

"A Concise Guide to Observational Studies in Healthcare"

Allan Hackshaw, 2015, 242 pages, Wiley Blackwell, \$49.95

Review by Norman M. Goldfarb

"A Concise Guide to Observational Studies in Healthcare" is a solid introduction to observational studies. Controlled, double-blinded clinical trials are the gold standard, but with the price of gold what it is, observational studies are a legitimate and affordable way to answer many questions.

The book lays out a taxonomy of observational studies:

Studies are conducted among two different types of participants:

1. **Population:** Participants are approached from the general population. They may or may not have the disorder of interest. Researchers sometimes use the word *healthy* individual or *control* when describing some study participants, but this usually only means that the participants do not have the disorder of interest. They may have other disorders. Better terms could be *affected* and *unaffected*.
2. **Patients:** Only people who have already been diagnosed with a specific disorder are recruited to a study.

The study objectives are usually quite different for each of these two types. For studies of the *population*, interest is often in risk factors that lead to the occurrence of a disorder, but for *patient* studies, interest could be in how an existing disorder develops, including the management of it. Both can be used when describing characteristics of a group(s).

A variety of study designs can be used to examine associations, risk factors, and interventions:

- A *cross-sectional survey*: face-to-face interviews with participants or collecting self-completed participant surveys.
- A (*retrospective*) *case-control study*: people with and without a disorder of interest are identified and asked about their past habits, possibly also obtaining data from their medical records.
- A *prospective cohort study*: people without the disorder of interest are identified, baseline characteristics are measured, and participants are followed up for a period of time (several months or years), during which specific data is collected regularly.
- A *retrospective cohort study* is essentially a prospective cohort study that has already been conducted.
- A *longitudinal study*: a prospective cohort study in which exposures and often outcomes are measured repeatedly during follow-up.
- Studies based on routinely collected data: these could come from *regional or national registries or databases* (e.g., cancer or death notification systems) and contain a few key factors on each individual (e.g. age, sex, city of residence), as well as the disease status. Many such databases have adequate or good data quality processes in place, but a common limitation is that potential confounding factors are unavailable.

These terms for types of study designs should not be regarded as fixed. There may be occasions when one type could be used synonymously with another, a design is nested within another, or there are variations on a specific design. For example:

- There are nested case-control studies, which involve selecting and only analyzing cases and controls (individuals with and without a disorder of interest) from a cohort study.
- Cases and controls could provide information about their current or past characteristics, but they might also be followed up for a certain length of time for other outcome measures, so these data are collected prospectively (similar to a prospective study).

Researchers simply need to be clear where the participants for a particular study have come from and how data are collected from or about them.

The book includes the following 11 chapters:

- Fundamental concepts
- Outcome measures, risk factors, and causality
- Effect sizes
- Regression analyses
- Cross-section studies
- Case-control studies
- Cohort studies
- Quality of care studies
- Prognostic markers for predicting outcomes
- Systematic reviews and meta-analyses
- Conducting and reporting observational studies

The book is available in bookstores.

Reviewer

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