

**(62) Valerie Miké and Kenneth E Stanley (eds) (1982)**

***Statistics in Medical Research: Methods and Issues, with Applications in Cancer Research***

**New York: John Wiley and Sons**

***Preamble***

The book is dedicated to the memory of Jerome Cornfield and was published in the Wiley series in probability and mathematical statistics. In the frontispiece there is a quotation from Lewis Thomas, "From here on, as far ahead as one can see, medicine must be building, as a central part of its scientific base, a solid underpinning of statistical knowledge. Hunches and intuitive impressions are essential for getting the work started, but it is only through the quality of the numbers at the end that the truth can be told."

***Aims***

*There is a growing need in medical research for the contributions of professionals trained in biostatistics and epidemiology, and there is a nationwide shortage of adequate manpower. The subject was discussed at length in the course of a workshop on epidemiology and biostatistics organized by the National Cancer Institute in 1979. Since there are not enough professionals in these fields to meet the needs of medical schools and cancer centers around the country, the recommendation was made that special seminars and teaching materials be developed to enhance the effectiveness of individuals now filling many of the positions. In response to the general recommendation a summer conference on statistics in cancer research was held at Memorial Sloan-Kettering Cancer Center during the week of June 22-26, 1981. This book is based on the lectures and discussions presented at the conference. The book offers a comprehensive overview of the field of biostatistics. Although the emphasis of the meeting was on cancer research, nearly everything discussed is applicable to other areas of medical investigation. Since there are currently many opportunities in biostatistics, this volume can provide useful information for classically trained statisticians interested in entering the field, and it can help those new to the field to become more effective collaborators. It can serve as stimulus for graduate students in statistics, to nurture their interest and to prepare them for careers in biostatistics. It can also be read with benefit by clinical investigators seeking a better understanding of statistical concepts and related multidisciplinary aspects of medical research (Preface, pages ix and x).*

***Contents (xxi + 551 pages)***

[Sub-sub-headings omitted]

Preface (Valerie Miké, Kenneth E Stanley)

Part I Introduction

1. The role of statistics in medical research (Frederick Mosteller)
  - Importance of variance
  - Problem formulation
  - Design of investigations
  - Nonsampling errors
  - Analysis
  - Reporting
  - Schools of thought
  - Tabulation
  - To sum up
  - References

Part II Epidemiology

2. Cancer epidemiology (Theodore Colton, E Robert Greenberg)
  - Introduction
  - Descriptive epidemiology
  - Ecologic relationships
  - Analytic epidemiology
  - Cohort studies
  - Case-control studies
  - Association to causation
  - Appendix 1. Questions for assessment of a cohort study
  - Appendix 2. Questions for assessment of a case-control study
  - Appendix 3. Requirements for establishing causation from analytic observational studies
  - References
  - Bibliography
3. Trends in cancer mortality and incidence in the United States: is the future clear or clouded? (Marvin A Schneiderman)
  - Introduction
  - Materials and methods
  - Results
  - Discussion
  - References

### Part III Issues in clinical studies

4. Clinical studies in cancer: a historical perspective (Valerie Miké)
  - Early history of medicine
  - The nineteenth century
  - The twentieth century
  - The cancer program today
  - Accomplishments and future goals
  - The impact of statistical methodology
  - Major problems
  - Conclusion
  - References
5. Clinical trials: exploring ethical, legal, and psychological issues – panel discussion (Valerie Miké, George J Annas, Eric J Cassell, Jimmie CB Holland, Robert J Levine)
  - Legal aspects of clinical trials
  - Psychological aspects of clinical trials
  - Ethical aspects of clinical trials
  - The physician-patient relationship
  - Side effects versus benefits of chemotherapy
  - Phase I trials and the terminal patient
  - Social classes and clinical research
  - Personal savings for experimental treatment
  - Federal regulations: legal and ethical?
  - Randomized trials and the new federal guidelines
  - Concluding remarks
  - References
  - Nuremburg code
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6. Issues in the design of clinical trials – panel discussion (John C Bailar III, Byron W Brown, Jerome J DeCosse, Edmund A Gehan, James F Holland)

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The issues as seen by a statistician  
Views of a surgical oncologist  
A statistician responds  
The osteogenic sarcoma controversy  
The case for randomisation in clinical trials  
Patient acceptance of randomisation  
Differences in quality of historical controls  
The need for a balanced view  
Sequential designs  
Concluding remarks  
References

#### Part IV Practical considerations

7. Design and implementation of clinical trials (Martin L Lesser)
  - Types of clinical trials and their structure
  - Sample size and power determination
  - Implementation of clinical trials
  - References
8. Data management and quality control (Judith R O'Fallon)
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  - Data item selection
  - Forms design and testing
  - Data collection: personnel, materials, procedures
  - Data editing procedures
  - Monitoring data quality
  - Development of reports
  - Other procedures associated with data management
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9. Statistical software, data base management, statistical packages, and graphics (David W Brown Jr)
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  - Using a computer system
  - Statistical packages
  - Data base management systems
  - FORTRAN program libraries
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  - Appendix 2. SPSS
  - Appendix 3. BMDP
  - Appendix 4. Minitab
  - Appendix 5. P-STAT
  - Appendix 6. OSIRIS IV
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  - Appendix 10. GR-Z

#### Part V Statistical methodology

10. Estimation in survival analysis: parametric models, product-limit and life-table methods (Byron W Brown Jr)
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11. Inference in survival analysis: nonparametric tests to compare survival distributions (Stephen W Lagakos)
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  - A family of nonparametric tests
  - Derivations of tests from Cox's regression model
  - Properties of tests
  - Extensions
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12. Analysis of survival data: Cox and Weibull models with covariates (David P Byar)
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  - Screening for prognostic significance
  - Survival models incorporating covariates
  - Fitting interaction terms
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13. Analysis of categorical data: exact tests and log-linear models (Thomas A Louis)
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  - A problem with log-linear models
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14. Analysis of categorical data: logistic models (David A Schoenfeld)
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  - Asymptotic tests for treatment effect
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  - Coding variables
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15. Monitoring and stopping clinical trials (Mitchell H Gail)
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  - Monitoring data on pairwise treatment differences
  - Criticisms and comparisons of proposed boundaries
  - Monitoring time to response data
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### Part VI Communication

16. Interacting with the medical community: consulting, collaboration, teaching - panel discussion (Theodore Colton, Edmund A Gehan, Lawrence E Hinkle Jr, Carl M Pinsky, Kenneth E Stanley)
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  - Working as equals
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  - Professional interchange
  - Responsibility and collaboration
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