

Table of contents

Preface v

Contributors xxi

PART I. OVERVIEW

Ch. 1. Bioenvironment and Public Health: Statistical Perspectives 3

Pranab K. Sen

1. Introduction 3
2. Consolidation of bioenvironment and public health disciplines 7
3. Whither statistics? 20
4. Concluding remarks 28
References 29

PART II. GENERAL METHODOLOGY

Ch. 2. Some Examples of Random Process Environmental Data Analysis 33

David R. Brillinger

1. Introduction 33
2. Some basic concepts and methods 34
3. Point processes and marked point processes 34
4. Time series 40
5. Spatial-temporal processes 43
6. Particle processes 46
7. Other types of processes, data and techniques 54
8. Discussion 54
Acknowledgements 55
References 55

Ch. 3. Modeling Infectious Diseases – Aids 57

L. Billard

1. Introduction 57
2. The basic model 58
3. Right-shift models: Shifts to adjacent stages 61
4. Right-shift models: Shifts to non-adjacent stages 64
5. Other model structures 65
6. Incubation period 66
7. Inference 69
8. Conclusion 70
- References 70

Ch. 4. On Some Multiplicity Problems and Multiple Comparison Procedures in Biostatistics 75

Yosef Hochberg and Peter H. Westfall

1. Introduction 75
2. On different approaches to multiplicity problems 78
3. A tutorial on classical MCPs 82
4. Special topics in biostatistics 86
5. Other problems and approaches 104
- Acknowledgement 109
- References 110

Ch. 5. Analysis of Longitudinal Data 115

Julio M. Singer and Dalton F. Andrade

1. Introduction 115
2. Models for Gaussian data 119
3. Models for non-Gaussian data 137
4. Design, missing data and computational issues 142
5. Examples 145
- Acknowledgements 156
- References 156

Ch. 6. Regression Models for Survival Data 161

Richard A. Johnson and John P. Klein

1. Introduction 161
2. Censoring and truncation 164
3. Estimation for parametric regression models 165
4. Semi-parametric regression models 173
5. Additive hazards regression 186
- Acknowledgements 190
- References 190

Ch. 7. Generalised Linear Models for Independent and Dependent Responses 193

Bahjat F. Qaqish and John S. Preisser

1. Introduction 193
2. Generalized linear models 194
3. Marginal models for longitudinal data 200
4. Random effects models 207
5. Conditional models 213
- Acknowledgements 219
- References 219

Ch. 8. Hierarchical and Empirical Bayes Methods for Environmental Risk Assessment 223

Gauri Datta, Malay Ghosh and Lance A. Waller

1. Introduction 223
2. Examples 226
3. Classical estimation of relative risks 227
4. Empirical Bayes approach 228
5. Hierarchical Bayes approach 232
6. Application to waste sites and leukemia in upstate New York 237
7. Discussion 243
- References 243

Ch. 9. Non-parametrics in Bioenvironmental and Public Health Statistics 247

Pranab Kumar Sen

1. Introduction 247
2. Quantitative bioassays 248
3. Quantal bioassays 252
4. Generalized linear models 255
5. Correlated polychotomous response data models 262
6. Multivariate models in biostatistics 267
7. Longitudinal data models 280
8. Robust statistical inference in general linear models 283
9. Nonlinear regression analysis 290
10. Nonparametric regression analysis 291
11. Generalized additive models 297
12. Clinical trials and survival analysis 298
13. Design of bioenvironmental studies 307
14. Molecular biology and genetics 313
- References 319

Ch. 10. Estimation and Comparison of Growth and Dose-Response Curves in the Presence of Purposeful Censoring 325

Paul W. Stewart

1. Introduction 325
2. Simple paradigm for purposeful censoring 327
3. Conditions under which purposeful censoring is ignorable 331
4. Analysis methods 334
5. Examples 338
6. Generalizations 348
7. Discussion 350
- Acknowledgements 351
- References 351

PART III. ENVIRONMENTAL EPIDEMIOLOGY

Ch. 11. Spatial Statistical Methods for Environmental Epidemiology 357

Andrew B. Lawson and Noel Cressie

1. Statistical mapping and environmental epidemiology 357
2. The analysis of health risk related to pollution sources 373
3. The analysis of disease clustering 382
4. Ecological analysis 389
- Acknowledgements 391
- References 391

Ch. 12. Evaluating Diagnostic Tests in Public Health 397

Margaret Pepe, Wendy Leisenring and Carolyn Rutter

1. Introduction 397
2. Accuracy parameters 398
3. Comparisons of diagnostic accuracy 407
4. Regression analysis 411
5. Incomplete data issues 417
6. Concluding remarks 420
- References 421

Ch. 13. Statistical Issues in Inhalation Toxicology 423

E. Weller, L. Ryan and D. Dockery

1. Introduction 423
2. Designing an inhalation toxicology study 425
3. Optimal design 429
4. Discussion 437
- Acknowledgements 439
- References 439

Ch. 14. Quantitative Potency Estimation to Measure Risk with Bioenvironmental Hazards 441

