Chapter 1
Introduction and overview

The health gains in the last century have been unprecedented. Advances made in health research account for a significant part of these health gains. New scientific frontiers, now opening up, promise to transform medical practice in ways never imagined before, and to contribute to further improvements in health. However, health research is not only about the development of new tools and advancing our understanding about health and disease. Health research is important to inform policy and decision-making in health systems.

Health research is not a luxury, to be conducted only by countries with the resources to spare. When India gained independence, the country faced the problem of how to allocate its scarce resources to areas of most need. Jawahar Lal Nehru, in this context, made the following statement: “Because we are a poor country, we cannot afford not to do research”. The participation and contribution of developing countries in scientific research has been well expressed by the Pakistani Nobel Laureate Abdul Salam, as follows: “Science and technology are a shared heritage of all mankind; East and West, South and North have all equally participated in their creation in the past, as, we hope, they will in the future—the joint endeavour in science becoming one of the unifying forces among the diverse peoples on the globe.” (Salam, 1989.)

Health research may be pursued as a career in a public or private research organization. Research may be done in pursuit of prestige or under the pressure of the threat of “publish or perish” when climbing the ladder of a successful academic career. A strong argument can, however, be made that all health professionals should do some research, or at least get enough knowledge about the research process, even if they wish to spend the rest of their lives dealing with patients or health administration. A scientific approach is essential for health professionals. As the practice of medicine is advancing rapidly, the need for critical evaluation of new developments becomes more urgent. The medical past is littered with examples of possible major advances eventually being shown to be of no value, or even to be harmful. Research helps to develop a scientific critical attitude. A clinician will find that the faculties developed by doing research are those most needed in clinical diagnosis.

Health policy-makers, particularly in developing countries, may not appreciate the contribution which research can make. There is still a divide between the universe of research and the universe of policy-making. The stereotype of the researcher in her or
his ivory tower still prevails. In fact, health managers and policy-makers may be doing research without knowing it. Research can be defined as the systematic collection, description, analysis and interpretation of data to answer a certain question or solve a problem. Health research can also be defined as the process for systematic collection, description, analysis and interpretation of data that can be used to improve the health of individuals or groups. The research process changes “information” into “knowledge”, through critical assessment and relating it to other existing human knowledge. As they go through this research exercise, health managers and policy-makers need to understand more about the process of research.

There is a need to demystify the scientific process. Scientific inquiry is basically a potentiation of common sense, which is probably one of the most equitably distributed human gifts. Einstein said, “The whole of science is nothing more than a refinement of everyday thinking.” In a sense, most of us may be conducting some research in our daily life. When we, for example, want to buy a car in a proper way, we collect information about models and dealers, analyse it, then try to reach a “scientific” conclusion on which car to buy. The use of complex instrumentation is not a necessary requirement for good research. Key attributes of good research are proper planning, accuracy in data collection and proper unbiased interpretation.

There is only one type of research: good research. Bad research does not deserve the name of research. Badly done research is not only a waste of time, money and effort. It can be considered unethical if it exposes research subjects to the inherent risks of experimentation with no reward to them, to others or to their communities. This book is about how to do health research, and how to do it well.

The research process begins with selecting a field and topic for research, then planning the research, writing up the plan as a research protocol, and, where appropriate, submitting it as a research proposal for funding. Implementation of the research project is followed by describing and analysing the research results. The research results then need to be carefully and objectively interpreted. Research is not complete until it is communicated to those who may benefit from it. This commonly involves, but is not limited to, writing and publishing a scientific paper, and/or making a scientific presentation. The research process not only involves doing the research, but also assessing and evaluating research done by others. Throughout the research process, and particularly where the research involves human subjects, rules of ethical conduct must be carefully observed. All these steps in the research process are dealt with in detail in the different chapters of the book.

Because of the importance of ethics in health research, the next chapter of the book outlines the concerns about ethics in health research, general ethical principles, responsibility for maintaining ethical standards, and the duties of ethics committees which review and approve research. After this introduction to ethics, ethical considerations are
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discussed in more detail in subsequent chapters dealing with different stages of the research process. In addition, Annexes 1 and 2 provide documentation on the topic: The World Medical Association Declaration of Helsinki, in its latest version; and International Ethical Guidelines for Biomedical Research Involving Human Subjects prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO).

