

P.G.H. HANDBOOK ON MEDICAL RESEARCH

Editors:

Corazon A. Ngelangel, M.D. Mario R. Festin, M.D. Benigno F. Agbayani, M.D. Juanito S. Javier, M.D.





P.G.H. HANDBOOK ON MEDICAL RESEARCH

Editors:

Corazon A. Ngelangel, M.D. Mario R. Festin, M.D. Benigno F. Agbayani, M.D. Juanito S. Javier, M.D.



FOREWORD

Much has been said about the need to encourage research activities in a university hospital like the Philippine General Hospital. PGH has taken a healthy view of medical research within its walls for it subscribes to the view that research is part and parcel of quality training and service. Towards this goal, the hospital has sought research grants for its staff and provided the fora for research findings dissemination.

Quantity does not directly translate to Quality. The hospital through the Office of the Research Coordinator under the Assistant Director for Health Operations and the PGH Research Committee has actively supported and encouraged the editors of this research handbook to come out with a useful tool for the clinician who wants to take his first steps in doing a research work. There are so many pitfalls which may undermine the validity of a research work. Hopefully, this handbook could lend a helping hand.

Often, a new researcher is daunted by the fact that for a research work to generate valid results it has to adhere to strict standards. The researcher has to be at least familiar with the concepts/rules/standards in research for him to gain insights from consultations with his supervisor/adviser or epidemiologist. Hopefully, the researcher will find this handbook a readily available guide in making research work a little less daunting.

Research is the way by which we could answer the questions which arise frequently during our medical or health related careers. Hopefully, this handbook will help us in our search for the answers.

ANTONIO M. MONTALBAN, M.D., M.H.A., M.P.H., M.H.P.Ed Director Philippine General Hospital

Preface

This Handbook is prepared to simplify the process of medical research for the knowledge and needs of the clinical clerks, medical interns, residents, post-residency fellows, medical and para-medical staff of the Philippine General Hospital and other training hospitals in the country. Much of the text of this Handbook is lifted from the publications of the pioneers of medical research.

To the PGH Residents, we dedicate this handbook.

Table of Contents

	rage No.
OVERVIEW OF RESEARCH PROCESS	1
A. FROM BASIC TO CLINICAL RESEARCH	1
B. FROM CLINICAL MEDICINE TO EPIDEMIOLOGY	5
C. WRITING THE RESEARCH PROPOSAL	
(AND THE SCIENTIFIC PAPER)	8
D. ORAL PRESENTATION OF RESEARCH PROPOSAL/	
SCIENTIFIC PAPER	14
THE RESEARCH IDEA	18
A. INTRODUCTION	18
B. CHOOSING A RESEARCH IDEA AND A RESEARCH PROJ	ECT 18
STUDY VARIABLES	24
A. INTRODUCTION	24
B. RESPONSE VARIABLES	26
C. CONFOUNDING VARIABLES	27
THE RESEARCH QUESTION	30
A. WHAT ARE THE DIFFERENT PERSPECTIVES	20
THAT A RESEARCH QUESTION MUST ADDRESS	30
B. HOW TO WRITE THE RESEARCH QUESTION	30
RESEARCH DESIGNS	35
A. EXPERIMENTAL STUDY	35
A.1. CONDUCT OF EXPERIMENTAL STUDY	35
A.2. BIAS IN EXPERIMENTAL RESEARCH	54
A.3. ETHICS AND RESEARCH ON HUMAN SUBJECTS:	
GUIDING PRINCIPLES	63
B. COHORT STUDIES	74
B.1. PROSPECTIVE COHORT STUDIES	74
B.2. RETROSPECTIVE COHORT STUDIES	78 80
B.3. NESTED CASE-CONTROL STUDIES B.4. DOUBLE COHORT STUDIES	80
AND EXTERNAL CONTROLS	83
B.5. STEPS IN PLANNING A COHORT STUDY	85
C. CASE-CONTROL STUDIES	90
D. SYNTHESIZING RESULTS OF REPEATED STUDIES	
(AND META-ANALYSIS)	97
E. CROSS-SECTIONAL STUDIES	107
F. PANEL STUDIES	131
G. ECOLOGICAL STUDIES	133

H. DESCRIPTIVE CLINICAL STUDIESl. CLINICAL ECONOMICS STUDIES	138 138
THE STUDY POPULATION	142
A. STUDY POPULATION	142
B. SAMPLING HUMAN POPULATION	145
DATA MEASUREMENT, MANAGEMENT, AND QUALITY CONTROL	157
A. GUIDE TO FUNDAMENTALS OF MEASUREMENT IN HEALTH	
AND HEALTH CARE RESEARCH/ EVALUATION	157
B. WHAT IS A QUESTIONNAIRE	168
C. DATA MANAGEMENT AND QUALITY CONTROL	195
SAMPLE SIZE ESTIMATION	214
A. SAMPLE SIZE ESTIMATION FOR CROSS-SECTIONAL STUDIES	214
B. SAMPLE SIZE ESTIMATION FOR EXPERIMENTAL STUDIES	218
C. SAMPLE SIZE ESTIMATION FOR OBSERVATIONAL STUDIES	220
BIOSTATISTICS	226
VARIABLES	226
DESCRIPTIVE STATISTICS	228
INFERENTIAL STATISTICS	238
INTRODUCTION TO RESEARCH MANAGEMENT AND ORGANIZATION	259
MANAGEMENT BY OBJECTIVES	260
FUNCTIONS OF MANAGEMENT	263
ORGANIZING	264
APPENDIX 1 - STUDY PROGRESS REPORT	304
LABORATORY RESEARCH SKILLS	308
LITERATURE SEARCH	308
INTRODUCTION TO THE USE OF MICROCOMPUTERS	
AND DOS COMPOUNDS	325
USING RALLOC PROGRAM TO GENERATE A RANDOMIZATION LIST	342
USING EPI-INFO VERSION 6.02	343
APPENDICES	
1. LIST OF FOUNDATIONS, ORGANIZATIONS AND	
GOVERNMENT INSTITUTIONS GIVING RESEARCH GRANT	357
2. REVIEW OF RESEARCH PROTOCOLOS	365
3. GUIDELINES FOR PGH RESEARCH GRANT	367
THE PGH ADMINISTRATION	369
IN DEX	371