Research Methodology for Health Professionals

Including Proposal, Thesis and Article Writing

RC Goyal

Foreword
Vedprakash Mishra

JAYPEE

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Dedicated to

My Parents

and

My Esteemed Teacher, Guide and Mentor

Late Dr Sushila Nayar

(Former Union Health Minister, Government of India)
and
Founder, Mahatma Gandhi Institute of
Medical Sciences, Sevagram, Wardha)

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Foreword

The First Education Commission headed by legendary Dr Sarvapalli Radhakrishnan very categorically brought out that the objectives of higher education including medical education to be: (a) teaching and training, (b) Research and (c) extension activities, all cumulatively resulting in sustainable development conducive to the needs of the society and catering to actualization of the objectives of the 'Welfare State' enshrined in the Constitution of India.

As such, it is self-evident that 'Research' turns out to be one of the key objectives of the medical education as a whole. Realistically speaking, the contribution of medical institutions in the domain of research as evaluated from the publications in the indexed/peer reviewed journals, as against the contribution from the developed world, is insignificant.

This is a matter of concern that despite the fact that with enormous growth in number of medical colleges over a period of time, it has not resulted in a parallel contribution in the domain of research. Of the various reasons which limit the same, one of the important attributes is the lack of 'structured teaching' in the domain of research methodology at the various levels of Medical Education. This also entails non-availability of handy reading material to the students and the teachers, so as to update themselves in the context of research methodology. Operationally speaking, there is a palpable dearth on this count.

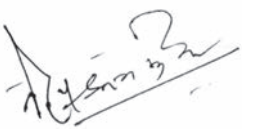
It is in this backdrop that the book titled *Research Methodology for Health Professionals* penned by learned Dr RC Goyal, Professor and Director, Department of Community Medicine at Jawaharlal Nehru Medical College, Sawangi (Meghe), Wardha under Datta Meghe Institute of Medical Sciences (Deemed University), Nagpur, is a desired addition,

which by virtue of its meaningful inclusion is bound to go a long way in clearing to the void, which is in operation as of now.

The author has very diligently and articulately attempted to cover all the aspects of research including special topics for thesis writing, publication of article, formulation of proposal for funding and a critical evaluation of a scientific article as well. The initiative undertaken by the author is not only significant but is also praiseworthy in terms of the free flowing and co-ordinated syntaxing, which has been articulated by him. A special mention is required for the incorporation of the ethical issues in health research in a very lucid manner.

I am sure that this notable attempt by the author is bound to successfully result in fulfilling the legitimate needs and expectations of the researchers in a subtle way in attaining the set objectives by them.

I record my gratitude and appreciation to the author for his herculean effort in dispensing this gigantic task.



Vedprakash Mishra
Pro Chancellor, DMIMS (DU)
Former Vice Chancellor, DMIMS (DU)
Former Chairman, Academic Cell
Medical Council of India, India

Preface

The main sources of inspiration to bring out this book have been my interaction with students and faculty from the disciplines of medicine, dentistry, nursing and public health, and health professionals engaged in public health services at various institutions in India and abroad. I have also experienced the gap of comprehensiveness in finding the basic resource material related to research methodology at one place while conducting the workshops/seminars on research methodology.

The book has been written in simple English without heavy technical jargons with the aim to provide readers with a book that will deliver key practical information in an efficient and effective manner and explain each topic in such a way that even someone without any health background can follow the subject and understand practical issues.

It covers a variety of topics, such as Identification and Prioritization of Research Problems; Literature Search: Formulation of Research Questions, Objectives and Hypotheses, Study Design Options, Research on Diagnostic Tests, Determination of Sample Size and Power, Data Collection Methods and Techniques, Analysis of Quantitative and Qualitative Data, Ethical Issues, *etc.* with special inclusion of Writing a Research Proposal, Steps in Thesis Writing and Writing an Article for Publication, which will help readers in designing and conducting research studies.

Students will find in it a clear and concise overview of the important topics in which they must become proficient to practice skillfully, efficiently, and ethically in their chosen fields. Wherever feasible, visual cues highlighting key points have been provided alongside systematic, step-by-step guidelines. All postgraduate students will find this book very helpful in writing thesis and publishing research work of international standards.

It is ideal for readers with basic knowledge of research as well as for those with intermediate knowledge who need a quick refresher regarding various aspects of the research methodology. For readers with an advanced knowledge of research-design and methodology, this book can be used as a concise summary of basic research techniques and principles, or as an adjunct to a more advanced research methodology textbook.

This book is the result of extensive literature search, discussions with experts and fellow colleagues.

I hope that it will fulfill the felt needs of not only postgraduate students and teaching faculty in Health and Allied Sciences but also public health professionals. However, the valued suggestions from the readers are welcome so as to enable to incorporate the same in future editions to make the book more reader compatible.

— RC Goyal

Acknowledgments

I am privileged to have experienced the vision and practice in community health of late Dr Sushila Nayar, the legend of Community Medicine in India. I am grateful to Dr Vedprakash Mishra, Pro Chancellor, DMIMS, (DU), Former Vice Chancellor, DMIMS (DU), and Former Chairman, Academic Cell, Medical Council of India, Nagpur, who wrote the Foreword for this book.

I am thankful to my colleagues at various institutions who inspired me to pen down this book specially Dr BS Garg, Dean, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha; Dr Deokinandan, Director, National Institute of Health and Family Welfare, New Delhi and Dr SP Zodpey, Director, Public Health Education, Public Health Foundation of India, New Delhi.

I am specially thankful to Dr Shushil Agrekar for helping me in writing the chapter on Analysis of Quantitative Data. My thanks are due to Mr Abhishek Goyal who has read initial draft and provided his valuable suggestions. My special thanks to Dr OP Lathwal, Professor, Department of Family and Community Medicine, Faculty of Medicine, Garyounis University, Benghazi, Libya, for meticulously reading the final draft of this book.

I am indebted to my postgraduate students (MD & MPH) specially at Datta Meghe Institute of Medical Sciences University, Nagpur, who insisted on writing this book for the benefit of all researchers.

Finally, it was not possible to come up with book without the moral support and constant encouragement of my wife, Baby; daughter, Abhilasha; and son, Abhishek.

Contents

Chapter 1

INTRODUCTION TO HEALTH RESEARCH

What Is Research? Why Do Research? How To Do Research?

"We are all working together to an end, some with knowledge and design and others without knowing what they do"

– Marcus Aurelius

"The faculties developed by doing Research are those most needed in diagnosis"

– FH Adler

"Discovery consists of seeing what everybody has seen, and thinking what nobody has thought"

– Albert Szent Gyorgyi

INTRODUCTION

Research is an integral part of any academic and non-academic learning, innovations, and developmental activities. Research is being done in all academic and developmental institutions but does not meet the expected level of scientific methodology. Moreover, the researches carried out are not need based, and lack in quality. The research should be directed towards major public health problems.

Medical and health curricula at undergraduate level do not deal with applied basic scientific aspect of research methodology. There is need to create awareness and impart training in research to undergraduate, post-graduate and health sciences students and professionals so as to motivate them for need-based quality research in desired areas.

Let's look at the following questions:

1. What is research, discovery, and invention?
2. Why to do research? (Objectives)
3. What are the types of research?
4. How to do research?
5. What is a good research?

An inherent feature of human being is to add something new, to expand the knowledge by his forethought, serendipity or scientific and systematic acquisition of the facts and figures.

Discovery can be done by various ways. It may be due to unexpected observations in ongoing work or by chance. The role of the chance in research had been discussed by many authors.

James Austin (1978) in "Chase, Chance and Creativity" analyzed the varieties of chance.

Some of them are as follows:

1. Chance I: It is purely blind luck which can provide an opportunity to any person motivated to do research (unexpected reporting of a patient with rare disease).
2. Chance II: People who firmly believe in an idea/thought and conduct some action to prove it. (Discovery of Salvarsan for treatment of syphilis by Paul Ehrlich and cause for Burkitt's by Epstein and Barr).
3. Chance III: Here chance is only a clue and favors a prepared mind. (Sir Alexander Fleming discovered penicillin but Florey and Chain revealed its practical importance).
4. Chance IV: This type of discovery is usually due to combination of persistence and lateral thinking.

Invention: It is a unique idea and thinking to create materialistic items (drugs, gadgets, machines) which never existed previously.

DEFINITIONS OF RESEARCH

Research has been defined by many authors in different ways. Some of the definitions are as follows:

1. **Dictionary meaning** of research is "A careful investigation or enquiry especially through searching for new facts in any branch of knowledge."
2. **Organization for Economic Co-operation and Development (OECD) has defined the research and development as:**
   "It is a creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of humanity, culture and society, and the use of this stock of knowledge to devise new applications".
3. **FN Kerlinger** defined scientific research as "A systematic, controlled, empirical and critical investigation of hypothetical propositions about the presumed relations among the natural phenomenon."
4. **Theobald Smith** defines research as "A fundamental state of mind involving continual re-examination of doctrines and axioms upon which current thoughts and actions are based. It is, therefore, critical of existing practice."
5. **Redman and Mory** defined research as "systematized efforts to gain new knowledge."
6. **Clifford Woody** states that research should comprise of "defining and redefining problems, formulating hypothesis or suggesting solutions, collecting, organizing and evaluating data, making deductions and research conclusions and carefully testing the conclusion."

   In brief, "Research is the systematic collection, analysis and interpretation of data to answer a certain question or solve a problem."

It is characterized by originality; should have investigation as a primary objective and the potential to produce results that are sufficiently general to increase the humanity's stock of knowledge i.e. theoretical and/or practical.

CHARACTERISTICS OF RESEARCH

- It demands clear statement of the problem.
- It establishes the relationship between cause and effect.
- It helps in generation of principles and theories of prediction.
- It is based on observational, experimental and empirical evidence.
- It requires deep knowledge of the subject.
- It should be objective and logical.
- It should be carefully recorded and reported.
- It is characterized by patience and unhurried activity.
- Researcher should avoid personal feeling and preferences.

WHY TO DO RESEARCH? (OBJECTIVES)

There are many motives for conducting the research. Some do it as service to mankind, to satisfy intellectual curiosity, to use it as a ladder for successful career, see as pursuit of prestige, and need for publication due to 'publish or perish' pressure but most of them do research to:

- Add to scientific knowledge.
- Improve the medical and health practice.
- Benefit the patients and community.
- Study new phenomenon for establishing the facts.
- Help in planning the medical and health programs.
- Support managerial aspects of health development.
- Improve diagnostic techniques by newer, cheaper and accurate tests.
- Help in effective patient care management.

Research inculcates scientific inductive thinking and promotes the development of logical habits of thinking and organization.

WHAT ARE THE TYPES OF RESEARCH?

The types of research depend on purpose, approaches, nature and area of research.

Weatherall (1981) categorized research into: I. Basic/fundamental/pure research; II. Applied research and development, and III. Clinical trials and monitoring.

I. **Basic/Fundamental/Pure Research:** Basic research has been fundamental to most of the major medical advances ever made. It differs from other types of research in being totally unpredictable, and often there is no initial connection between the research and its medical application.

Scientists have pursued their own ideas for a long time before medical application. Basic research requires a major commitment from the researchers, who must have a good training in research methods. This requires large funding since it is unlikely to be completed in a short period of time. Unfortunately, very few researchers are available in this field which may be due to complexity, uncertainties of a career, less remuneration as compared to private practice, and increasing rigidity of undergraduate and postgraduate medical education.

II. **Applied Research and Development:** Main objective of this type of research is to improve the medical and health practice and benefit the patients and community. There is a need to have various linkages between universities and medical colleges, centers developing new procedures and patients. The nucleus of the research team should not only be qualified in medicine and health but also scientifically trained personnel. Applied research areas could be operational, health service, health manpower, policy and economic analysis, decision linked, etc.

III. **Clinical Trials and Monitoring:** This type of research is done before new developments have reached the clinical level, commercial institutions usually become involved as they might have major commitment to having this product used, even before its value has been unequivocally demonstrated and funds are being provided by them to researcher.

OECD Classification

- Pure basic research
- Strategic basic research
- Applied research, and
- Experimental development.

Other Categories of Research

1. Historical research.
2. Correlation research.
3. Causal comparative research.
4. Content analysis research.
5. Quantitative (inferential and experimental) research.
6. Qualitative research [opinion, attitudes by Participatory Rapid Appraisal (PRA) Techniques].
7. Biomedical research.
8. Behavioral research.
9. Health service research.
10. Survey research.
11. Conceptual research: Related to some abstract idea/theory.
12. One time research/longitudinal.

13. Field setting research.
14. Laboratory research.
15. Simulation research.
16. Translational research.

HOW TO DO RESEARCH?

Some of the essential steps in the development of a health system research are given in the following Table 1.1.

TABLE 1.1 Steps in the development of a health systems research

Questions to be asked	*Step/s to be taken*	*Elements of each step*
What are the problems and why to study/research?	Selection, analysis and statement of research question	Problem identification Prioritizing problem Analysis justification
What information is available?	Literature review	Literature and other information available
Why do we want to carry out research? What do we hope to achieve?	Formulation of research objectives	General and specific objectives hypothesis formation
What additional data we need to meet our research objectives? How are we going to collect this information?	Research methodology	Variable/s, type of study, data collection techniques, sampling, plan for data collection, data processing and analysis, ethical considerations, pre-test/ pilot study
Who will do what and when	Work plan	Human resource, time.
What resources do we need and what do we have?	Budget allocation	Material support, equipment and money
How will the project be administered? How will utilization of result be ensured?	Plan for project administration and utilization of result	Administration, monitoring and identification of potential users
How will the study findings be presented?	Project summary	Briefing sessions and lobbying

NB: Development of a research process is a cyclical process. The double headed arrows indicate that the process is never linear.

MAJOR AREAS OF HEALTH SYSTEMS RESEARCH

- Policy (the role of health in the national development plan, priority health needs, equity in distribution of resources, respect of culture and humanitarian values)
- The environment (improvement of living conditions, provision of safe water and basic sanitation, disposal of waste, preservation of natural resources)

- Administration and management (agreement with policy, effectiveness and efficiency in supporting direct services, development of adequate monitoring and evaluation procedures)
- The community (development of institutions and practice promoting health, community participation)
- Individual and families (assessment of physical, mental and socio-economic needs, potential for addressing specific health problems)
- Direct services (appropriateness, effectiveness, efficiency, accessibility, acceptability).

All types of researches are multidisciplinary in nature and the researcher requires multidisciplinary skills in the following areas to understand and conduct research:

- Policy (political science, policy analysis, technology assessment, behavioral sciences, economics, epidemiology).
- The environment (epidemiology, environmental sciences, biology).
- Management (strategic planning, management studies, health economics).
- The community (behavioral sciences, epidemiology, social work, community development).
- Individual and families (epidemiology, behavioral sciences, social work).
- Direct services (clinical epidemiology, quality assurance, biomedical sciences, behavioral sciences, operational research and epidemiology).

What is a Good Research? (Criteria)

A good scientific research should satisfy the following criteria:

- The statement of problem or the purpose should be clear.
- It should have a plan (procedure to be described in detail).
- The research design should be in detail and clear.
- The researcher should be honest, transparent and committed and should report frank observations without distortion.
- The data should be collected as required and be analyzed appropriately.
- It should be systematic, logical, empirical and replicable.

SOME OF THE PROBLEMS ENCOUNTERED BY THE RESEARCHERS

- Lack of scientific training in research methodology.
- Insufficient interaction between the research institutions and other organizations/institutions.
- Duplication of research studies.
- There is no code of conduct for researchers.
- Inadequate secretarial assistance.
- Mismanagement otf library functioning and publications.
- Lack of infrastructure.

Chapter 2

IDENTIFICATION AND PRIORITIZATION OF RESEARCH PROBLEMS/AREAS

The first step and one of the most important requirements of the research process is to delineate the research study area clearly and state the problem concisely. This is also one of the most difficult tasks of the researcher, especially for the beginners.

Research on any topic should, ultimately, be directed to bring changes towards health of the population; it means addressing one or more determinants of health.

Whether a problem situation requires research depends on three conditions:

1. There should be a perceived difference or discrepancy between what exists and the ideal or planned situation;
2. The reason(s) for this difference should be unclear (so that it makes sense to develop research questions); and
3. There should be more than one possible answer to a question or more than one solution to the problem.

The sources for generating appropriate research question/problems are numerous. These may be personal experiences, literature sources, existing theories, and previous researches. Following factors may be considered for deciding the research problem/question as described by acronym **"FINER"**.

F = Feasible: The research area should be feasible in terms of technical, financial, and administrative capabilities. It should be able to answer the following questions: Can adequate number of subjects be available?
Is there adequate expertise to do the work?
Is the research affordable? Can it be managed well?
Will the administrative support be available?

I = Interesting: The selected problem area should be of interest to health policy managers and researcher.

N = Novel: It should be able to fill the gap in existing knowledge and /or able to solve the problem in an area. The aim is not trying to re-invent the wheel.

E = Ethical: In applied research, most of the time human beings are involved and hence it is necessary to fully observe ethical policies

and procedures. Never do a research which has a deleterious effect on human beings.

R = Relevant: Selected problem should be relevant and have priority for that geographical area, region and country.

The research questions can be placed in three broad categories, depending on the type of information sought:

1. **Description of the health situation required for planning interventions:** A researcher needs to know, e.g. the magnitude and distribution of health needs in a population as well as of services; the risk factors for certain problems and people's awareness; the utilization patterns and cost-effectiveness of available and potential interventions, in order to formulate adequate policies and adapt or plan interventions.
2. **Information required to evaluate ongoing interventions: e.g. with respect to:** coverage of priority health needs, coverage of target group(s), acceptability and quality, cost-effectiveness and impact on health, to assess progress and the need for adjustment on a routine basis.
3. **Information required to define problem in any of the fields mentioned below and to analyze possible causes in order to find solutions:** These causes may include lack or inequitable distribution of resources, vague policies, and any environmental factors affecting needs, interventions and resources (Fig. 2.1).

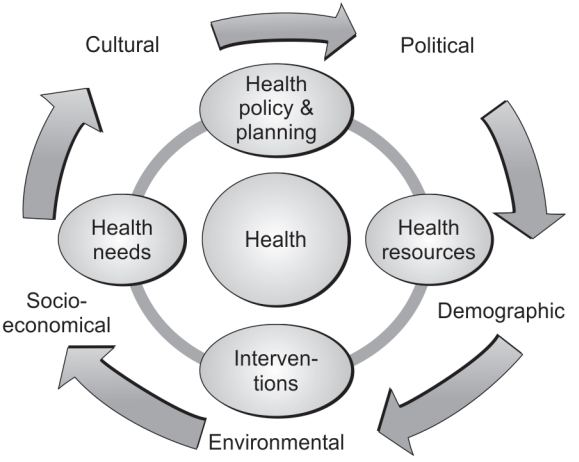


Fig. 2.1: Factors influencing health

CRITERIA FOR PRIORITIZING TOPICS FOR RESEARCH

Second step in conducting the research is to prioritize the topics for final research. Each topic that is proposed for research has to be judged according to certain guidelines or criteria. There may be several ideas to

choose before deciding on a research topic, each proposed topic must be compared with all other options. The following guidelines or criteria may help in this process:

Criteria for Selecting a Research Topic (Table 2.1)

1. Relevance
2. Avoidance of duplication
3. Urgency of data needed
4. Feasibility of study (timeliness)
5. Applicability of results
6. Ethical acceptability
7. Political acceptability of study

1. **Relevance:** It depends on the following: What is the magnitude of the problem? Who is affected? How severe is the problem? Who perceives the problem? Discuss the problem with all concerned persons involved and decide topic.
2. **Avoidance of Duplication:** Researcher should make sure that the suggested topic/question has not been investigated before, either within the proposed study area or in another area with similar conditions. If the topic has been researched, the results should be reviewed and analyzed to explore whether major questions that deserve further investigation remain unanswered. If not, another topic should be chosen.
3. **Urgency of Data Needed:** Is there any timeline for the research to be done? Are results needed for making a decision or developing interventions at hospital, health center, community, etc.? Depending on the urgency, researcher should decide the priority of the topics to be researched.
4. **Feasibility of Study:** It is important to find out the feasibility in terms of the following:
   a. Affordability, i.e., whether resources (manpower, time, equipment and money) are available or not.
   b. Geographical, i.e, difficult to reach or remote areas
   c. Administrative and peer support, availability of study subjects, etc.
5. **Applicability of Results:** Is it likely that the recommendations from the study will be applied? This will depend not only on the management capability within the team but also on the availability of resources for implementing the recommendations. Likewise, the opinion of the potential clients and of responsible staff will influence the implementation of recommendations.
6. **Ethical Acceptability:** Following ethical considerations should be kept in mind:
   - Informed consent must be obtained from the research subjects.
   - Cultural sensitivity.

- Will the condition of the subjects be taken into account? e.g. if individuals are identified during the study that requires treatment, will this treatment be given? What if such treatment interferes with the study results?
- Will the results be shared with those who are being studied? Will the results be helpful in improving the lives or health of those studied?

7. **Political Acceptability of the Study:** A research topic that has interest and support of the local/national authorities may increase the chances that the results of the study will be implemented.

Various methods are available to prioritize the research topic; however, rating scale and nominal group technique are discussed below.

Rating Scale: The criteria mentioned above can be measured by the following rating scales and topic with highest ranking should be selected for the research.

Relevance

1. = Not relevant
2. = Relevant
3. = Very relevant

Avoidance of Duplication

1. = Sufficient information already available
2. = Some information available but major issues not covered
3. = No sound information available on which to base problem-solving

Urgency

1. = Information not urgently needed
2. = Information could be used right away but a delay of some months would be acceptable
3. = Data very urgently needed for decision-making

Feasibility

1. = Study not feasible, considering available resources
2. = Study feasible, considering available resources
3. = Study very feasible, considering available resources

Applicability

1. = No chance of recommendations being implemented
2. = Some chance of recommendations being implemented
3. = Good chance of recommendations being implemented

Ethical Acceptability

1. = Major ethical problems
2. = Minor ethical problems
3. = No ethical problems

Political Acceptability

1. = Topic not acceptable to high level policy makers
2. = Topic more or less acceptable
3. = Topic fully acceptable

TABLE 2.1 Criteria for selection of research topic

*Proposed Topic**	*Relevance*	*Avoidance of duplication*	*Urgency*	*Political acceptability*	*Feasibility*	*Applicability*	*Ethical acceptability*	*Total Points*
1. Should we start Community health insurance scheme?								
2. Should we establish adolescent clinic ?								
3.								
4.								

Examples: Rating scale: 1=low, 2=medium, 3=high
*The topic with highest ranking should be selected for the research.

NOMINAL GROUP TECHNIQUE (NGT)

In order to select research topics, Nominal Group Technique (NGT) can also be adopted. It is a group discussion technique. The sequence of the group discussion is usually as follows:

- Individual expression, followed by 'voting', followed by discussion, and another round of 'voting' followed by discussion, etc.

The steps of the NGT process are summarized below:

1. Individual listing of ideas on paper.
2. Display of lists produced, followed by discussion.
3. Voting and ranking.
4. Summarizing the results.
5. Discussing the results.
6. Second vote and re-ranking.

Tips for selecting research question/topic:

1. Don't panic — keep things in perspective
2. Be organized — maximize research efforts
3. Choose a subject area first then a topic
4. Make sure the topic is interesting
5. Choose a solvable and manageable research problem
6. The research problem must be worthy of time spent.

7. Make research topic original, has not been done before? If no, select topic.
8. Sharpen the research skills
9. While reading—the following questions should be asked.
    - What is the research question in the study?
    - Did the researcher focus on the wrong group/subjects?
    - Did the research leave some group/something out?
    - Is the methodology faulty?
    - Were the findings faulty?
    - Can the author's recommendation be pursued for future research?
    - What are the limitations of the study?

Chapter 3

LITERATURE SEARCH

How to Find Out Available Information on the Research Problem/Area Under Study?

"Six hours in the library may save the researcher six months in the laboratory"

It is important to review already available information when preparing a research proposal because:

1. It prevents the duplication of the work that has already been done.
2. It helps to find out what others have learned and reported on the problem we want to study. This may assist in refining the statement of the problem.
3. It helps in becoming more familiar with the various research approaches that might be used in the study.
4. It should provide convincing arguments to justify the need for conducting a research project.

SOURCES OF INFORMATION

Whether an investigator/researcher is starting a short project or a research degree, there will be a need to carry out the retrospective search for discovering information. Discovering information on a new topic may involve use of both printed and electronic information published in formats such as journal articles, reports, books and documents on the Internet. Very often the most relevant information may be scattered, requiring a number of different approaches to identify it. Some of the sources are as under:

- Textbooks, monographs, modules, etc.
- Research surveys, reports and regulatory and policy documents produced by Government and Non-government agencies
- Review articles, original articles in journals or annual yearbooks
- Guidelines for best practice, clinical protocols, professional standards and reviews.

Always remember that books are approximately 2–3 years out of date when published, whereas review articles published in journals contain more current material. If there is a book, a chapter or a review article on the subject written by a renowned author, it may be used as a starting point.

Review articles are the best starting point, it is a written structured account of the subject with a comprehensive reference list. They are usually commissioned by the editor and will therefore be written by an authority in the field. Reviews may be published in review journals e.g. the Annual Reviews, Recent Advances, Current Opinion and Seminars series; or in primary journals, many of which now carry one or more reviews in an issue.

The initial objective of a search may be to compile an appropriate list of sources that will be used to review the subject of interest. With thousands of medical journals published, searching each one is impossible and you need to search the indexes and/or bibliographic databases. Other reference sources like the publications of governments, official agencies, and international bodies e.g. WHO, European Community, Center for Disease Control, etc. are valuable, and often unique sources of statistical data.

Using the Library

Familiarity with how the library works and what services it can provide will help to discover information more easily. This includes using the library's catalogue and the library's other resources to identify what is relevant to the present study.

The first thing to decide is the level of information needed and to determine if the subject is well covered in books and reports. Begin with the catalogue for books and reports on the topic. Use keyword searches, trying repeated searches with alternative search words. In the library, scan the contents of all likely books for pointers to other sources.

Searching Bibliographical Databases

Bibliographical databases enable the researcher to scan a large amount of information quickly. The databases are available both in hard copy and digital form—online and on CD ROM. There is a choice of indexing services and databases covering the biomedical area. Searching for quality health literature through the bibliographical database is a skill that requires time and energy. With planning and a systematic approach one can find the relevant information for conducting the study.

Formulate the Question and Plan Search

First of all, formulate the question, write down the question and underline the key concepts of interest. Brainstorm these key topics by drawing up a list of synonyms (e.g. if the topic deals with infants, note: neonate, baby, newborn), acronyms, and related popular and scientific terms. Use nursing, medical, or health related dictionaries to confirm exact meanings and note any related terms. Consider any limits that could be applied to

the search (e.g. articles published in the last five years, the age of patient group, and the language of the article).

The Bibliographical Database

Print Version

- **Index Medicus** (National Library of Medicine (NLM),US): Abridged Index Medicus was published by the National Library of Medicine from 1970–1997. It covered approximately 2,900 journals in biomedical sciences, clinical medicine, psychology and dentistry. This used to be produced monthly and cumulated at the end of each year. Apart from the subject index, it also used to have the author index, journal index, and reviews used to be separate from primary articles. Although NLM no longer produces Abridged Index Medicus as a separate publication, the value of the titles as a core list of "selected titles of biomedical journal literature of immediate interest to the practicing physician" is still recognized, and the titles continue to be searchable as a subset of the MEDLINE database.
- **Excerpta Medica (EM):** Excerpta Medica, which brought out 32 sections each year, covering range of subject areas in medicine and life sciences includes biochemistry, physiology, anatomy, microbiology as well as most clinical areas. Abstracts used to be available for all articles. Excerpta Medica is similar to Index Medicus in that both are information retrieval services concentrating on biomedical and especially clinical literature. Of course, the major difference between the two is that EM is also an abstracting service while the printed Index Medicus is an indexing service. Indexing services provide the article's "address"—a citation giving journal and article title, volume, issue, year of publication, pages. Abstracting services offer a brief summary of the article's content in addition to the citation. Abstracts save researchers time lost in tracking down articles that aren't as relevant as the titles alone may suggest.

The Electronic Versions

- **Medline:** Medline, the electronic equivalent of the printed Index Medicus, is a bibliographic database produced by the US National Library of Medicine (NLM). It is the most widely used database for information retrieval in biomedicine and health.

  Medline provides access to over 11 million references to research papers from over 4,600 international journals. It is updated weekly via Ovid and is available from 1966 onwards. It has extensive subject coverage with an emphasis on clinical medicine and biomedical research. It also covers dentistry, nursing, chemistry, pharmacology, biological and physical sciences, microbiology, nutrition, health care

delivery, psychiatry and psychology, environmental health, social science and education. PubMed provides the online interface for Medline. You can access PubMed with the web address www.ncbi.nlm.nih.gov/PubMed or by simply entering www.pubmed.gov. Important tips on how to browse PubMed is being given with this chapter in form of an Appendix/Box.

- **EMBASE:** EMBASE, the electronic equivalent of the printed Excerpta Medica, is a bibliographic database produced by Elsevier Science in the Netherlands. It is a major literature resource in the field of biomedicine and drug research.

  Embase provides references from over 4,000 international journals and is often described as the European counterpart to Medline, with more extensive coverage of the European literature. Over 1,700 journal titles are unique to EMBASE**.** It is updated monthly via Ovid and is available from 1980 onwards. It provides comprehensive coverage of pharmacy and pharmacology, toxicology, clinical and experimental medicine, biological sciences, biotechnology and biomedical engineering, health policy and management, public, occupational and environmental health, psychiatry and forensic science. Comprehensive inclusion of drug-related information makes EMBASE particularly valuable and should be the database of choice when carrying out drug-related searches. The EMBASE database can be accessed online on the web address www.embase.com. One needs to subscribe to EMBASE database, which reduces its access.
- **The Cochrane Library:** The Cochrane Library is the premier resource for evidence-based information on the effectiveness of health-care interventions. The Cochrane Collaboration, the NHS Centre for Reviews and Dissemination and related organizations, compile it.

  It includes the Cochrane Database of Systematic Reviews: (full text of completed reviews plus protocols for reviews in preparation) and the Database of Abstracts of Reviews of Effectiveness (abstracts of other systematic reviews). It is made up of seven databases:
  - Cochrane Database of Systematic Reviews includes full text systematic reviews on the effectiveness of health care and protocols for reviews currently being prepared.
  - The Database of Abstracts of Reviews of Effectiveness provides information on quality assessed systematic reviews published in the medical literature.
  - The Controlled Trials Register is a list of references to controlled trials in health care.
  - The Cochrane Database of Methodology Reviews includes the full text of systematic reviews of methodological studies.
  - NHS Economic Evaluation Database provides abstracts on the economic evaluations of health care interventions.

– Health Technology Assessment Database (HTA) contains abstracts on developments and use of health technology.
– The Cochrane Methodology Database provides references to the methods of systematic reviews.

The Cochrane Library is accessible via its own unique web based interface. It is a partially paid website; and requires a username and password.

NLM's MEDLARS Databases

- **AIDS DRUGS:** It deals with the descriptive information about agents being tested in AIDS related clinical trials.
- **AIDSLINE:** It is a bibliographic citations to literature published on AIDS since 1980.
- **AIDSTRIALS:** Detailed information on AIDS-related clinical trials is available.
- **AVLINE:** It covers bibliographic citations covering ethics and related public policy issues in health care and biomedical research.
- **CANCER LIT:** Bibliography record of cancer related documents including articles in journals monographs, serials, and abstract of papers published at meetings, reports and dissertations.
- **CCRIS:** It is related to carcinogenicity, tumor promotion and mutagenicity test results.
- **CHEMID:** It is a dictionary of compounds of regulatory and biomedical interest.
- **CHEMLINE:** Interactive chemical dictionary files are available on this site.
- **CLINICAL ALERT:** It releases significant findings of National Institutes of Health, SA funded clinical trials where such release can affect morbidity and mortality. This is full text data describing the clinical application, which includes charts and tables.
- **DART:** It contains references on biological, chemical and physical agents that may cause birth defects.
- **DBIR:** A multi-component databank information on a wide range of resources related to biotechnology.
- **DENTALPROJ:** It contains database of ongoing dental research projects.
- **DIRLINE:** It is a directory of information resources including organizations, research, resources, project database and electronic bulleting boards concerned with health and biomedicine.
- **DOCLINE:** It deals with the NLM's online documents requesting and referral network.
- **EMICBACK:** Database containing citations to publications concerning chemical, biological and physical agents that have been tested for genotoxic activity.

- **ETICBACK:** A bibliography database that contains citations to literature on agents that may cause birth defects.
- **GENE-TOX:** It is a database of chemicals tested for mutagenicity.

Health Planning and Administration

It provides references to literature on health planning, organization, financing, management, manpower, diseases of chronological periods and geographic area.

- **Histline:** It deals with citations on history of medicine and related sciences, professionals, individuals, drug and diseases of chronological periods and geographic areas.
- **HStar:** It is a database of Health Services Research bibliography citations
- **HSDB:** It contains toxicology information related to environment, emergency situations and regulatory issues.
- **IRIS:** It is a database of potentially toxic chemicals.
- **Medline:** It contains over 8 million references from articles published in over 3,700 biomedical journals since 1966. The citations of pre 1966 cumulative Index Medicus are also available.
- **PDQ:** It is a physician's data query system designed to assist physicians in the treatment of cancer patients.
- **Popline:** It deals with citations to world wide literature on population and family planning including research in human fertility, contraceptive methods, community based medicine services, programs, etc.
- **Rtecs:** Contains toxicity data for approximately 95,400 substances.
- **Serline:** It is a bibliographic record of biomedical serials cataloged for the NLM collection.

Sequences Databases

Information on Gene, DNA, protein subset and nucleotide sequences database plus eukaryotic prompter and transcription database of National Center of Biotechnology are available.

- **Spaceline:** The bibliographic information on space life science research compiled by NASA in collaboration with NLM is available.
- **Toxlit:** It contains bibliography information on toxicological, pharmacological, biochemical and physiological effects of drugs and other chemicals.
- **Toxline:** It is a collection of bibliographic information on toxicity studies including carcinogenicity and environmental pollution.
- **Toxnet:** It is a computerized system of toxicology oriented databanks.
- **TRI:** This is a series of non-bibliographic database of annual releases of toxic chemicals to the environment and amount transferred to waste sites.

- **Trifacts:** It contains factual information on health, ecological effects, safety and handling of most of the chemicals listed in TRI.

United Nations Databases

Several of the UN entities working in the Public Health Nutrition (PHN) sector provide information via their websites. The following is a list of UN sites, which may be of interest:

- **Unicef (http://www.unicef.org):** This site includes a database of indicators from the most recent edition of The Progress of Nations. Statistics are shown by country and users can download the database. Following the basic tables more detailed information is shown on immunization rates, malnutrition, water and sanitation.
- **Unfpa (http://www.unfpa.org):** The State of the World Population, 1997 is accessible for downloading from this site, however, the extensive set of tables and figures are in Acrobat pdf format and require a lot of time even for fast computers.
- **UNAIDS (http://www.unaids.org):** This site contains no data tables or figures. A fact sheet section contains textual information like an article on Children and AIDS in Thailand. Some potentially useful quantitative facts can be found by region under the HIV/AIDS Figures and Trends and HIV Epidemiology.
- **UN Deptartment of Humanitarian Affairs (http://www.reliefweb.int docs/ descript.html):** Access is provided in a Lotus format to the Financial Tracking Database which uses a 14-point system for tracking Humanitarian Assistance from Donors globally by country and year.
- **UNDP (http://www.undp.org):** This site is mentioned for what it does NOT contain. UNDP's Human Development Report is not yet available via Internet.
- **FAO (http://www.fao.org):** Occasionally, economic and agricultural information is useful to Public Health & Nutrition (PHN) Officers. At the FAO site, there is a database called FAOSTAT which provides on-line, time series data on Production, Trade, Food Balance Sheets, Food Aid Shipments, Fertilizer and Pesticides, Land Use and Irrigation, Forest Products, Fishery Products, Population and Agricultural Machinery.
- **World Health Organization (http://www.who.org):** WHO provides a great deal of information via Internet, including a set of very user-friendly PHN database called WHOSIS (WHO Statistical Information System). The database on Global Indicators, Health for All is organized by region and country and includes sources, definitions of indicators, trends and reference years. One cannot make direct comparisons of these indicators between countries. WHO also maintains a database on mortality that includes rates and causes of death, but information from this database must be obtained by making queries to WHO.

Other Web Resources

Apart from the bibliographic databases available online, lots of other resources are available on the Internet, which is increasing daily at lightning speed. In December 1993, an e-mail message sent to a newsgroup included a list of all the websites that were available on the Internet; the list detailed just 623 sites. Nine years later, the number of websites is estimated to exceed 8 million, while the number of pages on the World Wide Web is well in excess of 2 billion. Various surveys indicate that well over 1,00,000 websites are exclusively dedicated to issues related to health

To be able to exploit this wealth of resources all health professionals need to become highly skilled in information retrieval. Although on one level the Internet is incredibly easy to search, it is very difficult to restrict to search to relevant materials you actually want. Therefore, the art required is to limit your search to few most relevant pages.

Search Engines

To search the Internet for information, we require a search engine. There are hundreds of search engines available, e.g. Google, AltaVista, Lycos, Northern Light, etc. Out of the above Google has rapidly become one of the most respected search engines. Important tips on how to use Google are being given with this chapter in the form of an Appendix/ Box. Remember, the search you do at Google gives you search results from the entire World Wide Web, while search at PubMed will give you search result from only the bibliographic database maintained at National Library of Medicine.

Web Directory

Another approach to finding medical information is to browse, or search, a range of Internet subject directories. There are many ambitious projects,

which attempt to arrange the resources of the Internet in the fashion of a library where like resources are co-located. For general medical and health information, two of the best web directories are the Yahoo! Health pages and the Health pages on the Open Directory. You can visit these sites by the web address www.yahoo.com/Health and www.dmoz.org/Health.

Help for PubMed Searching

You can reach the PubMed site with the address www.pubmed.gov. PubMed searching is easy, just enter search terms in the query box, and press the Enter key or click Go. If more than one term is entered in the query box, PubMed automatically combines significant terms together using automatic term mapping. The terms are searched in various fields of the citation. You can modify your current search by adding or eliminating terms in the query box or by clicking details. The Features bar directly beneath the query box provides access to additional search options: Limits, Preview/Index, History, Clipboard and Details.

Automatic Term Mapping

Unqualified terms that are entered in the query box are matched (in this order) against a MeSH (Medical Subject Headings) Translation Table, a Journals Translation Table, a Phrase List, and an Author Index.

MeSH Translation Table contains MeSH Terms, terms derived from the Unified Medical Language System (UMLS) that have equivalent synonyms or lexical variants in English. If a match is found in this translation table, the term will be searched as MeSH and as a Text Word. For example, if you enter vitamin h in the query box, PubMed will translate this search to: ("Biotin"[MeSH Terms] OR vitamin H [Text Word]).

Journals Translation Table contains the full journal title, the MEDLINE abbreviation, and the ISSN number. These map to the journal abbreviation, which is used to search journals in PubMed. For example, if you enter the journal title, New England Journal of Medicine in the PubMed query box, PubMed will translate this search to: "N Engl J Med"[Journal].

If no match is found in the MeSH or Journals Translation tables, PubMed consults a Phrase List. Phrases on this list are generated from MeSH, the UMLS, and Supplementary Concept Substance Names, e.g., cold compresses.

If the phrase is not found in the above tables or list, and is a word with one or two letters after it, PubMed then checks the Author index.

Searching for Author

You can also force the computer to search by an author's name. For this, enter the name in the format of last name plus initials (no punctuation), e.g., garg bs, gangane n. To search for an author in the author field when

only the last name is available qualify the author with the author search field tag [au], e.g., goel rc [au].

Using Boolean and Syntax

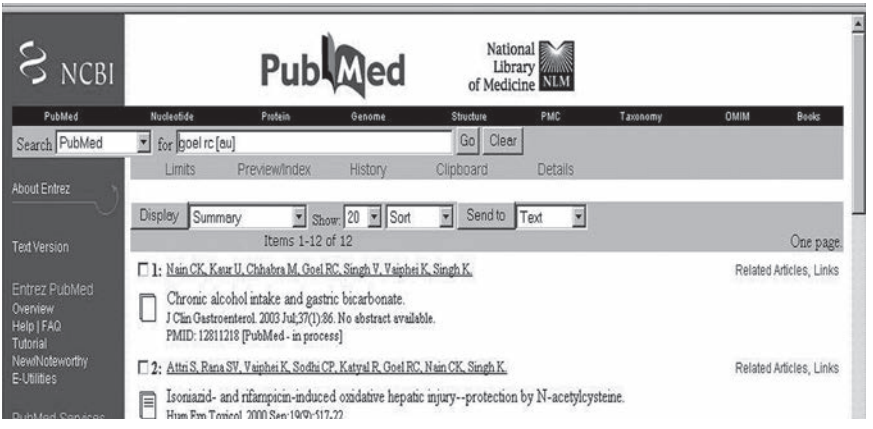
1. Boolean operators, AND, OR, NOT must be entered in upper case, e.g., vitamin C OR zinc.
2. PubMed processes all Boolean connectors in a left-to-right sequence. You can change the order that PubMed processes a search statement by enclosing individual concepts in parentheses.
3. If PubMed finds a phrase within a search strategy string that uses unqualified terms, it will automatically search the terms as a phrase. For example, if you enter air bladder fistula in the PubMed query box, PubMed will search "air bladder fistula" as a phrase. If you do not want this automatic phrase parsing, enter air AND bladder AND fistula.

Examples of Boolean Search Statements

- Find citations on DNA that were authored by Dr Crick in 1993. dna [mh] AND crick [au] AND 1993 [dp]
- Find articles that deal with the effects of heat or humidity on multiple sclerosis, where these words appear in all fields in the citation. (heat OR humidity) AND multiple sclerosis
- Find English language review articles that discuss the treatment of asthma in preschool children. asthma/therapy [mh] AND review [pt] AND child, preschool [mh]AND english [la]
- Find citations about arthritis excluding the Publication Type Letter. arthritis NOT letter [pt]

Search Field Qualification

Terms can be qualified using PubMed's Search Field tags. Rules while adding search field qualifications are:



1. Search tag should be added after the term
2. Search field tags must be enclosed in square brackets, e.g., aromatherapy [mh].

Dates and Date Ranging: PubMed uses three types of date fields:

Date of Publication [DP]: Entrez Date [EDAT]: The date the citation first entered PubMed.

MeSH Date [MHDA]: The date the citation was indexed with MeSH terms.

Dates or date ranges must be entered using the format YYYY/MM/DD; e.g., 1997/10/06 [edat] or 1998/03/15 [dp]. The month and day are optional, e.g., 1997 [edat] or 1997/03 [dp] can be used.

Date ranging is also available from the fill-in-the-blank selection on the Limits screen.

Subsets

PubMed's subsets provide an easy way to limit retrieval to particular citations. There are four types of PubMed subsets: Subject, Citation Status, Journal/Citation, and PubMed Central. PubMed's Limits screen has a Subsets pull-down menu from which many of these subsets can be selected.

Subject Subset

Citations to articles on the specialized topics, the following subject subsets are available: AIDS, Bioethics, Complementary Medicine, History of Medicine, Space Life Sciences, Systematic Reviews, and Toxicology. Example: asthma AND cam [sb]

Limits

Click Limits from the features bar to limit your search to specific age group, gender, or human or animal studies. Limits also allow you to restrict to articles published in a specific language, and to specific types of articles such as review articles. You can limit by either Entrez or Publication Date. Lastly, you may limit your retrieval to a specific subset of citations within PubMed, such as AIDS-related citations or nursing journals.

