

STATISTICAL ISSUES IN THE ANALYSIS OF OUTCOMES IN CRITICAL CARE
MEDICINE

A THESIS FOR THE DEGREE OF DOCTOR OF MEDICINE

JOHN LEITH MORAN

DEPARTMENT OF INTENSIVE CARE MEDICINE, THE QUEEN ELIZABETH
HOSPITAL, 28 WOODVILLE ROAD, WOODVILLE SA 5011, AUSTRALIA

STATEMENT OF AUTHOR

This work contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and , to the best of my knowledge and belief, contains no material previously published or written by any other person, except where due reference has been made in the text

I give my consent to this copy of my thesis , when deposited in the University Library, being available for loan and photocopying.

John L Moran

February , 2006

TABLE OF CONTENTS

1. INTRODUCTION	6
2. P-VALUES, PRESENTATION OF RESULTS AND DATA ANALYSIS	11
2.1 P-values	
2.2 Normality of data, parametric and non-parametric tests	
3. CLINICAL TRIALS: DESIGN AND CONDUCT	36
3.1 Introduction	
3.2 Design and monitoring of clinical trials	
3.3 Equivalence	
4. CLINICAL TRIALS IN CRITICAL CARE: INTERPRETATION	79
4.1 Introduction	
4.2 Sample size and interpretation	
5. CRITIQUE OF TRIALS IN CRITICAL CARE	93
5.1 Learning new lessons or repeating old mistakes	
5.2 Hypothermia as therapy in cerebral injury	
5.3 Selective decontamination	
5.4 Nutrition as therapy: the evidence	
6. MULTIVARIABLE ANALYSIS OF PHOSPHATE METABOLISM IN CRITICALLY ILL PATIENTS WITH RESPIRATORY FAILURE	136
6.1 Introduction	
6.2 Methods	
6.3 Statistical methodology	
6.4 Results	
6.5 Discussion	

6.6 Conclusions	
7. ANALYSIS OF COST DATA	159
7.1 Introduction	
7.2 Methods	
7.3 Statistical methodology	
7.4 Results	
7.5 Discussion	
7.6 Conclusions	
8. OUTCOME OF PATIENTS ADMITTED TO ICU WITH HAEMATOLOGICAL AND SOLID MALIGNANCIES	179
8.1 Introduction	
8.2 Methods	
8.3 Statistical methodology	
8.4 Results	
8.5 Discussion	
8.6 Conclusions	
9. METHODOLOGY IN META-ANALYSIS	199
9.1 Introduction	
9.2 Methods	
9.3 Statistical methodology	
9.4 Results	
9.5 Discussion	
9.6 Conclusions	
10. OVERVIEW AND CONCLUSIONS	226
11. ACKNOWLEDGMENTS	230

12. APPENDICES: bound papers 231

13. REFERENCES 232