A. John Bailer and Walter W. Piegorsch

1. Introduction 441
2. Dose-response/concentration-response models 442
3. Levels of response – Population, individual, community 444
4. Observed-effect levels in population-level risk assessment 444
5. Assessing population-level impact – Potency estimation 445
6. Other potency measures 454
7. Evaluating risks of hazardous agents 456
8. Conclusions 459
- Acknowledgements 460
- References 460

Ch. 15. The Analysis of Case-Control Data: Epidemiologic Studies of Familial Aggregation 465

Nan M. Laird, Garrett M. Fitzmaurice and Ann G. Schwartz

1. Introduction 465
2. Case-control studies in the study of risk factors for disease 466
3. A study of familial aggregation of lung cancer in nonsmokers 469
4. Analytic models and methods 470
5. Results 473
6. Discussion 479
- References 481

Ch. 16. Cochran–Mantel–Haenszel Techniques: Applications Involving Epidemiologic Survey Data 483

*Daniel B. Hall, Robert F. Woolson, William R. Clarke
and Martha F. Jones*

1. Introduction 483
2. CMH techniques: A review 484
3. The Iowa PGW Study 486
4. Simulation study 495
- References 499

Ch. 17. Measurement Error Models for Environmental and Occupational Health Applications 501

Robert H. Lyles and Lawrence L. Kupper

1. Introduction 501
2. Notation and general modeling framework 502
3. Adjustment methods under the multiplicative-lognormal paradigm 504
4. An application in occupational epidemiology 510
5. Discussion 514

Acknowledgements	515
Appendix	515
References	516

Ch. 18. Statistical Perspectives in Clinical Epidemiology 519

Shrikant I. Bangdiwala and Sergio R. Muñoz

1. Introduction	519
2. Elements of clinical epidemiology	520
3. Diagnostic and screening tests	521
4. Observational studies of the etiology of disease	526
5. Design, conduct and analysis of clinical trials	531
6. Conclusion	541
References	542

PART IV. CROSS-OVER DESIGNS

Ch. 19. ANOVA and ANOCOVA for Two-Period Crossover Trial Data: New vs. Standard 547

Subir Ghosh and Lisa D. Fairchild

1. Introduction	547
2. Subgroups	549
3. Model for ANOVA	552
4. ANOVA under Model I	553
5. Normality assumption under ANOVA	553
6. Nonparametric ANOVA under Model II	558
7. Model for ANOCOVA	558
8. ANOCOVA under Model I	562
9. Normality assumption under ANOCOVA	563
10. Nonparametric ANOCOVA under Model II	567
11. Conclusions	567
Acknowledgements	569
References	570

Ch. 20. Statistical Methods for Crossover Designs in Bioenvironmental and Public Health Studies 571

Gail E. Tudor, Gary G. Koch and Diane Catellier

1. Introduction	571
2. A two-treatment, two-period crossover study with duration of exercise and time to an angina as response variables for patients with ischemic heart disease	574
3. A three-treatment, three period crossover study with dichotomous and ordinal response variables for respiratory impairment from exposure to air pollution	586

4. A three treatment, two period crossover study with a continuous rating and dichotomous classification for pain relief for two headaches per period 596
- Acknowledgements 602
- Appendix: Mathematical background for statistical methods 603
- References 611

PART V. HUMAN REPRODUCTION

Ch. 21. Statistical Models for Human Reproduction 617

C. M. Suchindran and Helen P. Koo

1. Introduction 617
2. Approaches to model building 618
3. Background to reproductive models 619
4. Continuous-time discrete state models 620
5. Semi-Markov models 635
6. Computer-intensive statistical methods 640
7. Computer simulation models 641
8. Models and data considerations 642
9. Discussion and conclusion 642
- References 644

Ch. 22. Statistical Methods for Reproductive Risk Assessment 649

*Sati Mazumdar, Yikang Xu, Donald R. Mattison,
Nancy B. Sussman and Vincent C. Arena*

1. Introduction 649
2. Reproductive toxicology and biomarkers of reproduction 650
3. Current statistical methods for characterizing reproductive toxicity 651
4. Extensions of the QRRE method 654
5. Illustrative applications 658
6. Discussion 668
- References 669

PART VI. GENETIC MODELS

Ch. 23. Selection Biases of Samples and their Resolutions 675

Ranajit Chakraborty and C. Radhakrishna Rao

1. Introduction 675
2. Some sources of selection bias in samples 677
3. Formulation of likelihood functions and parameter estimation in the presence of truncation and censoring in observations 679
4. Probability (density) functions and related properties for weighted distributions 684
5. From specified to arbitrary ascertainment probabilities 688

6. Effect of selection bias on distributional properties of continuous traits and method of moments for ill-specified sample selection schemes 694
7. Some numerical examples of effects of selection bias and their remedies 698
8. Further examples of inherent selection bias in observational sciences 703
9. Discussions and conclusions 708
 - Acknowledgements 710
 - References 710

Ch. 24. Genomic Sequences and Quasi-Multivariate CATANOVA 713

*Hildete Prisco Pinheiro, Françoise Seillier-Moiseiwitsch,
Pranab Kumar Sen and Joseph Eron Jr*

