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## Preface

Clinical epidemiology provides the scientific basis for the practice of medicine, because it focuses on the diagnosis, prognosis, and management of human disease. Therefore, issues of research design, measurement, and evaluation are critical to clinical epidemiology. This volume, *Clinical Epidemiology: Practice and Methods*, is intended to educate researchers on how to undertake clinical research and should be helpful not only to medical practitioners but also to basic scientists who want to extend their work to humans, to allied health professionals interested in scientific evaluation, and to trainees in clinical epidemiology.

This book is divided into six parts. The first three introductory chapters focus on how to frame a clinical research question, the ethics associated with doing a research project in humans, and the definition of various biases that occur in clinical research. Parts II–IV examine issues of design, measurement, and analysis associated with various research designs, including determination of risk in longitudinal studies, assessment of therapy in randomized controlled clinical trials, and evaluation of diagnostic tests. Part V focuses on the more specialized area of clinical genetic research. Part VI provides the basic methods used in evidence-based decision making including critical appraisal, aggregation of multiple studies using meta-analysis, health technology assessment, clinical practice guidelines, development of health policy, translational research, how to utilize administrative databases, and knowledge translation.

This collection provides advice on framing the research question and choosing the most appropriate research design, often the most difficult part in performing a research project that could change clinical practice. It discusses not only the basics of clinical epidemiology but also the use of biomarkers and surrogates, patient-reported outcomes, and qualitative research. It provides examples of bias in clinical studies, methods of sample size estimation, and an analytic framework for various research designs, including the scientific basis for multivariate modeling. Finally, practical chapters on research ethics, budgeting, funding, and managing clinical research projects may be useful.

The content of this book can be divided into two categories: The basics of clinical epidemiology and more advanced chapters examining the analysis of longitudinal studies (Chapters 5–8) and randomized controlled trials (Chapters 13–15). Examples and case studies have been encouraged.

All the contributors to this volume are practicing clinical epidemiologists, who hope the reader will join them in doing research focused on improving clinical outcomes.

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