Research Methods for Medical Graduates

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Basics of Medical Research

Research in any field is an enterprise that carries its own risks and benefits. One may make a heavy investment in terms of time, money, and expertise, yet the returns are not ensured 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 more so in medicine. Let us first understand 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.

1.1 What Is Medical Research?

Research is discovery of new facts, enunciation of new principles, or fresh interpretation of the known facts or principles. It is an attempt to reveal to the world something that was either never thought of, or was in the domain of the conjectures – at best being looked at with suspicion. It is a systematic investigation to develop or contribute to generalizable knowledge. Research is a step in the relentless search for truth – it is an organized and systematic approach to finding answers to the intriguing questions. The basic function of research is to answer the why and how of a phenomenon, but searching for answers to questions such as what, when, how much, is also part of research endeavors. All these questions have relevance to any discipline, but medicine seems to have special appetite for such enquiries. The purpose of medical research is to learn how systems in the human body work, why we get sick, and how to get back to health and stay fit. It is a logical process to better understand the etiology, pathophysiology, diagnosis, therapy, and prognosis of health and diseases. Research is the very foundation of improved medical care. It can also provide evidence for policies and decisions on health development at the community level.

Besides the core activities just mentioned, sometimes an established regimen is used in a new setting or on a new kind of subject to test its applicability to the new environment. This kind of confirmatory work is not hard-core research, but is accepted for graduate

thesis because the objective there is training in research methodology and new results if any are considered bonus. A large number of medical theses are based on such confirmatory research.

Much of human biology is still speculative, and its interaction with the environment is intricate. Thus, medical science has enormous potential for useful research. At the same time it has its own risks. This is illustrated by the reports questioning established modalities. Tamoxifen, a selective estrogen-modifying agent and a popular breast cancer therapy for women, was found to carry an increased risk of endometrial cancer. Menopausal women who took estrogen for a long time were found to be at higher risk of getting ovarian cancer. Arthroscopic surgery for osteoarthritis of the knee was found to be a useless procedure. A high level of cholesterol is no longer considered as much a risk as it used to be. These are not isolated examples. There are many instances when established medical practices were overturned. Some recent advances have indeed been bivalent – potentially useful as well as potentially harmful. As discussed later in this chapter, this happens because most of modern medical research is empirical. It depends on the interpretation of what we observe, and neither observations nor their interpretation are infallible.

1.1.1 Medical Research and Empiricism

Medicine is a delicate science because it is concerned with vitalities of life such as health, disease, and death. Thus, it brooks no error. Ironically, no theories are available that can make it infallible. There are no lemmas and no theorems, and it must depend on evidence provided by observations and experience. Medicine is largely an inductive science and has very little space, if any, for deductive methods. It is individualized yet participatory. If a treatment regimen has worked in Mr. Somebody and nine others of his clan, there is a high likelihood that it would also work in the 11th person of that type. The past experience and present evidence provide an insight into the future. Such empiricism (Box 1.1) is the backbone of medical science. In dealing with a new case, or an old case with a new set of conditions, past knowledge and experience are applied, and it is hoped that they will also work in the new setup. Often they do, but sometimes not. There is no assurance. Miscues cited earlier are examples of such errors.

Empiricism is often contrasted with rationalism. Rational knowledge comes from the exploration of concepts, deduction, intuition, and revelation. For these, sensual experience is not necessary. However, it can be argued that all these also initially come from primary experiences. Empiricists argue that the knowledge we cannot sense does not exist – it could be just a guess or a presumption.

Without entering further into this debate, let us emphasize that empiricism and rationalism are complementary to each other for expansion of knowledge. This is more so in the context of medical research because much of it is on cause and effect. Mental illumination stipulated in theories may provide a clue to what may be really going on, but this needs support from actual observations. Only then can you hope to convince colleagues to accept your theory. Thus, most medical research has no escape from evidence base and empirical process. This book is restricted to the data-based research that is tangible and based on experience rather than intuition.

1.1.2 Types of Medical Research and the Scope of This Book

Medical research encompasses a whole gamut of endeavors that ultimately help to improve the health of people. Although nomenclature exists, such as qualitative and quantitative research, and public health and clinical research, functionally it can be divided into

BOX 1.1 EMPIRICISM AND RATIONALISM

Two basic forms of expansion of knowledge are empiricism and rationalism. Empiricism is based on induction from sensual learning: it is based on observations and experience as these arise from our senses. These observations and experience form what we call the evidence, and require that we do our best with whatever we have. Empirical evidence could arise from experiments, trials, natural occurrences, experiences, records, and such other sources. It refers to the actual facts as currently present or occurred in the past. You can see that empiricism emphasizes the tentative and probabilistic nature of knowledge. In contrast, mathematics and some other physical sciences are based on theories and theorems that are considered rational. For example, we postulate that the numbers that do not divide by any other number except 1 and themselves are prime, and deduce that 3 and 7 are two prime numbers less than 8. Such arguments are deductive and not empirical. Deductive science holds that the mind can directly perceive truth without going through the process of sensual experience.