Preview/Index

Preview/Index works like advanced search option. It allows you to—

- Preview the number of search results before displaying the citations
- Refine search strategies by adding one or more terms one at a time
- Add terms to a strategy from specific search fields, and
- View and select terms from the Index to develop search strategies.

To search for terms from specific search fields use the Add Term(s) to Query text box. Select a search field from the All Fields pull-down menu and enter a term in the text box. Click AND, OR, or NOT to add the term to the query box with the appropriate search field tag, or click Preview to see the number of results.

History

PubMed holds all your search strategies and results in History. You can see your search History by clicking on History from the Features bar. History lists and numbers your searches in the order in which they were run.

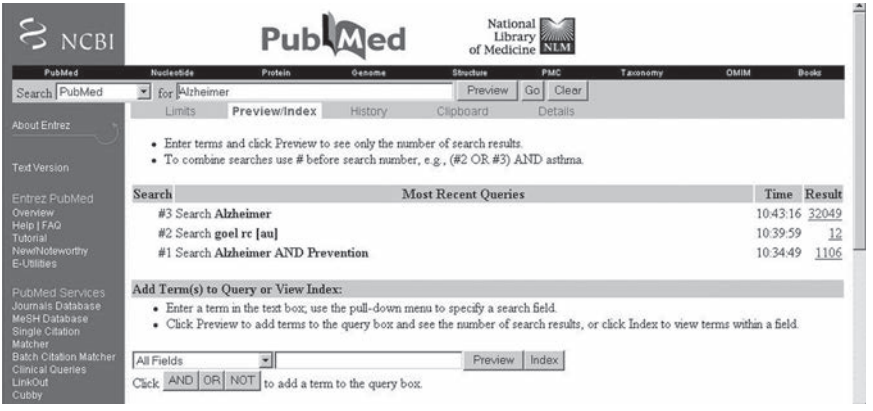
One can combine searches or add additional terms to an existing search by using the pound sign (#) before the search number, e.g., #2 AND #6, or #3 AND (drug therapy OR diet therapy).

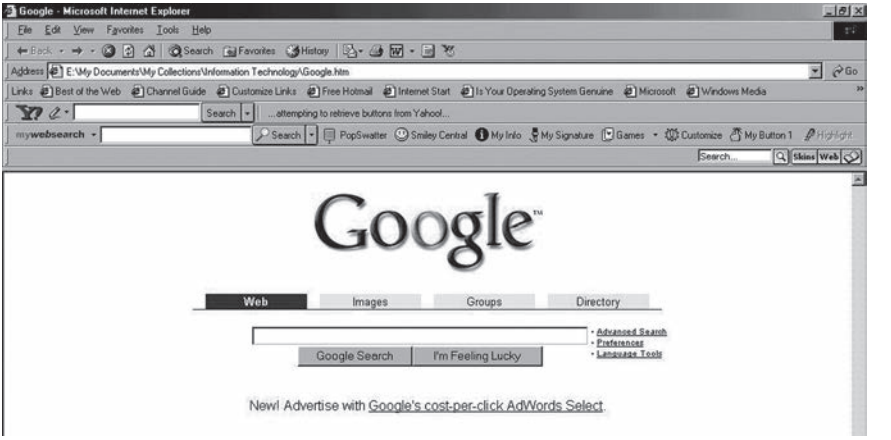
Clipboard

The Clipboard gives you a place to collect selected citations from one search or several searches. After you add citations to the Clipboard you may then want to use the print, save, or order buttons. The maximum number of items that can be placed in the Clipboard is 500. To place an item in the Clipboard, click on the check box to the left of the citation and then click Clip Add.

Details

Details lets you view your search strategy as it was translated using PubMed's automatic term mapping, search rules and syntax. Also, from Details, you can save a search query or edit the search query and resubmit it.





Display

PubMed displays your search results in batches—the default is 20 citations per page. The show pull-down menu allows you to increase the number of citations displayed on a single page up to a maximum of 500 words.

Help for Google Searching

You can reach the Google site with the address www.google.com. To enter a query into Google, just type few descriptive words and hit the 'enter' key (or click on the Google Search button) for a list of relevant web pages. Since Google only returns web pages that contain all the words in your query, if you want to refine or narrow your search, add more words to the search terms already entered.

Automatic "and" Queries

By default, Google only returns pages that include all of your search terms. There is no need to include "and" between terms. Automatic Exclusion of Common Words: Google ignores common words and characters such as "where" and "how", as well as certain single digits and single letters. If a common word is essential to getting the results you want, you can include it by putting a "+" sign in front of it. (Be sure to include a space before the "+" sign.). Another method for doing this is conducting a phrase search, which simply means putting quotation marks around two or more words.

Capitalization: Google Searches are Not Case Sensitive

Word Variations (Stemming): To provide the most accurate results, Google does not use "stemming" or support "wildcard" searches. In other words, Google searches for exactly the words that you enter in the search box.

Search By Category

The Google Web Directory (located at directory.google.com) is a good place to start if you're not exactly sure which search keywords to use.

Advanced Search Option

You can increase the accuracy of your searches by adding operators that fine-tune your keywords. Most of the options listed on this page can be entered directly into the Google search box or selected from Google's Advanced Search page.

With the advanced options, you can do phrase searching, exclude searches containing a particular work, specify language, restrict your results to the past three, six, or twelve months. Apart from this you can also specify where your search terms occur on the page, specify the file types or specify searches only from a specific website or exclude that site completely from your search.

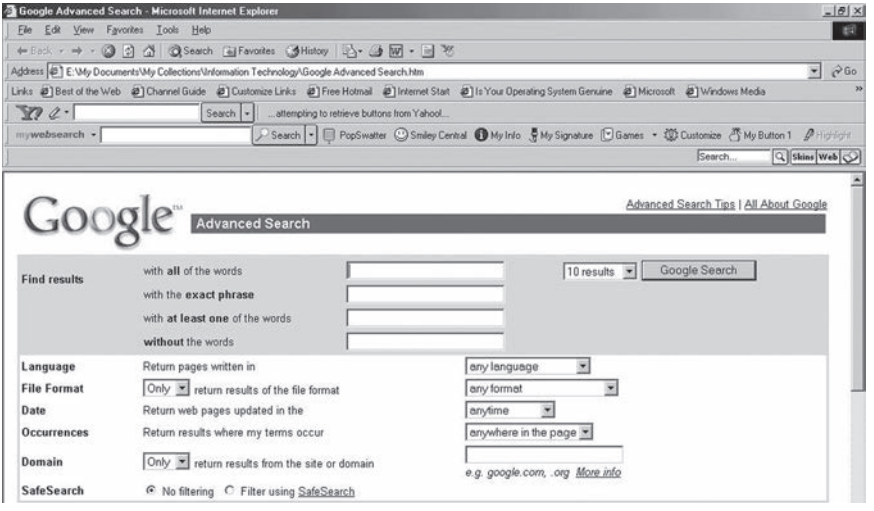
Choosing Keywords: It is important to choose your keywords wisely. Keep these tips in mind:

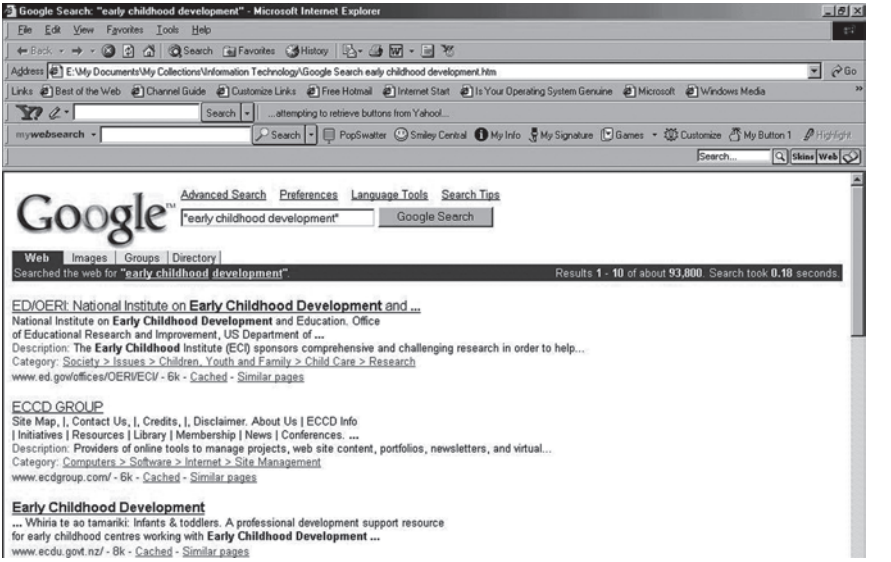
1. Try the obvious first.
2. Use words likely to appear on a site with the information you want.
3. Make keywords as specific as possible.

For example, if you want to search about programs, which work for creating conducive environments for proper psychosocial development of children, you can better search it with the entry program "early childhood development".

Reproductive Health Library (RHL)

The Reproductive Health Library (RHL) is supported by WHO. The current RHL 6 supersedes the previous issues. It has 10 new Cochrane Reviews,





their original commentaries, practical aspects and implementation aids. These sections and how to access them are described in detail below.

Editorials section includes editorials relating to evidence-based health care, reproductive health problems of developing countries, current controversies in the field and new innovative approaches.

Research and research synthesis methodology section includes articles that address methodological issues. In this issue we have an article on advantages of large simple randomized controlled trials and a whole section on conduct and analysis of randomized controlled trials published in the Lancet earlier in 2002.

Beneficial and harmful care replaces the effectiveness summaries for decision-making heading, and classifies and summarizes the findings from the Cochrane Reviews into six categories: beneficial forms of care; forms of care likely to be beneficial; forms of care with a trade-off; forms of care of unknown effectiveness; ineffective forms of care, and forms of care likely to be harmful. In preparing these summaries, account is taken of both the reviews and the corresponding commentaries. This section is most useful for busy clinicians or policy makers who are interested in knowing which interventions work and those that do not. All statements are updated and linked to the Cochrane reviews, commentaries and practical aspect documents.

Systematic reviews and commentaries (previously titled Reproductive Health Database) contains Cochrane Reviews, expert commentaries on the reviews, practical recommendations on the management of specific reproductive health problems and implementation aids. The Cochrane Reviews included in RHL cover topics considered to be of high priority for

reproductive health care in developing countries. In this issue there are 10 new Cochrane reviews with accompanying commentaries and practical aspects documents. Also 14 Cochrane Reviews were updated during 2002. Four reviews that have not been updated despite the availability of new data have been excluded. These reviews will be included again when they are updated.

The commentaries on the reviews present opinions on the reviews of individuals with knowledge of conditions in developing country settings. The aim of these commentaries is to provide a developing-country perspective on the findings of the Cochrane Reviews, which in most cases have been derived from studies done in developed countries. Note that the opinions expressed in the commentaries may not apply universally to all developing countries. They should be seen as the opinion of the author(s) about the validity of the review findings in his/her (their) country or region.

The sections on practical aspects of management of specific problems provide recommendations on the practical application of the findings in the reviews. Like the commentaries, not all recommendations may be valid for all developing-country settings. The editors welcome comments and criticisms of readers on the commentaries as well as on the practical aspects of management of reproductive health problems.

RHL implementation aids are tools to facilitate the implementation of effective, beneficial practices. It has videos describing the application of external cephalic version and discussing the benefits of companionship during labor, a detailed description of how to implement the new WHO Antenatal Care Model and how to administer magnesium sulphate to women with eclampsia. Links to useful Internet sites, and a list of agencies that fund reproductive health research and nongovernmental organizations active in the field of reproductive health complete the contents of RHL.

CONCLUSION

Initially, it may be worth asking for help from a librarian or an experienced researcher. An hour or two spent learning how to search efficiently and effectively will save you many hours in the future. If this is not possible, on-line tutorials are available from the Internet.

If you are ready to go for it alone remember to:

- Know at least some basics about your topic and plan your search strategy carefully.
- Break the searching into task size pieces and record what you do.
- Know how to use the databases and use the tools and limiters.
- Search in more than one place and evaluate the information that you find.

Do not be frightened by searching literature databases. The difficulty in searching is not in moving through the database—this will become easier with practice and most people can soon master the mechanics of literature searching. The challenge and skill lies in the initial preparation of the question, the lateral thinking that is involved in coming up with search terms, and evaluating the results of your search.

Chapter 4

FORMULATION OF OBJECTIVES, RESEARCH QUESTIONS AND HYPOTHESES

RESEARCH OBJECTIVES

Objectives are closely related to the statement of the problem. They can be divided as general objectives (the essence of the study is worded in declarative form which gives general direction of the enquiry) and Specific objectives (general objective is divided into smaller, logically connected parts).

In a quantitative study, the statement of objective identifies the key study variables and their inter-relationship as well as nature of the population of interest, e.g. to examine the relationship between high blood pressure and BMI in executives.

In a qualitative study, the statement of objective indicates the nature of inquiry, the key concept/phenomenon under investigation and the group, community or setting under study, e.g. to describe terminal care in intensive care unit as perceived by critical care givers who have been taking care of dying patients.

Specific objectives explain what, where and for what purpose. The formulation of objectives will help to focus on the study (narrowing it down to essentials), avoid unnecessary collection of data and organize the study in clearly defined parts or phases.

The objectives should cover different aspects of the problem and its contributing factors in a coherent way having logical sequence, clearly phrased in operational terms, realistic considering local conditions and use action verbs that are specific enough to be evaluated.

Examples of action verbs are: To determine, to compare, to verify, to calculate, to describe, to establish, to demonstrate, to prove, etc.

Avoid the use of vague non-action verbs such as: to appreciate, to understand, to discover, to develop, to study.

Keep in mind that when any project is evaluated, the results are compared to the objectives. If the objectives have not been spelled out clearly, the project cannot be evaluated. Generally, an acronym SMART is used to describe the characteristics of a good objective:

S = Specific
M = Measurable
A = Achievable
R = Relevant
T = Time bound

Example: To reduce Infant Mortality Rate (IMR) in India from present level of 57/1000 live births to 35/1000 live births in next two years.

RESEARCH QUESTIONS

Research question may be sometimes direct re-wording of the general objective, which is phrased interrogatively rather than declaratively.
Example:

1. **General objective:** To examine the relationship between high blood pressure and BMI in executives.
   Research question: What is the relationship between high blood pressure and BMI in executives?
2. **General objective:** To compare the perceived levels of stress, social support and immune responses between healthy and asthmatic adolescents.
   Research Question: Are there group differences in the perceived levels of stress, social support and immune responses between healthy and asthmatic adolescents?

Other Examples of Research Question

1. Do rural and urban Community Home Based Care (CHBC) projects differ with respect to the adequacy, quality, affordability and sustainability of Home Based Care (HBC) provided?
2. How satisfied are AIDS patients, relatives and service providers with the care provided?
   Are there differences in perceptions between those groups?
3. Is the stigma attached to being HIV positive equally strong for women as for men? Or are there gender differences in the stigma?
4. What impact does the care provided to AIDS patients have on the economy of the family? Is there competition with other basic needs (e.g. schooling of children, purchases of food)?

HYPOTHESES

Hypothesis is specific version of the research question that summarizes the main elements of the study—the sample, predictor and outcome variable – in a form that establishes the basis for the tests of statistical significance.

It is a tentative proposition which is subjected to verification through subsequent investigation. It may also be seen as a guide to the researcher in that it depicts and describes the method to be followed in studying the problem. In many cases, those hypotheses are launched where researcher knows about the relationship between variables".

Medawar (1972) has said, "All advances in scientific understanding … begin with a speculative adventure, an imaginative preconception of what might be true … It is the invention of a world [that is]… exposed to criticism to find out whether or not that imagined world is anything like

the real one. Scientific reasoning is, therefore, at all levels of interaction between two episodes of thought—a dialogue between two voices, the one imaginative and the other critical; a dialogue, if you like between the possible and the actual, … between what might be true and what is fact."

Thus hypothesis is a tentative prediction of a relationship between one or more factors/variable and the problem under study that can be tested. It is applied to majority of the observational (except descriptive) and experimental studies.

If any of the following terms appear in the research question, then the study is not simply descriptive and hypothesis should be formulated: greater than, less than, causes, leads to, compared with, more likely than, associated with, related to, similar to, correlated with, different from, etc.

Functions of the Hypothesis

1. It translates the research question into a prediction of expected outcome.
2. It forces researcher to think logically.
3. It exercises critical judgment.
4. It ties together earlier study findings.

CHARACTERISTICS OF GOOD HYPOTHESIS

A good hypothesis must be based on a good research question. It should be simple, specific, capable of being tested, unambiguous, stated in advance, ideally worded in present tense, and state the expected relationship between the independent (cause or antecedent) and dependent (outcome/effect) variable.

Depending on these characteristics, a hypothesis can be categorized as:

1. **Simple Hypothesis:** A simple hypothesis contains one predictor (independent) and one outcome (dependent) variable.
   Example: Lower level of exercise (predictor variable) during postpartum will be associated with greater weight retention (outcome variable).
2. **Complex Hypothesis:** It contains more than one (multiple) predictor or outcome variables. Example of complex hypothesis with multiple predictor variables:
   - A sedentary life-style and alcohol consumption (predictor variables) are associated with an increased risk of ischemic heart disease and neuropathy (outcome variables) in patients with diabetes.
3. **Specific Hypothesis:** Any hypothesis should not leave any ambiguity about the subject and the variables. It should use concise operational definitions that summarize the nature and source of subject and how variable will be measured.
   Example: Use of tri-cyclic antidepressant medications, assessed with pharmacy record is more common in patients hospitalized with an admission diagnosis of myocardial infarction in civil hospital in the past year than in controls hospitalized for asthma.

This is a long sentence but it communicates nature of the study and variables to be measured.

4. **In-advance and after-the-Effect Hypothesis**
   The hypothesis should be stated in advance (at the beginning of the study), which will keep the research focused. Hypothesis made during or end of the analysis of data can lead to over interpretation and hence to be avoided (post hoc hypothesis).
5. **Primary and Secondary Hypothesis**
   Primary hypothesis is a hypothesis around which the study has been designed but sometimes especially in randomized trials more than one hypothesis may be needed (secondary hypothesis). These secondary hypotheses should be written in advance to increase the credibility of the results.

TYPES OF HYPOTHESIS (TABLE 4.1)

Directional Hypothesis (One Sided or One Tailed)

It specifies the expected direction of the relationship between predictor and outcome variables.

Non-Directional Hypothesis (Two Sided or Two Tailed)

It states only that an association exists; it does not specify the direction.

Null Hypothesis (Statistical Hypothesis) H_o

It states that there is no relationship/association between predictor and outcome variable in the population. The null hypothesis is the formal basis for testing statistical significance.

Alternative Hypothesis (Ha)

It proposes that there is an association between predictor and outcome variable. Statistical tests attempt to reject the null hypothesis of no association in favor of alternative hypothesis. These hypothesis could be one sided or two sided.

There is a difference between research hypothesis and null hypothesis. Research hypothesis (substantive, declarative or scientific hypothesis) is statement of expected relationship between two variables. It is often directional hypothesis usually one sided.

Testing the Hypothesis

Hypothesis testing is concerned with testing whether the value of a population parameter is equal to some specific value. Null hypothesis states that any observed differences are entirely due to chance /sampling errors.

TABLE 4.1 Examples of various hypotheses

Nature of the statements	*Type of hypothesis*
Lower levels of exercise during postpartum are associated with greater weight retention.	Directional/one sided
There is a relationship between level of exercise during postpartum and weight retention.	Nondirectional/two sided
There is no association between level of exercise during postpartum and weight retention.	Null hypothesis
Young people like junk food more than the traditional food.	Directional
There is no association between drinking well water and coronary heart disease.	Null hypothesis
Patients with myocardial infarction will have a higher rate of coffee drinking than control patients.	Directional/one sided
Patients with myocardial infarction will have a different rate of coffee drinking—either higher or lower than control patients	Directional/two sided

In hypothesis testing, null hypothesis is either rejected or accepted depending on whether the 'P' value is above or below the determined cut-off point, known as significance level of test.

The investigator, based on data collected, uses statistical tests to determine whether there is sufficient evidence to reject the null hypothesis in favor of alternative hypothesis that there is an association in the population. The standard for these tests is known as the **Level of statistical significance (Table 4.2).**

If the P value is less than the cut-off point, the null hypothesis is rejected. If the P value is more than or equal to the cut-off point, the null hypothesis is accepted. It is usual to choose either 0.05 (5%) or 0.01(1%) as the level of significance, for testing the null hypothesis.

TABLE 4.2 Truth in the population versus the results in the sample: The four possibilities

	Truth in the Population	
Results in study population	***Association between predictor and outcome variable***	***No Association between predictor and outcome variable***
Positive (Reject null hypothesis)	Correct (1-β) decision True positive	α (Type I error) False positive
Negative (accept null hypothesis)	β (Type II error) False negative	Correct (1-α) decision True negative

Type I (α) Error

It occurs if an investigator rejects a null hypothesis that is actually true in the population. It is the error of falsely stating that two drug effects are

significantly different when they are actually equivalent. The probability of making α error is called as level of significance.

Type II (β) Error

It occurs if the investigator fails to reject a null hypothesis that is actually false in the population. It is the error of falsely stating that two drug effects are equivalent when they are actually different.

Power (1-β): Probability that the test will correctly identify a significant difference/effect/association in the sample, should one exist in the population or correctly reject the null hypothesis.

Chapter 5

PLANNING THE MEASUREMENTS

MEASUREMENT

It is often viewed as being the basis of all scientific inquiry, and measurement techniques and strategies are therefore an essential component of research methodology. As per Kaplan (1964) and Pedhazur & Schmelkin (1991), measurement can be defined as a process through which researchers describe, explain, and predict the phenomena and constructs of our daily existence.

For example, we measure that how long we have lived in years, our financial success in dollars, distance between two points in miles, etc. Important life decisions are based on performance on standardized tests that measure intelligence, aptitude, achievement, or individual adjustment. We predict that certain things will happen as we age, become more educated, or make other significant lifestyle changes. In short, measurement is as important in our daily existence as it is in the context of research design.

The concept of measurement is important in research studies in two key areas. First, measurement enables researcher to quantify abstract, constructs and variables. Research is usually conducted to explore the relationship between independent and dependent variables. Variables in a research study typically must be operationalized and quantified before they can be properly studied. Further the level of statistical sophistication used to analyze data derived from a study is directly dependent on the scale of measurement used to quantify the variables of interest (Anderson, 1991).

An operational definition takes a variable from the theoretical or abstract to the concrete by defining the variable in the specific terms of the actual procedures used by the researcher to measure or manipulate the variable.

For example, in a study of weight loss, a researcher might operationalize the variable "weight loss" as a decrease in weight below the individual's starting weight on a particular date. The process of quantifying the variable would be relatively simple in this situation—for example, the amount of weight lost in kilograms or grams or pounds and ounces during the course of the research study. Without measurement, researchers would be able to do little and make unsystematic observations.

There are two basic categories of data: non-metric and metric. Non-metric data (also referred to as qualitative data) are typically attributes, characteristics, or categories that describe an individual and cannot be quantified. Metric data (also referred to as quantitative data) exist in differing amounts or degrees, and they reflect relative quantity or distance. Metric data allow researchers to examine amounts and magnitudes, while nonmetric data are used predominantly as a method of describing and categorizing.

SCALES OF MEASUREMENT

There are four main scales of measurement, i.e., nominal scales, ordinal scales, interval scales, and ratio scale under the broader categories of non-metric and metric measurement:

Non-Metric Measurement Scales (Qualitative Data)

a. Nominal scales are the least sophisticated type of measurement and are used only to qualitatively classify or categorize. They have no absolute zero point and cannot be ordered in a quantitative sequence, and there is no equal unit of measurement between categories. In other words, the numbers assigned to the variables have no mathematical meaning beyond describing the characteristic or attribute under consideration—they do not imply amounts of an attribute or characteristic. This makes it impossible to conduct standard mathematical operations such as addition, subtraction, division, and multiplication.

   Common examples of nominal scale data include gender, blood type, religious and political affiliation, place of birth, city of residence, ethnicity, marital status, eye and hair color, and employment status. Notice that each of these variables is purely descriptive and cannot be manipulated mathematically.

b. Ordinal scale measurement is characterized by the ability to measure a variable in terms of both identity and magnitude. This makes it a higher level of measurement than the nominal scale because the ordinal scale allows for the categorization of a variable and its relative magnitude in relation to other variables. Variables can be ranked in relation to the amount of the attribute possessed. In simpler terms, ordinal scales represent an ordering of variables, with some number representing more than another.

   Like nominal data, ordinal data are qualitative in nature and do not possess the mathematical properties necessary for sophisticated statistical analyses.

Metric Measurement Scales (Quantitative Data)

a. The interval scale of measurement builds on ordinal measurement by providing information about both order and distance between values

of variables. The numbers on an interval scale are scaled at equal distances, but there is no absolute zero point. Instead, the zero point is arbitrary. Because of this, addition and subtraction are possible with this level of measurement, but the lack of an absolute zero point makes division and multiplication impossible. It is perhaps best to think of the interval scale as related to our traditional number system, but without a zero.

In the Fahrenheit or Celsius scale, zero does not represent a complete absence of temperature, yet the quantitative or measurement difference between 10 and 20 degrees is the same as the difference between 40 and 50 degrees. There might be a qualitative difference between the two temperature ranges, but the quantitative difference is identical—10 units or degrees. Other examples are height and weight.

b. Ratio scale of measurement has the properties identical to those of the interval scale, except that the ratio scale has an absolute zero point, which means that all mathematical operations are possible. Numerous examples of ratio scale data exist in our daily lives. Money is a pertinent example. It is possible to have no (or zero) money or a zero balance while checking account. This is an example of an absolute zero point. Unlike with interval scale data, multiplication and division are now possible. Ten Euros/Dollars is 10 times more than 1 Euros/Dollar, and 20 Euros/Dollars is twice as much as 10 Euros/Dollars. Other examples include height, weight, and time. Ratio data is the highest level of measurement and allows for the use of sophisticated statistical techniques.

Choosing a Measurement Scale

A good general rule is to prefer continuous variable, because the additional information improves the statistical efficiency. For example: Blood pressure in millimeters of mercury allows investigator to observe the magnitude of the change in every subject whereas measuring as hypertensive vs normotensive is unclear.

However, there are some exceptions to the rule. Example: determination of low birth weight babies, when there are options of designing the number of response categories in ordinal scale (taste of food – tasty, very tasty, fairly tasty, etc.)

The process of classification and measurement is to increase the objectivity of knowledge, reduce bias and provide means of communication.

Reliability and Validity and their Relationship to Measurement

Reliability is also called as precision, reproducibility, consistency and repeatability.

The reliability of a variable is the degree to which it is reproducible, with nearly the same value each time it is measured. It has a very important influence on the power of the study.

In general, reliability refers to the consistency or dependability of a measure- ment technique. More specifically, reliability is concerned with the consistency or stability of the score obtained from a measure or assessment technique over time and across settings or conditions. If the measurement is reliable, then there is less chance that the obtained score is due to random factors and measurement error.

Measurement error is uncontrolled for variance that distorts scores and observations so that they no longer accurately represent the construct in question. Scores obtained from most forms of data collection are subject to measurement error.

Essentially, this means that any score obtained consists of two components. The first component is the true score, which is the score that would have been obtained if the measurement strategy were perfect and error free.

The second component is measurement error, which is the portion of the score that is due to distortion and imprecision from a wide variety of potential factors, such as a poorly designed test, situational factors, and mistakes in the recording of data. Although all measures contain error, the more reliable the method or instrument, the less likely it is that these influences will affect the accuracy of the measurement.

There are three sources of random error or chance variability or measurement error.

1. **Observer variability:** Errors in measurement due to investigator usually due to skill variation or choice of words used for the interview.
2. **Instrument variability:** Variability lies with the instrument due to old machines, reagent lot, etc.
3. **Subject variability:** It refers to intrinsic biologic variability of study subject/an individual due to swings of mood, stress, etc.

Reliability is usually expressed as a correlation coefficient, which is a statistical analysis that tells us something about the relationship between two sets of scores or variables. Adequate reliability exists when the correlation coefficient is 80 or higher.

Strategies for Increasing Reliability and Minimizing Measurement Error

1. Use standardized instrument or measurement strategy.
2. Make sure that the participants understand the instructions and content of the instrument or measurement strategy.
3. Training of all investigators in the use of the measurement strategy.
4. Make sure that data are recorded, compiled, and analyzed accurately.

Validity

The absence of bias in data measurement is called validity, or accuracy. It is the ability to accurately assess and represent the construct of interest of a test or measurement tool/strategy. It focuses on what the test or measurement strategy measures and how well it does so. Validity and reliability are interconnected concepts. This can be demonstrated by the fact that a measurement cannot be valid unless it is reliable. Reliability, or consistency, is therefore a hallmark of validity.

The most common methods for demonstrating validity are referred to as content-related, criterion-related, and construct-related validity.

Content-Related Validity

It refers to the relevance of the instrument or measurement strategy to the construct (hypothesis) being measured. The approach for determining content validity starts with the operationalization of the construct of interest. The test developer defines the construct and then attempts to develop item content that will accurately capture it.

For example, an instrument/questionnaire designed to measure Infant mortality should contain item content that reflects the construct of infant survival. If the content does not accurately reflect the construct, then chances are that there is little or no content validity.

Criterion Validity

It is determined by the relationship between the measure and the performance on an outside criterion or measure. The outside criterion or measure should be related to the construct of interest, and it can be measured at the same time the measure is given or sometime in the future. If the measure is compared to an outside criterion that is measured at the same time, it is then referred to as concurrent validity.

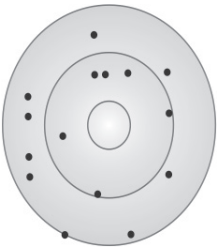
If the measure is compared to an outside criterion that will be measured in the future, it is then referred to as predictive validity.

Construct Validity

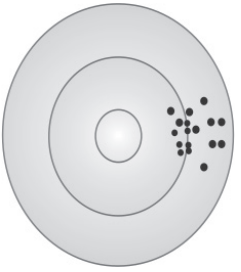
It is to find out the extent to which the test or measurement strategy measures a theoretical construct or trait.

Following is the graphic presentation of possible combinations of validity and reliability:

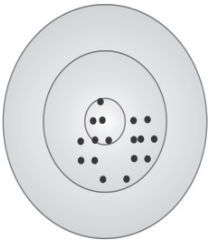
1. **Neither valid and nor reliable:** The research methods do not hit the heart of the research aim (not 'valid') and repeated attempts are unfocused.



2. **Reliable but not valid:** The research methods do not hit the heart of the research aim, but repeated attempts get almost the same (but wrong) results



3. **Fairly valid but not very reliable:** The research methods hit the aim of the study fairly closely, but repeated attempts have very scattered results (not reliable).



4. **Valid and reliable:** The research methods hit the heart of the research aim, and repeated attempts all hit in the heart (similar results).

Threats to Validity

1. Confounding factors
2. History
3. Differential subject loss in various groups
4. Selectivity (or bias) in assigning subjects to various groups.

STRATEGIES TO DEAL WITH THREATS TO VALIDITY

Triangulation

Approaching a research problem from different angles (e.g., by selecting complementary study populations or using different research techniques at the same time).

Control Group

Observing a control group who is not exposed to the risk factor or intervention reduces threats due to unexpected and confounding factors.

Appropriate sampling procedures and assignment of subjects to research groups
This reduces threats due to selectivity.

Before and After Measurements

This allows us to assess whether there has been selectivity as well as differential loss of subjects. If there has been an inevitable loss of subjects, it may enable assessment of the dropouts to determine whether they had peculiar characteristics that distinguished them from those who did not drop out.

Unobtrusive methods of data collection and allowing adaptation time for subjects to get used to being observed or interviewed.

Careful design and pre-testing of instruments, stressing the participation of health managers, staff and community members, reduce bias due to instrumentation. Training of interviewers and standardization of interview techniques and tools such as questionnaires are also important in reducing this bias.

Knowledge of the environment events enables the researcher to be sensitive to the external events that could affect validity, e.g. history. In case of an expatriate researcher, local key informants can contribute a lot to the validity of the study.

Stratification and matching for confounding variables during the analysis of the results is to be done.

Chapter 6

STUDY DESIGN OPTIONS IN MEDICAL AND HEALTH RESEARCH

Once the investigator/researcher has determined the specific question to be answered and has operationalized the variables and research question into a clear, measurable hypothesis, it is time to consider a suitable research design. Although there are endless ways of classifying research designs, commonly used study designs are as follows:

Type of study	*Alternate name*	*Unit of study*
A. Observational Studies (Non Experimental)		
Descriptive Studies		
Case report	–	Individuals
Case series	–	Individuals
Ecological	Co-relational	Populations
Cross-sectional	Prevalence	Individuals
Analytical Studies		
Case-control	Case-reference	Individuals
Cohort	Follow-up/ Longitudinal	Individuals
B. Experimental/Intervention Studies		
Randomized Controlled studies	Clinical trial	Patients
Field trial		Healthy persons
Community trial	Community intervention studies	Communities
Non-Randomized	—	Patients

The main aim of various study designs:

1. Descriptive studies: to generate/formulate hypothesis.
2. Analytical studies: to test hypothesis.
3. Experimental studies: to prove hypothesis.

Based on the existing state of knowledge about a problem that is being studied, different types of research questions may be asked which require different study designs (Table 6.1). Some examples are given in the following Table 6.2.

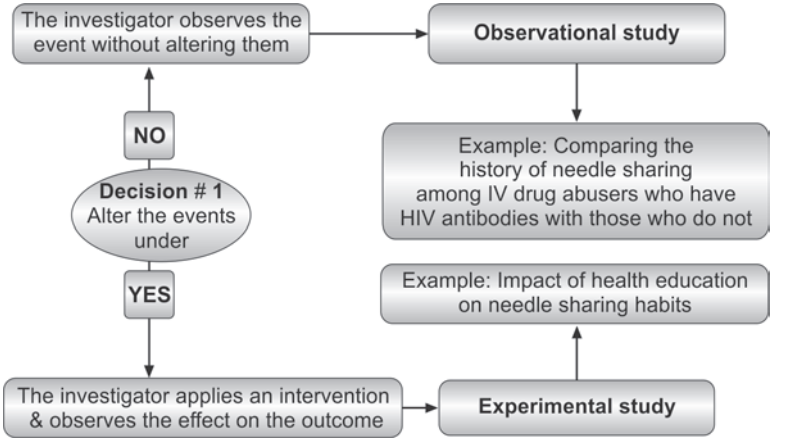
TABLE 6.1 Research questions and types of studies

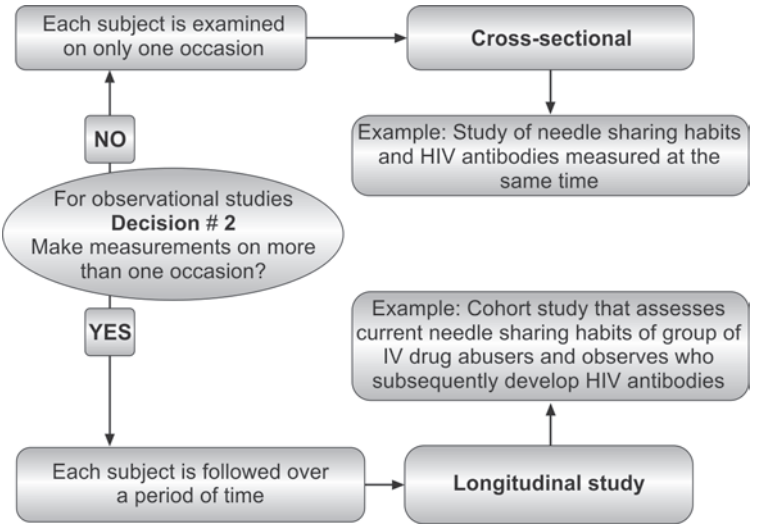
State of knowledge of the problem	*Type of research questions*	*Type of study*
Problem exists but knowledge about its characteristics or possible causes is not much known	• What is the nature magnitude of the problem? • Who is affected? • How do the affected people behave? What do they know, believe, and think about the problem and its causes?	Exploratory studies, or Descriptive (case studies/ cross-sectional studies)
Suspecting that certain factors contribute to the problem	• Do certain factors really associate with the problem?	Analytical studies Case-control/cohort studies
Wish to establish the extent to which a particular factor causes or contributes the problem	• What is the cause of the problem • Can diseases be prevented, if causal factor is removed?	Cohort studies Experimental studies

TABLE 6.2 Examples

State of knowledge of the problem	*Type of research questions*	*Type of study*
Problem of under-nutrition exists but role of zinc is less known	What is the role of Zinc? Whether it helps or not? How does it work?	Descriptive studies Exploratory study
Knowing that anti-oxidants may prevent cardiovascular disease	Are anti-oxidants useful in prevention of CVS diseases?	Analytical studies: Case control/cohort studies
Having adequate knowledge about a factor to develop and assess intervention.	What is the effect of a particular intervention?	Randomized/non-randomized controlled trials.

DECISION ALGORITHM FOR STUDY TO BE CHOSEN





OBSERVATIONAL/NON-EXPERIMENTAL/NON-INTERVENTIONAL STUDIES

Exploratory Studies

An exploratory study is a small-scale study of relatively short duration, which is carried out when little is known about a situation or a problem. It may include description as well as comparison.

Exploratory studies gain in explanatory value if we approach the problem from different angles at the same time. This is called triangulation. In a study that is looking for causes of the low percentage of supervised deliveries, it may be very useful to include observations and interviews with health staff in the maternity centers that should serve the mothers in question and interviews with their supervisors, as well as with the mothers themselves. In this manner, information from different independent sources can be cross-checked.

If the problem and its contributing factors are not well defined, it is always advisable to do an exploratory study before planning a large-scale descriptive or comparative study.

Descriptive Studies

A descriptive study involves describing the characteristics of a particular situation, event or case. Descriptive studies can be carried out on a small or larger scale. It always describes the event in time, place and person. The descriptive study can answer the research question by asking what, when, where, who, and how for an event (Table 6.3).

TABLE 6.3 Describing the disease in terms of time, place and person (Some characteristics)

Time	*Place*	*Person*	
Year, season Month, week Day & hour of onset Duration of illness	Climatic zones Country, region Urban, rural Towns, cities, institutions	Age Sex Marital status Occupation, social status, education	Birth order Family size Height, weight Blood pressure, blood cholesterol personal habits like brushing of teeth, smoking, etc.

Case Studies

Case studies describe in-depth the characteristics of one or a limited number of 'cases'. A case may be, for example, a patient, a health center, or a village. Such a study can provide quite useful insight into a problem. Case studies are common in social sciences, management sciences, and clinical medicine. For example, in clinical medicine the characteristics of a hitherto unrecognized illness may be documented as a case study. This is often the first step toward building up a clinical picture of that illness.

Case Report Series

Objective and brief report of a clinical characteristic or outcome from a group of clinical subjects. Generalization is not possible due to biased selection or unrepresentativeness of subjects, lack of control group, etc.

Correlation Studies

This study uses data from entire populations to compare disease frequency between different groups during the same period of time or in the same population at different points in time.

Example

1. Correlation between per capita meat intake and colon cancer in women. The study showed that the higher intake of meat was associated with increased risk of colon cancer.
2. It cannot estimate the individual's risk but helps in stimulating hypothesis for under-taking analytic studies. It can be done quickly and less expensively as data are readily available on demography product, consumption which can be related to disease incidence, mortality or utilization of health services, etc.
3. However, if one wishes to test whether the findings pertain to a larger population, a more extensive, cross-sectional survey has to be designed.

Cross-Sectional Studies

Cross-sectional study is also known as instantaneous study, Prevalence study and Simultaneous study.

A cross-sectional study is an observational study and the investigator has no control over the exposure of interest (e.g. diet). It includes identifying a defined population at a particular point in time, measuring a range of variables on an individual basis and at the same time measuring outcome of interest.

The Study may Cover:

- Physical characteristics of people, materials or the environment, as in prevalence surveys of tuberculosis, leprosy, HIV, etc. Evaluation coverage of immunization, sanitary latrines, etc.
- Socio-economic characteristics of people such as their age, education, marital status, number of children and income.
- The behavior or practices of people and the knowledge, attitudes, beliefs, opinions which may help to explain that behavior (KAP studies
- Events that occurred in the population.

There is no in-built directionality as both exposure and outcome are present in the study subject for quite some time. It deals with the situation existing at a given time (or during a given period) in a group or population.

These may be related with the presence of disorders such as diseases, disabilities and symptoms of ill-health, dimensions of positive health, such as physical fitness, other attributes relevant to health such as blood pressure and body measurements, factors about health and disease such as exposure to specific environmental exposure or defined social and behavioral attributes and demographic attributes, determining the workload of personnel in a health program as given by prevalence, etc.

Census is an example of cross-sectional surveys. A cross-sectional survey may be repeated in order to measure changes over time in the characteristics that were studied. The surveys may be very large, with hundreds or even thousands of study units. In these cases only a limited number of variables will usually be included, in order to avoid problems with analysis and report writing. If cross-sectional surveys are smaller they can be more complex. Small surveys can reveal interesting associations between certain variables, such as between having tuberculosis and socio-economic status, sex, and ways of coping.

Cross-sectional surveys of morbidity and the health services utilization in different countries often give varying results, usually reflecting variations in survey methods as well as true difference between populations. Comparisons of morbidity and utilization rates can be masked by the absence of standardization in survey methods. Attention must be given to the purpose of the surveys; questionnaires must be well designed and sample chosen must be appropriate and representative.

Analytical Studies

Case-Control Studies

Case control studies are relatively simple and economical to carry out and are increasingly used to investigate causes of diseases, especially rare diseases. They include cases (people with disease of interest) and a suitable control group (people without that disease or outcome variable). The occurrence of the possible causes is compared between cases and controls. Case control studies are also called as retrospective studies since the investigator is looking backwards from the disease to a possible cause (Fig. 6.1).

Controls should come from the same 'source' population as the cases. For example, in a hospital based case-control study where cases are being sought in the hospital, controls should normally be selected from patients attending the same hospital. If controls are selected from another hospital, they might not be from the same source population because the referral pathways may be different, and therefore they would not really be comparable to the cases. Matching of cases and controls is the heart of this study design.

For example, in a study of the causes of neonatal death, the investigator will first select the 'cases' (children who died within the first month of life) and 'controls' (children who survived their first month of life). (S)he then interviews their mothers to compare the history of these two groups of children, to determine whether certain risk factors are more prevalent among the children who died than among those who survived.

An important aspect of case-control study is the determination of the start and duration of exposure for cases and controls. In the case-control design, the exposure status of the cases is usually by direct questioning of the affected person or relative or friend. This informant's answer may

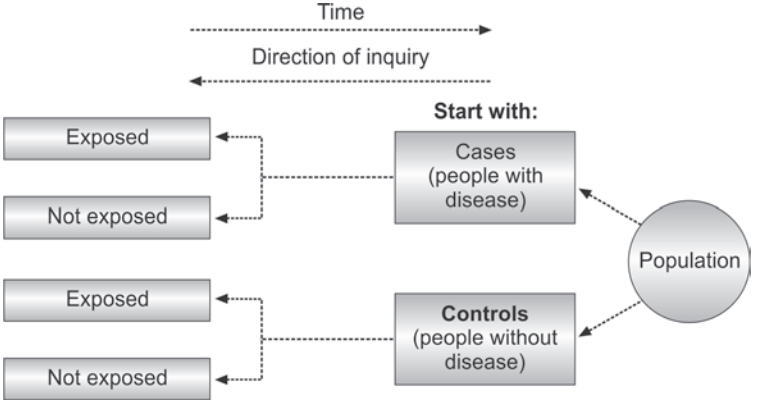


Fig. 6.1: Diagram of a case-control study

be influenced by knowledge about the hypothesis under investigation or disease experience itself. Exposure is sometimes determined by the biochemical measurement, which can be affected by the diseases. This problem can be avoided if accurate data is available.