The first decision a researcher needs to make is what research to do. This is dealt with in Chapter 3. There are different fields of health research, all of which can make a contribution to improvement of health, and all are needed. In these days of specialization and sub-specialization, the investigator may have already landed in one of the disciplines. But it is important that s/he should be aware of the other disciplines and what they can contribute. Collaboration between researchers from different disciplines is one of the most effective mechanisms in advancing health research. The distinction between basic and applied research is probably more a function of time. Basic research provides the pool of knowledge from which leads for applied research can be picked up. Also, the strong interest in quantitative research should not lead us to ignore the potential contribution of qualitative research. Qualitative research can provide insights that will not be apparent from quantitative methodologies.

The selection of a topic for research is influenced by what drives the research. Research is driven by curiosity, health needs, profit and/or opportunity. Scientists, on the one hand, are happy to pursue their own lines of interest, enjoy academic freedom and follow scientific curiosity. They can say, and they are right, that many significant discoveries in the field of health were made by serendipity, and not through targeted research. Policy-makers and funders of research, on the other hand, would like to see research targeted to respond to priority health needs. Private industry, now a major actor in health research, is driven by profit, and pursues lines of research that are likely to lead to the development of products that sell in large profitable markets. Governments in developed countries often encourage and support research for wealth creation, not just for health. The selection of topics for research may be driven by the opportunity for funding. A major concern in health research today is the 10/90 gap. Of the total funds spent worldwide each year on health research by both the private and public sectors, it has been estimated that only about 10% are devoted to the health problems of 90% of the world’s population. Opportunities for research may arise through participation in collaborative international research. For developing country researchers, this is a good opportunity but not without concerns. Concerns include distortion of country priorities in research, internal brain drain where the brains of researchers in the country are working for the problems of other countries, and ethical considerations that need to be addressed. Participation in pharmaceutical company research is another opportunity. Collaboration between academia and industry is to be encouraged, but there are concerns that need to be addressed, whether the collaborative research is at the discovery stage, during clinical
testing or after marketing of the product.

Ideas for topics for research come from different sources that need to be pursued by researchers. Familiarity with the research literature is important, not only for identifying where gaps for research are, but also during the planning, implementation and writing up of the research. Annex 3 provides notes on searching the literature, using different sources, in the new information age. As will be discussed in Chapter 3, whatever the topic of research selected may be, it should satisfy the criteria of being feasible, interesting, novel, ethical and relevant.

After deciding on what research to do, Chapter 4 deals with the planning of the research. Time spent on proper planning is never lost. There are different types of research design, whether for observational or experimental intervention studies. All types of research design have their place. The investigator has to select the type of research design that will give the most definitive answer to the research question, and at the same time would be feasible to conduct. In most cases, more than one design will be possible, but a trade off has to be made between the ideal and the possible. In this context, as in others, the best should not be made the enemy of the good. In planning the research, the research topic has to be narrowed down into a well defined research question. The more refined the question, the better will be the plan. Investigators should resist the temptation to broaden the scope of inquiry beyond what can realistically be answered by the research.

With a well defined and refined research question, a research hypothesis can be generated. In proper scientific methodology, we do not develop a research hypothesis in order to prove it; we develop a hypothesis in order to test it. Scientists doing research adopt a sceptical attitude. They start with the assumption that the research hypothesis is not true, using the term “null hypothesis”. If the results do not support the “null hypothesis”, then the research hypothesis is more likely to be true. Probability is another feature of the scientific methodology. There is usually no certainty about the validity of scientific results. It is only a high level of probability that is sought. This level depends on the magnitude of the finding, as well as the size of the study. Analytical statistical methods help in assessing the level of probability.

In planning the research, a crucial question is the type and size of sample to be studied. We cannot study all the population. We need to define a target population, as well as an accessible population. The term population in scientific methodology does not necessarily refer to people; it refers to the material for the research, be it people, animals or non-animates. There are different ways of sampling. The sample size appropriate to provide the answer to the research question has to be defined. A larger sample size than needed is an inappropriate use of research resources. A smaller sample size than needed is a waste of effort and money on a study that will not provide definitive answers. The types of measurements to be used have to be carefully identified in the planning stage of the research to ensure validity and reliability. The methodologies for qualitative research
need to be appreciated and applied, as appropriate, by researchers. A research topic may be better addressed by quantitative research, qualitative research, or both.

The planning phase is also the time to think carefully about ethical considerations. Different categories of health research have their ethical implications. There are important considerations in research designs involving experimentation on human subjects, in epidemiological, field and qualitative studies, and in research involving experimentation on animals.

