# Research Methods for Medical Graduates

Chapter Abstracts

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**1 Basics of Medical Research**

Research in any field is an enterprise that carries its own risks and benefits. One may make heavy investment in terms of time, money and expertise yet the returns are not assured in this endeavor. This is particularly so for medical research where we deal with unpredictable human beings and vitals such as health and life are at stake. First time research is daunting anyway but it is more so in medicine. This chapter first describes what medical research is and what it is about in our context, so that the contents of this book are properly demarcated. This chapter gives an overview of medical research endeavors, including the pre-eminent role of empiricism, the dominance of uncertainties, broad steps, and the essential ingredients of good research. This would help in maintaining high standards in the research process so that the findings are believable and replicable. Details of all these aspects are provided in the subsequent chapters.

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**2 The Topic of Medical Research**

The first problem faced by a researcher, particularly at graduate level, is the selection of an appropriate topic for a thesis. This chapter lists the parameters on which the selection can be made after review of literature and after examining the available resources, and then describes steps that sharpen the topic by precise statement of the objectives and hypothesis.

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**3 Study Designs: An Overview**

All empirical studies are based on a set of evidence collected from different sources, and this process is expected to follow a design to optimise the resources and to achieve sufficient validity and reliability. This chapter gives an overview of various designs that are generally followed in medical studies: details are in subsequent chapters. The meaning of a design of a study is explained at the outset and the types of design such as descriptive and analytical are also explained. Essential features of further classification of analytical studies into interventional and observational are subsequently described. Next section discusses reliability and validity of a design to give believable results, and the last section gives a guideline of where to use which design.

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## 4 Clinical Trials

Medical experiments on human beings are called clinical trials. The objective of a clinical trial is to discover or verify the clinical or pharmacological effect of an intervention and to identify its adverse effects. The end-point could be safety and/or efficacy. The intervention must be potentially beneficial and not harmful. This could be a drug, a surgical procedure, a medical device, some behavioral change, a process of care, or any such intervention.

Regimen research environment is rapidly changing. Safety is increasingly getting precedence over efficacy. The current paradigm seems to be that a new regimen should be free of toxicity while also be efficacious.When carefully conducted, clinical trials are the fastest and the safest way as of today to evaluate efficacy and safety of a new regimen under controlled conditions. Since the subjects are humans in clinical trials, a large number of issues crop-up ranging from ethics to profound variations. A human experimentation cannot be conducted unless sufficient reasons for doing so are present. This chapter describes various types of clinical trials, their basics, and the conditions under which they provide valid results. The chapter ends with tips for choosing a right design of a trial depending on the resources.

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## 5 Observational Studies

Nature is a great experimenter. Many interventions or changes occur naturally that require no human intervention. Some people are naturally exposed to iodine deficiency in water and some women naturally have low haemoglobin (Hb) level. Study of such naturally occurring events can provide invaluable help in studying cause–effect relationship with conviction. Such a study can be based on records or on actual observations, or a combination of both. This is generally categorized as an observational study because it requires recording of observations only: sometimes also referred to as an epidemiological study. Whereas both beneficial and harmful ‘natural interventions’ can be studied by observational studies, such studies are particularly helpful in studying the effect of harmful processes and conditions because, for them, human intervention is ruled out.

There are three basic formats in which an observational study can be carried out – prospective, retrospective and cross-sectional. This chapter describes these formats and discusses their merits and demerits so that a judicious choice can be made depending on the problem at hand.

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## 6 Assessment of Medical Factors

Medical factors can be broadly classified into (i) etiological factors that give rise to the risk

factors, (ii) risk factors that promote or inhibit a health condition, (iii) diagnostic factors that help to identify the presence or absence of a disease, (iv) treatment modalities that aim to alleviate the suffering and bring the patient back to health, and (v) prognostic factors that determine the outcome (outcome can be complete relief, dissatisfaction, discomfort, disability, disease or death). In a research setup, all or a subset of these may require assessment.

