“Planning Clinical Research”

By Robert A. Parker and Nancy G. Berman, 2016, 419 pages, Cambridge University Press, $44.99

Review by Norman M. Goldfarb

“Planning Clinical Research” is an excellent introduction to clinical research for academic researchers and anyone else seeking a clear understanding of how clinical research works. The book focuses on designing studies that will pass muster with the biostatisticians but has the grace to include not a single formula.

The book also includes chapters on topics like ethics review and subject recruiting, which also need planning. In fact, it’s unclear that any aspect of a clinical study can safely skip the planning stage. It would be an understatement to say the book includes numerous examples, many of which evolve during the course of the book.

The following section illustrates the book’s clear writing and understanding of the academic researcher’s needs:

**Different Questions May Represent Different Designs in the Same Study**

Given how difficult it is to do a study, often an investigator will try to use the data collected for multiple research questions, each with a different focus. These different research questions might represent different study designs, as shown in the following example.

**Example 4A:** To study the effect of a new therapy in individuals with a specific disease, individuals were randomized to receive either the new therapy or standard of care (SOC) until death from any cause. The primary endpoints of this study were time until death from the disease of interest (with deaths from other causes being considered a censoring event) and adverse events from the new therapy. This study, when published, will be a randomized parallel group interventional study.

As part of the study, baseline data were collected on all participants before therapy. Specific baseline characteristics could be summarized and reported in a separate publication - for example, a study of the nutritional status of participants with this disease. This reflects a cross-sectional design.

The detailed course of the disease in those participants receiving SOC could be described in another publication. Such a publication could include the duration from diagnosis until first hospitalization for the condition, the number and duration of hospitalizations, palliative care needs of participants, and so forth. Here, all participants have the same exposure, so one is describing the outcome for the total population. Such a report would reflect a prospective (or concurrent) cohort design.

In the SOC group, there might be some participants who have long-term survival despite the disease. This group could be compared to those who succumb quickly to the disease, to identify prognostic factors predicting long-term survival with the disease, which could be analyzed as if the data came from a case-control study.
This example illustrates that the paradigms that we use in this book are just that: ideals of a pure form. Clinical research often does not fall into these neat designs. Particularly for larger, long-term studies, there will often be a dominant feature (in Example 4A it is the randomized parallel group interventional design), but in addition some of the data may be used in other ways for other purposes, and would be interpreted as if it came from a different design altogether. This is not inappropriate or misleading. Indeed, given the difficulty in recruiting and retaining participants in studies, it would be wasteful not to attempt to gain as much information as possible.

In an observational study, however, there is no intervention that can be compared in a secondary study. Some of the data in a cohort study could perhaps be treated as if it was collected as part of a cross-sectional study, and a subset of the data could be used for a case-control study. This is called a nested case-control study, since the case-control study is nested inside the cohort study. The ability to use data as if it arose from multiple designs is less likely to occur in a case-control study or a cross-sectional study.

The book includes 30 chapters in six parts:

- Introduction
- Study Designs
- Core Concepts Applicable to All Study Designs
- Additional Concepts for Interventional Studies
- Additional Concepts for Observational Studies
- Practical Issues

The book is available in bookstores.

**Reviewer**

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