The predictor variable and outcome variable can be presented in a standard 2 × 2 contingency table and measurement of exposure can be calculated. The design of the same is given below:

Standard 2 × 2 Table contingency Table

		Outcome variable/Effect/Disease		*Total*
		Present(cases)	*Absent (control)*	
Predictor Variable: Cause	Present	a	b	a + b
	Absent	c	d	c + d
	Total	**a + c**	**b + d**	**a + b + c + d**

Cohort Studies

The word 'cohort' has its origin in the Latin 'cohors' which refers to a group of warriors and gives notion of a group of persons proceeding together in time, i.e., group of persons with a common statistical characteristic; e.g. age, birth date, year of marriage, exposed to common event like cyclone, earthquake, etc.

Cohort study is also known as Follow-up, Longitudinal, Prospective and Incidence study. The cohort study is an observational epidemiological study which, after the manner of an experiment, attempts to study the relationship between a purported cause (exposure) and the subsequent risk of developing disease.

Characteristics of cohort design

- Groups are exposure based: The group or groups of persons to be studied are defined in terms of characteristics manifest prior to the appearance of the disease under investigation.
- The study is conceptually longitudinal: The study groups so defined are observed over a period of time to determine the frequency of disease among them.
- A definite beginning and end.
- It is efficient for examining:
  - When there is good evidence of exposure and disease.
  - When exposure is rare but incidence of disease is higher among exposed.
  - When follow-up is easy and cohort is stable.
  - When ample funds are available.
  - Common outcomes.
  - Many different outcomes for same exposure.

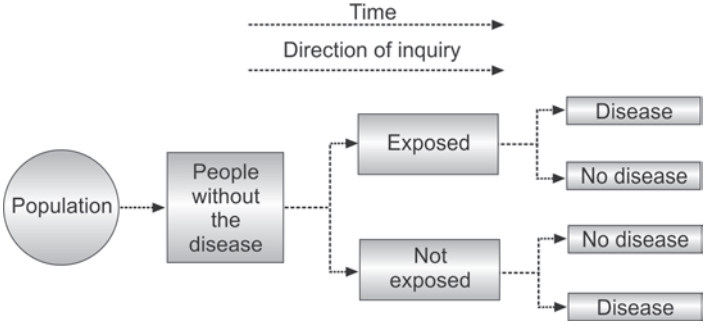
- The dynamic nature of many risk factors and their relations in time to disease occurrence can be studied.
- Associations (not cause and effect) may be studied.
- Can estimate incidence within risk factor groups.
- Cannot estimate prevalence of risk factor.

Types of cohort studies

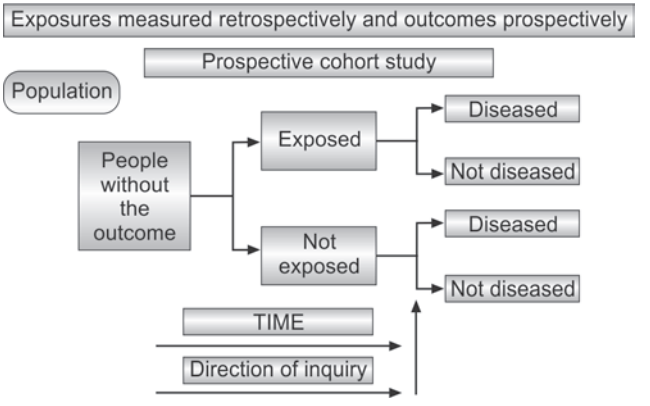
- Historical/Retrospective/Non-concurrent
- Prospective/Concurrent
- Combined

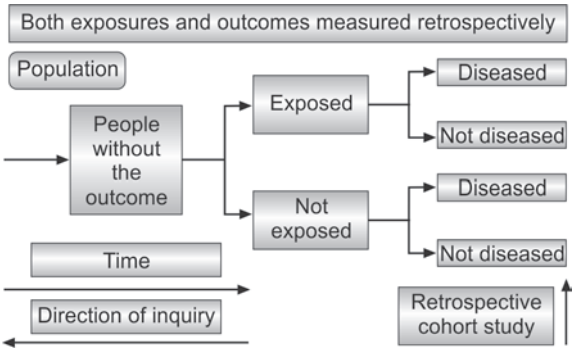
The distinction between retrospective and prospective cohort studies depends on whether or not the diseases have occurred in the cohort at the time the study begins. In a retrospective cohort study, all the relevant exposures and health outcomes have already occurred when the study is initiated. In a prospective cohort study, the relevant causes may or may not have occurred at the time the study begins, but the cases of disease have not yet occurred, and, following selection of the study cohort, the investigator must wait for the disease to appear in the cohort members.

Design of cohort study



Types of cohort studies





Steps in conducting cohort study

- Select suitable study and control cohorts
- Data collection and measurement of exposure
- Follow-up of cohort and outcome measurement.

Study Cohorts

There are various types of cohorts, following are some of the cohorts used for the studies.

1. **Special Exposure Cohorts:** Samples are chosen on the basis of a particular exposure e.g. Radiologists, victims of Bhopal gas tragedy, etc.
2. **General Population Cohorts:** Population groups offering special resources for follow-up or data linkage are chosen, and the individuals are subsequently allocated according to their exposure status, e.g. professionals, obstetricians, etc.
3. **Exposures** may be a particular event, a permanent state or a reversible state.
4. **Closed or Fixed Cohorts:** Fixed group of persons followed from a certain point in time until a defined endpoint, starting point-exposure defining event, endpoint—occurrence of the disease, loss to follow-up and death.
5. **Open or Dynamic Cohorts:** Subjects may enter or leave the study at any time and exposure status may change over time.

Control Cohort

Selection of the control/comparison cohort depends on the type of comparison, e.g.

1. **Internal Comparison:** Only one cohort identified and later on, classified into study and comparison cohort based on exposure, e.g. smokers in lung cancer study (mild, moderate or heavy smokers depends on number of cigarettes per day and duration).

2. **External comparison:** More than one cohort in the study for the purpose of comparison, e.g. Cohort of radiologist compared with ophthalmologists.
3. **Comparison with general population rates:** If no comparison group is available we can compare the rates of study cohort with general population, e.g. Cancer rate of uranium miners with cancer in general population.

Exposure Measurement

Exogenous and/ or endogenous are important in a cohort study but there are challenges of prospective data collection with reference to choice of reference period, frequency of exposure update, changes in instrument over time, use of repeated measures and data collection costs (cost-efficient measurement methods).

Sources of Information for Data Collection

Data can be collected from records, cohort members (self-administered questionnaires, interviews, telephone interviews, mailed questionnaires), medical examination and biomarkers, clinical examinations and lab tests and measures of the environment (level of air pollution, quality of drinking water, airborne, radiation), etc.

Follow Up of Cohort and Outcome Measurement

Follow up may be done for single event like mortality, first occurrence of a disease or health-related outcome (Incidence, cumulative incidence, ratios (incidence density and cumulative incidence) or multiple occurrences (disease outcome, transition between states of health/disease, transitions between functional states). Follow-up is to be done with equal intensity in both the groups.

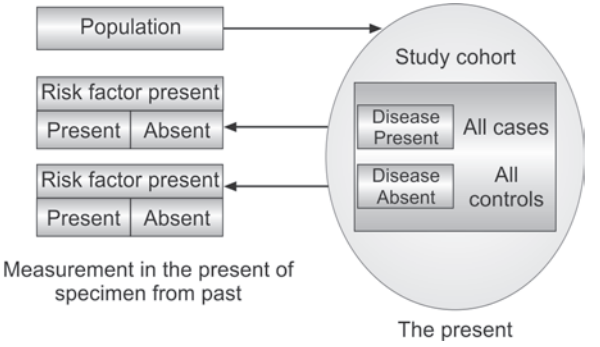
Nested Case-Control Study Design

In nested case-control study design (or the case-control in a cohort study) cases of a disease that occur in a defined cohort are identified and, for each, a specified number of matched controls is selected from among those in the cohort who have not developed the disease by the time of disease occurrence in the cases. For many research questions, the nested case control design potentially offers impressive reductions in costs and efforts of data collection and analysis compared with the full cohort approach, with relatively minor loss in statistical efficiency. The nested case-control design is particularly advantageous for studies of biologic precursors of disease. To advance its prevention research agenda, we might be encouraged to maintain a registry of new and existing cohorts, with an inventory of data collected for each; to foster the development of specimen banks; and to serve as a clearing house for information about optimal storage conditions for various types of specimens.

Nested Case-Cohort Study Design

It is same as nested case-control except that the controls are a random sample of all the members of the cohort regardless of outcome. This means that there will be some cases among those sampled for the comparison group, who will also appear among the cases to be analyzed. This approach has the advantage that the controls represent the cohort in general, and therefore provide a basis for estimating the incidence and prevalence in the population from which it was drawn. It means that this cohort sample can be used as a comparison group for more than one type of outcome provided that it is not too common.

SCHEMATIC DIAGRAM OF NESTED CASE-CONTROL STUDY DESIGN



Choice of Study

TABLE 6.4 Investigator can choose one of the following studies based on the research question/situation

Basis	*Cohort*	*Case control*	*Cross-sectional*
Rare condition	Not practical	Bias	Not appropriate
To determine a precise risk	Best	Only estimate possible	Gives relative prevalence, not incidence
To determine whether exposure preceded disease	Best	Not appropriate	Not appropriate
For administrative purposes	Not appropriate	Not appropriate	Best
If attrition is a serious problem	Not appropriate	Attrition is usually minimal	Attrition may have occurred before the study
If selective survival is problem	Best	Not appropriate	Not appropriate
If all factors are not known	Best	Not appropriate	Less appropriate
Time and money	Most expensive	Least expensive	In between

TABLE 6.5 Advantages and disadvantages of different observational study designs

Probability of	*Ecological*	*Cross-sectional*	*Case-control*	*Cohort*
Selection bias	NA	Medium	High	Low
Recall bias	NA	High	High	low
Loss to follow up	NA	NA	Low	High
Confounding	High	Medium	Medium	Low
Time required	Low	Medium	Medium	High
Cost	Low	Medium	Medium	High

TABLE 6.6 Application of different observational designs

Purpose	*Ecological*	*Cross-sectional*	*Case-control*	*Cohort*
Investigation of rare diseases	++++	-	++++	-
Investigation of rare causes	++	-	-	+++++
Testing multiple effects of cause	+	++	=	+++++
Study of multiple exposures and determinants	++	++	+++++	++++
Measurement of time relationship	++	-	+	+++++
Direct measurement of incidence	-	-	+	+++++
Investigation of long latent periods	-	-	+++	-

TABLE 6.7 Types of the studies and strength to prove causation of a disease

Type of the study	*Ability to prove causation*
Randomized controlled trials	Strong
Cohort studies	Moderate
Case control studies	Moderate
Cross-sectional studies	Weak
Ecological studies	Weak

TABLE 6.8 Advantages and disadvantages of case-control and cohort studies

Advantages	*Disadvantages*
Case–Control Study	
• Cheap and quick • Data is frequently available through current records or statistics • Useful for rare outcome • Short duration and require small sample size • Yields odds ratio	• Temporal weakness: – Cannot determine if cause preceded the effect or the effect was responsible for the cause. Does not yield incidence or excess risk – Bias and confounding from sampling of two populations.

Contd...

Contd...

Cohort Study	
• It can measure direct estimate of risk and rate of disease occurrence over time • Can assess multiple outcomes of a single exposure • Easy to establish temporal relationship between exposure and outcome • Exposure definitely precedes the outcome • Avoids recall bias, survival bias • Does not require strict random assignments of subjects • Can be done with original data or secondary data	• It requires very large sample sizes, especially for rare outcomes • Expensive and time-consuming • Attrition problems (Loss to follow-up are present. • Differences in the quality of measurement of exposure or disease between the cohorts may introduce misclassifi- cation (information bias) • Cannot infer causal relation • Complexity of data analysis • Ethical issues may arise
Nested Case-Control Study	
• Follow up in the past • Relatively inexpensive • Much more efficient	• Suitable cohort and specimen many not be available
Nested Case-Cohort Study	
• Can use single control group for multiple case-control studies	• Suitable cohort and specimen many not be available

MEASUREMENTS IN VARIOUS STUDY DESIGNS

Measurement for various study designs in terms of prevalence, incidence, odds ratio, relative risk , attributable risk are essential to arrive at conclusion of a study.

A. **Prevalence rate:** It can be measured by cross-sectional study and calculated as follows:

$$\text{Prevalence Rate} = \frac{\text{Number of all cases (old + new) of a disease under study, existing at a specified time in a specified population}}{\text{Number of persons in the population at risk at a specified time}} \times 1000$$

B. **Incidence rate:** It is calculated as follows:

$$\text{Incidence Rate} = \frac{\text{Number of new cases of a disease under study during a specified period of time}}{\text{Total susceptible population or population at risk of developing the disease under study during a specified period of time.}} \times 1000$$

C. **Odds ratio (OR)**

The odds ratio is a measure of effect size, describing the strength of association or nonindependence between two binary data values. Odds ratio is measured in case control studies. It is the ratio of the odds among exposed to the odds among unexposed, i.e.

[Odds (Exp) / [Odds (Unexp)]

According to standard 2 × 2 contingency table

- Odd of disease among exposed = [a/b]
- Odd of disease among unexposed = [c/d]
- OR = [a/ b] / [c/ d] = ad/bc
- Relative Ratio (RR)= [a/a+b] / [c/c+d], for null hypothesis, risk ratio will be equal to 'one'.
- Under most circumstances, the OR is a good estimate of risk ratio and thus may be used as an estimate of risk ratio.

The odds ratio can also be defined (in terms of group wise odds) as the ratio of the odds of an event occurring in one group to the odds of it occurring in another group, or to a sample based estimate of that ratio These groups might be men and women, an experimental group and a control group, or any other dichotomous classification. If the probabilities of the event in each of the groups are p_1 (first group) and p_2 (second group), then the odds ratio is:

$$\frac{p_1 / (1 - p_1)}{p_2 / (1 - p_2)} = \frac{p_1 / q_1}{p_2 / q_2} = \frac{p_1 q_2}{p_2 q_1}$$

where $q_x = 1 - p_x$. An odds ratio of 1 indicates that the condition or event under study is equally likely in both groups. An odds ratio greater than 1 indicates that the condition or event is more likely in the first group. and an odds ratio less than 1 indicates that the condition or event is less likely in the first group. The odds ratio must be greater than one, and as OR increases, the strength of association also increases.

D. **Relative risk (RR), attributable risk (AR) and population attributable risk (PAR) are measured in cohort studies:**

i. **Relative risk or Risk Ratio:** RR is the risk of an event (or of developing a disease) relative to exposure. Relative risk is a ratio of the probability of the event occurring in the exposed group versus a non-exposed group.

According to standard 2 × 2 contingency table:

- Risk of disease among exposed = [a/[a+ b)]
- Risk of disease among unexposed = [c/[c +d)]
- RR = [a/ [a +b)] / [c/ [c +d)]
- For null hypothesis, risk ratio will be equal to 'one'
- RR more than one shows an association (weak association–RR = >1 and <2, moderate to strong – RR = 2–4 and very strong – RR >4).

ii. **Attributable risk or risk difference (absolute differences in risks or rates):** The Attributable Risk (AR) of a disease is simply the rate of disease (incidence) in the exposed people minus the rate in the unexposed people. So the attributable risk for lung cancer in smokers, in essence, simply the rate of lung cancer amongst smokers minus the rate of lung cancer amongst non-smokers. In fact AR shows what proportion of the disease in exposed subjects is due to exposure. This is also frequently referred to as the "risk difference" when dealing with risk data or "rate difference" with rate or person-time data.

According to standard 2 × 2 contingency table:

- Risk among exposed – Risk among non-exposed
- Risk of disease among exposed = [a/[a + b)]
- Risk of disease among unexposed = [c/[c + d)]
- Risk difference = [a/[a + b)] – [c/[c + d)]
- For null hypothesis, risk difference will be equal to 'zero'

iii. **Attributable risk percent (AR %) among exposed:**
AR% (Exposed) = [Risk (Exp) – Risk (Unexp)]/Risk (Exp) × 100 = (RR – 1)/RR × 100 = (OR – 1)/OR × 100 (if risk is small)

iv. **Population attributable risk (PAR):** Population attributable risk (PAR) is the incidence of a disease in a population that is associated with (or attributed to) an exposure to a risk factor (Last 1995). This measure is useful for determining the relative importance of exposures for the entire population and is the proportion by which the incidence rate of the outcome in the entire population would be reduced if exposures were eliminated.

It is usually expressed as a percentage and estimated by the formula: $PAR = I_p - I_u / I_p$

where Ip is the incidence of the disease in the total population
I_u is the incidence of the disease among the unexposed group

Population attributable fraction estimates may help policy makers in planning public health interventions. Population attributable fraction (PAF), population attributable risk proportion, and population attributable risk percent all are same as the PAR.

▶ PAR% = [Risk (Total) – Risk (Unexp)] / Risk (Total) × 100
= [Pe (RR – 1)] / [1+ Pe (RR – 1)] × 100

v. **Combined PAR:** The PAR for a combination of risk factors is the proportion of the disease that can be attributed to any of the risk factors studied. The combined PAR is usually lower than the sum of individual PARs since a disease case can simultaneously be attributed to more than one risk factor and so be counted twice.

When there is no multiplicative interaction (no departure from multiplicative scale), combined PAR can be manually calculated by this formula:

Combined PAR = 1 – (1–PAR1)*(1–PAR2)*(1–PAR3)

Examples for Calculating Measures for Various Study Designs

1. **Prevalence rate in a cross-sectional study:**

		Outcome variable/Effect: (Infant colic)		*Total*
		Present	***Absent***	
Predictor variable: Cause: smoking among mother	Present	a = 15	b = 167	a + b = 182
	Absent	c = 111	d = 2477	c + d = 2588
	Total	a + c = 126	b + d =2644	a + b + c + d = 2770

Prevalence of colic with smoking mothers = a/a+b = 15/182
= 8.2%

Prevalence of colic with nonsmoking mothers = c/c+d
= 111/2588 = 4.3%

Prevalence overall = (a + c)/(a + b + c + d) = 126/2770 = 4.5%

Relative prevalence = Prevalence among smokers/Prevalence among nonsmokers = 8.2% / 4.3% =1.9

Excess prevalence = Prevalence among smokers – Prevalence among nonsmokers = 8.2% – 4.3%
= 3.9%

(Relative and excess prevalence are the cross-sectional analogs of relative risk and excess risk)

2. **Odds ratio in a case-control study**

		Outcome variable: Presence of leukemia		*Total*
		Study group	***Control group***	
Predictor variable: IM vitamin K:	Given	a = 69	b = 63	a + b = 132
	Not given	c = 38	d = 44	c + d = 82
	Total	a + c = 107	b + d = 107	a + b + c + d = 214

Odds ratio = ad/bc = 69 × 44/63 × 38 = 1.27

3. **Incidence rate, relative risk and attributable risk in a cohort study**

Outcome variable			
Cigarette smoking	***Developed lung cancer***	***Did not develop lung cancer***	***Total***
Yes	70	6930	7000
No	03	2997	3000

Incidence Rate

Incidence among smokers = a/(a + b) = 70/7000 = 10 per 1000
Incidence among nonsmokers = c/(c + d) = 3/3000 = 1 per 1000
Relative Risk (RR) = a/(a + b) ÷ c/(c + d) = 10/1 = 10

A relative risk of 10 indicates that the incidence rate of disease is 10 times higher in the exposed group as compared with the unexposed group.

Attributable Risk (AR) = a/(a + b) – c/(c + d)
= (10–1)= 9
AR % = [Risk (Exp) – Risk (Unexp)]
Risk (Exp) × 100 = [(10 – 1) / 10] × 100
= 90%

Attributable risk indicates as to what extent the disease under study can be attributed to the exposure. 90% of lung cancer among smokers was due to their smoking which indicates that the association between smoking and lung cancer is causal. It means that 90% of lung cancer can be eliminated if the factors under study could be controlled or eliminated.

EXPERIMENTAL/INTERVENTION STUDY DESIGNS

It is a type of prospective study where some action, intervention or manipulation is involved such as deliberate application or withdrawal of suspected cause or changing one variable in the causative chain in the experimental group while no change in the control group, and observing and comparing the outcome of the experiment in both the groups.

The objectives of experimental studies are as follows:

1. To provide scientific proof of etiological (or risk) factors which may permit the modification or control of those diseases.
2. To provide a method of measuring the effectiveness and efficiency of health services for the prevention, control and treatment of disease and improve the health of the community.

The researcher/investigator using an experimental design is an active agent rather than passive observer. In intervention studies, the researcher manipulates a situation and measures the effects of this manipulation. Usually (but not always) two groups are compared, one group in which the intervention takes place (e.g. treatment with a certain drug) and another group that remains 'untouched' (e.g. treatment with a placebo).

The clinical trial is an example of an experimental study in which the investigator introduces some form of treatment. Other examples include animal studies or laboratory studies that are carried out under experimental conditions. Experimental studies provide most convincing evidence for any hypothesis, as it is generally possible to control the factors that may affect the outcome.

A good research design is often characterized by adjectives like flexible, appropriate, efficient, and economical and so on. The design which minimizes bias as well as experimental error (variation) and maximizes the reliability of the data collected and analyzed is considered a good design. The following three basic principles are applied to achieve the above goals while designing experimental studies.

1. The principle of replication,
2. The principle of randomization; and
3. The principle of local control.

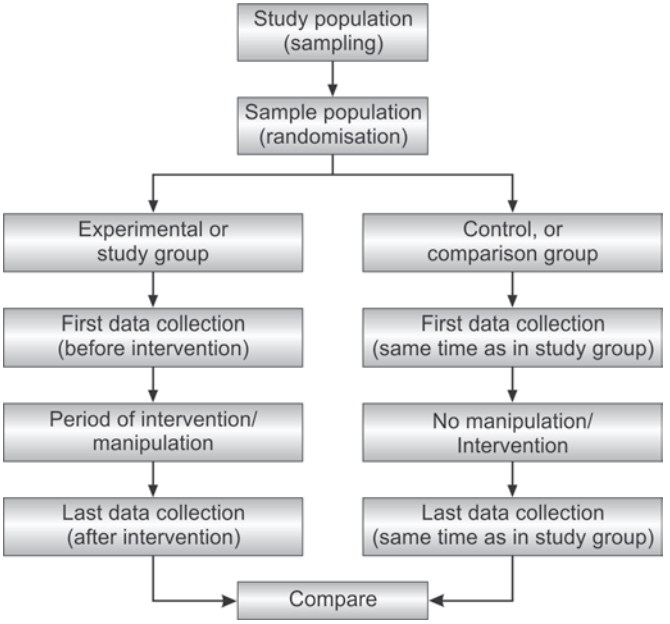
The principle of replication underlines the importance of repeating the experiment, or readings of the experiment more than once, in order to avoid/neutralize experimental errors and maximize the reliability of the data. It means that each treatment is applied in many experimental units, or each phenomenon should be studied in different locations/centers (multi-centered studies).

The principle of randomization provides protection, when we conduct an observational study or experimental study, against the effects of extraneous factors and bias. Eliminating bias, which is mainly caused due to human beings involved in the study (observer bias, selection bias, information bias, assessment bias, recall bias, response bias, healthy entrant effect) is the basic aim of a research design.

The techniques of randomization help us to reduce this bias. In other words, this principle of randomization indicates that we should design or plan the study/experiment in such a way that the variations caused by extraneous factors can all be combined under the general heading of "chance". The principle of randomization is achieved through selecting the sample units of a study/experiment randomly. In observational studies, it is achieved by following probability-sampling techniques (simple random sampling stratified random sampling, systematic random sampling, multi-stage/phase random sampling, etc). In clinical trials, randomization is achieved through single/double blind trials, cross-over trials, etc.

The principle of local control also helps us to eliminate the variability due to extraneous factors. It is achieved through blocking/ stratifying. It is often possible to group observational subjects/experimental units that share similar characteristics into a homogeneous block or stratum (e.g. blocks may represent different age groups). The variation between units in a block is less than that between units in different blocks. The individuals within each block are randomly assigned to treatments; we compare treatments within each block rather than making an overall comparison between the individuals in different blocks. We can, therefore, assess the effects of treatment more precisely than if there was no blocking.

Diagram of an Experimental Study



Important Experimental Designs

Experimental design refers to the framework of an experiment. These can be classified into two broad categories viz., informal and formal experimental designs. Informal experimental designs are those designs that normally use a less sophisticated form of analysis based on differences in magnitudes, whereas formal experimental designs offer relatively more control and use precise statistical procedures for analysis.

A. **Non-Randomized or Informal Experimental Designs**

i. **Before-and-after without control design (Pretest–post-test design):** In this design only one experimental group of patients is selected and the dependent/outcome variable is measured before and after the treatment. The effect of the treatment is measured as the difference in the dependent/outcome variable before and after the treatment.

Experimental group	Level of phenomenon before treatment (X) **Treatment Effect = (Y) – (X)**	Treatment introduced →	Level of phenomenon after treatment (Y)

ii. **After-only with control design (post-test):** In this design two groups of patients are selected (experimental and control) and the treatment is introduced into the experimental group only. The dependent variable is then measured in both the groups of patients at the same time. The impact of the treatment is measured from

the difference in the dependent variable between the experimental and control group of patients.

Experimental control	Treatment introduced ⟶ **Treatment Effect =(Y)–(Z)**	Level of phenomenon after treatment (Y) Level of phenomenon without treatment (Z)

iii. **Before and after with control design:** In this design two groups of patients are selected (experimental and control) and the dependent variable is measured in both the groups for an identical time-period before the treatment. The treatment is then introduced in experimental group of patients only, and the dependent variable is measured in both for an identical time period after the introduction of the treatment. The treatment effect is determined by subtracting the change in the dependent variable in the control group from the change in the dependent variable in the experimental group.

	Time period I		Time period II
Experimental group	Level of phenomenon before treatment X	Treatment introduced ⟶	Level of phenomenon after treatment Y
Control	Level of phenomenon without treatment A **Treatment Effect = (Y – X) – (Z – A)**	⟶	Level of phenomenon group without treatment Z

B. **Randomized or formal experimental designs**

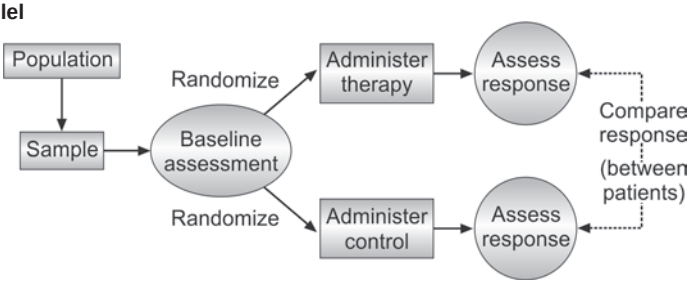
i. **Completely randomized design (CRD):** This involves only two principles viz., the principle of replication and the principle of randomization. The essential characteristic of this design is that the subjects are randomly assigned to experimental treatments (or vice-versa), using either single blind or double blind trial. One way analysis of variance (ANOVA) is used to analyze such a design. Such a design is used when experimental groups happen to be homogeneous.

There can be two types of CRDs. They are:

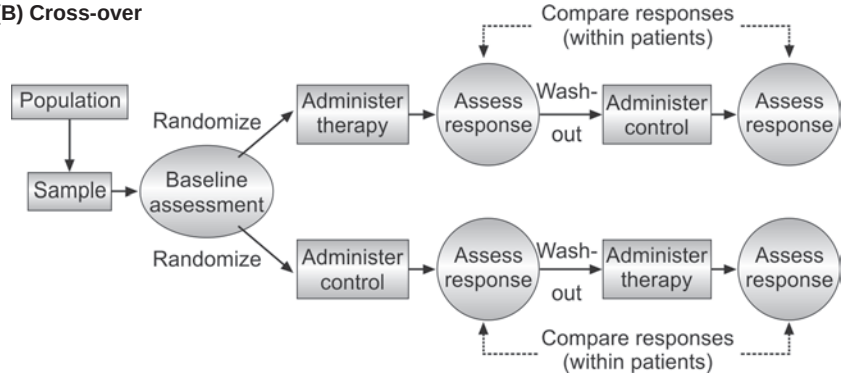
- Two-group simple randomized design
- Random replication design. The two-group simple randomized design can be further classified as:
  - Parallel trials, and
  - Cross-over trials.

There can be two types of CRDs: They are (i) Two-group simple randomized design, (ii) Random replication design. The two-group simple randomized design can be further classified as (i) Parallel trials and (ii) Cross-over trials.

(A) Parallel



(B) Cross-over



RANDOMIZED CONTROLLED TRIAL (RCT)

A true experiment, in which the researcher randomly assigns some patients to at least one maneuver (treatment) and other patients to a placebo, or usual treatment. It is the classic way to evaluate efficacy or effectiveness of drugs (or exercise, diet, counseling) and patients are followed over time (prospective). The ideal clinical trial is one that is randomized and double-blind.

"Randomized, double-blind, controlled trial" is considered as research design par excellence and "Gold standard" amongst research designs with which results of other studies are often compared. Deviation from this standard has potential drawbacks.

Steps in Conducting the Rct

- Appropriate protocol development
- Selecting reference and experimental populations
- Randomization
- Intervention/Manipulation
- Follow-up
- Assessment

Appropriate Protocol Development

Protocol is blue print of the research study to be done which includes aims and objectives, research questions, selection criteria, sample size, procedures up to the evaluation of outcome. It prevents bias and reduces the sources of errors. Preliminary test runs are to be conducted to find out feasibility or operational efficiency of the research.

Selecting Reference and Experimental Populations

- **Reference or target population:** Population to which the findings of the trial, if found successful, are expected to be applicable, e.g. drugs, vaccines, etc.
- **Experimental or study population:** Actual population that participates in the experimental study. Study participants must fulfill the following criteria:
  - Must give informed consent
  - Should be representative of the population
  - Should be qualified or eligible for the trial
  - Should be available to follow up as far as possible.

Randomization

Randomization is the heart and soul of the RCT. Participants are allocated into study andcontrol groups on random basis. It eliminates bias and allows comparability. Both groups (study and control) should be alike with regards to certain variables that might affect the outcome of the experiment. Randomization is best done by using table of random numbers.

Randomization tends to produce study groups comparable with respect to known as well as unknown risk factors, removes investigator bias in the allocation of subjects and guarantees that statistical tests will have valid significance levels.

Manipulation/Intervention

It is defined as deliberate application or withdrawal or reduction of a suspected causal factor. It creates an independent variable e.g. giving a drug or withdrawal of any risk factor, etc.

Follow-Up

It implies examination of the experimental and control group subjects at defined intervals of time, in a standard manner, with equal intensity, under the same given circumstances. Attrition (lost to follow-up) is inevitable. It means that some of the subjects may leave the study or the place of residence or refuse to participate at a later stage or die during the study, etc.

Assessment

It may produce a positive results or negative results.

TYPES OF RANDOMIZED CONTROLLED TRIALS

1. **Clinical Trials:** Concerned with evaluating therapeutic agents, mainly drugs, e.g. evaluation of beta-blockers in reducing cardiovascular mortality. All clinical trials are not susceptible to being blinded.
2. **Preventive Trials:** Preventive trial is related to assessing the efficacy of primary preventive measures, e.g. Vaccines, a drug as chemoprophylaxis, etc. Analysis of preventive trials should result in clear statement about benefits to community, risk involved and cost to health system.
3. **Risk Factor Trials:** Here investigator intervenes to interrupt the usual sequence in the development of disease for those individuals who have risk factor for developing the disease, e.g. primary prevention of CHD by using clofibrate to lowering the serum cholesterol.
4. **Cessation Experiment:** An attempt is made to evaluate the termination of a habit which is considered to be causally related to disease, e.g. Cigarette smoking and lung cancer.
5. **Trials of Etiological Agents:** It is to confirm or refute an etiological hypothesis.
6. **Evaluation of Health Services:** RCT helped in evaluation of the feasibility and effectiveness of domiciliary treatment of pulmonary tuberculosis whether it was as effective as more costly hospital or sanatorium treatment.

CLINICAL TRIALS

A clinical trial is operationally defined as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, procedure, or devices, process-of-care changes, preventive care, etc.). It measures causalty in terms of the effect of an intervention, i.e., if one alters the risk factor, does one alter the occurrence of the event/injury? "The most definitive tool for evaluation of the applicability of clinical research".

Importance of Clinical Trials

Clinical trials are important because they often lead to the development of more effective treatments. If a new treatment proves effective in a study, it may become a new standard treatment that can help many patients. Also, if the new treatment proves more effective than the standard treatment, study patients who receive it, may be among the first to benefit.

In addition, these studies answer important scientific questions, which can lead to future advances in care. Almost all progress in treatment has been gained through clinical trials.

Phases of Clinical Trials

Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious and effective. Clinical trials of experimental drug, treatment, device or behavioral intervention may proceed through four phases:

Phase I Clinical Trial: Phase I clinical trials are done to test a new biomedical or behavioral intervention in a small group of people (e.g. 20–80) for the first time to evaluate safety (e.g. determine a safe dosage range, and identify side effects).

Phase II Clinical Trial: Phase II clinical trials are done to study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.

Phase III Clinical Trial: Phase III clinical trial studies are done to study the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

Phase IV Clinical Trial: Phase IV clinical trial studies are done after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

PRINCIPLES FOR MAXIMIZING FOLLOW UP AND ADHERENCE TO THE PROTOCOL

1. Choose subjects who are likely to be adherent to the inter- vention and protocol.
2. Make the intervention easy.
3. Make study visit convenient and enjoyable.
4. Make measurement study painless, useful and interesting.
5. Encourage subjects to continue in the trial.
6. Find subjects who are lost to the follow-up.

ELEMENTS TO MONITOR CLINICAL TRIALS

1. Recruitment and randomization.
2. Adherence to intervention and blinding.

3. Follow-up completeness.
4. Important variables
5. Outcomes
6. Adverse effects
7. Potential co-interventions

(i) **Randomized Block Design (RBD):** It is an improvement over the Completely Randomized Design. In the RBD the principle of local control can also be applied along with the other two principles of experimental designs. In this design, sample subjects are first divided into groups (blocks/strata), such that within each group the subjects are relatively homogeneous in respect to some selected variable. The number of sample subjects in a given block would be equal to the number of treatments and one subject in each block would be randomly assigned to each treatment. Here two-way ANOVA is used.

(ii) **Latin Square Design (LSD):** When we are interested to study more than one treatment/therapy to be compared simultaneously to understand the efficacy of each, LS Design is applied.

Facts about the LSD

- It can be able to control variation in two directions.
- Treatments are arranged in rows and columns
- Each row contains every treatment.
- Each column contains every treatment.

The most common sizes of LSD are 5×5 to 8×8

Advantages of the LSD

These types of studies can control variation in two directions and increase efficiency as compared to the RCBD.

Disadvantages of the LSD

- The number of treatments must be equal to the number of replicates.
- The experimental error is likely to increase with the size of the square.
- Small squares have very few degrees of freedom for experimental error.
- It can't evaluate interactions between:
  a. Rows and columns
  b. Rows and treatments
  c. Columns and treatments.

(iii) **Factorial Design:** This research design is applied in experiments where the effects of varying and more than one factor are to be determined. Factorial designs can be of two types:

i. Simple factorial design, and
ii. Complex factorial design.

Most outcomes in research are likely to have several causes that interact with each other in a variety of ways that cannot be identified through the use of two-group experimental designs. For example, as discussed, the two-group pretest-posttest design might result in an undetectable interaction effect between pretest and the independent variable, such that post-test differences, if found, could not be confidently attributed to the independent variable. The Solomon four-group design, which may also be viewed as a factorial design, was able to control for this potential interaction.

The primary advantage of factorial designs is that they enable us to empirically examine the effects of more than one independent variable, both individually and in combination, on the dependent variable. The factorial design has several important strengths.

- It permits the simultaneous examination of more than one independent variable.
- It is more efficient because it allows us to test several hypotheses in a single research study.
- It is more economical to use a factorial design than to conduct several individual studies, in terms of both number of participants and researcher effort.
- It allows us to look for interactions between independent variables.

An investigator must choose a study design based on the research question, logistics and its applicability for the benefit of human race.

Chapter 7

RESEARCH ON DIAGNOSTIC TESTS

> Appearances to the mind are of four kinds. Things either are what they appear to be; or they neither are, nor appear to be; or they are and do not appear to be; or they are not, yet appear to be. Rightly to aim in all these cases is the wise-man's task.
>
> *– Epictetus, 2nd century AD*

INTRODUCTION

Medical tests, such as those performed to screen for a risk factor, diagnose a disease or estimate a patient's prognosis, are important for clinicians. There are some basic principles with which a clinician should be familiar when interpreting diagnostic tests. A diagnostic test is ordinarily taken to mean a test performed in a laboratory. But the principles are equally applicable to clinical information obtained from history, physical examination, and imaging procedures. They are also applied where a constellation of findings serves as a diagnostic test, thus one might speak of the value of prodromal neurological symptoms, headache, nausea, and vomiting in diagnosing classic migraine or hemoptysis and weight loss in a cigarette smoker as indicators of lung cancer.

For a test to be useful it must address the questions like accuracy, reproducibility, feasibility and effects on clinical decision and outcomes. Each test should be evaluated before administering to the human being. Following are the criteria for tests evaluation:

1. **Technological Capability:** Can the test be done in a laboratory setting?
2. **Range of Possible Use:** Does the test provide important diagnostic information in a number of different clinical situations?
3. **Diagnostic Accuracy:** Does the test provide information which allows a more accurate assessment of the presence or severity of a disease?
3. **Impact on Clinicians:** Does the result of the test make clinicians more confident of their diagnosis?
4. **Therapeutic Impact:** Will the result of the test alter our therapeutic decisions?
5. **Patient Outcome:** Does the patient benefit from the result of the test, in terms of altered morbidity and mortality?

The Accuracy of a Test Result

A simple way of looking at the relationships between a test's results and the true diagnosis is shown in Table 7.1. The test is considered to be either positive (abnormal) or negative (normal) and the disease is either present or absent. There are then four possible interpretations of the test results, two of which are correct and two wrong. The test has given the correct answer when it is positive, in the presence of disease or negative in the absence of the disease. On the other hand, the test has been misleading if it is positive when the disease is absent (false positive) or negative when the disease is present (false negative).

Assessment of the test's accuracy rests on its relationship to some way of knowing whether the disease is truly present or not—a sound indication of the truth often referred to as the 'Gold Standard'. Sometimes the standard of accuracy is itself a relatively simple and inexpensive test, such as throat culture for group A, β-hemolytic streptococcus to validate the clinical impression of Streptococcal throat infection or an antibody test for human immunodeficiency virus. However, this is usually not the case. More often, one must turn to relatively elaborate, expensive, or risky tests to be certain whether the disease is present or absent. Among these are biopsies, surgical exploration and autopsies.

For diseases that are not self-limiting and ordinarily become overt in few years after they are first suspected, the results of follow up can serve as a gold standard. Most cancers and chronic degenerative diseases fall into this category. For them, validation is possible even if on the spot confirmation of a test's performance is not feasible because the immediately available gold standard is too risky or expensive. Some care must be taken in deciding the length of the follow up period, which must be long enough for the disease to manifest, but not so long that cases can arise after the original testing.

TABLE 7.1 The gold standard

		Gold standard			
		Disease			
		Present	***Absent***	***Total***	
Test	Positive	a. True Positive	b. False positive	a + b	Positive Predictive Value (PPV) = a/ a + b
	Negative	c. False Negative	d. True Negative	c + d	Negative Predictive Value NPV = d/ c + d
Total		a + c	b + d	a + b + c + d	
		Sensitivity = a/ a + c	Specificity = d/ b + d		

Because it is almost always more costly and more dangerous to use these more accurate ways of establishing the truth, clinicians and patients prefer simpler tests to the rigorous gold standard, at least initially. Chest X-ray and sputum smears are used to determine the nature of pneumonia rather than lung biopsy with examination of the diseased lung tissue. Similarly, electrocardiograms and serum enzymes are often used to establish the diagnosis of acute myocardial infarction, rather than catheterization or imaging procedures.

The simpler tests are used as proxies for more elaborate but more accurate ways of establishing the presence of a disease, with the understanding that some risk of misclassification exists. This risk is justified by the safety and convenience of the simpler tests. But simpler tests are only useful when the risks of misclassification are known and found to be acceptably low. This requires sound data that compare their accuracy to an appropriate standard.

LACK OF INFORMATION ON NEGATIVE TESTS

The goal of all clinical studies in describing the value of the diagnostic tests should be to obtain data for all four of the cells shown in Table 7.1. Without all these data, it is not possible to assess the risks of misclassification. Given that the goal is to fill in all four cells, it must be stated that sometimes this is difficult to do in the real world. It may be that an objective and valid means of establishing the diagnosis exists, but it is not available for the purposes of formally establishing the properties of a diagnostic test for ethical or practical reasons. Consider the situation in which most information about diagnostic tests is obtained. Published accounts come primarily from clinical, and not research setting. Under these circumstances, physicians are using the test in the process of caring for patients. They feel justified in proceeding with more exhaustive evaluation, in the patient's best interest, only when preliminary diagnostic tests are positive. They are naturally reluctant to initiate an aggressive workup, with its associated risks and expenses, when the test is negative. As a result, information on negative tests, whether true negative or false negative, tends to be much less complete in the medical literature.

This problem is illustrated by an influential study of the utility of the blood test that detects Prostate Specific Antigen (PSA) in looking for prostate cancer. Patients with PSAs above a cutoff level were subjected to biopsy while patients with PSAs below the cutoff were not biopsied. The researchers understandably were reluctant to subject men to an uncomfortable procedure without supporting evidence. As a result, the study leaves us unable to determine the false-negative rate for PSA screening.

LACK OF OBJECTIVE STANDARD FOR DISEASE

For some conditions, there are simply no hard and fast criteria for diagnosis. Angina pectoris is one of these. The clinical manifestations were described nearly a century ago, yet there is still no better way to substantiate the presence of angina pectoris than a carefully taken history. Certainly, a great many objectively measurable phenomena are related to this clinical syndrome, for example, the presence of coronary artery stenosis seen on angiography, delayed perfusion on a thallium stress test, and characteristic abnormalities on electrocardiograms both at rest and with exercise. All are more commonly found in-patient believed to have angina pectoris. But none is so closely tied to the clinical syndrome that it could serve as the standard by which the condition is considered present or absent.

Sometimes, usually in an effort to be 'rigorous', circular reasoning is applied. The validity of a laboratory test is established by comparing its result to a clinical diagnosis based on a careful history of symptoms and a physical examination. Once established, the test is then used to validate the clinical diagnosis gained from history and physical examination. An example would be the use of manometry to 'confirm' irritable bowel syndrome, because the contraction pattern demonstrated by manometry and believed to be the characteristic of irritable bowel syndrome was validated by clinical impression in the first place.