A 'factor' in our terminology is a characteristic of the subjects, and 'indicator' is its measurement. Obesity is a factor and body-mass index (BMI), waist-hip ratio (WHR), and skin-fold thickness its indicators. Indicator converts a factor into its operational definition. This distinction is important for proper implementation of research.

This chapter first discusses the intricacies of assessment of medical factors such as univariate and multivariate assessments, and the assessment in the implementation and the results phase of the study. Next section is on the type of medical factors and the choice of indicators, and the last section provides the details of the assessment of mortality, various durations, and quality of life that require special handling.

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## 7 Methodology of Data Collection

All empirical research is based on data. These are not necessarily quantitative: they could be qualitative also. Signs and symptoms are qualities yet are 'measurements' in statistical sense. Qualitative data too convert to numerics when summarized for a group.

Where from to get the data for a medical research? In a clinical setup, they come from patients' interview and examination, and their laboratory and radiological investigations. These are called primary data and recorded in a questionnaire, schedule or proforma such as an Excel sheet. Secondary data are existing records of the previous patients and other subjects. These can also be used for meaningful research.

All measurements are easily understood statistically as variables since they do vary from person to person. Thus there are qualitative variables and there are quantitative variables. These could be on nominal, ordinal or metric scale. This distinction is important since the method of inference is different for different types of variables. Merits and demerits of various types of measurements will help to decide which ones to use for different kinds of assessment in a research. All these issues are discussed in this chapter.

Types of measurements such as different scales and qualitative–quantitative, discrete–continuous, and other types are discussed in the first section. Tools of data collection such as questionnaire, schedule, record, interview, and examination are in the second section. Quality of data such as reliability and validity is discussed in the third section, and assessment of validity of medical tools such as pilot study and pretesting, sensitivity–specificity and ROC curves are presented in the last section.

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## 8 Sampling and Sample Size

Medical decisions are almost invariably based on samples. Sample of blood, urine, sputum, stool, and biopsies are everyday occurrences. Sampling is the only feasible method in this situation since complete material of these biological substances for anybody cannot be studied.

The thrust in this chapter is on sample of individuals. Whether the research is descriptive or analytical, it is conducted on a sample of subjects. Sample is the statistical term for the group of subjects included in the study, and that almost invariably would be a fraction of the target population.

There are two dimensions of adequacy of a sample. First, it should represent the full spectrum of subjects in the target population. Various methods of sampling are adopted in different situations to meet this objective. These methods are discussed in the first section for descriptive studies and in the second section for analytical studies. Second, the sample size must be reasonably large to give reliable results, without being excessively large. Sample size is discussed in the last section. In between there is a discussion on non-sampling errors in contrast to sampling errors. Controlling non-sampling errors many times assumes more importance because these have potential to vitiate the results beyond redemption, whereas sampling errors can be handled by choosing the representative sample of adequate size.

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## 9 Research Protocol

Once through with the steps mentioned in the preceding chapters, a researcher is ready to develop a protocol for the research project. Protocol is the document that outlines the proposed research, gives its full rationale including the objectives and the hypotheses, and the complete methodology including the system for reaching to an unbiased and credible conclusion. This is the final step in planning a research and is the backbone that supports it in all steps of its execution. It serves as a reference for the members of research team whenever needed.

This chapter describes the structure and contents of a medical research protocol, and is divided into two sections. The first section is on the structure of the protocol such as title, collaborators and supervisors, executive summary, and logistics, and the second section is on the contents of the main body of the protocol such as background, review of the literature, objectives and hypothesis, target population, sampling and sample size, method of eliciting the information, data collection and analysis, and the system of reaching to a valid conclusion.

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## 10 Processing of Data

After a research protocol is prepared and approved by a competent authority comes the stage of actual collection of information from the subjects selected for this purpose on the lines proposed in the protocol. All precautions stated in the protocol must be taken to ensure data quality and

completeness. The data are generally entered into a spreadsheet, called the master chart. Some of the individual data are sometimes converted to a more useful quantity such as body mass index from height and weight. Some researches require calculation of scores for assessing severity of the disease. These are discussed at the outset in this chapter.