1. Introduction 713
2. Biological background 714
3. Statistical motivation 717
4. Variation in categorical data and genomic sequences 720
5. Partitioning the diversity measure: A single position 723
6. Partitioning the diversity measure: Multiple sites 724
7. The probabilistic model 726
8. Moments of diversity measures 727
9. The test statistic 730
10. A Hamming distance detour 735
11. Power of the test 736
12. Simulations 738
13. Data analysis 740
 - Appendix 741
 - References 745

PART VII. SURVIVAL ANALYSIS AND COMPETING RISK

Ch. 25. Statistical Methods for Multivariate Failure Time Data and Competing Risks 749

Ralph A. DeMasi

1. Introduction 749
2. Competing risks 751
3. Multivariate survival models 759
4. Stochastic stratification and generalized competing risks 766
 - References 779

Ch. 26. Bounds on Joint Survival Probabilities with Positively Dependent Competing Risks 783

Sanat K. Sarkar and Kalyan Ghosh

1. Introduction 783
2. Notations and definitions 785

- 3. Bounds on $\bar{F}(x_1, \dots, x_k)$ 788
- 4. An application 793
- 5. Concluding remarks 797
- Appendix 799
- References 800

Ch. 27. Modeling Multivariate Failure Time Data 803

Limin X. Clegg, Jianwen Cai and Pranab K. Sen

- 1. Introduction 803
- 2. Univariate failure time data analysis 804
- 3. Models for multivariate failure time data 806
- 4. Model misspecification and robust inference 824
- References 835

PART VIII. HEALTH CARE

Ch. 28. The Cost–Effectiveness Ratio in the Analysis of Health Care Programs 841

Joseph C. Gardiner, Cathy J. Bradley and Marianne Huebner

- 1. Introduction 841
- 2. Measures of cost-effectiveness 844
- 3. Estimation of the cost-effectiveness ratio 847
- 4. Constructing confidence intervals for the CER 852
- 5. Hypothesis tests and statistical power 857
- 6. Discussion 862
- Acknowledgement 866
- References 866

Ch. 29. Quality-of-Life: Statistical Validation and Analysis An Example from a Clinical Trial 871

Balakrishna Hosmane, Clement Maurath and Richard Manski

- 1. Introduction 871
- 2. Methods 873
- 3. Discussion 887
- Acknowledgement 888
- References 888

PART IX. CANCER

Ch. 30. Carcinogenic Potency: Statistical Perspectives 895

Anup Dewanji

1. Introduction 895
2. Life table methods for estimating TD50 897
3. Regression coefficient based measure and its estimate 901
4. Survival adjusted methods 903
5. Discussion 905
- References 909

PART X. CARDIOVASCULAR RISK

Ch. 31. Statistical Applications in Cardiovascular Disease 915

Elizabeth R. DeLong and David M. DeLong

1. Introduction 915
2. Common methods for analysis of cardiovascular disease studies 916
3. Specialized applications 924
4. Issues 935
5. Conclusion 938
- References 938

PART XI. MEDICAL INFORMATICS

Ch. 32. Medical Informatics and Health Care Systems:
Biostatistical and Epidemiologic Perspectives 943*J. Zvárová*

1. Introduction 943
2. Medical informatics and health care systems 945
3. Decision support in health care 951
4. Role of biostatistics and epidemiology in information society 963
- Appendix A: CORE – The software tools for extracting relevant information from medical databases 965
- Appendix B: E.T. – The software tools for epidemiology 968
- Acknowledgements 971
- References 971

PART XII. DRUG-RESEARCH

Ch. 33. Methods of Establishing In Vitro–In Vivo Relationships for Modified Release Drug Products 977

David T. Mauger and Vernon M. Chinchilli

1. Introduction 977
2. In vitro–in vivo studies 982
3. Methods of quantifying in vitro–in vivo relationships 991
4. Discussion 997
References 1000

PART XIII. PSYCHIATRY

Ch. 34. Statistics in Psychiatric Research 1005

Sati Mazumdar, Patricia R. Houck and Charles F. Reynolds III

1. Introduction 1005
2. Statistical methods in psychiatry 1005
Acknowledgement 1023
References 1024

PART XIV. EPIDEMIOLOGY

Ch. 35. Bridging the Biostatistics–Epidemiology Gap 1029

Lloyd J. Edwards

1. Introduction 1029
2. Historical perspective 1030
3. Common aspects of biostatistics and epidemiology 1034
4. Differences between biostatistics and epidemiology 1037
5. Bridging the gap between biostatistics and epidemiology 1046
6. Joint future of biostatistics and epidemiology 1053
7. Summary 1053
References 1054

PART XV. BIODIVERSITY**Ch. 36. Biodiversity – Measurement and Analysis 1061***S. P. Mukherjee*

1. Introduction 1061
2. Measures of diversity 1062
3. Generalised measures of diversity 1063
4. Ecosystem diversity 1068
5. Species diversity 1070
- References 1075

Subject Index 1077**Contents of Previous Volumes 1087**