Contents

List of Contributors, ix
Preface, xvi
Acknowledgements, xx

PART I Introduction, 1
1 What is Pharmacoepidemiology?, 3  
   Brian L. Strom
2 Basic Principles of Clinical Pharmacology Relevant to Pharmacoepidemiologic Studies, 23  
   Jeffrey S. Barrett and Athena F. Zuppa
3 Basic Principles of Clinical Epidemiology Relevant to Pharmacoepidemiologic Studies, 38  
   Brian L. Strom
4 Sample Size Considerations for Pharmacoepidemiologic Studies, 52  
   Brian L. Strom
5 When Should One Perform Pharmacoepidemiologic Studies?, 62  
   Brian L. Strom

PART II The Role of Pharmacoepidemiology in Different Sectors, 71
6 The Role of Pharmacoepidemiology in the Health-Care System and Academia, 73  
   Jerry Avorn
7 The Role of Pharmacoepidemiology in Industry, 84  
   Jingping Mo, Nicolle M. Gatto, Rachel E. Sobel, and Robert F. Reynolds
8 The Role of Pharmacoepidemiology in Regulatory Agencies, 107  
   Gerald J. Dal Pan and Peter Arlett
9 Pharmacoepidemiology and the Law, 117  
   Aaron S. Kesselheim

PART III Sources of Data for Pharmacoepidemiologic Studies, 135
Section A: Spontaneous Reporting
10 Postmarketing Spontaneous Pharmacovigilance Reporting Systems, 137  
   Gerald J. Dal Pan, Marie Lindquist, and Kate Gelperin
Section B: Automated Data Systems

11 Overview of Automated Databases in Pharmacoepidemiology, 158
   Brian L. Strom

12 Health Maintenance Organizations/Health Plans, 163
   Susan E. Andrade, Marsha A. Raebel, Denise Boudreau, Robert L. Davis,
   Katherine Haffenreffer, Pamala A. Pawloski, Sengwee Toh, and Richard Platt

13 Commercial Insurance Databases, 189
   John Seeger and Gregory W. Daniel

14 US Government Claims Databases, 209
   Sean Hennessy, Cristin Palumbo Freeman, and Francesca Cunningham

15 Medical Record Databases, 224
   Alexis Ogdie, Sinéad M. Langan, John Parkinson, Hassy Dattani, Karel Kostev, and
   Joel M. Gelfand

16 In-hospital Databases, 244
   Brian T. Fisher, Peter K. Lindenauer, and Chris Feudtner

17 Canadian Provincial Databases, 259
   Yola Moride and Colleen J. Metge

18 Pharmacy-based Medical Record Linkage Systems, 270
   Ron M.C. Herings and Lars Pedersen

Section C: Ad Hoc Studies—Ongoing Systems for
Pharmacoepidemiologic Studies

19 Case–Control Surveillance, 287
   Lynn Rosenberg, Patricia F. Coogan, and Julie R. Palmer

20 Prescription–Event Monitoring, 301
   Deborah Layton and Saad A.W. Shakir

21 Registries, 331
   Nancy A. Dreyer and Priscilla Velentgas

Section D: Ad Hoc Studies—De Novo Studies

22 Field Studies, 347
   David W. Kaufman

Section E: Choosing Among the Available Alternatives

23 How Should One Perform Pharmacoepidemiologic Studies?
   Choosing Among the Available Alternatives, 364
   Brian L. Strom

PART IV Selected Special Applications
of Pharmacoepidemiology, 377

24 Studies of Drug Utilization, 379
   David Lee and Ulf Bergman

25 Evaluating and Improving Physician Prescribing, 402
   Sumit R. Majumdar, Helene Levens Lipton, and Stephen B. Soumerai
26 Pharmacoepidemiologic Studies of Vaccine Safety, 423
   Robert T. Chen, Jason M. Glanz, and Claudia Vellozzi

27 Epidemiologic Studies of Medical Devices: Methodologic Considerations for Implantable Devices, 469
   Danica Marinac-Dabic, Sharon-Lise Normand, Art Sedrakyan, and Thomas Gross

28 Studies of Drug-Induced Birth Defects, 487
   Allen A. Mitchell

29 Risk Management, 505
   Gerald J. Dal Pan, Stella Blackburn, and Claudia Karwoski

30 FDA’s Sentinel Initiative: Active Surveillance to Identify Safety Signals, 534
   Judith A. Racoosin, Melissa A. Robb, Rachel E. Sherman, and Janet Woodcock

31 Pharmacoepidemiology and Pharmaceutical Reimbursement Policy, 555
   Mitchell Levine and Jacques LeLorier

32 Comparative Effectiveness Research, 561
   Brian L. Strom, Rita Schinnar, and Sean Hennessy

PART V Selected Special Methodologic Issues in Pharmacoepidemiology, 581

33 Assessing Causality of Case Reports of Suspected Adverse Events, 583
   Judith J. Jones

34 Molecular Pharmacoepidemiology, 601
   Stephen E. Kimmel, Hubert G. Leufkens, and Timothy R. Rebbeck

35 Bioethical Issues in Pharmacoepidemiologic Research, 623
   Antoine C. El Khoury, Jason Karlawish, Elizabeth Andrews, and Arthur Caplan

36 The Use of Randomized Controlled Trials for Pharmacoepidemiologic Studies, 640
   Samuel M. Lesko and Allen A. Mitchell

37 The Use of Pharmacoepidemiology to Study Beneficial Drug Effects, 655
   Brian L. Strom and Kenneth L. Melmon

38 Pharmacoeconomics: Economic Evaluation of Pharmaceuticals, 678
   Kevin A. Schulman, Henry A. Glick, Daniel Polsky, and Shelby D. Reed

39 Using Quality-of-Life Measurements in Pharmacoepidemiologic Research, 709
   Holger Schünemann, Bradley C. Johnston, Roman Jaeschke, and Gordon H. Guyatt

40 The Use of Meta-analysis in Pharmacoepidemiology, 723
   Jesse A. Berlin, M. Soledad Cepeda, and Carin J. Kim

41 Validity of Pharmacoepidemiologic Drug and Diagnosis Data, 757
   Suzanne L. West, Mary Elizabeth Ritchey, and Charles Poole

42 Studies of Medication Adherence, 795
   Trisha Acri and Robert Gross
43 Risk Evaluation and Communication, 810
   Susan J. Blalock and Betsy L. Sleath

44 Studying Effects of Antibiotics, 827
   Darren R. Linkin and Ebbing Lautenbach

45 The Pharmacoepidemiology of Medication Errors, 840
   Hanna M. Seidling and David W. Bates

46 Sequential Statistical Methods for Prospective
   Postmarketing Safety Surveillance, 852
   Martin Kulldorff

47 Advanced Approaches to Controlling Confounding
   in Pharmacoepidemiologic Studies, 868
   Sebastian Schneeweiss and Samy Suissa

PART VI Conclusion, 893

48 The Future of Pharmacoepidemiology, 895
   Brian L. Strom, Stephen E. Kimmel, and Sean Hennessy

Appendix A: Sample Size Tables, 904
Appendix B: Glossary, 921

Index, 931