked for signs of bias. When comparing studies, clinicians should be aware that the outcomes being studied may vary greatly from one study to another, and some outcomes are much more reliable and valuable than others. The definition of clinical response should also be scrutinized, as it may be too lenient. Surrogate outcomes should be viewed cautiously, and their use should be well justified. Clinicians should also note that statistical significance, as defined by a *P*-value cutoff, may be the result of a large sample size rather than a clinically significant difference. The treatment effect can be estimated by calculating the number needed to treat, which will demonstrate whether changes in clinical practice are worthwhile. Finally, this article discusses some common issues that can arise with figures.

In the last decade, the number of publications dedicated to research in gastroenterology has expanded dramatically.¹ In parallel, the number of clinical trials has been increasing, with more than 18,000 ongoing clinical trials in the United States alone.² With this rapid growth in research, clinicians find themselves trying to keep up with wave after wave of studies and trying to determine how these studies apply to their patients. As researchers learn more about disease processes, clinical trial design is also changing and becoming more complex. Medical school and subsequent clinical training provide limited education on how to evaluate these stud-

Keywords

Statistics; clinical trials; randomized controlled trials; outcomes; clinical research

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Suggestions for Paper-mulch Trials Lewis Herrick Flint, 1929 *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.

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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 *Pearson's Magazine* ,1902

Field Trials of Health Interventions Peter G. Smith,Richard H. Morrow,David A. Ross,2015 This is an open access title available under the terms of a CC BY NC 4 0 International licence It is free to read at Oxford Scholarship Online and offered as a free PDF download from OUP and selected open access locations Before new interventions are released into disease control programmes it is essential that they are carefully evaluated in field trials These may be complex and expensive undertakings requiring the follow up of hundreds or thousands of individuals often for long periods Descriptions of the detailed procedures and methods used in the trials that have been conducted have rarely been published A consequence of this individuals planning such trials have few guidelines available and little access to knowledge accumulated previously other than their own In this manual practical issues in trial design and conduct are discussed fully and in sufficient detail that Field Trials of Health Interventions may be used as a toolbox by field investigators It has been compiled by an international

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