The next step is to use the entire dataset and prepare group summaries. The methods to obtain epidemiological summary indices such as rates and ratios, including relative risk and odds ratio, and for measures such as mean and standard deviation (SD) are presented. The last section is on tabular and graphical representation of data, including a brief on Gaussian and non-Gaussian distributions. A medical research many times requires that the quantitative measurements obtained for individual subjects be classified as normal or abnormal. This also is discussed at the end as it requires an understanding of the shape of the distribution of the values.

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**11 Data Analysis**

After the data are collected, entered, cleaned and collated, they are ready for the rigors of analysis. This includes procedures such as generating correct estimates of various parameters (e.g., incidence and prevalence), building up confidence intervals, testing statistical significance, and assessing the strength and type of relationship. Actual methods depend on the nature of data, the type of hypotheses to be examined, and the theoretical conjectures that form the foundation of the study.

Statistical analysis of data is done in several ways. For descriptive studies and for some analytical studies, the primary objective is to find the percentage of cases that have a particular outcome, or the average level of a medical measurement. This is called estimation. This estimate is accompanied by, what is called, the confidence interval that delineates the range of values beyond which a sample summary is unlikely to lie in repeated samples. Common methods for obtaining this are provided in this chapter. The other important activity under data analysis is the test of hypothesis whereby we find how likely the values obtained in our study can be from a presumed population. This requires the concept of *P*-value and power. These also are briefly discussed. The basic methods for testing significance (this term seems to be on way out) such as chi-square for qualitative data and Student's *t*-test for quantitative data are presented. The next discussion is on regression which is used to study the relationship between two or more characteristics. This includes both the ordinary least square where the dependent is a quantitative measurement and the logistic where the dependent is binary. This section also contains a brief on correlation coefficient. The methods for assessing the cause–effect relationship and for validation of results are presented later in this chapter and statistical fallacies that so commonly arise in medical research are discussed in the end.

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**12 Writing a Thesis or a Paper, and Oral Presentation**

After completing a research, it is time to let the world know what new has been achieved or could not be achieved. No research is complete unless it is read, discussed, and evaluated. The dissemination could be in a conference through PowerPoint or any other kind of presentation but most medical researches culminate into a written report that could take a form of a paper, a thesis, a dissertation, or a full-fledged project report. Successful researchers are skillful biomedical communicators too and they celebrate their research.

This chapter starts with the general principles of effective writing. The actual contents of a paper or a thesis in terms of what to write and how to write from the beginning to the end, including the IMRaD format, are presented in subsequent sections. The last section discusses oral or poster presentation in a conference. Reporting ethics, including plagiarism, are separately discussed in the last chapter.

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## 13 Reporting Guidelines

A large number of guidelines are available for reporting of various kinds of studies. There is one for clinical trials, called CONSORT, one for observational studies, called STROBE, and one for diagnostic accuracy studies, called STARD. In addition, for statistical reporting, there are SAMPL guidelines because many authors falter on statistical reporting and are unable to properly draft the thesis or paper despite doing a good work. We discuss all these guidelines in this chapter so that a researcher does not have to face inconvenient questions when the research is reported for publication in a reputed journal, or when a thesis is examined.

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## 14 Reporting Ethics and Peer Reviews

Ethics is conforming to the standards of conduct. In the context of medical research, it has several facets. Research ethics is in terms of sufficient reasons to start a new investigation and using an appropriate design including adequate sample size so that the efforts do not go waste and there is no unnecessary exposure to the subjects. This was discussed in Chapter 8 and concern for the welfare of the study subjects was expressed in Chapter 2. Now we discuss about reporting ethics in this chapter. Some of it too has already been discussed but some aspects of reporting ethics have still remained undiscussed. These include duplication and plagiarism, copyrights and permission, conflict of interest, and peer review. All these are the subject matter of this chapter.