CONSEQUENCES OF IMPERFECT STANDARD

Because of the difficulties mentioned earlier, it is sometimes not possible for physicians in practice to find information on whether they used a good test or not as compared to thoroughly trustworthy standard. They must choose as their standard of validity another test that admittedly is imperfect but is considered the best available. Just such a situation occurred in a comparison of real-time ultrasonography and oral cholecystography for the detection of gallstones. In five patients, ultrasound was positive for stones that were missed on cholecystography. Two of the patients later underwent surgery and gallstones were found, so that for at least those two patients, the standard oral cholecystogram was actually less accurate than the newer real-time ultrasound. Similarly, if the new test is more often negative in patients who really do not have the disease, results for those patients will be considered false negatives compared with the old test. Thus, if an inaccurate standard of validity is used, a new test can perform no better than that standard and will seem inferior when it approximates the truth more closely.

MEASURES OF DIAGNOSTIC ACCURACY

Various measures of diagnostic accuracy are usually determined by applying the test to one group of persons having the disease and to a

reference group not having the disease. A simple way of looking at the relationships between the test results and the true diagnosis **(by Gold Standard)** is shown in Table. 7.1. The test is considered to be either positive (abnormal) or negative (normal) and the disease either present or absent. There are then four possible interpretations of test result, two of which are correct, and two wrong. Thus when a gold standard is available, the categorization of test results into 'true positives' (disease present by both the tests), 'false positives' (disease present only by the test but not by the gold standard), 'true negatives' (disease absent by both the tests) and 'false negatives' (disease absent by the test but present by the gold standard) is best done by constructing a 2 × 2 table (Table 7.1).

From the table the following statistical parameters of diagnostic accuracy can be calculated:

1. **Sensitivity: *Synonyms*:** PiD rate (Positivity in Disease) and TP rate (True Positive rate)
   Definition: It has been defined as the ability of a test to identify correctly all those (true positive) who have the disease.
   Estimation: (Table 7.1) : Sensitivity= a/(a + c) × 100
   Calculation and Interpretation: (refer Table. 7.2)
   Sensitivity = 27/37 × 100 = 72.97% (Nearly 73.00%)
   A 73 percent sensitivity means that 73 percent of diseased people (culture positive) screened by the test (clinical diagnosis) will give a "true positive" result and the remaining 27 percent a "false negative" result.
   Use
   A sensitive test, i.e. one that is usually positive in the presence of disease, should be chosen when there is an important penalty for missing a disease. If the disease is very lethal (e.g. cervical cancer, breast cancer) and early detection markedly improves prognosis, test with a greater degree of sensitivity should be chosen and work-up can be relied on to rule out the disease in the false positives. That is, a proportion of false positives is tolerable but not false negatives. However, there are several other criteria, which need to be taken into consideration while choosing optimal sensitivity of a test.
2. **Specificity: Synonyms:** NiH rate (Negativity in Health) and TN rate (True Negative rate)
   Definition: It has been defined as the ability of a test to identify correctly those who do not have the disease, that is, "true negatives".
   Estimation: (Table 7.1): Specificity = d/(b + d) × 100
   Calculation and Interpretation: (refer Table 7.2):
   Specificity = 77 /112 × 100 = 68.75% (Nearly 69.00%)
   A 69 percent specificity means that 69 percent of the non-diseased persons **(culture negative)** screened by the test (clinical diagnosis) will give "true negative" result, and the remaining 31 percent "false

TABLE 7.2 Comparison of clinical diagnosis with throat culture results for *Streptococcal pharyngitis*

	Throat culture for group 'A' β-hemolytic streptococcus		
Clinical diagnosis of Streptococcal throat infection pharyngitis.	Positive	Negative	Total
Positive	a = 27	b = 35	a + b = 62
Negative	c = 10	d = 77	c + d = 87
Total	a + c = 37	b + d = 112	a + b + c + d = 149

positive" result. In other words, 31 percent of non-diseased people screened by the test (clinical diagnosis) will be wrongly classified as "diseased" when they are not.

Use

Specific tests are useful to confirm (or "rule in") a diagnosis that has been suggested by other data. This is because a highly specific test is rarely positive in the absence of disease—that is, it gives few false positive results. Highly specific tests are recommended in following situations.

For diseases like diabetes for which treatment does not markedly alter outcome, specificity must be high and early cases may be missed, but false positives should be limited; otherwise the health system will be overburdened with diagnostic demands on the positives, both true and false.

Highly specific tests are particularly needed when false positive result can harm the patient physically, or financially. Thus before patients are subjected to cancer chemotherapy, with all its attendant risks, emotional trauma, and financial costs, tissue diagnosis is generally required instead of relying upon less specific tests. That is, high specificity is necessary when false positive errors must be avoided.

Bias

Sometimes the sensitivity and specificity of a test are not established independently of the means by which the true diagnosis is established leading to biased assessment of the test's properties. This may occur in several ways. As already mentioned, if the test is evaluated using data obtained during the course of a clinical evaluation of patients suspected of having the disease in question, a positive test may prompt the clinician to continue pursuing the diagnosis, increasing the likelihood that the disease will be found. On the other hand, a negative test may cause the clinician to abandon further testing making it more likely that the disease if present will be missed.

In other situations, the test result may be part of the information used to establish the diagnosis or conversely, the results of the test may be interpreted taking other clinical information of the final diagnosis into

account. Radiologists are frequently subject to this kind of bias when they read X-ray. Because X-ray interpretation is somewhat subjective, it is easy to be influenced by the clinical information provided. All clinicians experience the situation of having X-rays over read because of a clinical impression, or conversely, of going back over old-X-ray in which a finding was missed because a clinical event was not known at the time and therefore attention was not directed to the particular area in the X-ray. Because of these biases, some radiologists prefer to read X-rays twice, first without and then with the clinical information. All of these biases tend to increase the agreement between the test and the standard of validity. That is, they tend to make the test seem more useful than it actually is, as for example, when an MRI of the lumbar spine shows a bulging disc in a patient with back pain.

Chance

Values for sensitivity and specificity (or likelihood ratios and other characteristics of diagnostic test discussed later in this chapter) are usually estimated from observations on relatively small sample of people with and without the disease of interest. Because of chance (random variation) in any one sample, particularly if it is small, the true sensitivity and specificity of the test can be misrepresented, even if there is no bias in the study. The particular values observed are compatible with a range of true values, typically characterized by the '95% confidence interval'. The width of this range of values defines the degree of precision of the estimates of sensitivity and specificity. Therefore, reported values for sensitivity and specificity should not be taken too literally if a small number of patients are studied.

The 95% confidence interval of a proportion is easily estimated by the following formula based on the binomial theorem:

$p = 1.96 \sqrt{p (1–p)/N}$, where 'p' is the observed proportion and 'N' is the number of people observed. The precision of estimates of sensitivity increases as the number of people on which the estimate is based increases.

False Negatives and False Positives

Whereas the epidemiologist thinks in terms of sensitivity, the clinician thinks in terms of false negatives and false positives. However, laboratory physician has to think in terms of both the characteristics, i.e. sensitivity and specificity of a test (pretest considerations) and false negative and false positives (post-test considerations).

3. **False Negative Rate:** The term "false negative" means that patients who actually have the disease (Gold standard positive) are told that they do not have the disease (Test result negative). A diagnostic test, which is very sensitive, has few "false negatives". The lower the sensitivity, the larger will be the number of "false negatives".

Estimation (Table 7.1): False negative rate = $c/(a + c) \times 100$

Calculation and Interpretation (Table 7.2): $10/37 \times 100 = 27.02\%$
Of all the diseased people (culture positive) screened by the test (clinical diagnosis), 27 percent showed false negative results. The sensitivity of a test (clinical diagnosis) is 73 percent and false negative rate is 27 percent.

Implications

False negative result means giving "false reassurance". The patient with a "false negative" test result might ignore the development of signs and symptoms and may postpone the treatment. This could be detrimental if the disease in question is a serious one and the test is unlikely to be repeated within a short period of time.

4. **False Positive Rate:** The term "false positive" means that persons who do not have the disease (Gold Standard) are told that they have disease (test result positive). A screening test with high specificity will have few false positives.

   Estimation (Table 7.1): False positive rate = $b/(b + d) \times 100$

   Calculation and Interpretation (Table 7.2): $35/112 \times 100 = 31.25\%$
   Out of all the non-diseased persons (culture negative) screened by the test (clinical diagnosis), 31 percent showed false positive results. The specificity of a test (clinical diagnosis) is 69 percent and false positive rate is 31 percent.

   Implications

   In this case, normal healthy people may be subjected to further diagnostic tests, at some inconvenience, discomfort, anxiety and expense—until their freedom from disease is established. Thus, false positives not only burden the diagnostic facilities, but they also bring discredit to screening/diagnostic program.

   Predictive Accuracy

   Our clinical concern is not a vertical one of sensitivity and specificity, but a horizontal one, i.e., meaning of positive and negative test results. For the clinician, the dilemma is to determine whether or not the patient has the disease, given the results of a test. We are thus more concerned to know—what is the probability of having the disease when test is positive? and what is the probability of not having the disease when test is negative? These properties of diagnostic tests are called as positive predictive value and negative predictive value respectively.

5. **Positive Predictive Value:**

   Synonyms: Predictive value of a positive test.
   Post-test likelihood of the target disorder following a positive test
   Posterior probability of the target disorder following a positive test
   Post-test probability of the target disorder following a positive test

Definition: The "predictive value of positive test" indicates the probability that a patient with a positive test result has, in fact, the disease in question or this is the proportion of patients with positive test results who have the target disorder.

Estimation (Table 7.1): Positive predictive value = a/(a + b) × 100 Calculation and Interpretation (Table 2): 27/62 × 100 = 43.55%. Nearly 44 percent of patients with positive test results (clinical diagnosis of strep throat) had really the disease (throat culture positive for group A beta-hemolytic streptococcus).

Features

- It reflects the diagnostic power of a test.
- The more specific the test is, the better will be the positive predictive value of the test.
- It depends on sensitivity, specificity and disease prevalence.
- The positive predictive value is directly proportional to the disease prevalence in population. This is in concordance with the Bayes' theorem of conditional probability.

Effect of Disease Prevalence

The predictive value of a test is not a property of the test alone; it is determined by the sensitivity and the prevalence of disease in the population being tested, where prevalence has its customary meaning—the proportion of persons in a defined population at a given point in time with the condition in question. Prevalence is also called prior (or P/pretest) probability of disease before the test result is known. The mathematical formula relating sensitivity, specificity, and prevalence to positive predictive value is derived from the Bayes's theorem of conditional probabilities:

$$\text{Positive predictive value} = \frac{\text{Sensitivity} \times \text{Prevalence}}{(\text{Sensitivity} \times \text{Prevalence}) + (1 - \text{Specificity}) \times (1 - \text{Prevalence})}$$

The more sensitive a test is, the better will be its negative predictive value (the more confident the clinician can be that a negative test result rules out the disease being sought) conversely, the more specific the test is, the better will be its positive predictive value (the more confident the clinician can be that a positive test confirms or rules in the diagnosis being sought). Because predictive value is also influenced by prevalence, it is not independent of the setting in which the test is used.

Positive result even for a very specific test, when applied to patients with a low likelihood of having the disease, when applied to patients with a higher chance of having the disease, are likely to be false negative. In sum the interpretation of a positive or negative diagnostic test result varies from setting to setting, according to the estimated prevalence of disease in the particular setting.

It is intuitively obvious what prevalence has to do with an individual patient. For those who are skeptical it might help to consider how a test would perform at the extremes of prevalence. Remember that no matter how sensitive and specific a test might be (short of perfection), there will still be a small proportion of patients who are misclassified by it, imagine a population in which no one has the disease.

In such a group all the positive results even for a very specific test, will be false positives. Therefore as the prevalence of disease in a population approaches zero, the positive predictive value of a test also approaches zero. Conversely, if everyone in a population tested has the disease, all negative results will be false negative even for a sensitive test. As prevalence approaches 100%, negative predictive value approaches zero.

6. **Negative Predictive Value:**

Synonyms: Predictive value of a negative test.
Post-test likelihood of not having the target disorder following a negative test
Posterior probability of not having the target disorder following a negative test
Post-test probability of not having the target disorder following a negative test

Definition: The "predictive value of negative test" indicates the probability that a patient with a negative test result does not, in fact, have the disease in question or this is the proportion of patients with negative test results who do not have the target disorder.

Estimation (Table 7.1): Negative predictive value = $d/(c + d) \times 100$

Calculation and Interpretation (Table 7.2): $77/112 \times 100 = 88.50\%$. Nearly 88 percent of patients with negative test results (clinical diagnosis of strep throat – negative) did not have the disease (throat culture negative for group A β-hemolytic streptococcus)

Features

- It reflects the diagnostic power of a test.
- The more sensitive a test is, the better will be the negative predictive value of the test (the more confident the clinician can be that a patient with a negative test result does not have the disease being sought).
- It depends on sensitivity, specificity and disease prevalence.
- It is inversely proportional to the disease prevalence in population.

Likelihood Ratio

As the prevalence of disease in a population approaches zero, the positive predictive value of a test also approaches zero and if the prevalence of disease in a population approaches 100 percent, the positive predictive value of a test also approaches 100 percent. However, as prevalence approaches 100 percent, negative predictive value approaches zero and if prevalence approaches zero, negative predictive

value approaches 100 percent. Thus predictive values are quite susceptible to prevalence. But, sensitivity and specificity are usually not affected by varying prevalence rates, Even if they are affected, much less so than the predictive values. In most clinical situations sensitivity and specificity are stable. However, predictive values are far more relevant to clinical and laboratory decision making, as they are patient oriented and focus attention on the probability of disease in a given patient rather than the probabilities of different test results. A clinician is, therefore, more likely to use predictive values and hence should be clear about the manner in which the prevalence of the disease in different clinical settings alters them. Likelihood ratios are also patient-oriented but are even more stable than sensitivity and specificity and are therefore likely to become more popular as diagnostic test evaluation statistics.

7. **Likelihood Ratio of a Positive Test Result**

Definition: This is the ratio of the proportion with a positive test result in those with disease to the proportion with a positive test result in those without disease, i.e. the odds that a positive test result would be expected in a patient with disease as opposed to one without it.

Estimation

$$\text{Likelihood ratio of a positive test result} = \frac{a/a+c}{b/b+d} = \frac{\text{Sensitivity}}{1-\text{Specificity}}$$

$$= \frac{\text{True positives}}{\text{False positives}}$$

Calculation and Interpretation (Table 7.2): 0.729/0.312 = 2.33 The likelihood ratio for a positive test result (clinical diagnosis of strep throat) is 2.33, and that means that clinical diagnosis of this sort is 2.33 times as likely to come from patients with throat culture +ve as from patients without throat culture +ve.

8. **Likelihood Ratio of Negative Test Result**

Definition: This is the ratio of proportion with a negative test result in those with disease to the proportion with a negative test result in those without disease, i.e. the odds that a negative test result would be expected in a patient with disease as opposed to one without it.

Estimation:

$$\text{Likelihood ratio of a negative test result} = \frac{c/a+c}{d/b+d} = \frac{1-\text{sensitivity}}{\text{Specificity}}$$

$$= \frac{\text{False negatives}}{\text{True negatives}}$$

Calculation and Interpretation (Table 7.2): 0.270/0.687 = 0.39 The likelihood ratio for a negative test result (negative clinical diagnosis) is 0.39, and that means that clinical diagnosis of this sort is 0.39 times

as likely to come from patients with throat culture positive as from patients without throat culture positive.

Properties of Likelihood Ratios

a. Because the proportions that make up the likelihood ratio are calculated "vertically" like sensitivity and specificity, likelihood ratios need not change with changes in the prevalence (or pretest probability) of the target disorder.
b. Likelihood ratios can be calculated for several levels of the sign, symptom, or laboratory test result.
c. It can be used in a very powerful way to shorten a list diagnostic hypotheses, because:

The pretest odds for the target disorder × the likelihood ratio for the diagnostic test result = the post-test odds for the target disorder.

As a result, if you start from your clinical estimate of the odds that your patient has a certain target disorder, and then carry out a diagnostic test and apply the likelihood ratio that corresponds to your patient's test result, you can calculate new, post-test odds for the target disorder.

With likelihood ratios, it is possible to summarize the information contained in a test result at different levels. One can define likelihood ratios for any number of test results, over the entire range of possible values. In this way, information represented by the degree of abnormality, rather than the crude presence or absence of it is not discarded. In computing likelihood ratios across a range of test result, sensitivity refers to the ability of that particular test result to identify people with the disease, not individuals with that result or worse. The same is true for the calculation of specificity. Thus likelihood ratios can accommodate the common and reasonable clinical practice of putting more weight on extremely high (or low) test result than on borderline ones when estimating the probability (or odds) that a particular disease is present.

9. **Receiver Operating Characteristic (ROC) Curve:** When the test result is expressed as a continuous variable (mg % or international units), there are obviously varying sensitivity and specificity rates for differing values of the test. The choice of cut-off points usually depends on the relative merits of sensitivity and specificity for the diagnosis of the disease in question.

The ideal cut-off values are those with the greatest net benefits of making a diagnosis and instituting therapy. However, generally there is a trade-off between the sensitivity and specificity of a diagnostic test. It is obviously desirable to have a test, which is both highly sensitive and highly specific. Unfortunately, this is frequently not possible. In order to evaluate the performance of a test over a range of possible cut-off values and also to compare different diagnostic tests, the Receiver Operating Characteristic (ROC) Curve is a very useful mode of analysis.

Properties of Roc Curve

a. **Best Cut-off:** The upper left-hand corner of Figure 7.1 denotes a perfect diagnostic test: a TP rate of 1.00 and FP rate of 0. It follows that the point on ROC curve that is closest to this upper left hand corner is the 'best' cut-off in terms of making the fewest mistakes when prevalence is around 50% (that is, its use minimizes the sum of false-positives and false-negatives). It is where (sensitivity + specificity) / 2 attains its highest value.

b. **Area Under Roc Curve:** Area under ROC curve can be calculated by either Wilcoxon statistics or trapezoidal rule. It indicates the overall predictive accuracy of a test.

c. Comparison of different diagnostic tests for the same disease:

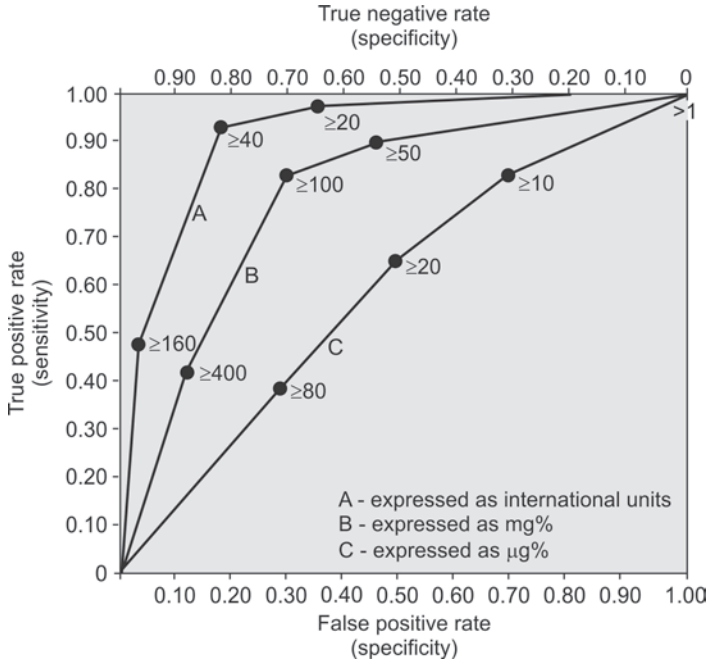


Fig. 7.1: ROC curve

The ROC curve can be used to compare the usefulness of two or more different signs, symptoms, or diagnostic tests for the same target disorder. All you need to do is plot their ROC curves: the one that lies farthest to the "north-west" is the more accurate. The curve, which goes diagonally across, is a very poor test. In comparing two or more different tests for the same disease, the areas under the respective curves should be compared for assessing relative diagnostic accuracy. The diagnostic test whose ROC curve encloses the largest area is the most accurate one.

10. **Agreement:** When a diagnostic test is being compared with a Gold standard, establishment of agreement between two is important. How much is the agreement between positive and negative results of two tests, has to be answered. It is also essential to evaluate the reproducibility of test interpretation by many different observers. If there is a wide disagreement between observers in interpreting the same set of test results, it renders the test useless for widespread clinical application. Two or more observers should independently evaluate the test results without having access to the clinical data. If the results are dichotomous, a chance-corrected index of agreement like Kappa should be calculated (Refer Tables 7.3 to 7.5).

    Observed agreement = a + d/N %

    As, agreement (observed) in part may be true agreement and in part it could be because of chance.

    Observed agreement = Chance agreement + actual (true) agreement

    = Agreement expected on the basis of chance + Actual agreement beyond chance.

    Agreement expected on the basis of chance = A + D / N

    Where, A = (a+c) (a+b) / N, D = (b+d) (c+d) /N

    Actual agreement beyond chance = Observed agreement – agreement expected on the basis of chance.

    Potential agreement beyond chance = 100% agreement expected on the basis of chance

    Kappa = Actual agreement beyond chance/Potential agreement beyond chance

TABLE 7.3 Agreement between two tests/observers

		Gold standard/First observer		*Total*
		Positive	***Negative***	
Test/Second	Positive	a	b	a + b
Observer	Negative	c	d	c + d
	Total	a+c	b+d	N = a+b+c+d

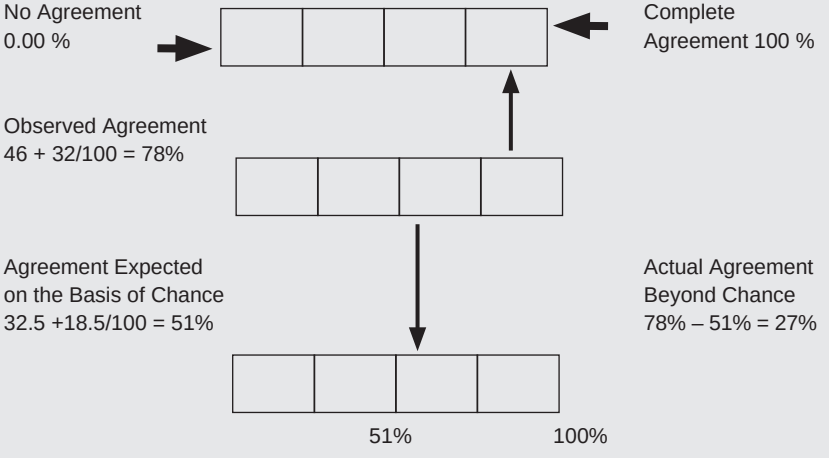
Quantitative terms to Kappa's

Landis & Koch		***Fleiss***	
0 – 0 .2	slight agreement	<0.4	Poor
0.2 – 0 .4	fair agreement	0.4-0.75	Fair to Good
0.4 – 0 .6	moderate agreement	>0.75	Excellent
0.6 – 0.8	substantial agreement		
0.8 –1.0	almost perfect agreement		

TABLE 7.4 Calculation of observed agreement in a 2 × 2 table

			Second Observer-Chlamydial inclusion bodies on Giemsa staining		
			Positive	***Negative***	***Total***
First Observer	Chlamydial inclusion bodies on Giemsa staining	Positive	46	10	56
		Negative	12	32	44
			58	42	100

TABLE 7.5 Developing a useful index of clinical agreement (Refer Table 7.4)



Kappa = $\frac{\text{Actual agreement}}{\text{Potential agreement}}$

= 27% / 49% = 0.55

(mod. agreement)

Potential Agreement Beyond Chance = 100% – 51% = 49%

Study Designs for Diagnostic Tests

For a test to be useful it must pass muster on a series of increasingly difficult questions that address its reproducibility, accuracy, feasibility, effects on clinical decisions and outcomes. Following are some questions to help to choose appropriate study design to solve research question.

Questions	*Possible Designs*	*Statistics for Results*
How reproducible is the test?	Studies of intra- and inter-observer and laboratory variability	Proportion agreement, Kappa, coefficient of variation, mean and distribution of differences
How accurate is the test?	Cross-sectional, case control or cohort type designs in which a test result is compared with Gold Standard.	Sensitivity, specificity, positive predictive value, negative predictive value, ROC, and likelihood ratio
How often do test results affect clinical decisions?	Diagnostic yield studies, Studies of pre-and post-test clinical decision making	Proportion abnormal, proportion with discordant results. Proportion of the tests leading to change in the clinical decision. Cost per abnormal result or decision change
What are the costs, risks and acceptability of the tests?	Prospective and retrospective studies	Mean costs, proportions, experiencing adverse effects, proportions willing to undergo test
Does doing the test improve clinical outcome or have adverse effects?	Randomized trials, cohort or case-control studies in which predictor variables are receiving the test and the outcome variable includes the morbidity, mortality or cost related to disease or to its treatment	Risk ratio, odds ratio, hazard ratio, number needed to treat, rates and ratios of desirable and undesirable outcomes

Sample Size Consideration in Research on Diagnostic Tests

Approaches

1. Sample size requirements for statistical comparisons of two performance characteristics
   - Comparing two variable proportions
   - Comparing two variable proportions, one with a fixed sample size
   - Comparing a variable and a fixed proportion
2. Sample size requirements for controlling confidence intervals to set confidence intervals to a desired size
3. Area under ROC curve and sample size
4. Likelihood ratios and sample size
5. Agreement and sample size:
   - Percent agreement
   - Kappa statistic

Sample Size Considerations

Specifications: Test Performance Characteristics:

- *Type I Error:* Error of falsely stating that two proportions are significantly different when they are actually equivalent.

- *Type II Error:* Error of falsely stating that two proportions are not significantly different when they are actually different.

Statistical Comparisons of Two Performance Characteristics

Test performance characteristics: Sensitivity, Specificity, Positive predictive value and Negative predictive value are used to determine the performance of a test to be applied. Proportions approach is used to calculate the sample size.

To determine the optimal sample size for comparing test A with test B, we need information on following parameters:

- An estimate of the expected value of the performance characteristic of interest for the reference test
- The smallest proportionate difference between the reference and the new tests considered to be medically important
- The level of significance required to accept two proportions as different, which is α (type I error), and
- The level of certainty desired to detect the medically important difference (statistical power).

Comparing Two Variable Proportions

$$n = [Z\alpha 2 \sqrt{(2\pi 0 - (1 - \pi 0))} + z\beta 1 \sqrt{(\pi a - (1 - \pi a))} + \pi b (1 - \pi b)) / (\pi a - \pi b)]2$$

where: n - sample size, πa—the estimated or assumed proportion of reference test A, πb—the proportion selected to be excluded in candidate test B π0—the combined proportion assuming no difference between πa and πb, So that if the same sample size is used in determining πa and πb, then π0 is (πa+ πb)/2

Zα2—is the two-tailed confidence interval for 1—α, expressed in terms of SD

Zβ1 – is the one-tailed confidence interval for 1—β

Biases in Research on Diagnostic Tests

Observer Bias

Blinding: Investigators should be blinded to the test results when interpreting the reference test, and blinded to the reference test results when interpreting the test.

Spectrum Bias: Indeterminate results dropped from analysis.

Reference Test Bias: Various Gold Standards are available for diagnostic tests. What happens when these Gold Standards are not available or What if the 'Gold Standard' is not gold after all? There are various methods to deal with the absence of a gold standard:

1. Correcting for Reference Test Bias (Gart and Buck)
2. Bayesian estimations (Joseph, Gyorkos, Coupal)
3. Latent class modeling (Walter, Cook, Irwig)

Bias Index: What if the test itself commits a certain type of error more commonly than the other? BI = (b–c)/N

Work-Up (Verification Bias)

It occurs when a test efficacy study is restricted to patients in whom the disease status is known. Bias is directly proportional to the association between selection for verification and the result of the test under study.

A study by Borrow et al (Am Heart J, 1983) on patients who were referred for valve surgery on the basis of echocardiography assessment reported excellent diagnostic agreement between the findings at echocardiography and at surgery (Table 7.6).

TABLE 7.6 Comparison of clinical diagnosis with throat culture results for *Streptococcal pharyngitis*.

Prevalence (Pretest likelihood or prior probability of disease)	Predictive value of a positive test (Posterior probability of disease following a positive test result)	Predictive value of a negative test (Posterior probability of no disease test result)	(Posterior probability of disease following a negative test result)
99 %	99.9 %	16 %	84 %
95 %	99.7 %	50 %	50 %
90 %	99.4 %	68 %	32 %
80 %	99 %	83 %	17 %
70 %	98 %	89 %	11 %
60 %	97 %	93 %	7 %
50 %	95 %	95 %	5 %
40 %	93 %	97 %	3 %
30 %	89 %	98 %	2 %
20 %	83 %	99 %	1 %
10 %	68 %	99.4 %	0.6 %
05 %	50 %	99.7 %	0.3 %
01 %	16 %	99.9 %	0.1 %
0.5 %	09 %	99.97 %	0.03 %
0.1 %	02 %	99.99 %	0.01 %

Diagnostic Suspicion Bias

The 'Test' and 'Gold Standard' should follow a randomized sequence of administration. This tends to offset the Diagnostic Suspicion Bias that may creep in, when the Gold Standard is always applied and interpreted. It will also balance any effect of time on rapidly increasing severity of the disease and thereby avoid a bias towards more positives in the test which is perfohrmed later.

Chapter 8

QUALITATIVE RESEARCH–CONCEPTS AND METHODS

"A form of social inquiry that focuses on the way people interpret and make sense of their experiences and the world in which they live."

– Immy Holloway

'Individuals are not in a vacuum but a whole life context'.

– Myers, Michael D (97)

INTRODUCTION

According to Denzin and Lincoln (2000), Qualitative research is a situated activity that locates the observer in the world. It consists of a set of interpretive, and material practices that make the world visible. These practices transform the world. They turn the world into a series of representations, including field notes, interviews, conversations, photographs, recordings and memos to the self. At this level, qualitative research involves an interpretive, naturalistic approach to the world. This means that qualitative researchers study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them.

Immy Holloway states that Qualitative Research is "a form of social inquiry that focuses on the way people interpret and make sense of their experiences and the world in which they live". Focusing upon the social reality of individuals, groups and cultures, **qualitative research** is used in the exploration of behavior and the perspectives and experiences of people studied. Behavior is determined by the way in which people interpret and make sense of their subjective reality. The basis of Qualitative Research lies in the interpretive approach to social reality.

Individuals do not live in a vacuum but within the context of their accumulated knowledge, life experiences and surroundings. Understanding, as opposed to explanation, can be gained from an empathetic approach rather than from the reflective reconstruction of others.

Qualitative research has traditionally been used predominantly in the social sciences, in the fields of sociology, anthropology and psychology, business and organizational studies, health care, social care and education.

Qualitative Research is also called, **naturalistic inquiry, field research, case study approach, interpretive (or interpretative) research, participant observation, interviewing and ethnography.**

Qualitative Researchers are sometimes seen as 'story tellers', because their findings are often presented in the form of a story line. [Immy Holloway-97].

The fundamental realities of qualitative research are that it is a multi-method discipline where no single method serves as a panacea for any given situation. Various approaches to qualitative research are: **Ethnography, grounded theory, phenomenology, conversation analysis, discourse analysis and cooperative inquiry.**

Qualitative research presupposes examination processes and meanings that do not gain sufficient description for the investigator by using quantitative methods or where quantitative methods alone are inappropriate.

Understanding the interaction between disease and society and delivering effective health care services relies not only on understanding the nature of health and disease, but also on understanding people and their beliefs about health, their health behavior and how they work in organizations such as health services. Social science is playing an increasing role in public health.

PURPOSES OF QUALITATIVE METHODS

- To emphasize on quality rather than quantity by understanding why do people do the things they do.
- To find out how behaviors, systems and relationships are maintained or change.
- To understand how social organizations function and ideology behind use of qualitative/PRA techniques.
- To stimulate action-experience-learning cycle of participants and community.

RESEARCH METHODS AND PHILOSOPHICAL PERSPECTIVES

A research method is a strategy of inquiry which moves from the underlying philosophical assumptions, to research design and data collection [Myers–99].

Qualitative research methods within social sciences have a number of recognizable characteristics which identify it from other areas of research: These are as follows:

i. Natural settings: Research is carried out in everyday life situations.
ii. Primacy of data: Theoretical framework is not pre-determined but derived from data as it is collected.
iii. Context bound: Researchers are sensitive to the context of research and immerse themselves in the 'setting' and 'situation'.
iv. Contextualism: Participants are grounded in the context of their history and temporality. Events and actions are studied as they occur in real life settings.

v. Immersion: Deals with familiarization and location, as far as possible, within 'the action' or within similar situations. This can include the reading of document and by observation.
vi. Thick description: Develops from the data and context, factual plus theoretical and analytic description. Grounded theory emphasises conceptualism rather than description. "Description is the cornerstone of Qualitative Research." Thick description generates empathetic and experiential understanding.

Relationship between researcher and researched/or listener and informer, aimed at being nonjudgmental where the goal is to pursue knowledge. There exist variations in approach to the manner in which relationships are conducted.

Underlying Assumptions: A valid research (quantitative or qualitative) is based upon some basic assumptions which relate to underlying epistemology (the theory of knowledge) which guides the research. Following are the 'paradigms' (epistemologies) for qualitative research (Table 8.1).

TABLE 8.1 'Paradigms' (epistemologies) for qualitative research

According to Guba and Lincoln	***According to Orlikowski and Baroudi***
Positivism	Positivism
Post-positivism	Interpretive
Critical theory	Critical
Constructivism	

Positivism

It is based on the natural sciences. Theories and hypotheses are tested and verified or falsified. Neutrality and objectivity are characteristics of this approach where personal biases are intended to be avoided. 'Interpretivist' researchers criticize this approach, as it is lacking in everyday subjective interpretations or context.

Post-positivism

A recent development of positivist ideas is that where complete objectivity (truth) is recognized as unachievable and that results are true, if all procedures to establish validity have been exhausted. Findings are viewed as not being absolute.

Interpretive (or Interpretative) Research

It explains how human beings interpret and make sense of reality, from the philosophy and human sciences, particularly history and anthropology.

Researcher approaches the participants not as individual who exist in a vacuum, but within the whole context of their lives.

Critical Theory

Critical theory takes the view that human beings are able to critically assess and change society and become emancipated. Objective reality is criticised. It is strongly influenced by 'values, judgments and interests of humankind'. The Feminist standpoint, action research and phenomenology are influenced to some extent by critical theory.

Constructivism

A break from the positivist tradition, the central issue in Constructivism is trustworthiness. Trustworthiness consists of four components Credibility, transferability, dependability, and conformity [Denzin & Lincoln (1998)].

TABLE 8.2 Typologies/Taxonomy of qualitative research methods

Evelyn Jacob (1987- 88)	*Atkinson, Delamont and Hammersley (1988)*	*Denzin and Lincoln (1994)*
Human Ethnology	Symbolic Interactionism	Case Studies
Ecological psychology	Anthropology	Ethnography
Holistic Ethnography	Sociolinguistic	Phenomenology and Ethnomethodology
Cognitive Anthropology	Ethnomethodology	Grounded Theory
Ethnography of Communication	Democratic evaluation	Biographical Method
Symbolic Interactionism	Neo-Marxist Ethnography	Historical Social Science
	Feminism	Participative Inquiry
		Clinical Research

Typologies/Taxonomy of Qualitative Research Methods (Table 8.2)

Naturalistic inquiry: The goal here is scientific explanation; in qualitative research naturalism means the study of people in their natural environment, not in a controlled or laboratory situation.

Field Research: It is the study and data collection in natural settings i.e. outside laboratories or libraries. It is an immersion of the researcher in the culture of the community. Data takes the form of field notes on the patterns of interaction as well as the rules and rituals they observe.

Case Study Approach: It is the study of a single unit that has clear boundaries, e.g. an organization, event, process, program, etc. This is used in quantitative and qualitative research. An event is studied in its context. Observation and documented research are the most common form of strategy used in case study research.

Ethnography: In ethnography 'Knowledge' is increased rather than 'application' in practice. It is the direct description of a culture or sub-culture. Ethnography is the research method of anthropology. It differs from other qualitative research methods because of its emphasis on Culture.

Ethnography is undertaken by observations, interviews and examination of documents. The main features of ethnography are: Collection of data from interviews, thick description and the naturalistic stance. In addition, work is undertaken with key informants and the emic/etic dimension considered.

In ethnography researchers observe their collaborators without prejudice or prior assumptions. No hypothesis is being tested. Implicit meaning and 'invisible' knowledge is uncovered.

Cognitive Ethnography: It has been proposed for the study of software tool development. This has been proposed because one of the criticisms of classical ethnography is that it fails to provide feedback into practice.

Emic/Etic Perspective: These terms were coined by Pike 1954 and widely used in ethnography. The emic perspective is the insider's or native's perception, while the etic perspective is the imposed framework of the researcher or outsider.

Epistemology: This is the theory of knowledge. Epistemological considerations depend on beliefs about the nature of knowledge.

Grounded Theory: This theory was developed by Barney Glaser and Anselm Strauss in the 1960's. Researchers start with an area of interest, collect the data and allow relevant ideas to develop. Rigid pre-conceived ideas are seen as to prevent development of research. Grounded theory is useful in such situations where little is known about a topic or problem area, or to generate new and exciting ideas in settings that have become static or stale.

Phenomenology: This is not a research method but a philosophical approach to the study of phenomena (appearances) and human experience. The exploration of the live experience of people which is mainly used in the areas of health, psychology and education. An analytical description of the phenomena is not affected by any prior assumptions. Phenomenological research is "what it means to be human".

Contextualism: In this, participants are grounded in the context of their history and temporality. Events and actions are studied as they occur in real life settings. Researchers' endeavor is not to change the context.

An understanding of context helps to locate the actions and perceptions, and hence grasp the meaning to be communicated. Context includes the economic, political and cultural framework.

Conversation Analysis: It is an examination of ordinary language. It questions, how everyday conversations and interactions work. Researchers

primarily examine speech patterns, facial expressions, gestures and body language.

Discourse Analysis

A discourse analysis considers what people do with words and how they achieve certain ends. Extra information can be contained within the text, i.e. neutrality, resentfulness, enthusiasm.

According to Immy, a discourse analysis is an analysis of text and language, often used in media and communication research to analyze message data. A discourse analysis focuses on the structure of 'talk' in social action. Emphasis is placed upon the reading of documents and verbatim transcripts repeatedly until complete familiarization is gained with the data.

"The discourse analysis discovers the language which operates within the particular discourse under study." E.g. Professional jargon.

Business is carried out through a variety of means: letter, telephone, meetings, e-mails, etc. A discourse analysis explores the hidden influences at work within the discourse.

Cooperative Inquiry

An individual facilitates research and other participants become co-researchers. There is a recognizable life-cycle of reflection, action, full immersion, and reflection. The cycle is followed by further iterative cycles.

Symbolic Interactionism

It is the interaction of human beings and the roles which they have. This term was coined by Herbert Blumer (1900-1987) in 1937. Symbolic interactionism is said to be an active and creative rather than passive. Researchers attempt to explain how people 'Fit their lines of action to those of others'. In this, subjects take account of each other's acts and interpret and reorganize their own behavior to one another, or their group. Symbolic interactionism is linked to many areas of qualitative research such as grounded theory, ethnography and conversational analysis.

Multiview

Multiview can be said to be an exploration in the information systems development.

It is recognized that some methodologies are not always suitable for particular situations. Multiview offers a flexible framework, using a blend of methodologies, which provides an alternative for choosing between different methodologies. Multiview includes stages which relate to the human and social dimension as well as the technical aspect. Multiview

provides a contingent approach whereby the tools and techniques adopted depend upon the particular circumstances. Multiview addresses problems associated with the analyses and design activities of information system definition. Multiview is a methodology to structure the tasks for the analysts and users during the analysis and design activities.

Triangulation

Most researchers do quantitative or qualitative research work by combining of one or more research methods is called a triangulation. The use of multiple perspectives is to interpret a single set of data: Denzin in 1978 identified four types of triangulation:

1. Data 2. Investigator 3. Theory 4. Methodological

Multiple perspectives can be limited by cost, time, and political constraints. The chosen strategy must be reasonable and practical.

Selection of the right method or combination of methods is important in Triangulation as more than one methodology may warrant a drain on resources. In a constrained budget situation inadequate resources may be spread across the spectrum of selected methods, resulting in many poorly implemented methods rather than one well executed method. Traditional qualitative research assumes that:

- Knowledge is subjective rather than the objective of truth.
- Researchers learn from the participants to understand the meaning of their lives but researchers should maintain neutrality.
- Society is structured and orderly.

Recent perspectives on qualitative research focus upon the "complex interplay of our own personal biography, power and status, interactions with participants, and written word."

HOW TO DO QUALITATIVE RESEARCH?

It is necessary to have adequate communication practices and cultural environments to obtain data for qualitative research. The systematic observation of events inferring the meanings of these events from the self-observations of the actors and spectators and techniques of interviewing and interpreting the material traces that are left behind by the actors and the spectators are crucial for valid analysis and adequate presentation .

Steps in Research Process

- Research Design
- Data Elicitation/collection
- Data Analysis
- Knowledge Interests

Choosing a Research Design

Choosing of a research design will depend on the following:

- Type of the problem to be researched.
- What is the question at hand? (research question)
- Which design or combination of designs will answer the basic research question(s)?

Research Design

- Case Study/Comparative Study/Sample Survey/Panel Survey
- Experimental/interventional
- Participant Observation

Sources of Data Collection: Following are the sources and method of data collection/ elicitation including participatory inquiry.

- Systematic observations
- Participant observations (fieldwork)
- Interviews (Individual/family/group)
- Questionnaires
- Focus group discussions
- Film, AV recordings
- Documents and Texts
- Researcher's Impressions and Reactions

Data Analysis: Researcher may choose one of the following methods of analysis depending on the research question and objectives:

- Statistical modeling
- Structural analysis
- Content analysis, coding, indexing
- Semiotic analysis
- Rhetorical analysis
- Discourse analysis

CLASSIFICATION OF QUALITATIVE RESEARCH PROCEDURES/ TECHNIQUES (FIG. 8.1)

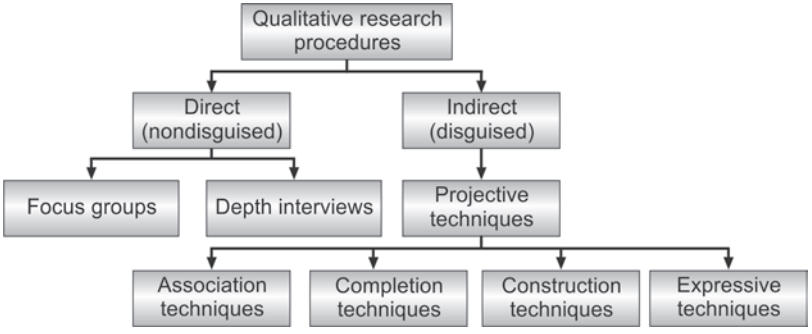


Fig. 8.1: Classification of qualitative research procedures/techniques

Qualitative research: One of the most common techniques is observational technique. Observation techniques may be classified as follows (Table 8.3):

TABLE 8.3 Observation techniques

Direct (Non-disguised) vs indirect (Disguised)	*Structured vs unstructured*	*Human vs Mechanical*
Direct: Observing behavior as it occurs **Indirect:** Observing the effects of behavior	**Structured:** Predetermine what to observe **Unstructured:** Monitoring of all behavior	**Human:** Observation done by human beings **Mechanical:** Observation by machine

Advantages of Observational Techniques: These are:

- ✓ Accuracy of data is better than direct questioning moreover, in natural settings people behave naturally
- ✓ Problems of refusal, not at home, false response, non-cooperation, etc. are absent
- ✓ No recall error
- ✓ In some situations, only way to get information.