Chapter 5 deals with writing the research protocol. After developing the plan for the research, it has to be written down as a protocol. This is particularly important if the study is done by a team of investigators, but is also important if there is only a single investigator. It helps to clarify the thinking about the plan, and is necessary for getting approval from ethics review committees. There is a traditional format for writing research protocols. It starts with a title and a summary. The project description should then include the rationale for the study, its objective, and methodology, including statistical methods used for sample size calculation and for data management and analysis. Ethical considerations should be spelt out, where appropriate, using an ethics checklist. Where relevant, gender issues should also be addressed. The protocol should include a small number of recent and relevant references to previous work on the topic.

Chapter 6 deals with the question of how to get funding for the research project. Investigators must make themselves familiar with potential sources of funding, their lines of interest and their procedures. A research proposal has to be prepared and submitted. It should include, in addition to the protocol, information to persuade the funding agency about the importance of the project, the relevance of the research to the priorities of the agency and the capacity of the investigators to undertake it. It should outline a timetable, and any problems anticipated. A budget should be submitted, properly itemized and justified. Information about the research institution, the curriculum vitae of the investigators, and any previous work on the topic will be needed to show the capability for carrying out the research.

In Chapter 7, we move to the question of how the project should be implemented with scientific rigour. The protocol may need to be pre-tested. Elements must be in place for monitoring the study during implementation, including record-keeping and handling of data, quality assurance and quality control, periodic tabulations and reports, checking of laboratory procedures, and checking the accuracy of data. In clinical trials, the principles of Good Clinical Practice (GCP) should be observed, and the trial may be subjected to auditing. Research on new pharmaceutical products should proceed in consecutive phases, as the safety and efficacy of the product is progressively established. Once the product is shown not to be safe or effective, the trial should be terminated, and not allowed to continue. In the implementation of any study, the protocol once approved should not be changed. Particularly in multi-centre studies, violations of the protocol
Ethical considerations are important in the implementation of the study, whether involving human subjects or experimentation on animals. The study should be monitored for adherence to ethical principles. In addition, scientific honesty in recording the results and fiscal honesty in research expenditure are basic ethical principles.

Chapter 8 deals with description and analysis of research results. Descriptive statistics are useful to summarize and present the data in a way that allows subsequent analysis. Tools of descriptive statistics include tabulation, calculations, graphs, and correlation. Tabulations include frequency distribution tables, and cross tabulations. Calculations estimate the central tendency in numerical data (the mean, median and mode), the variability (range, standard deviation and percentiles), as well as ratios and rates. Different ways are available to display the data visually in graphs. The frequency distribution curve is particularly important to show how the data are distributed, with implications for subsequent statistical analysis. A scatter diagram will show whether there is correlation between the variables, for which a correlation coefficient and a regression equation can then be calculated.

Inferential statistics try to answer the questions of whether we can infer with a good probability from the study findings, whether the findings from the sample of the study can be generalized beyond the population studied, and whether differences or associations found can be possibly explained by chance. Statistics are based on principles of common sense, which need to be understood, more than on mathematics. The investigator may not do the elaborate mathematics, but must fully grasp the underlying concepts behind the statistical method, and must make decisions about the questions that need to be answered by statistical analysis, and the degree of uncertainty that can be acceptable. The chapter includes a description of the concept of “standard error”, tests of statistical significance, the use of “confidence intervals”, the concept of “statistical power”, as well as a note on some common statistical methods.

Description and analysis of research results is much easier and less tricky than their interpretation. Chapter 9 deals with the many pitfalls, shortcomings, and misconceptions in the interpretation of results. It describes pitfalls in the interpretation of descriptive statistics, whether they deal with the mean, graphs or correlation. The term “statistical significance” should be understood only for what it stands for. It simply means that the finding or difference is unlikely to be due to chance. It does not necessarily mean that the finding is important. Bias, whether in selection or measurement, and confounding factors must be excluded before drawing any conclusions. Association of two variables should not be taken to mean a causal relationship. Scientific criteria for making the case for causation must be fulfilled. Care should be taken in trying to extrapolate from results using other end points, as a surrogate for the outcome in question.

Special studies need careful interpretation to avoid any misconceptions about the
results. When studies of risk factors are interpreted, we need to understand the concepts of basic risk, relative risk, confidence intervals, attributable risk, as well as the need to balance risks and benefits. In reporting studies of diagnostic tests, the investigators must report on sensitivity, specificity, predictive value, and efficiency. A trade-off may need to be made between sensitivity and specificity. Studies reporting the results of interventions need careful interpretation, including cost considerations. The concept of “the number needed to treat” in order to achieve the advantage of the intervention is a useful tool that is not always considered.

