(21) Walter J Burdette and Edmund A Gehan (1970) *Planning and Analysis of Clinical Studies* Springfield: Charles C Thomas

Preamble

This is the first textbook to include appendices of Tables for sample size calculations in clinical trials. It is also the first text to be *authored* by both a physician and a statistician.

Aims

The clinician must continually evaluate data reported by others and the results of his own work in order to decide the most effective therapy for his patients. As an investigator, he must plan clinical and laboratory studies in such a way as to provide meaningful results with an economy of clinical resources. This implies a good understanding of the general principles of design and analysis. Intuitive conclusions, although valuable, must be supplemented not only by tests of significance but also by an understanding of clinical trials, appropriate size of sample, procedures for randomisation, and some general knowledge of the design of experiments. It is hoped that this small volume will serve as a durable handbook, first, as a concise presentation of the contemporary approach to planning and evaluation of clinical investigations, and second, as a source of formulae, tables, and methods used frequently in the actual analysis of data (Preface, page v).

Contents (xii+104 pages)

Preface	
Acknowledgm	ients
List of Tables	
Chapter I.	Introduction
Chapter II.	General considerations
	Types of studies
	General principles of design
	General principles of analysis
Chapter III.	Retrospective studies
	Aims and advantages
	Simple retrospective study of cases and controls
	Retrospective study of matched samples
	Studies adjusting for difference in one factor in cases and controls, Problems in
	retrospective studies
	Inferences from retrospective studies.
Chapter IV.	Prospective studies
	Phase-I studies
	Phase-II trials
	The comparative clinical trial (phase III)
	Analysis of data.
Bibliography	•
Appendix i.	Definitions of terms and formulae
Appendix ii.	Chi-square (X^2) tests of association or difference in proportions
Appendix iii.	Measures of relative risk in retrospective studies

Appendix iv. The *t* test

Appendix v. Calculation of survival curves and test of the difference between two survival curves

Appendix vi. Randomization in clinical trials

Appendix vii. Informed consent

Appendix viii. Tables used frequently

Table of X^2

Table of *t*

Chart of X^2 and t

Number of patients needed in an experimental and a control group for a given probability of obtaining a significant result: one-sided test; two-sided test

Size of sample (n) required for a preliminary trial, phase-IIA in terms of given levels of the apeutic effectiveness and rejection error (B)

Number of patients required for specified relative precision

Multiplier to be used in determining size of sample for a comparative clinical trial with size fixed Significance level related to value of Z

Additional random digits

Author index

Subject index.

Authors

The authors are Walter J Burdette PhD, MD and Edmund A Gehan PhD, both from the University of Texas M. D. Anderson Hospital and Tumor Institute at Houston, Texas, USA.