Limitations of Observation Technique: These are:

- ✓ Time consuming,
- ✓ Too many things to observe
- ✓ May not be representative
- ✓ Difficulty in determining the root causes of the behavior.

PARTICIPATORY INQUIRY

Participatory inquiry is a structured methodology centered on the principle that participation is a moral right, in which multiple perspectives are sought through a process of group inquiry, developed for the specific context, and so using systematic methods to help people organize to bring about changes in problem situations that they see as improvements.

Participatory approaches offer a creative approach to investigating issues of concern to people, and to planning, implementing, and evaluating development activities. They challenge prevailing biases and preconceptions about people's knowledge. The methods used range from visualization, to interviewing and group work. The common theme is the promotion of interactive learning, shared knowledge, and flexible, yet structured analysis. These methods have proven valuable in a wide range of sectors and situations. Participatory approaches can also bring together different disciplines, such as agriculture, health and community development, to enable an integrated vision of livelihoods and well-being. They offer opportunities for mobilizing local people for joint action.

Systems of Inquiries: Researcher may choose one of the following systems of inquiry depending on the purpose of the study.

Community Action Planning (CAP); Beneficiary Assessment (BA); Development Education Leadership Teams Analysis (DELTA); Diagnosis and Design (D&D); Diagnostic Rural Rapid (DRR); Micro-Planning Workshops (MPW); Participatory Analysis and Learning Methods (PALM); Participatory Action Research (PAR); Participatory Monitoring and Evaluation (PME); Participatory Operational Research Projects (PORP); Participatory Policy Research (PPR); Participatory Research Methodology (PRM); Participatory Rural Appraisal (PRA); Participatory Rural Appraisal and Planning (PRAP); Participatory Social Assessment (PSA); Participatory Urban Appraisal (PUA); Planning for Real (PFR); Process Documentation; Rapid Appraisal; Rapid Assessment Procedures (RAP); Rapid Assessment Techniques (RAT); Rapid Catchments Analysis (RCA); Rapid Ethnographic Assessment (REA); Rapid Multi-perspective Appraisal (RMA); Rapid Organizational Assessment (ROA); Rapid Rural Appraisal (RRA).

Principles of Participatory Inquiry

The diversity and complexity is strength of these systems of inquiry. Despite the different ways in which these approaches are used, there are important common principles uniting most of them. These are as follows (Table 8.4):

TABLE 8.4 Methods for participatory inquiry

Group and team dynamic methods	*Sampling methods*	*Interviewing and dialogue methods*	*Visualization and diagramming methods*
- Team contacts	- Transect walks	- Semi-structured interviews	- Mapping and modelling
- Team reviews and discussions	- Wealth ranking and well-being ranking	- Direct observation	- Social maps and wealth rankings
- Interview guides and checklists		- Focus groups - Key informants	- Transects, Mobility maps - Seasonal calendars
- Rapid report writing	- Social maps	- Ethno histories and biographies	- Daily routines and activity profiles
- Work sharing (taking part in local activities) - Villager and shared presentations	- Interview maps	- Oral histories - Local stories, portraits and studies	- Historical profiles - Trend analyses and timelines, Matrix scoring
- Process notes and personal diaries			- Venn diagrams - Network diagrams - Systems diagrams - Flow diagrams, etc.

- ✓ A defined methodology and systematic learning process
- ✓ Multiple perspectives
- ✓ Group inquiry process
- ✓ Context specific
- ✓ Facilitating experts and stakeholders
- ✓ Leading to sustained action:

Eight-step approach in participatory enquiry:

Typically, participatory inquiry involves eight clearly defined steps. An outside team works with members of the local community to:

- Select a location and gain approval from local administrative officials and community leaders;
- Conduct a preliminary visit (steps 1 and 2 include community review and a planning meeting to share the purpose and objectives of the participatory inquiry and initiate dialogue between all parties as well as full participation);
- Collect both secondary and field data (spatial, time-related, social, environmental, economic and governance), and share information with selected communities;
- Synthesize and analyze that data;
- Identify problems and opportunities to resolve them;
- Use rank opportunities and prepare maps, action plans, reports and costing (including basic work plan for all members of the community);
- Adopt and implement the plan;
- Follow-up, evaluate and disseminate any findings, maintain momentum through addressing new issues.

Other Qualitative Techniques

In-depth Interview: An unstructured interview that seeks opinions of respondents on one-to-one basis. It is useful for sensitive issues like politics, rape, murder, menstruation, sex behavior, etc.

Protocol Analysis: Involves placing a person in a decision making situation and asking him/her to state everything he/she considers in making a decision. It is useful in:

- Purchasing which involves a long time frame (car, house), and
- Where the decision process is too short, e.g. buying a greeting card.

Projective Technique: It involves situations in which participants are placed in simulated activities hoping that they will divulge information about themselves that are unlikely to be revealed under direct questing.

- These are indirect interviewing methods which enable respondents to project their views, beliefs and feelings onto a third-party or into some task situation.
- The researcher sets up a situation for the respondents asking them to express their own views, or to complete/interpret some ambiguous stimulus presented to them.

Types of Projective Techniques

- Free word association
- Sentence completion
- Unfinished scenario/story completion
- Cartoon completion test

Free Word Association: In this technique, a list of carefully selected stimulus words or phrases related to the topic of research are read out, one at a time, to a respondent. The respondent is asked to respond with the first word or phrase that comes to his/her mind. The list of words should contain a mixture of test words and neutral words.

Sentence completion: This technique is an extension of the free-word association test. In this technique, the respondent is presented with some sentences containing incomplete stimuli and is asked to complete them. Like the free-word association method, interpreting and analyzing data obtained from this technique is also difficult.

Unfinished scenario Completion: This technique is similar to the sentence completion test. However, in this technique, the respondent is presented with a specific scenario containing incomplete stimuli and is asked to complete the scenario. Interpreting and analyzing data obtained from this technique is also difficult.

Cartoon completion test: In the cartoon technique, the respondent is shown a comic-strip like cartoon with two characters in a conversation. While the speech of one character is shown in his/her balloon, the other balloon is empty. The respondent is asked to assume the role of the other person and fill the empty balloon with a speech.

Some of the participatory inquiry methods are described below:

A. **Focus Group Discussion (FGD):** Focus Group Discussion (FGD) is a group discussion among approximately 6–12 persons guided by a facilitator, during which group members talk freely and spontaneously about a certain topic. A carefully planned discussion designed to obtain perceptions of a defined area of interest in a permissive and nonthreatening environment.

FGD can be Used

- To develop research hypotheses by exploring depth of the problem to be investigated and its possible causes.
- To formulate appropriate questions for more structured and larger scale surveys.
- To understand and solve unexpected problems in interventions.
- To develop appropriate messages for health education programs.
- To explore controversial topics.

An interview is conducted by a trained moderator, who have good observational, interpersonal, and communication skills, in a non-

structured and natural manner with a small group of respondents (6–12). The composition of the group should be homogeneous with pre-screened respondents. They should be relaxed in an informal setting. Time duration should be between 1–3 hours. The moderator should always use audio and video cassettes, if available.

PROCEDURE FOR FOCUS GROUP DISCUSSION

- Determine the objectives of the research project and define the problem.
- Specify the objectives of qualitative research.
- State the objectives/questions to be answered by the focus group.
- Write a screening questionnaire.
- Develop a moderator's outline and conduct the focus group interview.
- Review tapes, analyze data, summarize the findings and plan follow-up research.

TRAITS OF A GOOD FOCUS GROUP MODERATOR

A Good Focus Group Moderator–

- Must have experience in conducting focus group research.
- Should participate in conceptualizing the focus group research design, rather than simply executing the groups. Moderator should take responsibility for the recruitment, screening, and selection of participants.
- Must engage in advance preparation to improve overall knowledge of the area being discussed and prepare a detailed guide to moderate the focus group.
- Must demonstrate the enthusiasm and exhibit the energy necessary to keep the group interested and yet maintain control of the group without leading or influencing the participants.
- Should be open to modern techniques (e.g., attitude scaling, conceptual mapping, visual stimulation, or role-playing) which can be used to delve deeper into the minds of participants.
- Must share the feeling of urgency to complete the focus group while desiring to achieve excellent results of a research project; and
- Must provide some "added value" to the project beyond just conducting the session.

SEVEN ADVANTAGES OF FOCUS GROUP DISCUSSION (FGD)

1. **Synergism:** When a group of people with similar interests discuss an issue together, they are likely to produce a richer insight, wider

range of information, and innovative ideas than individual responses obtained privately.

2. **Snowballing:** In a group discussion, one person's comment often triggers a chain reaction from the other participants and generates more views.
3. **Stimulation:** Once the focus group discussion is underway, general level of excitement over the topic increases, and a large number of respondents want to express their ideas and expose their feelings.
4. **Security:** Because of homogeneity of composition, focus group participants have similar feelings. This enables them to feel comfortable and uninhibited to express their ideas/feelings.
5. **Spontaneity:** In focus groups participants are not required to answer specific questions. Their responses are spontaneous and unconventional reflecting an accurate idea of their views.
6. **Speed:** Because people discuss issues simultaneously, data collection and analysis in focus group proceed relatively quickly.
7. **Inexpensive:** Considering the richness of output, it is a relatively inexpensive method of data collection.

B. **Force Field Analysis (FFA):** It is used as a technique to uncover and analyze the pertinent positive and negative forces operating at field level and thus affecting the program implementation. It can be used to:
   - Investigate the balance of power involved in an issue
   - Identify most important player (Stakeholders)
   - Identify how one can influence each target group.

Process of FFA

- List all the forces driving change toward the desired situation.
- List all the forces resisting change toward the desired situation.
- Discuss and interrogate all forces: Are they valid? Can they be changed? Which are the critical ones?
- Allocate a score to each of the forces using a numerical scale, e.g. 1 is extremely weak and 10 is extremely strong.
- Chart the forces. List the driving forces on the left. And list the restraining forces on the right (Fig. 8.2).
- Determine whether change is viable and progress can occur.
- Discuss how the change can be affected by decreasing the strength of the restraining forces or by increasing the strength of driving forces.
- Remember that increasing the driving forces or decreasing the restraining forces may increase or decrease other forces or even create new ones.

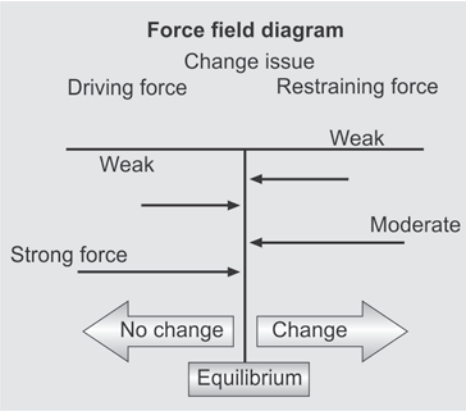


Fig. 8.2: Force field diagram

C. **Venn (Chapatti) Diagrams:** Venn diagrams provide a visual representation of the relationships and linkages between people and institutions. Circles of different sizes are allocated to different institutions, groups, departments, or programs, based on their importance. The bigger is the circle, the more important the institution or individual or event. The distance between circles, for example, may represent the degree of influence or contact between institutions or individuals.

Application

- The Venn diagram method has been found very useful to study and understand local people's perceptions of local institutions, individuals, programs, etc.
- The method provides valuable insights into power structures, decision-making processes, etc. Venn diagrams are particularly useful when analyzing:
  - Various institutions and individuals and their influence on local people
  - The influence of various groups and individuals in the locality
  - The relative importance and usefulness of services and programs
  - Social hierarchy in a locality, etc.

Process

- Explain the purpose of the exercise to the participants. Participants should list all local institutions, individuals, groups, etc. related to the research question on small cards.
- Participants should place the cards in a descending order according to the perceived importance of the institution. Encourage the participants to make changes, if necessary.

- Assign paper circles of different sizes (cut and kept ready) to the institutions or individuals. The bigger the circle, the more important the institution or individual is for them. Paste the circles and the name cards on paper.
- Draw a circle on the ground representing the community in the context of a specific variable, for instance accessibility.
- The circles should be close together if the ranking is high, while those ranking low on that variable can be kept far away.
- In some cases there are institutions/individuals that interact closely, they could be placed overlapping each other. The closer the circles, the higher the degree of interaction.
- Discuss and explain why participants placed the cards in such a manner. Note down the points of discussion and explanations. Copy the output onto a sheet of paper.
- Record the name of the village, participants, date, legends, what the size of the circle represents and what the distance represents.
- Thank the participants for their active involvement and time.
- Triangulate the diagram and the major findings with other community members.

Advantages and Limitations

- The Venn diagram is a simple but useful visual tool to study complex relationships between various institutions, groups, individuals, programs, etc.
- Despite its usefulness, it can be quite difficult to facilitate. If the facilitator approaches the exercise one step at a time.
- Venn diagram is quite manageable and neither the participants nor the facilitators get ahead of themselves in the process.

Example of drawing of Venn diagram (Fig. 8.3)

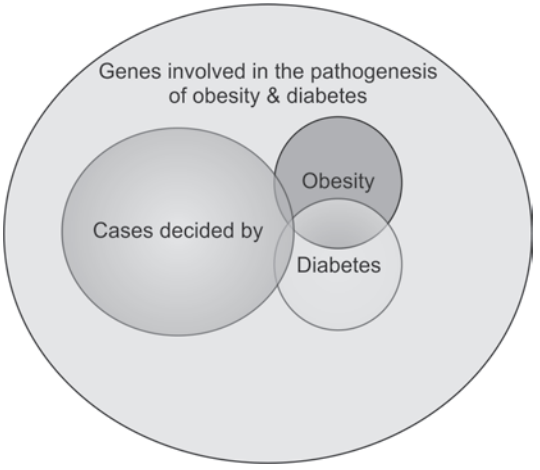


Fig. 8.3: Venn diagram

- The Venn diagram may also become a difficult exercise to conduct when the participants are in the presence of representatives from the institutions.

D. **Mapping:**

Why should We use Mapping?

Various types of maps can be used to analyze various aspects of a community life highlighting resources of importance (Tables 8.5 and 8.6). It is a good tool for stimulating debate over the importance of specific resources. Facilitators can locate or identify problem areas/important issues which could be prioritized in a long-term planning process. It can be used as baseline for impact analysis, monitoring and evaluation.

Who can Participate in Mapping?

Maps have been constructed with a range in group sizes, from one individual to around 50 (examples exist of up to 300 people!). Some facilitators prefer to work with smaller groups of around 8–10 individuals.

Some others have had experiences with larger groups where a high degree of participation still occurred. It is felt that maps made outside on the ground, and models, can cope with larger numbers. In many cases, large groups have been split along gender lines, with comparative maps made by men, women, and youth. Children have a great potential to act as analysts as well. Equally, there can be benefits in working with mixed groups to ensure debate and discussion.

When We should Use Mapping?

Maps have frequently been used early on, if not at the very start of, participatory exercises. They are generally easy to construct, and participants feel comfortable starting with mapping, before proceeding onto more complex diagrams. Social mapping leads easily into detailed social analysis of a location, which in turn, can be used for institutional analysis and a discussion of power structures within an area. Uses of maps include analyzing preferences for different items that have been identified on the map, such as crops or cropping patterns/treatments. Resource maps help to discuss flows of identified resources and movements in relation to both formal/informal markets.

Material to be Used for Mapping

Mapping is usually done with large number (25–50) representative of people from all the sections of the society of both genders and hence it is better to use ground as paper rather than actual paper. Ground paper has following advantages:

- The lack of boundary limitations
- Larger size and increased potential for participation, as well as greater ability to make alterations.
- The list of materials is endless, including the use of sticks to scratch marks in the soil, dust or mud, the use of twigs/sticks/branches, and the use of colored chalks or powders such as rangoli (colored powder), flour, ash or sawdust. Symbols can then be placed onto the map, or objects used such as stones, leaves, bits of wool, etc. After completion a photograph may be taken for further discussion and action.

Where paper is used, both flipchart and large rolls of paper such as wallpaper or newsprint have been useful, with a variety of colored pens and crayons. Additions to maps include the use of stickers of different shapes and colors, small labels, and so on. Beans and other counters can be laid onto maps to illustrate the relative importance of different elements.

Strengths and Weaknesses of Mapping

Weaknesses

- Facilitators and/or participants overly concerned with accuracy, neatness and presentation of the final product at the expense of process and discussion.
- Many facilitators express a difficulty in "getting started", particularly as this is often the first visual tool used, and participants (and facilitators) may lack confidence.
- The participants sometimes believe that they should reproduce a professional map of the area because it is more accurate.
- In areas where land tenure, rights or boundaries are uncertain, the process of mapping may raise underlying conflicts.
- In areas where security risks are high, people may feel threatened to open up in a mapping exercise. For instance, people may be concerned with revealing household assets to potential thieves.

Strengths

- Maps can provide a clear introduction to a discussion. This ensures that issues are not overlooked or ignored, while also establishing an outline for the discussion.
- This exercise ensures that the discussion is channeled through the map, and is therefore depersonalized to some extent.
- A participatory map can create a common orientation or understanding and provide a structure for ongoing analysis. They can become a basis for ongoing monitoring and evaluation.
- Specific issues or problems being discussed at a later stage in the process can be referred back to the initial maps, for example to see

if there is a relationship between a certain problem and social or resource aspects identified earlier.
- Maps can reflect strengths and potentials as well as weaknesses and problems, important for community reflection and confidence.

Social mapping: Social mapping is an ideal way to understand habitation patterns and the nature of infrastructure (such as drinking water facilities, drainage systems, etc.) within a community. Social mapping exercises are done by local people and not drawn to scale. Therefore, these exercises capture how community members perceive social dynamics within their locality.

Application

- Creating a basic understanding of the social and physical characteristics of a village .
- Collecting demographic data, such as detailed household specific information.
- Establishing a comfortable forum for discussion, where people are able to open up about the intricacies of social relations within their community.
- Social mapping provides the researcher with a visual picture of the area, and identifies the incidence and prevalence of different indicators.
- A social map is an interactive tool to gain insight on how different well-being groups live, and provides a means of comparison for factors such as proximity of different castes to water sources, government service-providers, etc.

Process of Social Mapping

- In order to conduct social mapping exercise, we must consult all stakeholders including community members to determine a convenient time and location. After gathering at a fixed day, date and time, explain the purpose to the participants and allow the participants to choose materials they would prefer to use. Now facilitator should invite participants to draw the prominent physical features of a locality.
- As the process unfolds, listen to the discussions carefully and take detailed notes of the proceedings. Facilitator should create an environment so that participants are able to take initiative, and become deeply involved in the process and proactively involve those who are left out of the process.
- If any clarification is required, wait for the appropriate moment, and be careful not to interrupt the process. Ask the community members, "What about. . . ?" or 'What does this symbol represent?".
- Once the mapping is complete, enumerate the households, and ask people to identify their homes. If specific information is required,

according to the purpose of the study, ask participants to depict the information interest. For instance, one may be interested in household-specific details, such as caste composition, number of school-age children, etc.
- Meticulously copy the map onto a large sheet of paper, making sure to include all details that the community has noted down.
- Be sure to include title of the exercise, names of the participants, characteristics of participants (socio-economic background, gender, occupation, etc.), location (i.e. locality name) names of the facilitators, legends and symbols necessary to interpret the output and then triangulate the information generated from the exercise with others in the locality.

Advantages of Social Mapping

- Social maps provide basis for discussion, as they provide a common orientation of the locality.
- Social maps can be utilized for problem identification, prioritization, and development of interventions for execution, monitoring and evaluation.
- This type of map in particular provides a great insight into the socio-economic stratification of a community, by analyzing the distribution and control of critical resources.
- Social map is a good exercise to break the ice with participants, because it involves a large number of people. Even the mostly shy person is eager to confirm whether his/her house is properly represented on the social map.
- Social mapping proves to be a non-threatening exercise that has the potential to build rapport with a community rather quickly.

Limitations of Social Mapping

- Sometimes reluctance from the community members.
- Lack of confidence, fear of being ridiculed by others, and the belief that maps are only made by experts, are the reasons of such hesitations.

Resource Mapping

Resource maps are one of the most commonly used PRA tools. The purpose of a resource map is to understand the natural resources of an area, such as the rivers, fields, vegetation, etc. Resource Maps are quite powerful tools, as it takes advantage of the community's unparalleled knowledge of their surroundings. Detailed visual representations of the position of resources, reflect candid perceptions of local people, and therefore are not drawn to scale. By avoiding precise measurement to scale, new insights into the realities of access to services and resources for different sectors of the community are illuminated.

Contents of Resource Mapping

Resource maps visually depict the location and condition of the natural resources of a community, such as:

- Water bodies, irrigation sources, drainage systems, etc.
- Crop development, cropping patterns, levels of productivity, etc.
- Topography, terrain, and slopes
- Forest, vegetation, and species
- Land and land use, tenure, boundaries, and ownership

Process of the resource mapping is similar to the social mapping.

Limitations of Resource Mapping

- In communities where issues like land holding and land tenure are sensitive to talk about, resource mapping is a difficult exercise.
- It is critical to be sensitive to these sentiments, and create a comfortable environment where community members are able to share their honest opinions.
- Many facilitators, particularly those who are not very experienced, find resource maps difficult to initiate. Although, once they start taking shape, the mapping proceeds rather smoothly.
- There can be a tendency to over-emphasize the final product, so it is important to be cognizant of the discussions during the mapping process.

Following are the figures of social map and resource map with details (Figs 8.4A and B).

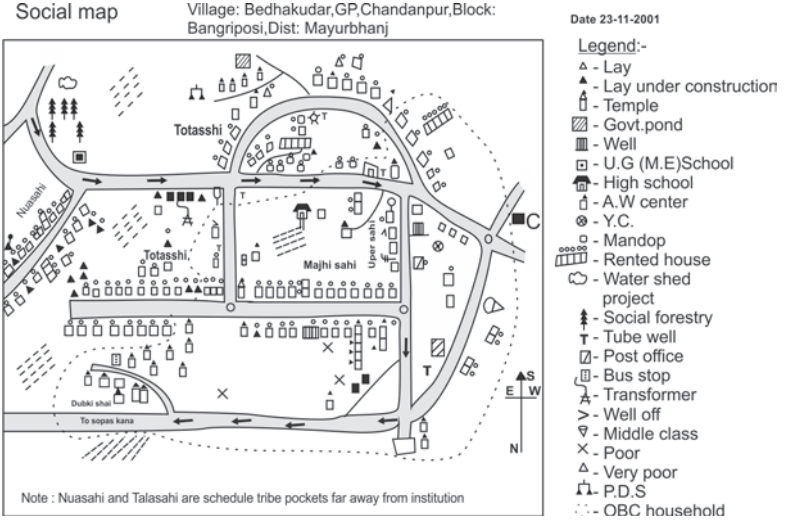


Fig. 8.4A: Social map

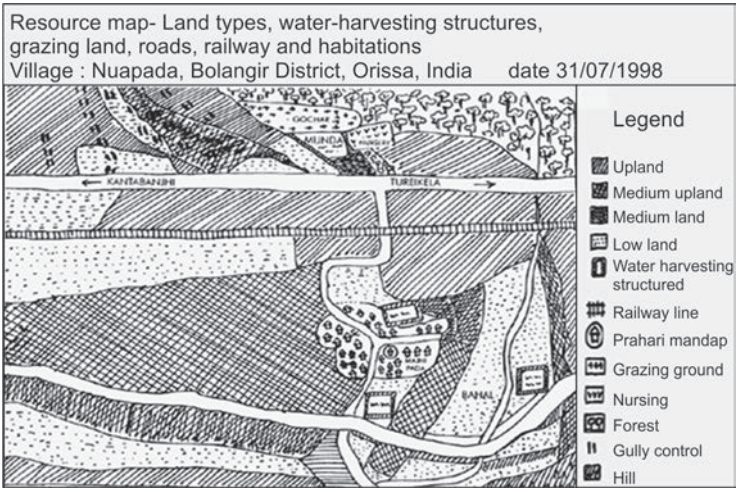


Fig. 8.4B: Resource map

TABLE 8.5 Types of mapping and uses

Name	*Key Terms/ Questions*	*People's Involvement*	*Any other Point*	*Scope for Improvization*	*Sequence*
Social Map	Habitation patterns, houses, social infrastructure A bird's-eye view of a locality The way people perceive their locality	Very high Allows a large number of participants to get actively involved Encourages creativity with regard to material and forms	Very useful to build the confidence of villagers Also useful for attitudinal change of facilitators	Very high People's creativity is at its best	Ideal for ice breaking Very useful in initial stages
Resource Map	Natural resources, land, fields, water resource	High	Useful for planning and management of natural resources	Very high People's creativity is at its best	Good for early stages
Transect	Cross-section view of an area Changes of land use across zones Natural resources	High	Physical verification as well as mapping	Moderate	Better after social and resource mapping

Contd...

Contd...

Name	*Key Terms/ Questions*	*People's Involvement*	*Any other Point*	*Scope for Improvization*	*Sequence*
Time Line/ Historical Profile	Major events in the life of an individual, organization, village, institution, country	High- especially of elderly persons	People speak their life story	Moderate	Useful in early stages for rapport building
Trend Analysis	Changes over time Magnitude of change Trends over time	Moderate—depends a lot on facilitation skills	Helpful in arriving at changes and causes there of	Moderate	Later stages
Seasonal Diagram/ Sea-sonality	Changes across seasons/ months Magnitude of change across seasons Period of scarcity, plenty/stress	High if simple steps and symbols are used	Useful for planning the timing of activities	High	Not in early stages

TABLE 8.6 Differences between qualitative and quantitative research

Qualitative research	*Quantitative research*
• Words used to represent and analyze social life • Focus on participants' perspective—what they see as important and significant • Researcher is close to research subjects so they can understand the world through their eyes • Theory emerges from the data • Research is in process—it unfolds over time, and considers the inter-relationships between activities, practices, and participants	• Numbers used to measure aspects of social life • Focus determined by researcher's agenda—what researcher believes is important and significant • Researcher is distant-uninvolved so as to maintain objectivity • Theory testing • Research is static—emphasis is on relationships between variables at one time, rather than as changing
• Research is unstructured—to discover actors' meanings; enables concepts to emerge from data • Aims to produce contextual understanding of behavior, values, beliefs • Data are rich, deep, contextualized • Focus on micro level-interaction • Focus on the meaning of action • Conducted in natural settings	• Research is structured to examine prescribed concepts and issues • Aims to produce results generalizable to relevant population • Data are hard, reliable, precise • Focus on macro level trends and connections between variables • Focus on behavior • Conducted in artificial environments

Chapter 9

VARIABLES

A variable is anything that can take on different values. For example, height, weight, age, race, attitude, and IQ are variables because there are different heights, weights, ages, races, attitudes, and IQs. By contrast, if something cannot vary, or take on different values, then it is referred to as a constant.

In other words, a VARIABLE is a characteristic of a person, object or phenomenon which can take on different values. These may be in the form of numbers (numerical) e.g. age, height, weight, etc. or non-numerical characteristics, e.g., sex, race, etc.

Types of Variables

Categorical variables are variables that can take on specific values only within a defined range of values. For example, "gender is a categorical variable. There is no middle ground when it comes to gender; you can either be male or female; you must be one, and you cannot be both. "race," "marital status" and "hair color" are other common examples of categorical variables. Although this may sound obvious, it is often helpful to think of categorical variables as consisting of discrete, mutually exclusive categories, such as "male/female," "white/black," and "single/married/divorced" (Table 9.1).

TABLE 9.1 Examples of categorical variables

Variable	*Categories*
Result of examination	Pass, fail.
Staple food eaten	Wheat, rice, potato, etc.
Color	Red, Blue, Green

Categorical variables can either be ordinal or nominal.

Ordinal variables: These are grouped variables that are ordered or ranked in increasing or decreasing order (Table 9.2):

Nominal variables: The groups in these variables do not have an order or ranking in them. They are mutually exclusive (Table 9.3).

Numerical variables: These variables are expressed in numbers e.g. person's age'. The variable 'age' can take on different values since a person can be 20 years old, 35 years old and so on. Other examples of

TABLE 9.2 Examples of ordinal variables

Stages of cancer	• Stage I, Stage II, Stage III, Stage IV
Disability	• No disability, partial disability, total disability • Mild • Moderate
Seriousness of a disease	• Severe
Agreement with a statement	• Fully agree, partially agree, fully disagree
Treatment outcome	• Completely treated • Partially treated • Not treated

TABLE 9.3 Examples of nominal variable

Sex	male, female
Main food crops	maize, millet, rice, etc.
Religion	Christian, Muslim, Hindu, Buddhism, etc.
Marital status	Married, unmarried

variables are: home-clinic distance, monthly income, number of children, etc. Numerical variables can either be continuous or discrete.

Continuous: These types of variables have fractions. One can develop more accurate measurements depending on the instrument used, e.g.: height in centimeters (2.5 cm or 2.546 cm or 2.543216 cm), temperature in degrees Celsius (37.2°C or 37.19999°C, etc.).

Discrete: These are variables in which numbers can only have full values without fractions, e.g.: number of visits to a clinic (0, 1, 2, 3, etc.), number of sexual partners (0, 1, 2, 3, etc.), number of children, etc.

Categorical Variables vs. Continuous Variables

The decision of whether to use categorical or continuous variables will have an effect on the precision of the data that are obtained. When compared with categorical variables, continuous variables can be measured with a greater degree of precision. In addition, the choice of which statistical tests will be used to analyze the data is partially dependent on whether the researcher uses categorical or continuous variables. Certain statistical tests are appropriate for categorical variables, while other statistical tests are appropriate for continuous variables. The choice of type of variable to be used partially depends on the question that the researcher is attempting to answer.

Independent Variables and Dependent Variables

The independent variable does not depend on the outcome being measured. More specifically, the independent variable is what causes or influences the outcome. The **dependent variable** is called "dependent"

because it is influenced by the independent variable. For example, in our hypothetical study examining the effects of medication on symptoms of anxiety, the measure of anxiety is the dependent variable because it is influenced by the independent variable (i.e. the medication).

The **dependent variable** is a measure of the effect /outcome (if any) of the independent variable.

Quantitative Variables vs. Qualitative Variables

Qualitative variables are variables that vary in kind, while **quantitative** variables are those that vary in amount. This is an important yet subtle distinction that frequently arises in research studies.

Examples: Rating something as "attractive" or "not attractive," "helpful" or "not helpful," or "consistent" or "not consistent" are examples of qualitative variables. In these examples, the variables are considered qualitative because they vary in kind (and not amount). For example, the thing being rated is either "attractive" or "not attractive," but there is no indication of the level (or amount) of attractiveness. By contrast, reporting the number of times that something happened or the number of times that someone engaged in a particular behavior are examples of quantitative variables. These variables are considered quantitative because they provide information regarding the amount of something.

It is important to note that a single variable may fit into several of the categories of variables. For example, the variable "height" is both continuous (if measured along a continuum) and quantitative (because we are getting information regarding the amount of height).

The variable "eye color" is both categorical (because there is a limited number of discrete categories of eye color) and qualitative (because eye color varies in kind, not amount).

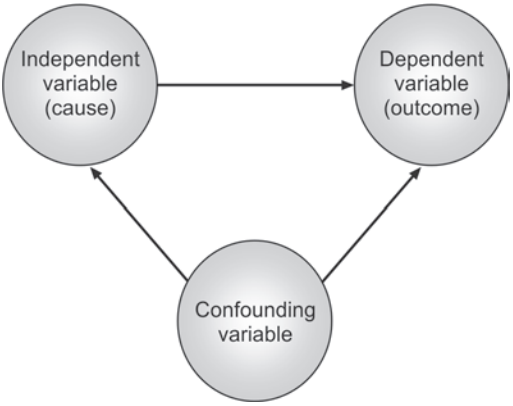
For example, in a study of the relationship between smoking and lung cancer, 'suffering from lung cancer' (with the values yes, no) would be the dependent variable and 'smoking' (varying from not smoking to smoking more than three packets a day) the independent variable.

Whether a variable is dependent or independent is determined by the statement of the problem and the objectives of the study. It is therefore important when designing an analytical study to clearly state which variable is dependent and which is independent one.

Note that if a researcher investigates why people smoke, 'smoking' is the dependent variable, and 'pressure from peers to smoke' could be an independent variable. In the lung cancer study 'smoking' was the independent variable.

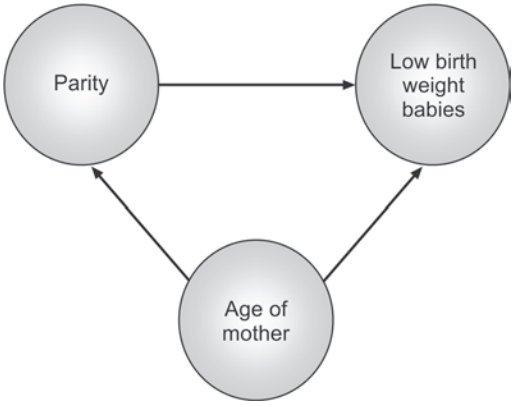
A variable that is associated with the problem and with a possible cause of the problem is a potential **confounding variable**.

A confounding variable may either strengthen or weaken the apparent relationship between the problem and a possible cause.



Therefore, in order to give a true picture of cause and effect, possible confounding variables must be considered, either at planning stage or while doing data analysis.

For example: A relationship is shown between parity and low birth weight babies. Mother's Age may be related to parity as well as to low birth weight babies.



Mother's age is therefore a potential confounding variable. In order to give a true picture of the relationship between parity and low birth weight babies, the influence of mother's age should be controlled. This could either be addressed in the research design, e.g. by selecting only mothers with a specific age, or it could be taken into account during the analysis of the findings by analyzing the relation between parity and low birth weight babies separately for age of mother.

Background Variables

In almost every study, background variables, such as age, sex, educational level, socio-economic status, marital status and religion are considered

(Table 9.4). These background variables are often related to a number of independent variables; so that they influence the problem indirectly (hence they are called background variables). Only background variables which are important to the study should be measured. Background variables are notorious 'confounders'.

TABLE 9.4 Example of a framework for defining variables

Variable	*Indicator*	*Scale of measurement*
Age	Age in completed years	Continuous: in years
Use of under-five clinic	Number of visits to under-five clinic	Discrete
Taste of food	Response to a specific question about his/her taste	Ordinal: Not tasty, tasty, very tasty
Religion	As reported by informant	Nominal: Hindu, Muslim, Buddhist, etc.

Example 1

In a study that is investigating why so many leprosy patients default from out-patient treatment, we first want to know, how much high the defaulter rate is: is it 10%, 30%, 50%? To obtain the defaulter rate we need a clear definition of what we mean by defaulting (how many times treatment was missed?).

We presume that dropout of leprosy treatment is strongly associated with the following factors:

- The patient's lack of knowledge concerning the actual duration of treatment and the danger of relapse or death when the full course is not completed.
- Living more than 10 km away from the clinic where the drugs have to be collected monthly; and wait for long time.
- Being between 20 and 40 years of age.

Factors Responsible for the Outcome are Rephrased as Variables

In the example 1: We can notice that most of what we called 'factors' are in fact variables which have negative values. We phrased the contributing factors negatively on purpose (e.g. lack of knowledge) as it is much easier to visualize these factors in the negative. However, in reality not everyone with good knowledge of leprosy treatment is a regular attender and not everyone with poor knowledge absconds from treatment. We can find-out by a study to determine to what extent these contributing factors play a role.

Therefore we have to formulate them in a neutral way, so that they can take on positive as well as negative values. The table below presents examples of negatively phrased 'factors' and how they can be rephrased as neutral 'variables'.

TABLE 9.5 Factors rephrased as variables (refer example. 1)

Factors for drop outs for treatment	*Variable*
• Poor knowledge about disease and its consequences	• Level of knowledge about disease and its consequences
• Long waiting time	• Waiting time
• Long distance	• Clinic distance from the residence
• Lack of monitoring	• Frequency of monitoring visit

OPERATIONALIZATION OF VARIABLES BY CHOOSING APPROPRIATE INDICATORS

Variables are more meaningful if they are made operational with one or more precise **Indicators**. Operationalizing the variables means to make them 'measurable':

In the example 1: The variable 'level of knowledge' cannot be measured as such. We need to develop a series of questions to assess the knowledge; the answers to these questions form an indicator of someone's knowledge on this issue, which can then be categorized. If 10 questions were asked, you might decide that the knowledge of those with:

0 to 3 correct answers is poor, 4 to 6 correct answers is reasonable, and 7 to 10 correct answers is good.

Defining variables and indicators of variables: To ensure that everyone understands exactly what has been measured and also to ensure consistency in the measurement, it is necessary to clearly define the variables and indicators of variables. For example, to define the indicator 'waiting time' it is necessary to decide what will be considered the starting point of the 'waiting period', e.g. is it when the patient enters the front door, or when he has been registered and obtained his card? Examples of common variables with different possible choices for indicators are given below in Table 9.6.

TABLE 9.6 Examples of variables with different options for indicators

Socio-economic status (Kuppuswamy classification)	Based on income, occupation , education
Income	Individual income, family income
Parity	Number of previous pregnancies, number of children delivered
Immunization	Number of infants immunized, total number of under-five children immunized

IDENTIFYING INDICATORS IN QUALITATIVE STUDIES

Certain variables cannot be defined with indicators before the study, because the information to do this is lacking. The purpose of the study may be to find this information. For example, policy makers in India would

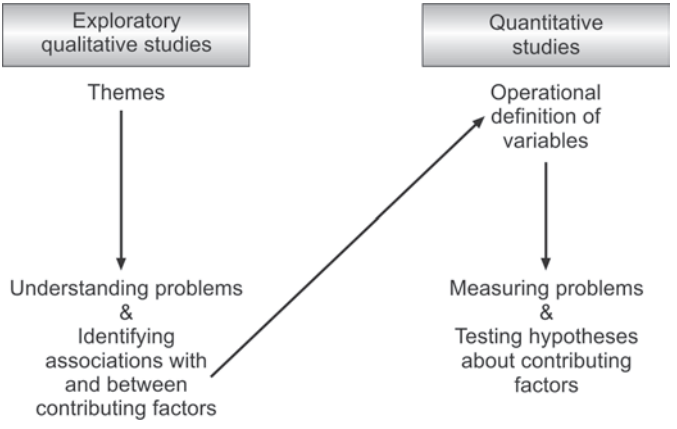
like to eliminate leprosy. They have noticed that fewer women report for leprosy treatment than men and would like to know whether stigma keeps women from reporting for treatment and/or whether the services have to be more sensitive to the needs of women for privacy at diagnosis.

Goffman (1963) defined stigma as an undesirable differentness that disqualifies a person from full social acceptance. However, we cannot fill in more precisely in what way men and women are discriminated against, as that has still to be studied. Some indicators for stigma could be the divorce rate of male and female patients, or the degree of isolation of the patient by the healthy spouse or by the community, but how the severity of this isolation should be measured is still unknown. Possibilities include, for example, whether patients and spouses still share a house, share food, share one bed? Do community members still accept leprosy patients as village leaders, do they welcome patients to attend village meetings, and, if so, do they still drink tea or eat together, and do they ask patients to bring their own cups?

One could state that in exploratory, qualitative studies, such as stigma, to understand better how patients suffer from stigma and how they cope with it, we can also discover contributing factors to stigma: in some societies women are more vulnerable to stigma than men; adolescents are more vulnerable than adults who have settled economically and socially; patients with deformities are always more vulnerable to stigma than those without visible signs.

With better understanding of the problem of stigma, we can operationalize the definition of the strength of stigma on a scale. This will enable us to measure through a quantitative study the degree of stigma male and female patients suffer from, and the most important contributing factors to stigma.

Relationship between qualitative and quantitative studies in understanding and measuring problems



Chapter 10

DETERMINATION OF SAMPLE SIZE

SAMPLE SIZE DETERMINATION

One of the most frequent problems in the application of statistical theory to practical applications is the determination of sample sizes for surveys and other empirical observations.

An appropriate sample size will produce accurate results. Using too large a sample creates more work, and may waste money. Using too small a sample may result in a difference not being detected or not being detectable. In most cases where the sample size is too small, no information is gained from the experiment at all, which implies that the effort, money and subjects (or material) involved are totally wasted. The patients/animals are subjected to unnecessary hardship; hence inappropriate sample size is definitely unethical.

One question statisticians are frequently asked is: "How large a sample must I take"? Decisions concerning the sample size for any experiment are based on the combination of statistics and common sense. In practice, the sample size is usually fixed by the number of subjects available, or the cost or time limits. However, even in the case where the sample size is determined by practical considerations, the sample size calculations are useful.

Sample size can indicate whether the experiment or survey is likely to be worthwhile, they will allow to determine what size differences is likely to be detected with the proposed experiment or survey. Adequacy of the sample size will depend on the following factors:

- **Degree of difference:** This is the difference between two groups, e.g. the difference between two means or proportions (control value and the expected test value).
- **Type I error:** This is alpha error- "the chances of detecting a difference which does not exist" (False Positive). It is usually set at 0.05 or 5%. This is also called the "level of significance".
- **Confidence level (CL):** The probability that an estimate of a population parameter is within certain specified limits of the true value. Denoted by $1-\alpha$ or $(1-\alpha) \times 100$ (in terms of %). When α is decided, Confidence Level is automatically fixed.

Alpha	*CL*
5%	95%
10%	90%

Confidence level is directly proportional to the sample size which means that 'Higher the confidence level, higher will be the sample size'.

- **Type II error:** This is beta error – "the chances of **NOT** detecting a difference which actually exists" (False Negative). It is usually fixed at 0.2 or 20%. 1–beta is called power (1–0.2 = 0.8)
- **Power of the test:** It is the probability of correctly rejecting a false null hypothesis. It is denoted by $1-\beta$. In terms of %, it is $100 \times (1-\beta)$ When β is selected, Power of Test is automatically fixed.

Beta	*Power*
10%	90%
20%	80%

- **Variation of results:** Standard Deviations of control mean and the test mean.
- **Drop out:** Expected drop out has to be determined and appropriate adjustment is done.
- **Non-compliance:** It will increase the variation and hence sample size has to be adjusted to the degree of expected non-compliance.

Z value (Standard Normal Distribution): $Z\ (1-\alpha)/2$, $Z(1-\alpha)$, and $Z(1-\beta)$ represent the number of standard deviations away from the mean. $Z(1-\alpha)/2$ and $Z(1-\alpha)$ are the functions of the confidence level, while $Z(1-\beta)$ is the function of the power of the test. Following are some of the commonly used 'Z' values at 95% confidence level:

a. Two sided test: $Z\ (1-\alpha)/2 = 1.96$ and one sided test: $Z(1-\alpha) = 1.65$
b. At 90% Confidence level: Two sided test: $Z\ (1-\alpha)/2 = 1.65$ and one sided test: $Z\ (1-\alpha) = 1.28$
c. At 90% Power: $Z\ (1-\beta) = 1.28$ and at 80% Power: $Z\ (1-\beta) = 0.84$

Sample size will also depend on the aim(s) of the study, reasonable guess of the expected result, how precise the result should be?, operational constraints and relevant information.

Methods: There are various methods to determine the sample size like:

- Arbitrary numbers (not recommended),
- From previous studies (may be/ may not be correct),
- Nomograms and tables can be used but may not be flexible and accurate,
- Formulas but they vary with study design and analysis
- Computer programs which are easy to use and usually based on formulae.

ESTIMATING SAMPLE SIZE WITH ABSOLUTE PRECISION

One Sample Situation

Example 1: To estimate the true immunization coverage in a community of under five children, the previous studies showed that immunization coverage is around 80%, where absolute precision, i.e., within 4% of the true value at confidence level = 95%.