Research is not complete before its results are communicated. This is dealt with in Chapter 10. Most of the communication done is to fellow scientists. But the beneficiaries of health research are much broader than the scientific community, and they are entitled to the information. Communication to scientists is commonly in the form of publication in peer reviewed scientific journals. The availability of expensive scientific journals is limited, particularly in developing countries. Thanks to the internet, new initiatives are underway to allow researchers to communicate their research findings to a much wider audience, with the ultimate hope that scientific information will be made freely available to all who want it. The age of paperless papers is now speeding up the process of submission, review and publication, making scientific information more up to date (apart from saving many trees in the process). Presentation of the results of scientific research in scientific meetings is another approach for exchanging scientific information, with advantages and disadvantages relative to publication. Research results should also be communicated periodically to the funding agency. Release of funding is generally contingent on receipt of satisfactory progress and financial reports.

For health research to influence the way health professionals practice, it should be communicated in a user-friendly but accurate way. The research findings may need to be synthesized in systematic reviews. Practice guidelines, developed after rigorous review of various studies, can be very useful. For many studies, it is more important to communicate the results to policy-makers. Submission of a report is generally not enough. Guidelines on how to make a presentation to policy-makers are given. If the research was based on a community study, the community involved has a right not only to know, but also to discuss the research results.

The millennium of cybermedicine promises a revolution in the availability of health information, not only for health professionals, but also for patients and for the public at large. Scientists should also learn how to communicate with the public, who are often paying the bill for the research. A constructive dialogue between scientists and the public is becoming increasingly important. A favourable scientific public environment is essential for science to thrive. Recently, there have been increasing signs of public mistrust in science. This has to be overcome through better communication between scientists and the public. The public needs to be adequately informed to make appropriate decisions.
Because of the importance of the scientific paper as a way of scientific communication, detailed guidelines are provided in Chapter 11 on how to write it. Guidelines deal with the selection of the title, writing the abstract, and following the classical article structure of introduction, methods, results (including the use of tables and illustrations) and discussion. Annex 4 provides detailed instruction on how to cite the references, from different sources, in the paper. The steps in writing the scientific paper should start before the research is implemented. The process should continue during the research, and is to be completed after the research. After writing, the manuscript should be revised for scientific content, using a checklist. After revision of the manuscript for scientific content, it should be carefully revised for style, revising paragraphs, sentences, and words. Revision for style is particularly important for those writing in a language that is not their first language, but should not be ignored by those writing in their first language. Writing a case report, and writing secondary scientific papers (narrative review, systematic review and meta-analysis) requires different formats. There are also special considerations for writing a paper on qualitative research, and for writing a dissertation or thesis.

After writing the scientific paper, comes the task of getting it published. Chapter 12 gives advice on how to get a paper published, based on defining its message, matching the topic with the interest of the journal, checking scientific validity of the results, and ensuring quality of the manuscript. The International Committee of Medical Journal Editors has agreed on uniform requirements for manuscripts to be submitted for publication. A summary of the technical requirements is given, as well as guidance on how to send the manuscript and how to deal with reviewers’ comments. The International Committee of Medical Journal Editors has also recommended guidelines on authorship, emphasizing that intellectual input in the study is a requisite for qualifying for authorship. Issues of potentially patentable findings need to be addressed, where appropriate, preferably by a special office in the institution, before submitting the findings for publication to be available in the public domain. Ethical considerations apply to research communication, and include questions of credit, conflict of interest, redundant or duplicate publication, protection of patient’s rights to privacy, release of information to public media before the publication, and the serious accusation of scientific fraud.

Chapter 13 provides detailed guidelines on how to make a presentation to a scientific meeting, by good planning, good preparation (including preparation of text and visual aids, as well as rehearsal), and presenting in style (getting ready, speaking well, managing the visual aids, keeping to the time and answering questions).

Researchers need to acquire the ability to assess and evaluate science, and to develop a critical attitude. Science is not to be admired; science is to be questioned. Chapter 14 provides guidance on how to read and review a scientific paper, how to evaluate the scientific evidence, how to assess scientific reviews and meta-analyses,
how to apply evidence to practice, and how to assess the appropriateness of health technologies. Evaluation of the investment in research should take into consideration, not only the impact on the advancement of science and the impact on wealth creation, but also, importantly, the impact on health promotion. The scientific quality of research, as assessed by scientists, does not necessarily go hand in hand with the impact on health promotion.

It should also be recognized that health is wealth, and that health research is important for overall development. Annex 5 provides the Bangkok Declaration on Health Research for Development.

Not all issues about health research can be covered in detail in this short guide. The book ends with a list of sources for each chapter for those who want to get more information on the particular subject.

References and additional sources of information


