

Observational Studies.

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Observational Studies. By Paul R. Rosenbaum. Springer-Verlag, New York, 1995. \$44.95. xv + 230 pp., hardcover. ISBN 0-387-94482-6.

Observational studies differ from designed experiments in that the investigator does not control the treatment assignment. Because they do not employ randomization, observational studies are generally less convincing than designed experiments. Yet in many areas of science they are the only practicable alternative. For example, the bulk of the evidence linking smoking to lung cancer came from observational studies.

Paul Rosenbaum has spent the last 15 years developing a rigorous statistical theory of observational studies. His theory illuminates the biases arising in observational research and leads to methods for measuring and minimizing the potential effects of such biases. This book provides a unified account of the theory, its origins, and its mathematical foundation.

The book is arranged in ten chapters. Chapter 1 introduces the main issues, Chapter 2 reviews the randomization theory of inference, and Chapter 3 applies the theory to observational studies that are free of hidden bias, i.e., where all the bias may be removed by adjusting for a known set of observed covariates.

The heart of the book is Chapter 4, "Sensitivity to Hidden Bias." In the conventional analysis of an observational study, we act as though the treatments were assigned by simple randomization within matched sets. When the treatment assignment probabilities differ within sets, typically through the influence of an unmeasured covariate, "hidden bias" can arise. To explore this bias, Rosenbaum assumes a maximum odds ratio $\Gamma \geq 1$ for the treatment assignment probabilities within matched sets. ($\Gamma = 1$ corresponds to equal assignment probabilities, the assumption underlying the conventional analysis.) For each Γ , he calculates the extreme values of the analysis that would result under the most pessimistic assumptions about the configuration of the unobserved covariate. An analysis is insensitive to hidden bias if it changes significantly only

for large values of Γ . Thus Rosenbaum gives us a coherent, objective method for characterizing sensitivity to hidden bias, the issue that lies at the bottom of every argument about the validity of observational data.

Chapters 5–8 apply this technique to studies with "known" effects, case-referent studies with multiple referent groups, studies with multiple control groups, and examination of the coherence of effects with scientific theories. Chapter 9 discusses methods for constructing matched sets and strata, and Chapter 10 discusses pragmatic "strategic" issues.

Rosenbaum's approach is resolutely frequentist in the sense of Fisher's randomization theory. Although his methods can be used with point and interval estimation, most of the examples concern significance tests. Thus there is a tendency to view sensitivity wholly in terms of "significance at the 5% level," which many will find a regrettable oversimplification. Overall I think the novelty of Rosenbaum's ideas, and the new perspectives they have opened up for statistics, far outweigh such criticisms.

Rosenbaum's writing is clear and concise, and he illustrates concepts with familiar examples, mostly from chronic-disease epidemiology. This would be an excellent text for an advanced graduate course in statistics or biostatistics, thanks in part to the inclusion of thought-provoking exercises. The arguments are presented in an abstract mathematical language that theoretical statisticians will appreciate but that unfortunately may be beyond the grasp of many scientists who conduct observational research.

The book is attractively typeset with only a moderate number of errors (my estimate: 1 per 4.5 pages). The index is sketchy (authors' names are not listed), and the placement of references at the end of each chapter means that readers cannot easily browse the entire reference list. I was surprised to find no mention of software, despite the evident difficulty of many of the calculations.

This is a unique, stimulating, and important book. Statisticians with an interest in the theory and practice of observational studies will find it essential reading.

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