

## "Study Design and Statistical Analysis: A Practical Guide for Clinicians"

Mitchell H. Katz, 2006, 188 pages, Cambridge University Press, \$56.00

Review by Norman M. Goldfarb

"Study Design and Statistical Analysis: A Practical Guide for Clinicians" is a valuable nuts-and-bolts guide for any medical professional thinking of conducting a clinical research study, or who wants to do it right the next time. It is also very useful for clinical research professionals who want to understand how their work fits into the big picture.

The book both demystifies the process from A to Z and identifies common challenges and pitfalls. The book includes numerous examples but very few formulae. It is written in clear, reader-friendly prose, for example:

This book has been selected for  
[The First Clinical Research Bookshelf](#)  
Essential reading for clinical research professionals

### **Randomization with unequal allocation**

There are times when it is advantageous to randomize subjects in an unequal fashion, such as a two-to-one randomization. For example, treatment trials of serious diseases (e.g., cancer or AIDS) may benefit from unequal allocation because subjects may be more motivated to participate if they have a greater than 50% chance of receiving the new treatment. Unequal randomizations may also be helpful in learning more about the side effects of a new treatment (because you can allocate more than half of the subjects to the new treatment group, you will have more data on the side effects of the drug).

When it comes to study design, advantages bring disadvantages. With unequal randomization, you lose power due to not having equal numbers of persons in each treatment group. With less power, it is harder to reject the null hypothesis when it is false. In addition, unequal allocation is inconsistent with the principle of equipoise. Equipoise refers to the belief of the investigator (or at least the research community) that the different arms of the study are equal. After all, if there is a clear indication that one arm is superior to the other, it is unethical to randomize patients. Unequal allocation may give an implicit message that the investigator believes one arm is superior to the other.

The chapter on determining causality rather than just correlation is especially interesting and useful in designing studies. Although causality cannot be proven mathematically, its likelihood can be increased by biological plausibility, presence of a strong dose-response effect, and absence of bias, confounding factors, and reverse causality.

The book consists of 12 chapters:

- Introduction
- Designing a study
- Data management
- Univariate statistics
- Bivariate statistics

- Multivariable statistics
- Sample size calculations
- Studies of diagnostic and prognostic tests (predictive studies)
- Statistics and causality
- Special topics
- Publishing research
- Conclusion

The book is available in bookstores.

### **Reviewer**

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