Empiricism has no conflict with rationalism. The observations must stand up to the reason, and should have an adequate rational explanation. After all, it is the logic of reasoning that separates humans from other species. Research results are more acceptable when the accompanying evidence is compelling, stands to reason, and inspires confidence. Without logic, research is reduced to storytelling.

BOX 1.2 EVIDENCE ANALYSIS AND SYNTHESIS

The kind of medical research discussed in this book depends mostly on the analysis of evidence from various sources. The objective of this analysis is to identify clear signals emanating from the varying and sometimes conflicting evidence from the study subjects. When these signals conform with one another, clear conclusions can be drawn.

There is another type of medical research that is very popular and very effective. This is collecting diverse evidence from various studies (not individual subjects) and synthesizing it to get a holistic picture after resolving any conflicts. Review articles and meta-analyses appearing in medical journals are of this type. The discussion section of a master's thesis, doctoral dissertation, or a research paper also tries to do such synthesis, although this is limited to integrating your findings with the results of others. Methods for research synthesis are not included in this text.

basic and applied types. **Basic research**, also sometimes termed "pure research," involves advancing the knowledge base without any specific focus on its application. The results of such research are utilized sometime in the future when that new knowledge is required. In medicine, basic research is generally done at the cellular level for studying various biological processes. Although this kind of research can provide a radical breakthrough, this book is not adequate for this kind of research. **Applied research**, on the other hand, is oriented to an existing problem. Applied medical research could be on the diagnostic and therapeutic modalities, agent–host–environment interactions, or health assessments, whether based on evidence analysis or synthesis (Box 1.2).

Primary and Secondary Research

Applied medical research can be classified into two major categories, although this is not a universally accepted classification. The first category can be called primary research and includes analytical studies such as case–control studies, laboratory experiments, and clinical trials. It also includes descriptive studies such as surveys, case series, and census. The second category is secondary research, which is quite common these days, and includes meta-analysis, decision analysis (risk analysis and decision theory), operations research (prioritization, optimization, simulation, etc.), evaluation of health systems (assessment of achievements and shortcomings), economic analysis (cost–benefit, cost-effectiveness, etc.), and qualitative research (focus group discussion). This text is confined to the methods used in primary research (Figure 1.1), but does not contain specialized methods required for pharmacokinetic and toxicological studies.

This book is designed to provide a holistic picture of the methodology of primary research that still forms the bulk of modern medical research. The text is for basic methods only and would be adequate for most research that is required to be collated as a master's thesis or doctoral dissertation, and for other such small-scale endeavors. Advanced methods would be different for, say, cancer research than for tuberculosis research and for a drug trial than for behavioral research. For such focused research, particularly if it is on a large scale, consult other relevant reference books and material.

The book describes all steps of primary medical research in simple language. We hope that this will help emerging scientists to learn the concepts and principles of designing and conducting such a research project with precision. It describes methods for formulating a research problem and setting objectives, for reviewing the existing literature and data, for identifying uncertainties, for designing the study to handle these uncertainties, for collection and collation of evidence, for measuring uncertainties, for assessing the antecedents and outcomes, for statistical analysis of data including significance and

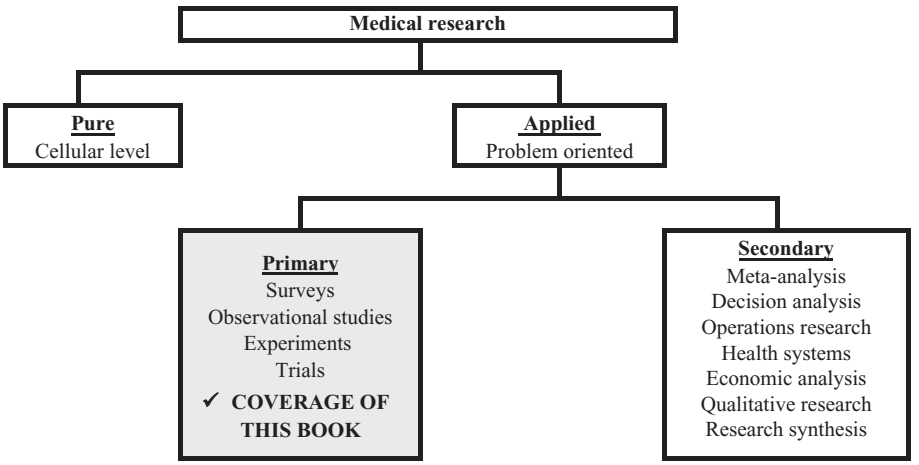

FIGURE 1.1
Types of medical research and coverage of this book.