Sample size 'n' = Z^2. p.(1–p)/d^2, where

- d = absolute precision = 0.04
- p = expected proportion in the population = 0.80
- Z (1–α)/2 = 1.96 = value of the standard normal distribution corresponding to a significance level of α (1.96 for a 2-sided test at the 0.05 level)

Hence 'n' = Z^2.p.(1–p)/d^2 = $(1.96)^2$ (.80) (.20)/$(0.04)^2$ = 384

Example 2: The medical officer wishes to estimate the prevalence rate of diarrhea among children aged less than 5 years in one of the localities of the primary health center. Calculate sample size if: True rate (p) = 20%, Absolute precision (d) = 5 percentage points (15% to 25%), Confidence level = (1–α)/2 = 95% i.e. 1.96.

n= Z^2(l–α)/2.p(l–p)/d^2 = Sample size (n) = 246 children

Estimating Sample Size with Relative Precision

Example 3: To estimate the true immunization coverage in a community of under five children, where previous studies showed that immunization coverage is around 80%, relative precision, i.e., within 10% of the true value at confidence level = 95%.

Previous studies tell us that there is 80% immunization coverage in a village

Relative Precision (e): Relative difference between sample coverage and true population coverage (we decide that we want this to be +/–10% of the anticipated population proportion of 80%)

Confidence level = 0.05, relative precision (e) = 10%
p = expected proportion in the population = 0.80, Z (1–α/2) = 1.96

a. For a relative precision of 10%
   n = Z^2. p .(1–p)/$(e.p)^2$ = $(1.96)^2$ (0.80)(0.20)/$(0.10 . 0.80)^2$ = 96
b. For a relative precision of 5%
   n = Z^2. p. (1–p)/$(e. p)^2$ = $(1.96)^2$ (0.80)(0.20)/$(0.05 . 0.80)^2$ = 384

Note: For p = 0.80, this is same as an absolute precision of 0.04.

Example 4: Calculate the sample size to estimate the proportion of pregnant women who seek prenatal care within the first trimester of pregnancy at a health center

- Percentage of women seeking such care (P) = 25% (as per the previous study)
- Relative precision (e) = 5% (of 25%), Confidence level = 95% (Z = 1.96),
- $n = Z^2.p(1-P)/(e^2P)$, Sample size = 4610 women

ABSOLUTE SIZE OF SAMPLE IS IMPORTANT, NOT THE SAMPLING FRACTION

P	*Sample size*
0.25	4610
0.30	3585
0.35	2854
0.40	2305

Estimating Sample Size Using Simple Random Sampling

- What is the approximate magnitude of the proportion (P)? e.g. Death due to diarrhea

  P = 2% [Q = 98%]
- What is the limit of accuracy (L) required? e.g. 25% of P, i.e., L = 0.5%
- What is the degree of confidence required ('Z' is appropriate factor)? e.g. 95% (Z = 1.96) i.e., the 95% confidence interval should be (Estimated percentage ± 0.5)
- What is the required sample size = $Z^2 PQ/L^2$ = $(1.96)^2 \times (0.02 \times 0.98)/(0.5)^2 = 3012$

Estimating Sample Size for One-sided Test

Example 5: A survey of a school in rural areas of Maharashtra, India showed that the prevalence rate of dental caries was 25%. How many children should be included in a new survey designated to test for a decrease in the prevalence of dental caries, if it is desired to be 90% sure of detecting a rate of 20% at 5% level of significance?

- Test caries rate = (Po) = 25%
- Anticipated caries rate = (Pa) = 20%
- Level of significance (α) = 5%
- Alternate hypothesis (one-sided) = (less than 25%)
- Power of the test ($1-\beta$) = 90%

$n = \{Z(1-\alpha)\sqrt{[P_o(1-P_o)} + Z(1-\beta)\sqrt{[P_a(1-P_a)}\}^2 \div (P_o-P_a)^2$

- Sample size

$$= \left[1.645\sqrt{25\times 75} + 1.283\sqrt{20\times 80}\right]^2 \div (25-20)^2 = 601$$

Estimating Sample Size for Two-sided Test

Example 6: In a hospital, success rate of a surgical treatment was 70%. How many patients are to be studied to test an alternative hypothesis that is not 70% at 5% level of significance? An investigator wants to have 90% power of detecting a difference between the success rate of 10 percentage point more in either direction.

- Test success rate = 70%
- Anticipated success rate = 60 or 80%
- Level of significance = 5%
- Power of the test = 90%
- Alternate hypothesis (two sided) = 70%

$n = \{Z\ (1-\alpha)/2\sqrt{}\ [P_o(1-P_o) + Z\ (1-\beta)\ \sqrt{}\ [P_a(1-P_a)\}^2 \div (P_o-P_a)^2$

$$\text{Sample size} = \left[1.96\sqrt{30\times 70} + 1.283\sqrt{40\times 60}\right]^2 \div (70-60)^2 = 233$$

TWO-SAMPLE SITUATIONS

Following information is required to calculate the sample size for two sample situations:

Estimating Sample Size for the Difference between Two Proportions with Absolute Precision

a.	Anticipated population proportions	P_1 and P_2
b.	Confidence level	100 (1–α)%
c.	Absolute precision required on either side of the true value of the difference between the proportions (percentage points)	d
d.	Intermediate value	$V = P_1\ (1-P_1) + P_2\ (1-P_2)$

Example 7: 40% of 50 coal mine workers in coal mining factory at digging point had anthracosis. 32% of 50 coal mine workers in coal mining factory at office had anthracosis. Estimate the true anthracosis risk difference within 5 percentage points with 95% confidence.

$$\text{Sample size} = Z^2\ P_1(1-P_1) + P_2(1-P_2)/d^2 =$$

$$(1.96)^2\ [40\times 60 + 32\times 68] \div (5)^2 = 707$$

Estimating Sample Size for the Difference between two Proportions with Standard Error

Example 8: It was found in a national survey that nurses leaving service and joining in another country for better prospects were as follows:

From District "A" 30% of nurses were leaving the job while in District "B" 15%. Investigator wished to find out the difference between two situations at 95% confidence limits 15% ± 10%, 2 × (s.e. of difference between proportions) = 10%, s.e = 5%

$$\text{s.e. of difference between proportions} = \sqrt{\frac{30 \times 70}{N} + \frac{15 \times 85}{N}}$$

$$= 5 \Rightarrow N = 135$$

Study size = 2 × 135 = 270

Sample Size for Two Population Proportions with One-tail Test

Proportion of patients developing complications after one type of surgery (P1) = 5%. Proportion of patients developing complications after another type of surgery (P2) = 15%. Determine that the second procedure has a significant higher complication rate than the first procedure at level of significance (α) = 5% (1–tail) , Power (1–β) = 90%

$$\text{Sample size} = \frac{\left\{\left[1.645\sqrt{2 \times 10 \times 90}\right] + \left[1.282\sqrt{5 \times 95 + 15 \times 85}\right]\right\}^2}{(5-15)^2}$$

= 53 in each group

Sample Size for Two Population Proportions with Two-tail Test

It can be calculated by the following formula:

$n = \{Z(1-\alpha)/2\sqrt{[2P(1-P)]} + Z(1-\beta)\sqrt{[P_1(1-P_1) + P_2(1-P_2)]}\}^2 / (P_1 - P_2)^2$

where

$P = (P_1 + P_2)/2$

Design Effect

A bias in the variance introduced in the sampling design, by selecting subjects whose results are not independent from each other; relative change (increase) in the variance due to the use of clusters. The design effect can be calculated after study completion, but should be accounted for at the designing stage

- The design effect is 1 (i.e., no design effect) when taking a simple random sample
- The design effect varies using cluster sampling; it is usually estimated that the design effect is 2 in immunization cluster surveys

Global variance: Variance simple random sampling (s r s) = p (1–p)/n

Cluster variance = $\Sigma(pi-p)^2 / k(k-1)$

p = global proportion, pi = proportion in each stratum

n = no. of subjects, k = no. of stratum

Design effect = cluster variance/variance s r s

Sample size for Simple Random/Systematic Sampling (As per example 1)

$n = Z^2 . P . (1–P)/d^2 = (1.96)^2 (.80) (.20)/(0.04)^2 = 384$

Sample size for Cluster Sampling: (As per example 1)

$N = g * Z^2. P. (1–P)/d^2 = 2*(1.96)^2 (.80) (.20)/(0.04)^2 = 768$

Z: alpha risk expressed in Z-score, P = expected prevalence, Q = 1–P

d: absolute precision, g = design effect = 2

Sample Size Estimation Based on Effect Size

An alternate approach to estimate sample sizes to control both Type I and Type II errors can be based on estimated effect size. Effect size is defined as the difference between a sample statistic, such as the mean, and the true value divided by the standard deviation.

Effect size = $\bar{x}\ \mu_0/s$

SAMPLE SIZE CALCULATION FOR VARIOUS EPIDEMIOLOGICAL STUDIES

A. Case-control Study

Estimating sample size based on odds ratio with specified relative precision

a. Two of the following should be known:
   - Anticipated probability of "exposure for people with disease" = a/ (a + b) = P_1*
   - Anticipated probability of "exposure for people without disease" = c /(c+d) =P_2*
   - Anticipated odds ratio = OR

b. Confidence level = 100 (l–α)%

c. Relative precision = *e*

When the number of people in the population who are affected by the disease is small relative to the number of people unaffected; c = (a + c) and d= (b + d), in this case, therefore the probability of exposure given no diseases (P_2*) is approximated by the overall exposure rate.

If the OR is more than 1, then P_2* and OR value are needed to calculate the sample size, Provided that P1* is known:

$OR = [P_1*/(1–P_1)*/P_2*/(1–P_2) + P_2]*$ and $P_2* = P_1*/[OR\ (1–P_1*) + P_2*]$

If OR < 1, the values of P1* and 1/O R should be used instead.

$n = Z^2\ (l–\alpha)/2\{l/[P_1(l–P_1)] + 1/[P_2(1–P_2)]\}/[\log_e(1–e)]^2$

Example 9: Calculate the sample size if an odds ratio of diarrhea is at least 3 in people who ate contaminated food as compared to those who did not eat, It is given (assumed) that 30% of people ate contaminated food.

$P_1 = 0.3$; $P_2 = 0.5625$; Type I error = 0.05(2-tail); Power = 90%

Food	*Diarrhea (case)*	*No diarrhea (Control)*
Contaminated	P_2	0.30
Not contaminated	$1–P_2$	0.70
	1.00	1.00

Odds ratio = $0.7P_2/0.3(1–P_2) = 3$; i.e. $P_2 = 0.5625$
Sample size required = 70 cases and 70 controls

B. Cohort Studies

Estimating sample size based on relative risk with specified relative precision

a. Two of the following should be known:
   - Anticipated probability of disease in people exposed to factor = P_1
   - Anticipated probability of disease in people not exposed to factor = P_2
   - Anticipated relative risk = RR

b. Confidence level = 100 $(1–\alpha)$%

c. Relative precision = e

$n = Z^2(1–\alpha)/2[(1–P_1)/P_1+(1–P_2)/P_2 \log._e (1–e)]^2$

SAMPLE SIZE CALCULATIONS FOR MEASURING ONE VARIABLE

Small letters in the formulae used below represent the following:

n – sample size
s – standard deviation
e – required size of standard error
r – rate
p – percentage

Single Mean

Example 10: Calculate the sample size for conducting the study to determine the mean weight of newborn babies. The mean weight is expected to be 2800 grams. Weights are approximately normally distributed and 95% of the birth weights are probably between 2000 and 3600 grams; therefore the standard deviation would be 400 grams. The desired 95% confidence interval is 2850 to 3000 grams, so the standard error would be 20 grams.

$n = s^2/e^2 = 400^2 /20^2 = 160000 /400 = 400$ newborn babies

Single Rate

Example 11: The maternal mortality rate in a country is expected to be 70 per 10,000 live births. A survey is planned to determine the maternal mortality rate with a 95% confidence interval of 60 to 80 per 10,000 live births. The standard error would therefore be 5/10,000. The required sample size would be:

$n = r/e^2 = 70/10000 \div (5/10000)^2 = 28000$ live births

Single Proportion

Example 12: The proportion of nurses leaving the health services within three years of graduation is estimated to be 30%. A study that aims to find causes for this, also aims to determine the percentage leaving the service with a confidence interval of 25% to 35%. The standard error would therefore be 2.5%. The required sample size would be:

$n = P(100–P)/e^2 = 30 \times 70 / 2.5^2 = 384$ nurses

Difference between Two Means (Sample size in each group)

Example 13: A study is being planned to find out the difference of the mean birth weights in district A and B. In district A the mean is expected to be 3000 grams with a standard deviation of 500 grams. In district B the mean is expected to be 3200 grams with a standard deviation of 500 grams. The difference in mean birth weight between districts A and B is therefore expected to be 200 grams. The desired 95% confidence interval of this difference is 100 to 300 grams, giving a standard error of the difference of 50 grams. The required sample size would be:

$n = s_1^2 + s_2^2/e^2 = 500^2 + 500^2/50^2 = 200$ newborn in each district

Difference between Two Rates (Sample size in each group)

Example 14: The difference in maternal mortality rates between urban and rural areas will be determined. In the rural areas the maternal mortality rate is expected to be 100 per 10,000 and in the urban areas 50 per 10,000 live births. The difference is therefore 50 per 10,000 live births. The desired 95% confidence interval is 30 to 70 per 10,000 live births giving a standard error of the difference of 10/10,000. The required sample size would be:

$$n = \frac{r_1 + r_2}{e^2} = \frac{100/10{,}000 + 50/10{,}000}{(10/10{,}000)^2}$$

$= 15{,}000$ live births in each area

Difference between Two Proportions (Sample size in each group)

Example 15: The difference in the proportion of nurses leaving the service is determined between two regions. In one region 30% of the nurses are estimated to leave the service within three years of graduation, in the other region 15%, giving a difference of 15%. The desired 95% confidence interval for this difference is 5% to 25%, giving a standard error of 5%. The sample size in each group would be:

$$n = \frac{p_1 (100 - p_1) + p_2 (100 - p_2)}{e^2}$$

$$= \frac{30 \times 70 + 15 \times 85}{5^2} = 135 \text{ nurses in each region}$$

Sample Size Calculations for Significant Difference between Two Groups

Small letters in the formulae used below represent the following:

n = samples size
s = standard deviation
e = required size of standard error
r = rate
p = percentage
u = one-sided percentage point of the normal distribution, corresponding to 100% - the power. The power is the probability of finding a significant result (e.g. if the power is 75%, u = 0.67,
v = percentage point of the normal distribution, corresponding to the (two-sided) significance level e.g. if the significant level is 5% (as usual), v = 1.96.

Comparison of Two Means (Sample size in each group)

Example 16: The birth weights in district A and B will be compared. In district A the mean birth weight is expected to be 3000 grams with a standard deviation of 500 grams. In district B the mean is expected to be 3200 grams with a standard deviation of 500 grams.

The required sample size to demonstrate (with a likelihood of 90%) a significant difference between the mean birth weights in district A and B would be:

$$n = \frac{(u + v)^2 (s_1^2 + s_2^2)}{(m_1 - m_2)^2}$$

$$n = \frac{(1.28 + 1.96)^2 (500^2 + 500^2)}{(3200 - 3000)^2}$$

$$= 131 \text{ newborn babies in each district}$$

Comparison of Two Rates (Sample size in each group)

Example 17: The maternal mortality rates in urban and rural areas will be compared. In the rural areas the maternal mortality rate is expected to be 100 per 10,000 and in the urban areas 50 per 10,000 live births. The required sample size to show (with a likelihood of 90%) a significant difference between the maternal mortality in the urban and rural areas would be:

$$n = \frac{(u + v)^2 (r_1 + r_2)}{(r_1 - r_2)^2}$$

$$= \frac{(1.28 + 1.96)^2 (100/10,000 + 50/10,000)}{(100/10,000 - 50/10,000)^2}$$

= 6299 live births in each area

Comparison of Two Proportions (Sample size in each group)

Example 18: The proportion of nurses leaving the health service is compared between two regions. In one region 30% of nurses are estimated to leave the service within three years of graduation, in the other region it is probably 15%.

The required sample size to show with 90% likelihood that the percentage of nurses is different in these two regions would be:

$$n = \frac{(u + v)^2 \{p_1 (100 - p_1) + p_2 (100 - p_2)\}}{(p_1 - p_2)^2}$$

$$n = \frac{(1.28 + 1.96)^2 (30 \times 70 + 15 + 85)}{(30 - 15)^2}$$

= 157 nurses in each group

Chapter 11

SAMPLING METHODS

Sampling is the process of selecting a number of study units from a defined population.

Some studies involve only a small number of people and thus all of them can be included. Often, however, research focuses on such a large population that, for practical reasons, it is only possible to include some of its members in the investigation. We then have to draw a sample from the total population.

In such cases we must consider the following questions:

- What is the reference and study population from which a sample is to be drawn?
- How many people are needed for the study?
- How will these people be selected?

The study population has to be clearly defined (for example, according to age, sex, and residence) otherwise we cannot do the sampling. Apart from persons, a study population may consist of villages, institutions, records, etc.

Each study population consists of study units depending on the problem to be investigated and the objectives of the study (Table 11.1).

TABLE 11.1 Examples of problems, study populations and study units

Problem	*Study population*	*Study unit*
Malnutrition related to breastfeeding	All children below 24 months of age in a given area	One child below 24 months of age in a given area
High drop out for DPT vaccination	All children below 24 months of age in a given area	One child below 24 months of age in a given area

REPRESENTATIVENESS

All study units in a sample should be drawn in such a manner so that it is representative of that population especially in case of quantitative research approaches. A representative sample has all the important characteristics of the population from which it is drawn.

Example: If 200 mothers are to be interviewed in order to obtain a complete picture of the breastfeeding practices in a District, these mothers

would have to be selected from a representative sample of villages. It would be unwise to select them from only one or two villages as this might give a distorted (biased) picture. It would also be unwise to only interview mothers who attend the under-fives clinic.

When using qualitative research approaches, however, representativeness of the sample is not a primary concern. In exploratory studies which aim at getting a rough impression of how certain variables manifest themselves in a study population or at identifying and exploring thus far unknown variables, one may try to select study units which give the richest possible information:

Example: Key informants should never be chosen at random, but purposively from among those who have the best possible knowledge, experience or overview with respect to topic of the study. Moreover, they should be willing to share this information.

Following figure 11.1 shows relationship between target population, intended sample and actual study sample:

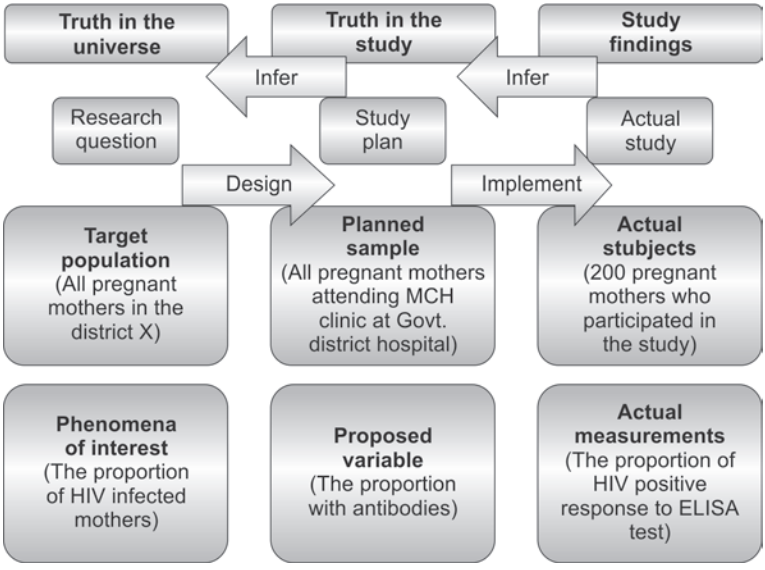


Fig. 11.1: Relationship between target population, intended sample and actual study sample

SAMPLING METHODS

As the rationale for the use of specific sampling methods in qualitative study designs is very different from the rationale underlying sampling methods in quantitative studies, These will be discussed separately, however, following are the major types of sampling methods used in medical and health research.

Probability Sampling (Random) Methods

- Simple random sampling
- Systematic sampling
- Stratified sampling
- Cluster sampling
- Multi-stage sampling
- Multi-phase sampling.

Non-probability Sampling (non-Random) Methods

- Convenience sampling
- Purposive sampling
  i. Extreme case sampling
  ii. Quota sampling
  iii. Homogeneous sampling
  iv. Typical case sampling
  v. Critical case sampling
  vi. Snowball or chain sampling.

PROBABILITY OR RANDOM SAMPLING STRATEGIES TO COLLECT QUANTITATIVE DATA

This type of sampling is useful to measure variables distributed in a population, e.g. diseases, disability, etc. or to test hypotheses, where factors are contributing significantly to a certain problems and we want to generalize the findings obtained from a sample to the total study population.

Probability sampling involves using random selection procedures to ensure that each unit of the sample is chosen on the basis of chance. All units of the study population should have an equal, or at least a known chance of being included in the sample.

Probability sampling requires that a listing of all study units exists or can be compiled. This listing is called the **sampling frame.**

Simple Random Sampling

This is the simplest form of probability sampling. Following procedure is to be adopted to select a sample unit:

a. Prepare or search for an existing numbered list of all the units in the population from which sample is to be drawn.
b. Decide on the size of the sample.
c. Select the required number of sampling units, using a 'lottery' method or tables of random numbers.

Example: A simple random sample of 50 students is to be selected from a school of 250 students. Using a list of all 250 students, each student

is given a number (1 to 250), and these numbers are written on small pieces of paper. All the 250 papers are put in a box, after which the box is shaken vigorously, to ensure randomization. Then, 50 papers are taken out of the box, and the numbers are recorded. The students belonging to these numbers will constitute the sample.

SYSTEMATIC RANDOM SAMPLING

In systematic sampling individuals are chosen at regular intervals, *e.g.* every 5th, from the sampling frame. Ideally we randomly select a number to tell us where to start selecting individuals from the list.

Steps to Achieve a Systematic Random Sample

- Number the units in the population (N)
- Decide on the n (sample size) that you want or need
- k = N/n = the interval size
- Randomly select an integer between 1 to k
- Then take every kth unit

Example: A systematic sample is to be selected from 1200 students of a school. The sample size selected is 100.

N = 1200, n = 100,

k = N/n = 1200/100 = 12

The sampling interval is, therefore, 12.

The number of the first student to be included in the sample is chosen randomly, for example by blindly picking one out of twelve pieces of paper, numbered 1 to 12. If number 6 is picked, then every twelfth student will be included in the sample, starting with student number 6, until 100 students are selected: the numbers selected would be 6, 18, 30, 42, etc.

Systematic sampling is usually less time consuming and easier to perform than simple random sampling. However, there is a risk of bias, as the sampling interval may coincide with a systematic variation in the sampling frame. For instance, if we want to select a random sample of days on which to count clinic attendance, systematic sampling with a sampling interval of 7 days would be inappropriate, as all study days would fall on the same day of the week (e.g., Tuesdays only, which might be a market day).

Stratified Random Sampling

The simple random sampling method described above has disadvantage that small groups in which the researcher is interested may hardly appear in the sample.

If it is important that the sample includes representative study units of small groups with specific characteristics (for example, residents from urban and rural areas, or different religious or ethnic groups), then the

sampling frame must be divided into groups, or strata, according to the characteristics. Random or systematic samples of a pre-determined size will then have to be obtained from each group (stratum). This is called Stratified sampling.

Stratified sampling is only possible if proportion of each group of the study population is known.

Example: A survey is conducted on household water supply in a district comprising 20,000 households, of which 20% are urban and 80% rural. It is suspected that in urban areas the access to safe water sources is much more satisfactory. A decision is made to include 100 urban households (out of 4000, which means 1 in 40 households) and 200 rural households (out of 16000, which mean 1 in 80 households). As the sampling fraction for both strata is now known, the access to safe water for all the district households can be calculated after the study (by multiplying the findings for the urban households by 40 and those for the rural households by 80, and then calculating statistics for the total sample).

Cluster (Area) Random Sampling

It may be difficult or impossible to take a simple random sample of the units from the study population at random, because complete sampling frame does not exist. Logistical difficulties may also discourage random sampling techniques (e.g. interviewing people who are scattered over a large area may be too time-consuming). However, when a list of groups of study units is available (e.g., villages or schools) or can be easily compiled, then a number of these groups can be randomly selected.
The selection of groups of study units (clusters) instead of the selection of study units (individuals) is called Cluster sampling.

Clusters are often geographic units (e.g., districts, villages) or organizational units (e.g., clinics, training groups).
In cluster sampling, we follow these steps:

- Divide population into clusters (usually along geographic boundaries)
- Randomly sample clusters
- Measure all units within sampled clusters

Example: In a study of the knowledge, attitudes and practices (KAP) related to family planning in rural communities of a region, a list is made of all the villages. Using this list, a random sample of villages is chosen and all study units in the selected villages are interviewed.

Multi-stage Sampling

For very large and diverse populations, sampling may be done in two or more stages. This is often the case in community-based studies, in which people are to be interviewed from different villages, and the villages have

to be chosen from different areas. This type of sampling is frequently used in Health System Research (HSR).

Example: In a study of utilization of pit latrines in a district, a total of 150 households are to be visited for interviews with family members as well as for observations on types and cleanliness of latrines. The district is composed of 6 wards and each ward has between 6 and 9 villages. The following sampling procedure could be performed:

1. Select 3 wards out of the 6 by simple random sampling.
2. For each ward select 5 villages by simple random sampling (15 villages in total).
3. For each village select 10 households. Since simply choosing households in the centre of the village would produce a biased sample, the following sampling procedure is proposed:
   - Go to the centre of the village.
   - Choose a direction in a random way: spin a bottle on the ground and choose the direction the bottleneck indicates.
   - Walk in the chosen direction and select every (or, depending on the size of the village, every second or third) household until you have the 10 you need. If you reach the boundary of the village and you still do not have 10 households, return to the centre of the village, walk in the opposite direction and continue to select your sample in the same way until you have 10. If there is nobody in a chosen household, take the next nearest one.

   Decide beforehand whom to interview (for example the head of the household, if present, or the oldest adult who lives there and who is available).

This is an adaptation of the method developed by the EPI division in WHO Geneva to measure EPI coverage in districts.

The main **advantages** of cluster and multi-stage sampling are that:

- A sampling frame of individual units is not required for the whole population. Existing sampling frames of clusters are sufficient. Only within the clusters that are finally selected is there a need to list and sample the individual units (if not using the bottle spinning method).
- The sample is easier to select than a simple random sample of similar size, because the individual units in the sample are physically together in groups, instead of scattered all over the study population.

However the **disadvantage** of Multi-stage sampling is:

Compared to simple random sampling, there is a larger probability that the final sample will not be representative of the total study population. The likelihood of the sample not being representative depends mainly on the number of clusters that is selected in the first stage. The larger the number of clusters, the greater is the likelihood that the sample will be representative. Further, the sampling units at community level should be selected randomly (avoid convenience sampling!).

Multi-phase Sampling

In this method, part of the information is collected from the whole sample and part from the sub sample. Example–Tuberculosis survey

Phase I

Mantoux test was performed on all cases of sample

Phase II

All persons positive for Mantoux test were subjected to X-ray chest(MMR)

Phase III

All those who were having clinical symptoms and X-ray positive were subjected to sputum examination for confirmation and diagnosis categorization.

NON-PROBABILITY OR NON-RANDOM SAMPLING

Convenience sampling is a method in which for convenience sake the study units that happen to be available at the time of data collection are selected in the sample. This may happen at the beginning of a study when researchers are merely orienting themselves, or, when there are many similar informants and the researchers do not have a preference for specific categories. When there seems no other choice (no one else available for an interview) researchers may also sample conveniently.

Purposive Sampling

Qualitative research methods are typically used when focusing on a limited number of informants, whom we select strategically so that their in-depth information will give optimal insight into an issue about which little is known. This is called purposive sampling. There are several possible strategies from which a researcher can choose. Often different strategies are combined, depending on the topic under study, the type of information wanted and the resources of the investigator(s).

In purposive sampling, we sample with a purpose in mind. We usually would have one or more specific predefined groups we are seeking. Some of the purposive sampling methods are as follows:

i. **Extreme case sampling:** Selection of extreme cases, such as good or very poor compliers to treatment, is a powerful and rapid strategy to identify contributing factors to poor compliance. In the same way, selection of well-nourished children of the same age will help to identify contributing factors for malnutrition.
ii. **Quota sampling:** In quota sampling, we select people non-randomly according to some fixed quota. There are two types

of quota sampling: Proportional and non-proportional. In **proportional quota** sampling we want to represent the major characteristics of the population by sampling a proportional amount of each. For instance, if we know the population has 40% women and 60% men, and we want a total sample size of 100, we will continue sampling until we get those percentages and then we will stop. So, if we've already got the 40 women for our sample, but not the 60 men, we will continue to sample men but even if legitimate women respondents come along, we will not sample them because we have already "met our quota." The problem here (as in much purposive sampling) is that we have to decide the specific characteristics on which we will base the quota. Will it be by gender, age, education race, religion, etc.?

Non-proportional quota sampling is a bit less restrictive. In this method, we specify the minimum number of sampled units we want in each category. Here, we're not concerned with having numbers that match the proportions in the population. Instead, we simply want to have enough to assure that we will be able to talk about even small groups in the population. This method is the non-probabilistic analogue of stratified random sampling in that it is typically used to assure that smaller groups are adequately represented in the sample.

Example: The stigma of leprosy, TB, HIV, epilepsy, is considered a complicating factor in the control of these diseases. In order to obtain insight in how stigma manifests itself in different cultures in males and females, in rural and urban areas, in well-to-do and poor patients, or in educated and illiterate ones, an investigator has to take care that all these groups are included in the sample. To assess whether social distance influences stigma, one could also interview blood relatives (parents or children), spouses, friends, near neighbors of patients and more distant community members. For leprosy and TB patients, it is useful to interview patients on treatment as well as patients declared cured, to assess if any reversal of stigma is experienced when patient's condition improves.

iii. **Homogeneous sampling:** If someone likes to have specific information about one particular group only, such as, a group which, for unclear reasons, is more at risk than others: For example, in a country, death registers indicate that suicide among adolescents is on the increase at an alarming rate and within that group twice as many boys as girls commit suicide. Researchers may, therefore, want to concentrate on the boys to identify what factors may be contributing to these suicides, conducting in-depth interviews with parents, other close relatives, teachers and friends of a number of boys who committed suicide.

In focus group discussions (FGDs), we usually select homogeneous groups because participants discuss more freely when they are amongst people of similar social status.

iv. **Typical case sampling:** It is sometimes illustrative to describe in-depth some cases which are 'typical' for the group one is interested in. For example, one may describe a 'typical' family in a rural area in a country A, or a 'typical' young school leaver who migrates from the rural area to town in search of work, or 'typical' health problems of miners or malnourished children. Such descriptions are merely illustrative; they cannot be generalized for the whole group. Typical examples can either be selected with cooperation of key informants who know the study population well, or from a survey that helps to identify the normal distribution and the pattern of the characteristics we are interested in.

v. **Critical case sampling:** Critical cases are those who 'can make the difference' with respect to an intervention you want to introduce or to evaluate.
Example: An investigator has developed a local weaning food that is considered to be affordable to all mothers. Before propagating it at a larger scale through MCH clinics, it is better to first interview and observe some low-income mothers as 'test cases'. If they manage to produce and use it, this will indicate that it is affordable to the whole group.

vi. **Snowball or chain sampling:** This approach is particularly suitable for locating key informants or critical cases. We start with one or two information-rich key informants and ask them if they know persons who know a lot about the topic of interest. If a particular person is recommended by two or three different people one can be quite sure that he or she will be a valuable key informant. The same approach can be used if an in-depth interview leads to discoveries, which seem rewarding to follow-up by a number of interviews with an additional group of informants.
Example: In an exploratory study on coping behavior among AIDS orphans, it seemed that child-headed households managed by girls survived better than those managed by boys. The researcher then interviewed more adolescent boys and girls heading households, to see whether this gender difference in ability to cope was real, and how it could be explained. Patton labeled this kind of additional sampling during the study **opportunistic sampling.**

Flexible sampling procedures, steered by the data one collects (in relation to the objectives) provide a major opportunity for qualitative researchers to optimally exploit the field situation and explore 'in-depth' interesting issues. It is exactly the opposite of the random sampling techniques discussed in the next section of

this module, which are used in quantitative research to ensure representativeness of the sample for the total population. Still, if qualitative researchers can choose from a group of seemingly similar informants they will also sample at random.

BIAS IN SAMPLING

BIAS in sampling is a systematic error in sampling procedures, which leads to a distortion in the results of the study.

Bias can also be introduced as a consequence of improper sampling procedures, which result in the sample not being representative of the study population.

Example: A study was conducted to determine the health needs of a rural population in order to plan primary health care activities. However, a nomadic tribe, which represented one-third of the total population, was left out of the study. As a result the study did not give an accurate picture of the health needs of the total population.

There are several possible sources of bias that may arise when sampling. The most well-known source is non-response.

Non-response can occur in any interview situation, but it is mostly encountered in large-scale surveys with self-administered questionnaires. Respondents may refuse or forget to fill in the questionnaire. The problem lies in the fact that non-respondents in a sample may exhibit characteristics that differ systematically from the characteristics of respondents.

There are several ways to deal with this problem and reduce the possibility of bias:

- Data collection tools (including written introductions for the interviewers to use with potential respondents) should be pre-tested. If necessary, adjustments should be made to ensure better cooperation.
- If non-response is due to absence of the subjects, follow-up of non-respondents may be considered.
- If non-response is due to refusal to cooperate, an extra, separate study of non-respondents may be considered in order to identify to what extent they differ from respondents.
- Another strategy is to include additional people in the sample, so that non-respondents who were absent during data collection can be replaced. However, this can only be justified if their absence was very unlikely to be related to the topic being studied.

  Other sources of bias in sampling may be less obvious, but may be serious:

  – **Studying volunteers only:** The fact that volunteers are motivated to participate in the study may mean that they are also different from the study population on the factors being studied. Therefore,

it is better to avoid using non-random selection procedures that introduce such an element of choice.

– **Sampling of registered patients only:** Patients reporting to a clinic are likely to differ systematically from people seeking alternative treatments.

- **Missing cases of short duration.** In studies of the prevalence of disease, cases of short duration are more likely to be missed. This may mean missing fatal cases, cases with short illness episodes and mild cases.
- **Seasonal bias.** It may be that the problem under study, for example, malnutrition, exhibits different characteristics in different seasons of the year. For this reason, data should be collected on the prevalence and distribution of malnutrition in a community during all seasons rather than just at one point in time. To take another example, when investigating health services' performance, one has to consider the fact that towards the end of the financial year shortages may occur in certain budget items which may affect the quality of services delivered.
- **Tarmac bias.** Study areas are often selected because they are easily accessible by car. However, these areas are likely to be systematically different from more inaccessible areas.

ETHICAL CONSIDERATIONS

If the recommendations from a study will be implemented in the entire study population, one has the ethical obligation to draw a sample from this population in a representative way. If during the research new evidence suggests that the sample was not representative, this should be mentioned in any publication concerning the study, and care must be taken not to draw conclusions or make recommendations that are not justified.

Chapter 12

ANALYSIS OF QUANTITATIVE DATA

The data collected in the study need to be systematically analyzed so that trend and patterns of relationship can be detected. Statistical procedures enable the investigator to summarize, organize, interpret and communicate numeric information. The statistics are classified in the following categories:

- **Descriptive statistics**
- **Inferential statistics**

DESCRIPTIVE STATISTICS

These are used to describe and synthesize data. Frequency counts, tables, graphs, averages, minimum, maximum, range, standard deviation, and percentages are some examples of the descriptive statistics.

A. Frequency Distribution

A frequency count is an enumeration of a certain measurement or certain answer to a specific question. From the data master sheets, simple counts, tables, and graphs, etc. are prepared for each variable.

B. Tables

Table is a set of data arranged in rows and columns. Almost any quantitative information can be organized into a table. Tables are useful for demonstrating patterns, exceptions, differences, and other relationships. A table should be self-explanatory.

Following are the guidelines to prepare a table:

- Use a clear and concise title that describes 'what', 'where', and 'when' of the data in the table. Table number should be placed before the title.
- Label each row and each column clearly and concisely and include the units of measurement for the data, e.g. years, mmHg, mg/dl, rate per 100,000.
- Show totals for rows and columns (as required).

- Explain any codes, abbreviations, or symbols in a footnote.
- Mention any exclusion in a footnote, e.g. 1 case and 2 controls with unknown family history were excluded from this analysis.
- Mention the source of the data in a footnote if the data are not original.

Types of tables:

a. One variable (Table 12.1)
b. Two or more variables (Table 12.2)

Example: One variable table

TABLE 12.1 Age-wise distribution of dengue morbidity by age, Wardha, India, 2008

Age groups (in years)	*Number of cases*
20-30	16
30-40	18
40-50	11
50-60	11
60-70	3
70-80	1
Total	60

Example: Two-Variable table

TABLE 12.2 Distribution of colon carcinoma patients by age and sex, Benghazi, 2009

Age in yrs	*Male*	*Female*	*Total*
< 30	1	0	1
31-40	0	4	4
41-50	5	4	9
51-60	6	8	14
61-70	15	4	19
>70	3	0	3
Total	30	20	50

Steps for preparation of frequency distribution table with class interval:

Divide the range into equal class intervals: This method is the simplest, most commonly used, and readily adapted to graphs. The following procedure may be adopted to apply this method:

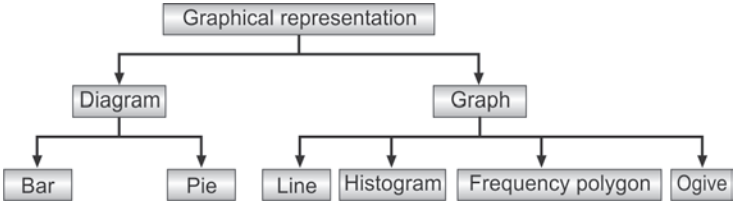
1. Find out the range of the values in the data set, i.e., to find out the difference between the maximum value and the minimum value.

2. Decide number of class intervals (groups or categories). Generally 4 to 8 class intervals for tables and 3 for graphs and maps. The number of class intervals will depend on the nature of the data.
3. Find out the size of class interval, i.e., the range divided by the number of class intervals.
4. Begin with the minimum value as the lower limit of first class interval and specify the size of class intervals until the maximum value in the data is reached.

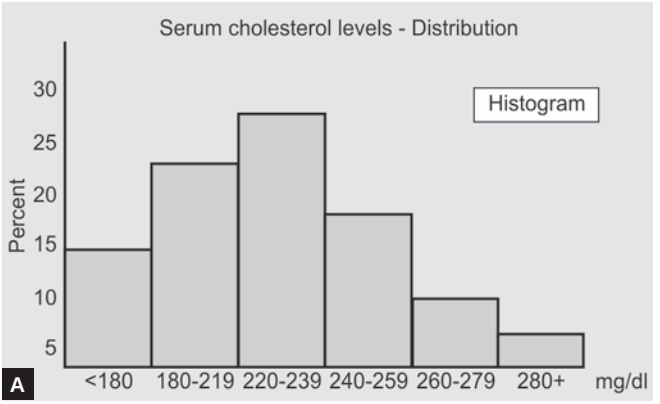
C. **Graphs and Diagrams**

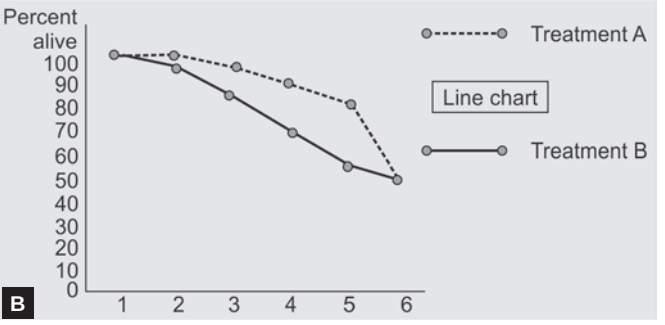
The graph is a way to depict quantitative data visually, using a system of coordinates. It is a kind of statistical snapshot that helps us to see patterns, trends, aberrations, similarities, and differences in the data. Also, a graph is an ideal way of presenting data to others. In epidemiology, commonly used graph is rectangular coordinate graphs, which have two lines—one horizontal and one vertical—that intersect at a right angle. These lines are referred as the horizontal axis (x-axis), and the vertical axis (y-axis). Horizontal axis is used to show the values of the independent variable, e.g. time, institution, etc. and vertical axis to show the dependent variable (frequency of outcome) e.g. number of cases or rate of disease. Labeling of each axis is done to show both the name of the variable and the units and mark a scale of measurement along the line.

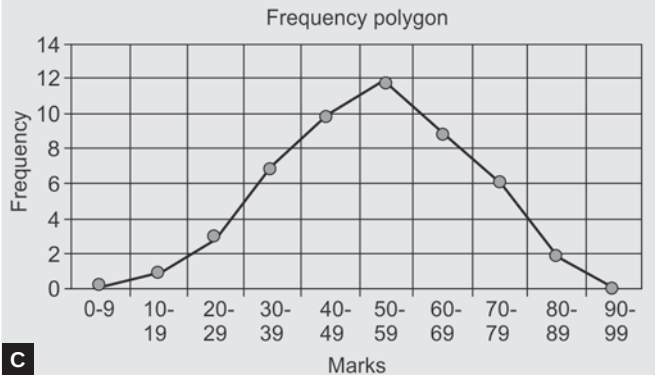
Types of Graphs (Figs 12.1A to F)

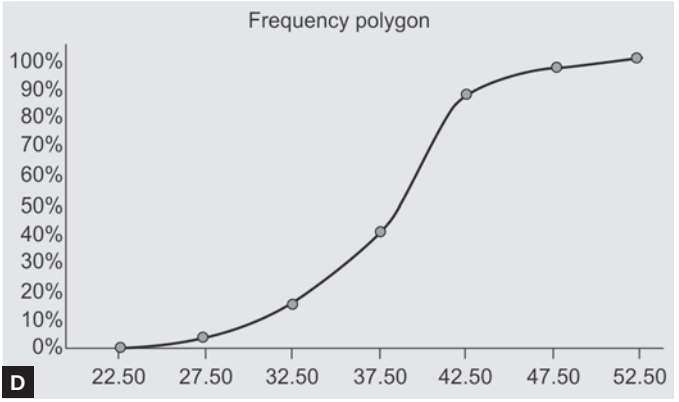


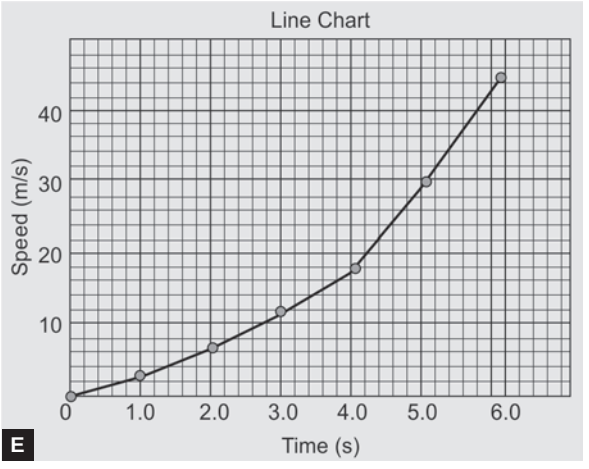
Purpose to prepare diagrams/graphs	***Appropriate Type of diagrams/ graphs***
Compare categorical data	Bar chart
Compare series of data over time	Area chart, line chart, column chart, multiple-bar diagram, component bar diagram
Percentage of total comparisons	Pie chart, column chart
Relationship between two variables	Scatter plot
Age-sex composition	Population pyramid

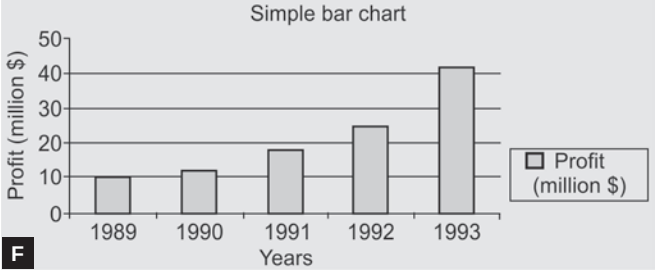

Serum cholesterol levels - Distribution
Histogram
Percent
30
25
20
15
10
5
<180
180-219
220-239
240-259
260-279
280+
mg/dl
A


Percent alive
100
90
80
70
60
50
40
30
20
10
0
1
2
3
4
5
6
Treatment A
Line chart
Treatment B
B


Frequency polygon
Frequency
14
12
10
8
6
4
2
0
0-9
10-19
20-29
30-39
40-49
50-59
60-69
70-79
80-89
90-99
Marks
C







Figs 12.1A to F: Types of graphs

PROPERTIES OF FREQUENCY DISTRIBUTIONS

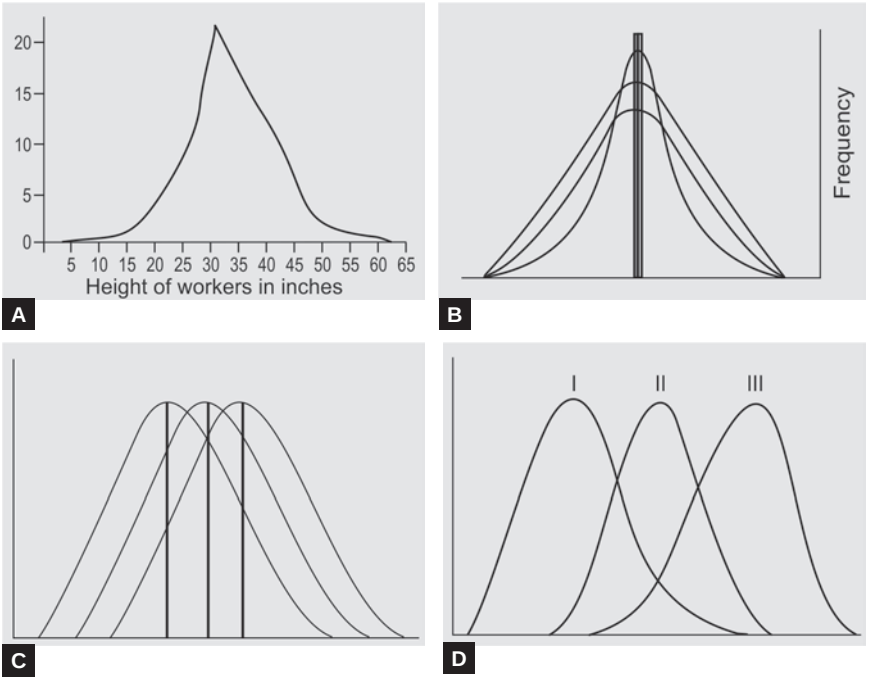
When researcher prepares a graph for frequency distribution data, we often find that the graph looks like figure 'A' given below with a large part of the observations clustered around a central value. This clustering is known as the central location or central tendency of a frequency distribution. The value that a distribution centers around is an important characteristic of the distribution. Once it is known, it can be used to characterize all of the data in the distribution. One can calculate a central value by several methods, and each method produces a somewhat different value. The central values that result from the various methods are known collectively as measures of central location/tendency (Fig. 12.2A). Of the possible measures of central location, the researcher commonly uses three measures in epidemiologic investigations: the arithmetic mean, the median, and the mode. Measures that researchers use less commonly are the midrange and the geometric mean.

A second property of frequency distributions is variation or **dispersion**, which is the spread of a distribution out from its central value. Some of the measures of dispersion are the range, mean deviation, interquartile range, variance, and the standard deviation. The dispersion of a frequency distribution is independent of its central location. This fact is illustrated by figure 12.2B which shows the graph of three theoretical frequency distributions that have the same central location but different amounts of dispersion.

A third property of a frequency distribution is its **shape**. The graph of the theoretical distribution in figure 12.2C is completely symmetrical. A distribution that is asymmetrical is said to be **skewed**. A distribution that has the central location to the left and a tail off to the right is said to be "**positively skewed**" or "skewed to the right." In figure 12.2D-I, distribution I is positively skewed.

A distribution that has the central location to the right and a tail off to the left is said to be "**negatively skewed**" or "skewed to the left." In figure 'D-III', distribution III is negatively skewed.

The symmetrical clustering of values around a central location that is typical of many frequency distributions is called the normal distribution (Figs 12.2D-II and 12.3). The bell-shaped curve that results when a **normal distribution** is graphed, as shown below, is called the normal curve. This common bell-shaped distribution is the basis of many of the tests of inference that we use to draw conclusions or make generalizations from data.



Figs 12.2A to D: (A) Graph of frequency distribution data with large part of the Observations clustered around a central value, (B) Three curves with same central location but different dispersion, (C) Three curves identical in shape with different central locations, (D) Three curves with different skewing

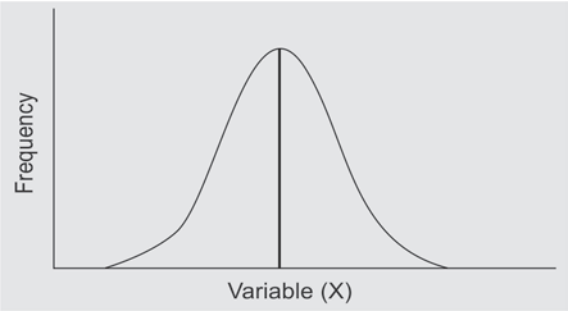
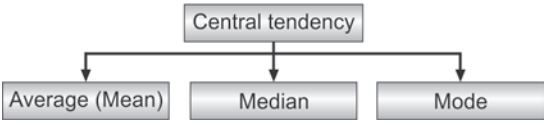


Fig. 12.3: Normal curve

D. Measures of Central Tendency

Average is a general term which describes the center of a series. There are three common types of averages or measures of central position or central tendency.

Characteristics of the Measures of Central Tendency



a. Arithmetic Mean ($\bar{x}$)

1. $\sum (X - \bar{x}) = 0$; ($\sum$ = summation), (X = observation);
2. $(X - \bar{x})^2$ = Minimum value;
3. It is the most familiar and most widely used measure;
4. It is based on all the observations;
5. It is rigidly defamed;
6. It is easily calculated and understood;
7. It is least affected by the fluctuations of sampling;
8. It is most suitable for further algebraic treatment;
9. It may be greatly affected by extreme values.
10. When the distribution has open-ended classes, its computation would be based on assumption and therefore, may not be valid.

b. Median

1. It is easy to define.
2. It is easy to understand.
3. Extremely high or low values will not distort the median.
4. Median is a better choice than the mean when a distribution is badly skewed.
5. It may be computed in an open-ended distribution.
6. It is generally less reliable than the mean for statistical inference purposes.

c. Mode

1. It may not exist in some sets of data. Or there may be more than one mode in other set of grouped data.
2. It can be located in an open-ended distribution.
3. It is not affected by extreme values in a distribution.
4. It is less popular measure than the mean or median.
5. In a small number of items the mode may not exist.
6. It is not capable of mathematical treatment.

a. Mean/Arithmetic Mean (AM)

The sample mean ($\bar{x}$) is the sum of all the observed values of a variable divided by the number of observations. The AM of a population is denoted by the symbol u. and AM of a sample is denoted by the symbol $\bar{x}$ (x bar).

i. Mean for Ungrouped Data

Let $x_1, x_2, x_3, ..., x_n$ be the sample observations, i.e. x_1 is the 1st observation, x_2 is the 2nd observation, x_n is the *n*th observation and so on. Then

$$\text{Mean} = \frac{\text{Sum of all observation}}{\text{Total observations}} = \frac{x_1 + x_2 + ... + x_n}{n} = \frac{\sum_{i=1}^{n} x_i}{n}$$

The symbol Σ means summation. The value of *i* beneath Σ gives the subscript of the first x_i to be included in the summation process. The value above Σ gives the subscript of the last x_i to be included in the summation. The value of *i* increases in steps of 1 from the beginning value to the ending value. Thus, all the observations with subscripts ranging from the beginning value to the ending value are included in the sum.

ii. Mean for Grouped Data

When a particular value (x) occurs more than once, the mean is then obtained by multiplying each value of (x) by frequency (f) of its occurrence and adding together. The products are then divided by the total number of observations.

Symbolically, x_1, x_2,..., x_k are the number of observations with frequencies $f_1, f_2, ..., f_k, ...$, then arithmetic mean is calculated by:

$$\text{Mean} = \frac{x_1 f_1 + x_2 f_2 + ... + x_k f_k}{f_1 + f_2 + ... + f_k} = \frac{\sum_{i=1}^{n} x_i f_i}{\sum_{i=1}^{n} f_i}$$

iii. Mean for Grouped Data with Class-interval

When the data is given in the form of class interval, then the first step is to find out the mid-point of each class-interval which will represent all the values falling within a particular class-interval. If we assume that the variable *y* represents the mid-point of the class-interval weighted by the frequencies. We multiply the mid-point of class-interval with frequencies, take the sum of all these products and divide it by the sum of all frequencies 'N' to find the mean.

Where x_i represents midpoints of the class-interval which is calculated as x_i = (Upper limit + Lower limit)/2 and $\sum_{i=1}^{n} f_i = N$

Examples

1. Calculate the mean for the following frequency distribution:

Class interval	0-8	8-16	16-24	24-32	32-40	40-48
Frequency	8	7	16	24	15	7

Calculation has been done as per the formula given under heading mean.

CI	x_i	f_i	$x_i f_i$
0-8	4	8	32
8-16	12	7	84
16-24	20	16	320
24-32	28	24	672
32-40	36	15	540
40-48	42	7	294
Total		**77**	**1942**

Mean = 25.2207792

2. Calculate the average number of children per family from the following data:

No. of children:	0	1	2	3	4	5	6
No. of families:	30	52	60	65	18	10	5

Calculation has been done as per the formula given under the heading mean.

x_i	f_i	$x_i f_i$	
0	30	0	
1	52	52	Mean = 2.1625 Average number of children per family is 2
2	60	120	
3	65	195	
4	18	72	
5	10	50	
6	5	30	
Total	**240**	**519**	

b. **Median**

It is a measure of central location or tendency of a data set. It is the value which splits the data set into two equal groups, i.e. one with values greater than or equal to the median, and other with values less than or equal to the median. It is generally denoted by M or Md.

i. Median for Ungrouped Data

The observation (n) values are arranged in the ascending or descending order of magnitude, then calculate median.

- if 'n' is odd, Md = $(n + 1/2)$th and if 'n' is even, then Md = $[(n/2\text{th}) + (n/2+1\text{th})]/2$.

ii. Median for Discrete Data

The following steps are followed to calculate median for such type of data:

- First arrange the data in an ascending order of magnitude.
- Find out the cumulative frequencies.
- Calculate the median by applying the following formula.
  Md = $(n + 1/2)$th value of term, where $n = \Sigma f$ = total frequencies.

iii. Median for Continuous Data

The following steps are to be followed:

- Compute the cumulative frequencies.
- Determine '$n/2$'value, i.e. one half of number of item.
- Find out the class interval in which the middle values are falling, and exact limits of this class interval.
- Calculate median by using the following formula.

$$\text{Median} = L + \frac{\frac{n}{2} - F}{f_m} \times h$$

Where, L = Lower limit of the class interval containing median.
f_m = Frequency of the class interval containing median.
F = Sum of all the frequencies above the class interval containing median.
n = Total number of frequency is = $\sum f$
h = Class interval

Examples

1. Find out the median weight of 590 infants born in a hospital in one year from the following table:
2. Find out the median for frequency distribution of given data.

Example: 1

Weights of infants (in kg) Class interval(CI)	***Number of infants Frequency(f)***	***cf****
2.0-2.4	37	37
2.5-2.9	117	154
3.0-3.4	207	361
3.5-3.9	155	516
4.0-4.4	48	564
>4.5	26	590
Total	**590**	

*cf = cumulative frequency
n/2 = 295 corresponding to 3.0-3.4
Median Class = 3.0-3.4
L (lower limit) = 3, F = 154
h(class interval) = 0.4, f_m=207
Md = 3.13623188
The Median weight of 590 infants born in a hospital in one year is 3.13.

Example: 2

Observations (X_i)	*Frequencies* (F_i)	*Cumulative frequencies (cf)*
1	8	8
2	10	18
3	11	29
4	16	45
5	20	65
6	25	90
7	15	105
8	9	114
9	6	120
Total	**120**	

(n + 1)/2th value of term = 60.5

60.5 is corresponding to observation 5, hence Md = 11

Calculate median for the following data:

3. Age (in years) of 10 students is as follows. Calculate median:

Ages:	18	18	22	21	20	18	19	20	18	22
Arrange in ascending order										
	18	18	18	18	19	20	20	21	22	22

Here 'n' (number of observations) =10 (even number)
The average of (n/2) i.e. 5th term = 19 and (n/2 + 1)th term, i.e. 6th term = 20
Therefore Md =19.5

4. Calculate median for given data:
5 7 8 9 10 13 15
Arrange values in ascending order (already arranged in ascending order) Here 'n' (number of observations) =7 (odd number)
The (n + 1)/2th term (i.e 4th term = 9), hence Md = 9

c. Mode

Mode is defined as the most frequently occurring value in a data series which occurs. In discrete frequency distribution, mode is the variate which has the maximum frequency.

Computation of Mode

i. **Simple series:** In the case of simple series the value which is repeated maximum number of times is the mode of the series.

ii. **Discrete frequency distribution series:** In the case of discrete frequency distribution, mode is the value of the variable corresponding to the maximum frequency. We calculate the mode by following formula for continuous frequency distribution.

$$\text{Mode} = L + \frac{f_m - f_1}{2f_m - f_1 - f_2} \times h$$

Where $L \rightarrow$ Lower limit of the modal class.
$h \rightarrow$ Class-width of modal class.
$f_1 \rightarrow$ The frequency of the class preceding modal class.
$f_m \rightarrow$ The frequency of the modal class.
$f_2 \rightarrow$ The frequency of the class succeeding modal class.

Modal class is the class in which the maximum frequency occurs.

Examples

1. Calculate mode for the following frequency distribution of 2000 child birth records.

Duration (in days)	240-250	250-260	260-270	270-280	280-290	290-300
Frequency	150	200	450	600	500	100

Class interval (CI)	*Frequencies (F_f)*	
240-250	150	Maximum frequency is 600 corresponding to 270-280, hence the Modal Class = 270-280, L = 270, f_1 = 450, f_2 = 500, h = 10, f_m = 600 ∴ Mode = 276
250-260	200	
260-270	450	
270-280	600	
280-290	500	
290-300	100	
Total	**2000**	

2. Find out the mode of the following frequency distribution:

Series A	8	5	15	23	8	15	28	20
Series B	8	10	13	15	17	19	21	20

Mode for series A = 15, but no mode for series B (as no frequency is repeated).

d. Measures of Dispersion

In the measures of central tendency, average represents the central position of data but it does not tell us about how the measurements are arranged from the center. It is also unable to describe scattering of the observations.

The scattering of the observations in the data is studied through measure of dispersion.
Following are the measures commonly used to describe the dispersion or variation.

I. Range
II. Quartile deviation (or semi-interquartile range)
III. Mean deviation (or average deviation)
IV. Standard deviation.

RANGE

It is the simplest measure of dispersion. The range is defined as the difference between the largest and the smallest measurement. In the statistical world, the range is reported as a single number, the difference between maximum and minimum. Among the epidemiologist community, the range is often reported as "from (the minimum) to (the maximum)," i.e. two numbers. Advantages:

- It is easy to understand and compute.
- It's units are the same as the units of the variable.

Disadvantages

- Range considers only the largest and smallest observation in the data.
- It does not depend upon the number of observations.

Examples

Calculate the range for the following data:

1. Pulse rates of 11 individuals are given below-

   58 66 70 74 80 86 90 100 79 96 88

   R = Highest Value – Lowest Value = 100–58 = 42

2. Hemoglobin level values (in mg %) of 11 patients are as under-

   4 10 15 12 11 9 13 14 4 7 8

   R = Highest Value – Lowest Value = 15–4 = 11

3. Records of BP of 10 students are given below.

   83 81 75 79 71 71 76 95 77 94

   R = Highest Value – Lowest Value = 95–71 = 24

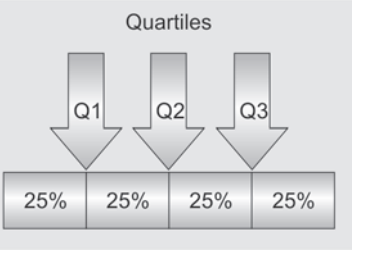
4. The following data gives the chest measurement of 50 MBBS students

Chest measurement	61-70	71-80	81-90	91-100
Number of students	2	10	20	18

   R = Highest Value – Lowest Value = 100–61 = 39

QUARTILE DEVIATION (INTERQUARTILE RANGE)

Percentiles, deciles, and quartiles are locations of an ordered data set that divides the data into parts. Quartiles divide the data into four equal parts. The first quartile (Q_1), or 25th percentile, is located such that 25 percent of the data lie below Q_1 and 75 percent of the data lie above Q_1. The second quartile (Q_2), or 50th percentile or median, is located such that half (50 percent) of the data lie below Q_2 and the other half (50 percent) of the data lie above Q_2. The third quartile (Q_3), or 75th percentile, is located such that 75 percent of the data lie below Q_3 and 25 percent of the data lie above Q_3. The interquartile range is the difference of the 75th and 25th percentiles (the third and first quartiles). This range includes about one-half of the observations in the set, leaving one-quarter of the observations on each side.



Steps for calculating the interquartile range from individual data:

1. Arrange the observations in increasing order.
2. Find out the position of the 1st and 3rd quartiles with the following formula:
   - Position of 1st quartile (Q_1) = $(n + 1)/4$
   - Position of 3rd quartile (Q_3) = $3(n + 1)/4 = 3 \text{ X } Q_1$
3. Identify the value of the 1st and 3rd quartiles
4. Calculate the interquartile range as Q_3 minus Q_1.

Example

Calculate interquartile range of the following data:

Weights (in kg) of eight under-five children are:

13, 7, 9, 15, 11, 5, 8, 4

1. Observations are arranged in the increasing order like:

   4, 5, 7, 8, 9, 11, 13, 15

2. Position of the 1st and 3rd quartiles. Since there are 8 observations, $n = 8$. Position of $Q_1 = (n + 1)/4 = (8 + 1)/4 = 2.25$ and

   $Q_3 = 3(n + 1)/4 = 3(8 + 1)/4 = 6.75$

3. Identify the value of the 1st and 3rd quartiles.

   Value of Q_1: The position of Q_1 was 2%; therefore, the value of Q_1 is equal to the value of the 2nd observation plus one-fourth the difference between the values of the 3rd and 2nd observations.

Value of 2nd observation = 5; Value and 3rd observation = 7, so

$Q_1 = 5 + \frac{1}{4}(7–5) = 5 + 2/4 = 5.5.$

Value of Q_3: The position of Q_3 was 6%; thus the value of Q_3 is equal to the value of the 6th observation plus three-fourths of the difference between the value of the 7th and 6th observations. Value of 7th observation is 13 and value of 6th observation = 11.

$Q_3 = 11 + 3/4\ (13 – 11) = 11 + 3 \times 2/4 = 11 + 6/4 = 12.5$

4. Calculate the interquartile range as Q_3 minus Q_1, i.e. Interquartile range = 12.5 – 5.5 = 7

MEAN DEVIATION (MD)

Mean deviation is also called as average deviation. It is defined as the arithmetic mean of the absolute deviations from its mean, i.e., Mean deviation = $\Sigma d/n$

Where 'd' is the deviation without considering the algebraic sign, i.e. $(x_i – \bar{x})$. Similarly, mean deviation about median and mode.

It is calculated by

$$\text{MD about median} = \frac{1}{n}\sum(x_i - \text{median})$$

$$\text{MD about mode} = \frac{1}{n}\sum(x_i - \text{mode})$$

In case of frequency distribution, mean deviation is calculated by

$$\text{MD about "A"} = \frac{1}{N}\sum f_i\,|\,x_i - A\,|\ \text{where "A" is the absolute value}$$

$$\text{MD about mean} = \frac{1}{N}\sum f_i\,|\,x_i - \bar{x}\,|$$

$$\text{MD about median} = \frac{1}{N}\sum f_i\,|\,x_i - \text{median}\,|$$

$$\text{MD about mode} = \frac{1}{N}\sum f_i\,|\,x_i - \text{mode}\,|$$

Example

Calculate mean deviation for the following data:

1. The incubation period (in days) for 10 patients of infectious hepatitis are given below:

26 22 36 15 27 19 24 18 23 25

Sr. No. of patient	x_i	$\lvert \bar{x}i - x \rvert$
1	26	2.5
2	22	1.5
3	36	12.5
4	15	8.5
5	27	3.5
6	19	4.5
7	24	0.5
8	18	5.5
9	23	0.5
10	25	1.5
	Total Mean = 23.5	41
	Mean deviation = 41/10 = 4.1	

$\Sigma \lvert x_i - \bar{x} \rvert / n$

Mean deviation
41/10 = 4.1

2. Calculate the mean deviation for following data with class interval:

Age group (yrs)	20-30	30-40	40-50	50-60	60-70	70-80	80-90
No.	61	132	153	57	36	140	03

Class interval (CI)	Frequency F_i	X_i = mid-point	$X_i f_i$	$\lvert x_i - \bar{x} \rvert$	$F_i \lvert x_i - \bar{x} \rvert$
20-30	61	25	1525	25.27	1541.47
30-40	132	35	4620	15.27	2015.64
40-50	153	45	6885	5.27	806.31
50-60	57	55	3135	4.73	269.61
60-70	36	65	2340	14.73	530.28
70-80	140	75	10500	24.73	3462.2
80-90	3	85	255	34.73	104.19
Total	**582**		**29260**	**124.73**	**8729.7**
Mean ($\bar{x}$) = 29260/582 = 50.27					
Mean Deviation = 8729.7/582 = 14.99					

STANDARD DEVIATION (SD)

The range is unstable, quartile deviation excludes half the data arbitrarily and mean deviation neglects algebraic signs of the deviation, a measure of dispersion that does not have any of these defects is known as standard deviation. It is represented by σ (lower case of Greek letter sigma).

The variance and standard deviation are measures of the deviation or dispersion of observations around the mean of a distribution. ***Variance*** is the mean of the squared differences of the observations from the mean. It is usually represented in formulas as S^2. The **standard deviation** is the square root of the variance. It is usually represented in formulas as 'S'. The following formulae are used to calculate variance and standard deviation:

$$\text{Variance} = S^2 = \frac{\sum (x_i - \bar{x})^2}{n-1}$$

$$\text{Standard Deviation} = S = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n-1}}$$

Characteristics of Standard Deviation

- It is rigidly defined.
- It is based on all the observations, i.e., the value of the standard deviation will change if any one of the values is changed.
- In case, the values lie close to the mean, the deviations are small and hence the variance and standard deviation are also small.
- Standard deviation is least affected from one sample to another as compared with other three measures of dispersion.

The formula for standard deviation:

$$SD = \sqrt{\frac{1}{n}\sum (x_i - \bar{x})^2} = \sqrt{\frac{1}{n}\sum dx^2}$$

In case of frequency distribution:

$$SD = \sqrt{\frac{1}{n}\sum f_i\,(x_i - \bar{x})^2} = \sqrt{\frac{1}{n}\sum f_i dx^2}$$

Steps for calculating the standard deviation:

- Compute $\bar{x}$ (x bar), i.e. mean
- Compute deviation from mean, i.e. $dx = x_i - \bar{x}$
- Take the sum of dx^2 to get $\sum dx^2$
- Divide by total number of items or observations
- Find out the square root of $\frac{\sum dx^2}{n}$

Example

Serum bilirubin levels (in mg/100 ml) of 9 individuals are given below. Calculate the standard deviation.

0.4 0.3 0.8 1.0 1.6 3.2 0.9 0.5 4.8

Sr. No.	X_i	$(X_i - \bar{x})$	$(X_i - \bar{x})^2$
1	0.4	-1.1	1.21
2	0.3	-1.2	1.44
3	0.8	-0.7	0.49
4	1	-0.5	0.25
5	1.6	0.1	0.01
6	3.2	1.7	2.89
7	0.9	-0.6	0.36
8	0.5	-1	1
9	4.8	3.3	10.89
	Total =13.5		18.54

Standard deviation (with sample, S) = $\sqrt{\frac{\sum (x_i - \bar{x})^2}{n-1}}$

n = 09 (No. of observations)

Mean = 1.5

S = $\sqrt{18.54/9-1} = \sqrt{18.54/8}$

= $\sqrt{2.3175} = 1.5223$

Standard deviation = 1.5223

COEFFICIENT OF VARIATION (CV)

By computing the variance of a variable one may have an idea about the extent of variability. Variances may not give adequate information about variability of the different sets of data. To make it more meaningful, the coefficient of variation is computed which expresses the standard deviation as percentage of the sample mean. It is independent of the units of observation. The formula for computation of the coefficients of variation is **Coefficient of variation = SD/Mean × 100 or $\sigma/\bar{x} \times 100$.**

Coefficient of variation can be computed for different groups of values with the same unit or for groups of values with different units. The group having the higher coefficient of variation shows more variability than the one with lower coefficient of variation.

Example

Following are the number of eligible couples protected by one of the family planning methods in villages A and B, in the last 9 months. Calculate coefficient of variation and comment which village performed better and more consistently?

Village A	12	115	6	73	7	19	119	36	84
Village B	47	12	76	42	4	51	37	48	13

	Village A	*Village B*
Mean	52.33	36.67
SD	46.11	23.05
CV	88.11	62.88

By comparing C.V's of two villages, Village B is more consistent than village A since its C.V. is less as compared to Village A.

INFERENTIAL STATISTICS

Inference involves making a generalization about a large group of individuals on the basis of a subset or sample population. If any inference is based on sample, then there is always the possibility that the inference will either be inaccurate or imprecise, simply because of the play of chance or sampling variability. It is possible to decrease the play of chance by increasing the sample size.

Tests of Significance

The experimenter is interested in testing the validity of an assumption about the unknown parameter. For example, it is of interest to check the superiority of a drug manufactured by two different companies. One group of patients has been given a specific treatment and other group has not been given any treatment. In this case, experimenter wishes to check whether the treatment has any effect or not? This is usually referred to as testing of hypothesis.

Hypothesis

It is an assumption about the parameter/factor before the test is applied.

Null Hypothesis (H_0)

It is hypothesis which assumes that there is no difference between two values such as population means or population proportions. It is denoted by H_0: $\mu_1 = \mu_2$
H_0: Mean of population A (P_1) = Mean of population B (P_2), i.e. H_0: $P_1 = P_2$ and so on.

Alternative Hypothesis (H_1 or H_a)

A hypothesis that differs from a null hypothesis is called an alternative hypothesis. In other words, alternative hypothesis is true when null hypothesis is false. It is denoted by H_1 or H_a. H_1: $\mu_1 \neq \mu_2$ or $\mu_1 < \mu_2$ or $\mu > \mu_2$ or H_1: $P_1 \neq P_2$ or $P_1 < P_2$ or $P_1 > P_2$ and so on.

Test statistics: It is the basis to test the hypothesis, i.e., to accept or reject null hypothesis (H_0) on the of a sample.

Degrees of freedom: The number of independent observations which are used in statistics is known as the degrees of freedom (d.f.).

Sampling errors: When inference about the population is drawn on the basis of sample, two types of errors can be committed; these are alpha and beta errors.

Decision based on sample	*Reality in population : Null hypothesis*	
	True	False
True	Correct decision	Type II error(β)
False	Type I error (α)	Correct decision

Level of Significance (α)

The probability of committing type I error is called level of significance. Researchers have used probability levels for deciding whether to accept or reject a null hypothesis. It is usually denoted by alpha (α) 0.05 (5%) and 0.01 (1%). Level of significance of 0.05(5%) means 95% chances for having made the correct decision or in other words, wrong decision only with probability of 0.05.

Power of the Test

The probability of committing type II error is denoted by β and (1–β) is called the power of the test. It depends on the alternative hypothesis. Power is probability of rejecting H_0 when H_0 is false, thus it is the probability of taking correct decision.

Steps in testing the hypothesis:

Step 1: Set up null hypothesis (H_0).

Step 2: Set up the alternative hypothesis H_1. This gives the idea whether to use one-tailed or two-tailed test.

Step 3: Choose the appropriate level of significance (α).

Step 4: Compute the value of test statistic "Z", (Z = Observed difference/ Standard error).

Step 5: Obtain the table value at given level of significance.

Step 6: Compare the value of Z calculated with that of table value.

For two-tailed test:				For one-tailed test			
P :	0.10	0.05	0.01	P :	0.10	0.05	0.01
|Z|:	1.64	1.96	2.58	|Z|:	1.28	1.64	2.33

Step 7: Draw the conclusion.

LARGE SAMPLE TESTS

i. **Test for single proportion:** $H_0 = p = P$ vs $H_1: p \neq P$

$$Z = \frac{p - P}{SE(p)} = \frac{p - P}{\sqrt{\frac{PQ}{n}}}$$

Where,

p – Sample proportion or percentage of positive characteristics.
q – Sample proportion or percentage of negative characteristics, i.e. q = 1–p
P – Population proportion of positive characteristics.
Q – Population proportion of negative characteristics.
n – Sample size.

ii. **Test for two sample proportions:** H_0: $p_1 = p_2$ vs H_1: $p_1 \neq p_2$

The test statistics, $Z = \dfrac{p_1 - p_2}{SE\,(p_1 - p_2)}$

Where SE (p_1, p_2) $= \sqrt{pq\left[\dfrac{1}{n_1} + \dfrac{1}{n_2}\right]}$

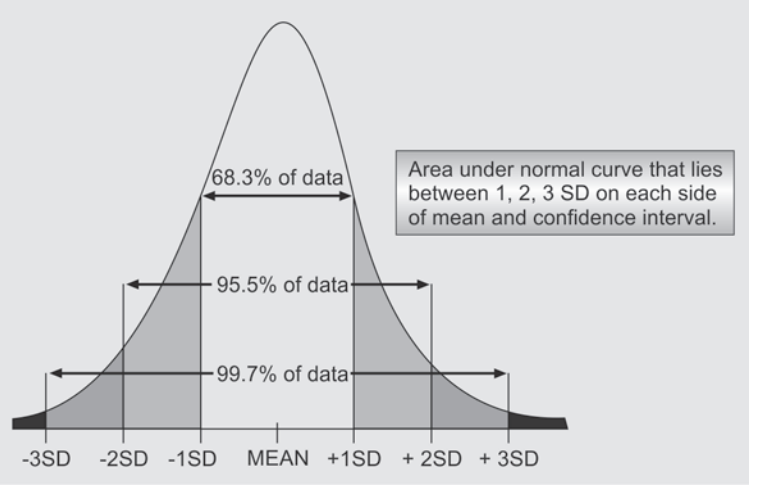
Where $p = \dfrac{n_1 p_1 + n_2 p_2}{n_1 + n_2}$

iii. **Sample of variables/tests for quantitative data:** H_0: $\bar{x} = \mu$

Z = Sample mean – Population mean/ SE of mean, $Z = \dfrac{\bar{X} - \mu}{\sigma / \sqrt{n}}$

iv. **Confidence interval:** The 95 % confidence interval for population mean is sample mean ± 1.96 SE of mean. Symbolically, the population means μ will lie between:

$$\bar{X} - 1.96 \times \frac{\sigma}{\sqrt{n}} \text{ and } \bar{X} + 1.96 \times \frac{\sigma}{\sqrt{n}}$$



Similarly, 99% confidence interval is given by the formula:

$$X - 2.58 \times \frac{\sigma}{\sqrt{n}} \text{ and } \bar{X} + 2.58 \times \frac{\sigma}{\sqrt{n}}$$

Examples

1. In a city A, 20% of a random sample of 900 school boys had defective eye sight, in another city B, 15.5% of a random sample of 1600 school boys had the same defect. Is the difference between the two proportions significant?

   n_1 = sample size of 1st sample = 900
   n_2 = sample size of 2nd sample = 1600
   p_1 = proportion of 1st sample = 20/100 = 0.20,
   p_2 = proportion of 2nd sample = 15.5/100 = 0.155
   $Z = (p_1 - p_2)/SE\,(p_1 - p_2) = (p_1 - p_2)$

   $$= (p_1 - p_2) / \sqrt{\{P \times Q\,[(1/n_1) + (1/n_2)]\}}$$

   $P = (n_1p_1 + n_2p_2)/(n_1 + n_2) = 0.17$,
   $Q = 1 - P = 0.63$

   By using formula for test of two proportions, Z = 2.81

   Z cal =2.81 > 1.96 at 5% level of significance, hence it rejects null hypothesis (H_0). It means there is significant difference in two proportions.

2. In a medical college, out of 120 admissions in 1st MBBS, 35 are girl students. Find out whether the proportion of girl students is 40% of all Students (boys & girls) for all the years i.e. I, II, III MBBS in the college.

   Let p be the sample proportion of girl students, i.e. p = 35/120 = 0.29, P(which is given) = 40% = 0.40 and H_0: the proportion of girl students is 40% .

   $$\text{The Statistic}, Z = (p_1 - p_2)/\sqrt{(PQ/n)} = (0.29 - 0.40)/\sqrt{(0.40 * 0.60/120)}$$

   Since absolute value of Z =2.46 is greater than 1.96 (table value), hence it rejects the null hypothesis at 5% level of significance. So the proportion of girl students is not 40%.

3. In a study conducted on a sample of 400 adults, it revealed that mean daily requirement of vitamin "A" was 900 IU. It was found from existing literature that the mean daily requirement of vitamin "A" was 930 IU. with SD of 90 IU. Comment whether finding of the study differs significantly or not.

   n = 400, Sample mean = 900, population mean = 930, population SD = 90

$Z = (x - \mu)/ (\sigma / \sqrt{(n)} = (900–930)/ (90 / \sqrt{(400)} = 6.67$

Z (calculated) is greater than 1.96 and hence H_0 is rejected at 5% level significance.

4. In two groups of hypertensive individuals, i.e., group A having 70 and B with 90 individuals had mean blood cholesterol levels of 320 mg% with SD of 18 mg% and 330 mg% with SD of 22 mg% respectively. Is this difference significant?

   1st sample mean = 320, 2nd sample mean = 330, SD 1 =18, SD 2 =22

   Z = 3.16 (using formula), Z cal 3.16 > 1.96 at 5% level of significance, hence the difference in means of two samples is significant.

SMALL SAMPLE TEST (t-STATISTICS) OR STUDENT'S 't' TEST

Mr WS Gosset (1908) was the first scientist who derived this test and published statistical papers under the pen name of 'Student'. Hence this test is known as **Student's 't' test.**

Assumption for t Test

- The sample must be random. In other words, the observations in the sample are independent.
- The population standard deviation is not known.
- The distribution of population from which the sample is drawn is normal.

i. Test Regarding Single Mean

This test is used for testing the significance of difference between sample mean and population mean or whether sample has been drawn from the population or not.

In case of small sample ($n<30$), the test statistics is:

$$t = \frac{\bar{X} - \mu}{S / \sqrt{n}} \qquad \text{where} \qquad S^2 = \frac{\sum(x - \bar{x})^2}{n-1}$$

The test statistics '*t*' has degrees of freedom, i.e. $(n - 1)$. If calculated value of '*t*' is greater than table value, then it rejects the null hypothesis and if less, then H_0 may be accepted.

ii. Tests Regarding Two Means

a. Unpaired *t* test
b. Paired *t* test

a. **Unpaired t test**

$$t = \frac{x_1 - x_2}{S\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}} \quad \text{where} \quad S^2 = \frac{\sum(x_1 - \bar{x})^2 + \sum(x_2 - \bar{x})^2}{n_1 + n_2 - 2}$$

Degree of freedom (df)

$df = (n_1 - 1) + (n_2 - 1) = n_1 + n_2 - 2$

b. **Paired t-test**

$$t = \frac{\bar{d}\sqrt{n}}{S} \qquad \text{where } d_i = x_i - y_i,\ \bar{d} = \frac{\sum d_i}{n},$$

$$S = \frac{\sqrt{\sum(d_i - \bar{d})^2}}{n-1}$$

Examples

Calculate '*t*' test for the following data:

1. In a clinical trial conducted on 13 patients with oral anti-diabetic agent, i.e. Repaglinide: following results showed the values of blood glucose in mg% before and after the medication. Test statistically whether the drug repaglinide is effective or not.

Before	180	210	220	250	190	200	170	300	330	280	230	245	215
After	160	140	180	140	160	140	120	170	190	165	155	135	112

Mean for before medicine = 230.30, SD = 47.68
Mean for after medicine = 151.30, SD = 22.72
Calculated '*t*' value = 7.385, Table 't' Value at df 12 = 2.18,
Significant and Drug is effective.

2. Apgar scores in two groups of newborns, one group born to high-risk mothers and the other to normal mothers, are given below. Comment whether there is significant difference in the Apgar scores of these two groups.

Newborns of high-risk mothers (*x*):
5 3 2 4 7 6 3
Newborns of normal mothers (*y*):
1 1 2 1 1 3 5
Mean for *x* = 4.28, SD = 1.79
Mean for *y* = 1.87, SD = 1.45
Calculated '*t*' value = 2.825, Table '*t*' Value at df 13 = 2.16,
Significant difference was found in two groups.

3. Following are the results of weight gain by pigs that were on two different diets A and B. Find out whether these two diets were different.

Diet A	25	32	30	34	24	14	32	24	30	31
Diet B	44	34	22	10	47	31	40	30	32	35

Mean of diet 'A' = 27.6 with SD = 5.9 and Mean of diet 'B' = 30.76 with SD = 10.6. Calculated '*t*' value= 0.907, Table '*t*' value = 2.08, No significant difference was found between two diets.

4. In an experiment, two types of drugs, i.e. A and B was administered to patients for pain relief. The following results were observed. Test whether drug A and B differ significantly.

A	49	53	51	52	47	50	52	53
B	52	55	52	53	50	54	53	51

Mean of 'A' = 50.8 with SD = 2.1 and Mean of 'B' = 52.5 with SD = 1.6
Calculated '*t*' value = 2.489, Table '*t*' Value = 3.37,
Significant difference was found between the effects of two drugs.

Chi-Squared Test

A chi- squared (χ^2) test is used to test whether the distribution of individuals among the categories of one variable is independent of their distribution among the categories of the other. In other words, whether there is an association between the row and the column variable.

Steps for Chi-Squared Test

1. Write down the null hypothesis.
2. Obtain the expected frequencies.
3. Compute the values of chi-square test statistic = $\chi^2 = \Sigma(O–E)^2/E$

$$\chi^2 = \frac{\Sigma(\text{Observed} - \text{Expected})^2}{\text{Expected}}$$

4. Find out the degrees of freedom.
5. Obtain the table value from Chi-square table.
6. Compare chi-square calculated with table value. If calculated value of χ^2 is greater than table value of χ^2, reject the null hypothesis otherwise accept it.
7. Write down the conclusion.

Expected Frequencies

Expected frequencies are the frequencies which are obtained from model.

$$E = \frac{RT \times CT}{GT}$$

where, E = Expected value, RT = Row total, CT = Column total, GT = Grand total

Degrees of freedom: When contingency table has column and row,

The degrees of freedom $= (r - 1) \times (c - 1)$

where r = row, c= column

2 × 2 Contingency Table:

A	*B*		*Total*
	Present	*Absent*	
Present	a	b	a + b
Absent	c	d	c + d
Total	**a + c**	**b + d**	**a + b + c + d = N**

The chi-square value for testing the independence of characters A and B simplifies to

$$\chi^2 = \frac{(ad - bc)^2 N}{(a + b)(c + d)(a + c)(b + d)}$$

where $N = a + b + c + d$

To improve the value of χ^2 the continuity correction **(Yates' continuity correction)** is applied which can be calculated by the formula $\chi^2 = \Sigma[(O-E)]^2/E$

Example

Normally university rules prohibit students with attendance less than 75% from appearing in the examination. Due to student agitation, all students were allowed to appear for examination. Following are the results of the examination. Comments whether the good attendance (more than 75%) has any effect on the results of examination.

Attendance	*Result in examination*		*Total students*
	Pass	*Fail*	
>75 %	100 (a)	50 (b)	150 (a + b)
<75%	20 (c)	80 (d)	100 (c + d)
Total	**120 (a + c)**	**130 (b + d)**	**250 (a + b + c + d = N)**

Calculation for Expected Value

Expected value for Cell (a) = RT × CT / GT = 150 × 120 /250 = 72
Expected value for Cell (b) = RT × CT/GT = 150 × 130/250 = 78
Expected value for Cell (c) = RT × CT / GT = 100 × 120 /250 = 48
Expected value for Cell (d) = RT × CT/ GT = 100 × 130 /250 = 52

Apply formula, $\chi^2 = \frac{\sum(\text{observed} - \text{expected})^2}{\text{Expected}}$

$\chi^2 = \Sigma\{(O_1-E_1)^2 \div E_1\} + \{O_2-E_2)^2 \div E_2\} + \{(O_3-E_3)^2 \div E_3\} + \{(O_4-E_4)^2 \div E_4\}$

$\chi^2 = \Sigma(100-72)^2 \div 72 + \{50-78)^2 \div 78 + \{(20-48)^2 \div 48 + (80-52)^2 \div 52$

$\chi^2 = 10.88 + 10.05 + 16.33 + 15.07 = 52.35$ ($p < 0.000001$)

Calculation for degree of freedom: df = $(r-1) \times (c-1 = (2-1)(2-1) = 1$

Calculated χ^2 value at df (1) = 52.33 (without Yates's correction), i.e., more than table value at P <0.05, hence it can be concluded that the good attendance (more than 75%) has positive effect on results in examination.

The chi-square test of significance is useful as a tool to determine whether or not it is worth the researcher's effort to interpret a contingency table. A significant result of this test means that the cells of a contingency table should be interpreted. A non-significant test means that no effects were discovered and chance could explain the observed differences in the cells. In this case, an interpretation of the cell frequencies is not useful.

Fisher exact test: Sometimes Chi-squared test and normal tests for 2 × 2 tables may not be valid if sample size is very small. Fisher's exact test is recommended, when

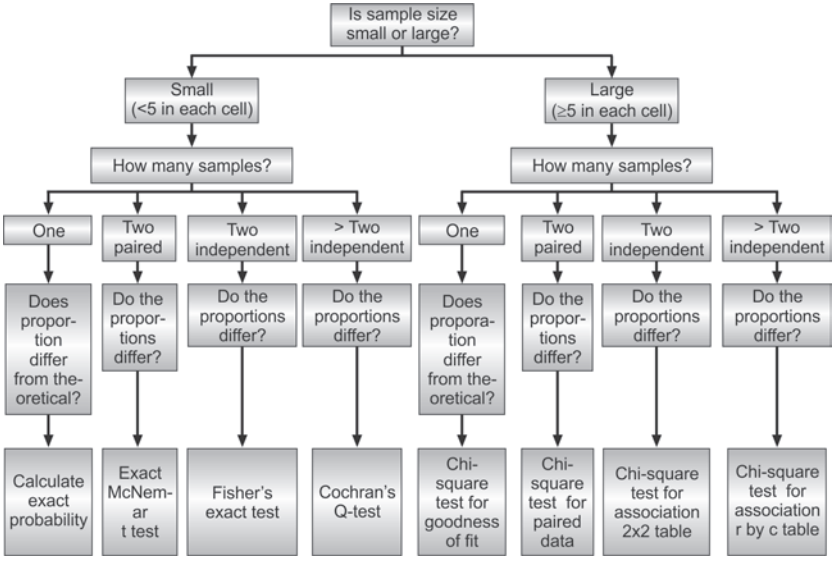
- The overall total of table is less than 20 or
- The overall total is between 20 and 40 and smallest of the four expected numbers is less than 5.

TESTS OF SIGNIFICANCE FOR LARGE AND SMALL SAMPLE (ANNEXURES I AND II)

Tests of significance for large samples, i.e. >30 is 'Z' statistics and for small sample size, i.e. < 30, '*t*' statistics are used for drawing the inferences on mean.

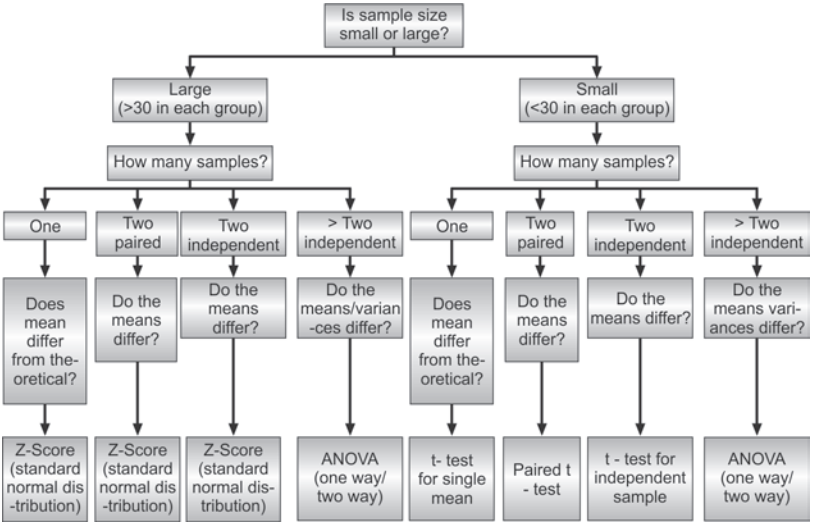
Annexure I: Selection of an appropriate test of statistical significance for discrete data:

Inference on proportions



Annexure II: Selection of an appropriate test of statistical significance for continuous data:

Inference on means



CORRELATION AND REGRESSION

A. Correlation

When more than one variables are related or correlated with each other, then their relationship is only studied through the help of correlation

analysis. The study of the relationship between two variables is called bivariate analysis. In correlation, change in the value of one variable will change the value of another variable. Such variables are called correlated variables.

Types of Correlation

i. Positive correlation
ii. Negative correlation

Positive Correlation

When the increase /decrease in the value of one variable may increase / decrease the value of another variable such a correlation is called positive correlation. In other words, the changes in both the variables are in the same direction, e.g. height and weight, income and expenditure, etc.

Negative Correlation

If the value of one variable increases then the value of the other variable decreases and vice-versa, e.g. price and demand.

Karl Pearson's Coefficient of Correlation

The coefficient of correlation is calculated by using the formula:

Karl-Pearson's coefficient

$$r = \frac{\text{Cov}(x,y)}{\sigma_x . \sigma_y} = \frac{\sum(x_i - \bar{x})(y_i - \bar{y})}{\sqrt{\sum(x_i - \bar{x})^2 (y_i - \bar{y})^2}}$$

Properties of Co-efficient of Correlation

- Correlation coefficient always lies between –1 and +1.
- The perfect and positive correlation is $r = 1$ and perfect and negative $r = -1$.
- If $r = 0$, it indicates that there is no correlation between the two variables and thus the variables are said to be independent.

Interpretation of the Correlation Coefficient

Correlation analysis is a measure of relationship between two variables. The higher value of V establishes high degree of relationship only and it should not be taken as a measure of cause and effect relationship. In some cases a casual relation may exist between two variables whereas in others a relationship may exist between two variables because both are related to a third variable. Sometimes the relationship may be purely due to chance, if another set of data is collected and a Pearson V is calculated, the resulting V may be meaningless.

For example: one may measure height of students and correlate it with their marks obtained. Even if $r = 0.77$, still it is meaningless as such high positive relationships are purely the result of chance.

Example

1. Computation of the correlation coefficient:

X	Y	$(X-\bar{X})$	$(Y-\bar{Y})$	$(X-X)(Y-\bar{Y})$
8	12	1	0	0
3	9	-4	-3	12
4	10	-3	-2	6
10	15	3	3	9
6	11	-1	-1	1
7	12	0	0	0
11	15	4	3	12
Σx = 49	**84**	**0**	**0**	**40**

$$n = 7$$

$$\bar{x} = \frac{\sum x}{n} = 7 \qquad \bar{y} = \frac{\sum y}{n} = 12$$

$$\textbf{Covariance (xy)} = \frac{\sum (x-\bar{x})(y-\bar{y})}{(n-1)} = \frac{40}{6} = 6.67$$

$$r = \frac{\text{Cov}(xy)}{\text{SD}(x)\,\text{SD}(y)} = \frac{6.67}{2.94 \times 2.31} = 0.98$$

2. Calculate Karl Pearson's coefficient for the following data.

Age of husband:	18	19	20	21	22	23	24	25	26
Age of wife:	17	17	18	18	18	19	19	20	21

Answer = r = 0.98

3. Following are the findings of temperature and pulse rate in 9 patients.

Temperature:	98	99	100	101	102	103	104	105	100
Pulse rate:	72	80	92	111	116	128	132	130	90

Answer = r = 0.967

4. The age (X) and systolic blood pressure (Y) of 9 persons are given below.

Age (X):	48	55	47	57	42	38	60	50	58
BP(Y):	136	151	138	148	126	166	152	148	150

Answer = r = 0.96

5. The IQ scores and daily intake in gms of proteins of 10 students is as below.

IQ:	100	110	120	130	90	60	70	80	90
Protein:	50	60	50	40	30	60	80	90	70

Answer = r = 0.531

B. Regression

The value of one variable can be calculated if we know the value of the other variable. We calculate this by the procedure known as regression coefficient. It is customary to denote the independent variable by x and dependent variable by y.

The formula for obtaining the regression coefficient is as follows:

$$y = b_0 + b_1 x$$

where,

y = Mean of $y_1, y_2, \ldots, y_n$
x = Mean of $x_1, x_2, \ldots, x_n$

$$b = \frac{\Sigma[(x_i - x) \times (y_i - y)]}{\Sigma(x_i - x)^2}$$

b is called as regression coefficient of y upon x.
Similarly, we obtain the regression of x upon y.

$$x = x + b' (y_i - y)$$

$$b' = \frac{\Sigma[(x_i - x) \times (y_i - y)]}{\Sigma(y_i - y)^2}$$

where b' is called regression coefficient of x upon y.

Properties of Regression Coefficient

1. The correlation coefficient is the geometric mean of the regression coefficient.
2. If one of the regression coefficients is less than unity, then other must be greater than unity.
3. Arithmetic mean of regression coefficient is greater than the correlation coefficient provided $r > 0$.
4. Regression coefficient is independent of the change of origin but not the scale.

Chapter 13

ANALYSIS OF QUALITATIVE DATA

There are several methods of qualitative data analysis which may be adopted according to the situation and nature of question to be answered. The data is collected through open-ended questions in an interview, self-administered questionnaires, in-depth interviews, key informant information, and focus group discussions or through observations during fieldwork. The data collected through testimonials (reactions and comments), log books (free flowing text and procedures), journals, diaries, documents, reports, stories, case studies, etc. can also be analyzed. Since the qualitative data consist of words and observations, not the numbers, hence the analysis requires a systematic approach.

PURPOSES OF QUALITATIVE ANALYSIS

1. To condense extensive and varied raw text data into a summary.
2. To establish clear links between the research objectives and the summary findings derived from the raw data and to ensure these links are both transparent and defensible.
3. To develop a model or theory about the underlying structure of experiences or processes, which are evident in the text data.

There are various methods of analyzing qualitative data but none of the methods is perfect, however, the most commonly used methods are described as under:

1. Content Analysis

This is the most commonly used method in the medical and health research. Following are the steps in analysis.

a. **Understanding the data:** Read data carefully so as to understand in the context of the research objectives and goal to be achieved. Focus should be on the analysis by question/topic, time period or event or place.
b. **Coding or indexing of data:** This is also known as categorization of information. For better understanding, identify themes or patterns, i.e. idea, concept, incident, terminologies or phrases used, attitude, behavior, etc. Codes have tags or labels, which are assigned to whole

documents or segments of documents (i.e. paragraphs, sentences, or words) to help catalogue the key concepts while preserving the context in which these concepts occur. The coding process includes development, finalization, and application of the code structure.

The development of the code structure is an iterative and lengthy process, which begins in the data collection phase. Coding may be inductive or deductive but a well-framed, clear, and comprehensive code structure promotes the quality of subsequent analysis.

i. Grounded Theory Approach to Developing Code Structure

The recommended approach to developing a set of codes is purely inductive. This approach limits researchers from erroneously "forcing" a preconceived result.

Data are reviewed line by line in detail and as a concept becomes apparent, a code is assigned. Upon further review of data, the analyst continues to assign codes that reflect the concepts that emerge, highlighting and coding lines, paragraphs, or segments that illustrate the chosen concept.

As more data are reviewed, the specifications of codes are developed and refined to fit the data. To ascertain whether a code is appropriately assigned, the analyst compares text segments to segments that have been previously assigned the same code and decides whether they reflect the same concept. Using this ''constant comparison'' method, the researchers refine dimensions of existing codes and identify new codes. Through this process, the code structure evolves inductively, reflecting ''the ground,'' i.e., the experiences of participants.

ii. Deductive Approaches to Developing Code Structure

Miles and Huberman (1994) have described a more deductive approach, which starts with an organizing framework for the codes. In this approach, the initial step defines a structure of initial codes before line-by-line review of the data. Preliminary codes can help researchers integrate concepts already wellknown in the extant literature. For example, a deductive approach of health service use might begin with predetermined codes for predisposing, enabling, and need factors based on the behavioral model. Great care must be taken to avoid forcing data into these categories because a code exists for them; however such a ''start list'' does allow new inquiries to benefit from and build on previous insights in the field.

iii. An Integrated Approach to Developing Code Structure

An integrated approach employs both inductive development of codes as well as a deductive organizing framework for code types (start list).

Generally, five code types are helpful in generating taxonomy, themes, and theory, all of which have practical relevance for health services research. These code types are:

- Conceptual codes and subcodes identifying key concept domains and essential dimensions of these concept domains.
- Relationship codes identifying links between other concepts coded with conceptual codes.
- Participant perspective codes, which identify if the participant is positive, negative, or indifferent about a particular experience or part of an experience.
- Participant characteristic codes, and
- Setting codes.

iv. Applying the Finalized Code Structure

First approach in applying the finalized code structure to the data is to have two to three members of the research team which re-review all the data, applying independently the codes from the finalized code structure.

The second approach is to establish the reliability of multiple coders from the research team with a selected group of data. Once coders have been established to be reliable with one another, one of the coders completes the remainder of the coding independently.

c. **Generating Outcome**

Researcher should focus on three types of output from qualitative studies i.e. taxonomy, themes, and theory. These outputs may be helpful in improving the measurement of multifaceted interventions; the generation of hypotheses about causal links among service quality, cost, or access; and revealing the context of events those might influence various health-related outcomes.

Taxonomy: It is a system for classifying multifaceted, complex phenomena according to common conceptual domains and dimensions.

Themes: These are general propositions that emerge from diverse and detail-rich experiences of participants and provide recurrent and unifying ideas regarding the subject of inquiry.

Theory: It emphasizes the nature of correlation or causal relationships, often delving into the systematic reasons for the events, experiences, and phenomena of inquiry.

Basic Framework of Content Analysis

Direction →	→	→	→	→	
Initial reading and understanding of information	Identify specific segments of information	Label and categorize	Reduce overlapping and reduce number of categories	Identify link and association, Few categories	Interpretation and report writing
Many pages of text	Many segments	20-25 categories	8-10 categories	5-6 categories	Few pages

2. Domain Analysis

This approach is based on the identification of key topics, referred to as domains, and the relationships between them, within the content of the data. It is focused entirely on the content of verbal or written communications. The following are the four steps in analyzing the data:

a. **Identifying the domains:** Here the researcher is to ensure that the domains that are defined do reflect the concerns of the study participants as indicated in their narratives, rather than merely reflecting the researcher's own pre-defined set of categories. The narrative data is classified or categorized.
b. **Constructing taxonomy of sub-categories:** This strategy groups actual phrases together and allows the identification of the subcategories to emerge directly from study participant's own words and thus is more likely to represent those topics most important to them.
c. **Specifying the components:** This is the crucial part of the content for defining where problems or successes lie in the public health aspect under study. By collating all phrases or whole narratives on various sub-categories in the second step, the bulk of the work for this stage has already been done. All that remains is to summarize the content into key issues for planners or policy-makers to address.
d. **Relating the domains:** This is to identify relations both between sub-categories, if this is appropriate within the research question, and, more importantly, between the primary domains.

3. Other Methods of Qualitative Data Analysis

A. **Typology:** This is a classification system of data depend on patterns, themes, or other kinds of groups of data. Ideally, categories should be mutually exclusive and exhaustive if possible, often they aren't. A list of categories includes acts, activities, meanings, participation, relationships, settings, etc.
B. **Logical analysis/Matrix analysis:** The information may be presented by visual techniques, i.e. models, diagrams, tables, outline of generalized causation, logical reasoning process, flow charts, etc.

C. **Quasi-statistics:** The researcher has to count the number of times something is mentioned in field notes as very rough estimate of frequency. Often enumeration is used to provide evidence for categories created or to determine if observations are contaminated.

D. **Hermeneutical Analysis (hermeneutics = making sense of a written text):** One should not look for objective meaning of text, but meaning of text for people in situation. Try to yourself out of analysis–tell their story, not yours. Use their words, less interpretive than other approaches. Different layers of interpretation of text. Knowledge is constructed, i.e. construction of meaning of text (from background and current situation–Social construction because of influence of others—symbolic interactionism). All ways mention time and place of writing to understand what was cultural situation, historical context, i.e. intent/purpose, context, and the encounter between author and reader to find themes and relate to dialectical context, and secondary level of analysis (Videotape).

E. **Discourse analysis:** It is linguistic analysis of ongoing flow of communication usually by using tapes so they can be played and replayed. Discussion takes place with several people, not with the Individual persons. It is to find patterns of questions, who dominates time and how, and other patterns of interaction.

F. **Semiotics analysis:** It deals with the science of signs and symbols, such as body language, gestures, etc. to determine the formulation and meaning of signs and symbols.

G. **Phenomenological analysis (how individuals experience the world?):** It emphasizes idiosyncratic meaning to individuals, not the shared constructions. Again, try to bracket self out and enter into the other person's perspective and experience. How does this affect the researcher? Some use the term "phenomenology" to describe the researcher's experience.

Following is the example of qualitative data. Reader may look at responses to open-ended question, e.g. 'Why do you smoke' from the study of student nurses on smoking. Reader should read, understand and analyse the data.

Following answers were given to questions:

1. I have tried to give up so many times but I have been unable to.
2. I like the feel of the cigarette in my hand.
3. Because it gives me pleasure.
4. I do not see why I should give up smoking!!
5. Because I like to blow the smoke through my mouth and nose.
6. Because I feel confident and in charge when I am smoking.
7. It helps me to think better.
8. I like the image that comes with smoking.

9. I feel that people respect me more as a smoker.
10. All my friends are smokers.
11. It helps to make people more friendly and comfortable, especially when offering a cigarette.
12. Why not?!!
13. Smoking makes me feel like a man.
14. I like to blow smoke rings.
15. I like the taste.
16. It is too difficult to give up.
17. It helps me to relax.
18. It helps me to reduce the pressure and tension at work.
19. My wife likes a man who smokes.

Analyze and interpret these answers as follows:

- Develop a coding system by categorizing the answers. First read all answers carefully. Then make rough categories of answers that seem to belong together. Try to limit yourself to 5–7 groups. Label each group of answers with a key word that seems to characterize the answers.
- List all answers again, but now in 5–7 groups under the labels you have selected.
- Identify whether the answers indeed belong together. You may split up some groups of answers and combine others. Find an appropriate 'label' for each category and count how many answers you have for each category.
- Come up with suggestions for interventions.

Websites for Qualitative Data Analysis Programs: Program name and Website address:

- AnSWR (freeware) http://www.cdc.gov/hiv/software/answr.htm
- ATLAS http://atlasti.de/
- Ethnograph http://qualisresearch.com
- Hyper Research http://researchware.com
- Nvivo http://www.qsrinternational.com
- NUD-IST http://www.qsrinternational.com

Chapter 14

DATA COLLECTION METHODS AND TECHNIQUES

Data collection method is different from data collection technique. Data collection method refers to the systematic approach to data collection whereas technique refers to the art of asking, listening, and interpreting.

Data collection techniques permit to systematically collect information on people, objects, phenomena, etc. and settings in which they occur.

Usually multiple sources of information are used, because no single source of information can be perfect to provide a comprehensive perspective on the issue being studied. By using a combination of observation, interview and document review, the researcher is able to validate and cross-check the findings. Each type and source of data has strengths and weaknesses. Using a combination of types of data (triangulation) increases the validity as the strengths of one approach can compensate for the weaknesses of another approach. Strategy for data collection generally depends on the research questions and the nature of the variables being investigated. Some of the data collection techniques are given in the following table:

Data collection techniques (The Three E's)		
Experiencing (through observation and field notes)	***Enquiring (through asking)***	***Examining (using and making records)***
Observation by active participation	Informal interview, structured formal interview	Archival document
Privileged active observer	Questionnaire	Journals
Passive observer	Attitude scales, e.g. global rating, Likert, semantic differentia, etc.	Maps
	Focus group discussion	Audio-video tapes
	Standardized tests	Artifacts, Field notes

EXPERIENCING (THROUGH OBSERVATION AND FIELD NOTES)

Observation is a technique that involves systematically selecting, watching and recording behavior and characteristics of living beings, objects or phenomena. Scientific inquiry using observational methods requires disciplined, trained and skilled observer. Qualities of a good observer include:

- Paying attention, seeing what to see, and hearing what to hear as per the objectives of the research question
- Good practice in writing descriptively
- Acquired expertise in recording field notes
- Knowledge of how to separate detail from trivia without being overwhelmed by the latter
- Use of rigorous methods to validate and triangulate observations
- Report the strengths and limitations of one's own perspective, which requires both self-knowledge and disclosure.

The Purpose of Direct Observation

- Describe the setting in order to understand the context.
- Find out things that would normally be taken for granted by someone who is routinely exposed to the setting.
- Observe what people may be unwilling to talk about in the interview.
- Confirm the perceptions reported by interviewees.
- Provide the researcher with first-hand knowledge of the setting during the analysis and interpretation stage. The impressions and feelings of the observer become part of the data. The observer takes the information and forms impressions that go beyond what can be fully recorded even in the most detailed field notes.

The descriptions should be factual, accurate, and thorough, without being cluttered by minute details. The description must enable the reader to enter into and understand the situation described.

OBSERVATIONAL METHODS

There are six dimensions that can describe the variations in observational methods.

1. **Participatory:** The first and most fundamental distinction that differentiates observational strategies concerns the level of observation, from full participant in the setting to complete onlooker. The extent of participation can change over time, as the study progresses, e.g. a researcher can start the study as onlooker and then become a full participant, or vice-versa. When conducting full participatory observations, this will most likely be implemented concurrently with other data collection method.
2. **Non-participatory, i.e. Emic vs. Etic Perspectives:** A participant observer shares as intimately as possible the life and activities of the setting under study in order to develop an insider's view of what is happening (emic perspective), using the language and categories for classification as identified by people in the setting. A researcher must stand far away from, or outside a particular setting in order to describe it and how it may differ from other settings, an outsider's view (etic perspective) is used to describe what has been observed.

3. **Solo vs. Team Observations (Participatory vs. Collaborative Approaches:** Degree of collaboration in observational methods varies along a continuum. At one end is the solo observer of a team of observers—what characterizes this end of the continuum is that the researchers completely control the inquiry. At the other end collaborations with people in the setting being observed, in a co-researcher role, helping to design the research, collecting data, and analyze the data. Along the middle of the continuum are various degrees of partial and periodic collaborations as opposed to continuous.
4. **Overt vs. Covert Observations:** A traditional concern about the validity and reliability of observational data has been the effects of the observer on what is observed. People may behave quite differently when they are being observed versus how they behave naturally when they don't think they are being observed. Thus, the argument goes, covert observations are more likely to find out what is really happening than overt observations where people in the setting are aware that they are being studied.
5. **Variations in the Duration of Observations:** The duration of observation will depend on the time and resources available, information needed and the outcome. On one end of the continuum are short-term studies that involve observations of a single segment of a program, sometimes for only one hour or two. On the other end of the continuum, observations are conducted over months or years. Observations should last long enough to answer the research questions being asked and to fulfill the purpose of the study.
6. **Variations in the Observational Focus of the Study:** The scope may be broad, encompassing virtually all aspects of the setting, or it can be narrow, involving only a small part of what is happening. The focus of the observation is provided by the study design and the nature of the questions being asked.

Observation–Sensitizing Concepts

A 'sensitizing concept' is a starting point of the research, and may include concepts such as: victim; stress; stigma; group process; leadership; power, etc. The six questions of 'what, why, when, how, where, and who' constitute a fundamental 'sensitizing framework' based on the central elements of good description.

Observation–Sources of Data

The following may be included in a 'sensitizing framework', depending on the research questions:

i. **Physical Setting:** It describes the physical environment, in sufficient detail, to permit the reader to visualize the setting. The physical

environment of a setting can be important with regards to what happens in that environment. A common mistake among observers is to take the physical environment for granted, e.g. a researcher may report that a program took place in a school. The researcher may have a mental image of a school that matches what was observed, but schools vary considerably in size, appearance, and neighborhood setting. Even more so, the interiors of schools vary considerably. The same may be true for criminal justice settings, health settings, and any other human service activity.

Use descriptive adjectives rather than interpretive adjectives. Vivid descriptive adjectives provide sufficient information that the reader does not have to speculate at what is meant. For example: Simply reporting 'a crowded room' requires interpretation. Contrast with this: "the meeting room had a three-person couch across one side, six chairs along the adjoining walls next to the couch, which included the door. With 20 people in the room, all standing, there was very little space between people. Several participants were overheard to say, "This room is really overcrowded". Such descriptive writing requires attention to detail and discipline to avoid vague, interpretive phrases.

ii. **Social Environment:** In describing the social environment, the observer looks for ways in which people organize themselves into groups and sub-groups. Patterns and frequency of interactions, the direction of communication patterns, and changes in these patterns enlighten about the social environment. How people group together can be illuminative and important. Decision making patterns may be important. An observer's description of a social environment may not be the same as the perceptions of that environment expressed by the participants. Nor is it likely that all participants will perceive the social climate in the same way. It is essential that the observer records participants' comments in quotation marks, indicating the source—who said what?—so as to keep the perceptions of participants separate from the observer's own descriptions and evaluations.

iii. **Historical Information:** Historical information is vital in part of describing the context in which the research is taking place. The kinds of questions that will be asked include: How was the program created and funded? Who were the original people targeted for program services, and how have the target populations changed over time? What have been staffing patterns over time? To what extent goals and proposed outcomes have changed over time? If the program is embedded in a larger organizational context, what is the history of that organization in relation to the program? How has the larger political and economic environment changed over time, and how have these changes affected program development?

iv. **Planned Program Activities:** Always build observations around the activities that have a kind of structure to them—a beginning, a middle point and a closure point, e.g. a class session, a counseling session, a meal time, a meeting, a home visit, etc. The following descriptive questions guide the researcher through the full sequence of observation: Who is involved? What is being said and done by all participants (e.g. staff and clients)? How do they go about what they do? Where do the activities occur? When do things happen? What are the variations in how participants engage in planned activities? How do behaviors and feelings change during the course of the activity? How is the activity ended? How do participants react to the ending of the activity? Each unit of activity is observed and treated as a self-contained event or unit for the purpose of managing the field notes. During analysis one looks across these discrete units of activity to find patterns and themes.

v. **Informal Interactions and Unplanned Activities:** During periods of informal interactions and unplanned activities it may be difficult to organize observations. At these times the researcher needs to remain open to opportunity sampling. The observer watches, listens and looks for opportunities to deepen observations, recording what people do, the nature of informal interactions (e.g. what sub-groups are evident) and what people are saying to each other. The latter is particularly important because during informal interactions and unplanned activities, people have the greatest opportunity to exchange views and talk with each other about what they are really feeling. The researcher may have an opportunity to converse with participants, employing informal, conversational, interviewing. How something is said should be recorded, along with what is said. It is these spontaneous interactions that often provide the most significant learning and insight. Thus it may be seen that observation is often combined with informal interviewing.

vi. **Local or "Native" Language of the Program:** The field notes and reports should include the exact language used by participants, as this provides an indication of the meaning that participants attach to something and explain their experiences. Observer must learn the language of participants in the setting they are observing in order to faithfully represent participants on their own terms and be true to their worldview.

vii. **Nonverbal Communication:** While recording the language of participants, the observer should also attend to nonverbal forms of communication because nonverbal behaviors are often misinterpreted, especially cross-culturally. Whenever possible and appropriate, having observed what appear to be significant non-verbal behaviors, some effort should be made to follow-up with those involved to find out directly from them what the non-verbal behaviors really meant.

viii. **Unobtrusive Observations:** While the persons are being observed it can make them self-conscious and generate anxiety. Regardless of how discretely observations are made, the possibility always exists that people will behave differently under conditions where an observation is taking place than they would do if the observer were not present. Rather than resorting to 'covert' observations (which are associated with ethical concerns) choose 'unobtrusive measures'. Unobtrusive measures are those made without the knowledge of the people being observed and without affecting what is observed.

ix. **Documents Review/Using Available Information:** Records, documents, artifacts and archives constitute a particularly rich source of information about many organizations and programs. In contemporary society, all kinds of entities have a trial of paper, a kind of spoor that can be mined as part of fieldwork, e.g. Families keep photographs, letters, sentimental objects; people who commit suicide leave behind suicide notes; gangs inscribe public places with graffiti; organizations produce records; service providers keep client files, etc. Indeed, and often intriguing form of analysis involves comparing official statements found in public documents (annual reports, policy statements) with private memos and what the observer actually hears or sees. At the very beginning of the study, access to important documents and records should be negotiated. The ideal situation would be to have access to all routine records, correspondence, financial and budget records, organizational rules, regulations, memoranda, and any other official and unofficial documents generated by or for the program.

Document review can be valuable in guiding the researcher to what needs to be pursued further in direct observation and interviewing. Confidentiality must be respected, as with all other information to which the researcher has access. The extent to which actual references to, and quotations from, records and documents are included in the final reports depends on whether the documents are considered part of a public record and therefore able to be publicized without breach of confidentiality. In some cases, with permission and proper safeguards to protect confidentiality, some information from private documents can be quoted directly and cited.

The use of key informants is another important technique to gain access to available information. Key informants could be knowledgeable community leaders or health staff at various levels and one or two informative members of the target group (e.g., adolescents on their sexual behavior). They can be involved in various stages of the research, from the statement of the problem to analysis of the data and development of recommendations. Other sources of available data are newspapers and published case histories, e.g., patients suffering from serious diseases, or their relatives, telling their experiences and how they cope.

x. **Observing what does not Happen:** If program goals, implementation design, and/or proposals suggest that certain things are expected to happen, and they don't, then it is appropriate for the observer to note the things that do not happen, e.g. If clinic supervisors are supposed to conduct monthly supervisory visits to the clinics, and these do not happen, then it is entirely appropriate for the observer to record this.

xi. **Observing Oneself:** The principle of reflexivity reminds the qualitative researcher to observe oneself, to be attentive to and conscious of the cultural, political, linguistic, ideological origins of his/her own perspective and voice and often in contrast to—the perspectives and voices of those s/he is observing. Reflexivity calls for critical self-reflection and self-knowledge, and a willingness to consider how one is affected by, and how one influences, what is observed. The observer must ultimately deal with issues of authenticity, reactivity, and how the observational process may have affected what was observed as well as how the background and predisposition of the observer may have constrained what was observed and understood.

ENQUIRY

The important methods of enquiry are as follows:

Interviewing

An interview is a data collection technique that involves oral questioning of respondents, either individually or as a group. Answers to the questions posed during an interview can be recorded by writing them down or by tape-recording the responses, or the combination of both.

The quality of the information obtained during an interview is largely dependent on the interviewer. It is important to develop controlled and rigorous interview techniques. It is also important to have a deep and genuine interest in what people have to say about their world.

Types of Interviews

There are three basic approaches to collecting qualitative data through open-ended interviews. Each approach has strengths and weaknesses, and each serves a somewhat different purpose. Each approach involves a different type of preparation, conceptualization and instrumentation. The three approaches differ in the extent to which interview questions are determined and standardized before the interview occurs.

i. **The Informal, Conversational Interview:** It relies entirely on the spontaneous generation of questions in the natural course of an interaction, often as part of participant observer fieldwork. It is also called 'unstructured interviewing'. This approach works particularly

well where the researcher can stay in the setting for some period of time so as not to be dependent on a single interview opportunity. Being unstructured does not mean that conversational interviews are unfocused. Sensitizing concepts and the overall purpose of the interview will guide the questions that are asked. The strengths of the informal conversational method are its flexibility, spontaneity, and responsiveness to individual differences and situational changes.

The weaknesses of the informal conversational interview are that it is time consuming, susceptible to interviewer effects, i.e. researcher may provide leading questions that result in biases, and also the difficulty in analyzing such data.

By contrast, interviews that are more systematized and standardized facilitate analysis but provide less flexibility and are less sensitive to individual and situational differences.

ii. **The General Interview Guide Approach:** It involves outlining a set of issues that are to be explored with each respondent before the interview starts. The guide serves as a basic checklist during the interview to make sure that all relevant topics are covered. The same basic line of questioning is pursued with each respondent. The interview guide provides topics within which the interviewer is free to explore, probe, and ask questions that will elucidate and illuminate that particular subject. The interviewer remains free to build a conversation within a particular subject area, to word questions spontaneously, and to establish a conversational style but with the focus on a particular subject that has been predetermined. The advantage of an interview guide is that the interviewer has carefully decided how to use the limited time available in an interview situation. The guide helps to make interviewing a number of different people systematic and comprehensive, by denoting in advance the issues to be explored. A guide is essential in conducting focus group discussions. Interview guides can be developed in more or less detail, depending on the extent to which the interviewer is able to specify important issues in advance and the extent to which it is important to ask questions in the same order to all respondents.

iii. **The Standardized Open-ended Interview:** It consists of a set of questions carefully worded and arranged with the intention of taking each respondent through the same sequence and asking each respondent the same questions with essentially the same words. The standardized open-ended interview is used when it is important to minimize variation in the questions posed to interviewees. In a fully structured interview instrument, the question would be completely specified, as would be the probes (designed to get deeper information) as well as the transition questions (designed to introduce the next topic). In multi-center studies, structured interviews provide comparability across sites. Structured

questions may also compensate for variability in researcher skills. Training in the interview approach will minimize variability due to differences in experience and skill. Structured open-ended interviews may also be used to collect data before, during and after a program of intervention. This also permits comparison across time periods.

Combining Approaches

These interview strategies are not mutually exclusive. A combined strategy offers the interviewer flexibility in probing and determining the appropriateness to explore certain subjects in greater depth, or even to pose questions about new areas of inquiry that were not originally anticipated in the interview instrument's development. A common combination strategy involves using standardized interview formats at the beginning of the interview and then leaving the interviewer free to pursue any subjects of interest during the latter parts of the interview. Another combination would include using the informal conversational interview early in an evaluation report, followed midway through by an interview guide, and then closing with a standardized open-ended interview to get systematic information from a sample of participants when concluding the study.

Types of Questions

Six kinds of questions can be asked of people depending on the topics/ subject. Different types of questions force the interviewer to be clear about what is being asked and helps the interviewee respond appropriately.

i. **Experience and Behavior Questions:** Questions about what a person does, has done, has experienced, and what activities would have been observable if the researcher were present, e.g. "If I followed you through a typical day, what would I see you doing?"
ii. **Opinion and Value Questions:** Answers to these questions enlighten about what people think about a certain action or experience, as opposed to their actions and behaviors. These questions help to understand people's goals, intentions, desires, and expectations, e.g. "What do you believe?" What do you think about ...?" What would you like to see happen?" What is your opinion of...?"
iii. **Feeling Questions:** The feeling questions aim at eliciting emotions, i.e. feeling responses to people to their experiences and thoughts. "How do you feel about that?" Opinions and feelings are often confused. It is critical that the interviewer understands the difference between the two in order to know that they have the kind of answer they want for the question they are asking. Sometimes an interviewer will ask, "How do you feel about that?" and the response will be, "I think it is the best we can do under the circumstances." The question about feelings has

not really been answered. The confusion sometimes occurs because the interviewer gives the wrong cues and does not ask the question correctly. When asking feeling questions, the interviewer has to ask and listen for feeling level responses.

iv. **Knowledge Questions:** The knowledge questions inquire about the respondent's factual knowledge.

v. **Sensory Questions:** The sensory questions ask about what is seen, heard, touched, tasted, and smelled. Sensory questions attempt to have the interviewees describe the stimuli they experience.

vi. **Background/Demographic Questions:** The standard background questions are age, education, occupation, place of residence, etc. Answers to these questions help the interviewer locate the respondent in relation to other people. Qualitative inquiry is particularly appropriate in finding out how people perceive and talk about their background.

Asking Questions: The researcher should be careful about the following aspects:

i. **The Time Frame of Questions:** It may be in the present, past or future tense.

ii. **Sequencing of Questions:** Always begin an interview with non-controversial present behaviors, activities and experiences. Such questions ask for relatively straightforward descriptions. They require minimal recall and interpretation, and are generally easy to answer. Then opinions and feelings may be solicited, building on and probing for interpretations of the experience. Opinions and feelings are likely to be more grounded and meaningful once an experience has been relived. Knowledge and skill questions can be quite threatening if asked too abruptly. They are best asked when rapport and trust have been established. Questions about the present are easier than questions about the past. Then ask about the future. Background and demographic questions, depending on how personal they are, may make the respondent feel uncomfortable. If asked at the beginning of the interview they may condition the respondent to give short answers. It may be best to save these questions until the end.

iii. **Wording of Questions:** How a question is worded affects the interviewee response. Asking questions is an art. They should be genuinely open-ended, neutral, singular and clear. A genuinely open-ended question minimizes the possibility of imposing predetermined responses, e.g. "How do you feel about... ?" is open-ended whereas "How satisfied are you with ...?" already presupposes an answer about satisfaction. Avoid questions that will lead to Yes/No answers, e.g., "Are you satisfied with ...?" Neutral questions refer to the non-judgementalism adopted by the interviewer. Singular questions ensure that not more than one idea is contained in any given question. "How

well do you know and like the staff in this clinic?" contains two ideas? The clarity of questions is enhanced by asking simple, understandable, unambiguous questions, using language and terminology that is familiar to the respondent.

iv. **Why Questions:** One should take care about asking 'why questions'. They imply causal relationships, which may be complex to unravel and may make respondents feel defensive. Think of other ways of asking what you want to know.

v. **The Final or Closing Question:** It provides the interviewee with the opportunity to have the final say, e.g. "That covers all I wanted to ask. Anything you would like to add?"

B. Global Ratings

Like interviews, global ratings are another form of self-reported data collection technique in research. Unlike an interview, this approach is an attempt to quantify a variable of interest by asking the participant to rate his or her response to a summary statement on a numerical continuum. If a researcher was interested in measuring attitudes toward a class in research methods, he or she could develop a set of summary statements and then ask the participants to rate their attitudes along a bipolar continuum. One statement might look like this:

On a scale of 1 to 5, please rate the extent to which you enjoy the fried foods.

1	2	3	4	5
Hate it	not much	Neutral	to some extent	Love it

In this example, the participant would simply circle the appropriate number that best reflects his or her attitude. The use of global ratings is also common when asking participants to rate emotional states, symptoms, and levels of distress. The strength of global ratings is that they can be adapted for a wide variety of topics and questions.

They also yield interval or ratio data. Despite this, researchers should be aware that such a rating is only a global measure of a construct and might not reveal its complexity or more subtle nuances.

C. Focus Group Discussion (FGD)

Details are given in the chapter on qualitative research methods:

Focus group is a complementary technique to individual interviews. It is a discussion on a specific topic, with a small group of people (6–10) with similar backgrounds who participate in the discussion for 1–2 hours. The objective is to get high quality data in a social context where people can consider their own views in the context of the views of others.

Two people need to conduct the focus group discussion–one who concentrates on moderating/facilitating the discussion, and the other who concentrates on taking detailed notes, and who also deals with mechanics, e.g. video cameras, tape recorders, and with any special needs that arise, e.g. someone leaving early, or becoming distraught during the discussion.

The advantages of focus group discussions:

- Cost effective: In an hour, one can gather information from eight people as opposed to just one person.
- Interactions between participants enhance the quality of the data. Participants tend to provide checks and balance for each other which reject false or extreme views.
- The extent to which there is a relatively consistent, shared view or great diversity of views can quickly be assessed.
- They tend to be enjoyable for participants, drawing on their natural social tendencies.

The limitations of focus group discussions are:

- The number of questions that can be asked is greatly restricted in the group setting.
- The available response time for each individual is constrained by having to hear from everyone. A rule of thumb: "With eight people and one hour for the focus group discussion aim to ask no more than 10 major questions".
- Facilitating a focus group requires considerable group process skill beyond simply asking questions. The moderator must manage the discussion so that one or two people do not dominate it, and enable those that are less verbal to share their views.
- Those who realize that their view is a minority perspective may not be inclined to speak up and risk negative reactions.
- Focus groups work best when people in the group, though sharing similar background, are strangers to each other. The dynamics are quite different and more complex when participants have prior established relationships.
- Controversial and highly personal issues are poor topics for focus groups.
- Confidentiality cannot be assured in focus groups.
- The focus group is beneficial for identification of major themes, but not so much for the micro-analysis of subtle differences.
- Focus groups have the disadvantage of taking place outside the natural setting where social interactions normally occur.

D. **Scaling**

It is a technique that allows researchers through their respondents to categorize certain variables that they would not be able to rank themselves.

For example, they may ask their informant(s) to bring certain types of herbal medicine and ask them to arrange these into piles according to their usefulness. The informants would then be asked to explain the logic of their ranking.

Mapping and scaling may be used as participatory techniques in rapid appraisals or situational analysis.

E. **Biological Measures**

It is another strategy for collecting research data. This approach is common in medical and psychobiological research. It often involves measuring the physiological responses of participants to any number of potential stimuli. The most common examples of responses include heart rate, respiration, blood pressure, and galvanic skin response. As with all of the forms of measurement that we have discussed, operationalization and standardization are essential. Consider a study investigating levels of anxiety in response to a certain aversive stimulus. We could use any of the other measurement approaches to gather the data we need regarding anxiety, but we chose instead to collect biological data because it is very difficult for people to regulate or fake their responses.

We operationalize anxiety as scores on certain physiological responses, such as heart rate and respiration. Each participant is exposed to the stimulus exactly in the same fashion and then is measured across the biological indicators we chose to operationalize anxiety. The data obtained from biological measures are frequently at the interval or ratio level.

EXAMINING

Archival of documents, journals, maps, field note are some of the examining methods for data collection.

Mapping: It is a valuable technique for visually displaying relationships and resources.

For example, in a water supply project, mapping is invaluable. It can be used to present the placement of wells, distance of the homes from the wells, other water systems, etc. It gives researchers a good overview of the physical situation and may help to highlight relationships hitherto unrecognized. Mapping a community is also very useful and often indispensable as a pre-stage to sampling.

Data Collection Techniques and Tools–Examples

Data collection techniques	*Data collection tools*
Using available information	Checklists. Data compilation forms
Observing	Eyes and other senses, pen/paper, watch, scales, microscopes, etc.
Interviewing	Interview guide, checklist, questionnaire, tape recorder
Administering written questionnaire	Questionnaire

Type of Study and Data Collection Techniques–Example

An assessment of effect of iron supplementation during pregnancy on birth weight:

Type of study	*Data collection techniques*
Cohort study: Examine all pregnant mothers who came for antenatal care and follow till delivery.	Through history taking, growth during pregnancy, other investigations, weighing babies at the birth, etc.
Or **Case control study:** Mother who received iron and mother who did not during pregnancy.	Interview with all mothers.

Time required for data collection: Following steps may be considered for time required to collect the data for a particular study:

Step 1: Consider the time required to reach the study area(s), to locate the study units (persons, groups, records) and the number of visits required per study unit.

Step 2: Calculate the number of interviews that can be carried out per person per day.

Step 3: Calculate the time and number of days needed to carry out the interviews.

For example: To carry out 200 interviews, a research team of 5 people can do $5 \times 4 = 20$ interviews per day, and hence 10 days required, i.e. $200 \div 20 = 10$ days for the interviews.

Step 4: Determine how much time you can devote to the study. Since the research team usually consists of very busy people, it is unlikely that team members can spend more than 30 working days on the entire study:

5 days for preparation (including pre-testing and finalizing questionnaires),

20 days for actual field work,

5 days for data processing and preliminary analysis.

If the team has 20 days for fieldwork, as in the example above, it could do the study without extra assistance. However, if the research team has

only five days available for the interviews, they would need an additional five research assistants to help complete this part of the study.

Data Collection Methods: Advantages and Disadvantages

Data collection methods	*Advantages*	*Disadvantages*
Surveys	• Good for gathering descriptive data • Can cover a wide range of topics • Are relatively inexpensive to use • Can be analyzed using a variety of existing software	• Self-report may lead to biased reporting • Data may provide a general picture but lack of in-depth data • May not provide adequate information on context
Interviews	• Permit face-to-face contact with respondents • Provide opportunity to explore topics in depth • Allow interviewer to explain or help to clarify questions, increasing the likelihood of useful responses	• Interviewer can influence the responses • Interviewee may distort information through recall error, selective perceptions, desire to please interviewer • Interviewer clarifications can result in inconsistencies • Volume of information very large; may be difficult to record and reduce data
Observations	• Provide direct information about behavior of individuals and groups • Permit evaluator to enter into and understand situation/ context • Exist in natural, unstructured, and flexible setting	• Expensive and time consuming • May affect behavior of participants • Observer may not be objective • Observed behaviors may not be typical
Tests (Achievement tests, performance assessments, etc.)	• Provide objective information on what the test taker knows and can do • Can be constructed to match a given curriculum or set of skills • Can be scored in a straightforward manner	• May be oversimplified and superficial • May be too complex; may not adequately test for student knowledge • May be very time consuming • May be biased against some groups of test takers • May be subject to corruption via coaching or cheating
Documents/ Products (Student grades, student portfolios, journals, meeting minutes, demographic information, etc.)	• Available locally • Grounded in setting and language in which they occur • Inexpensive and unobtrusive • Useful for determining value, interest, positions, political climate, public attitudes • Ongoing comparison with previous work	• May be incomplete • May be inaccurate or of questionable authenticity • Locating suitable documents may pose challenges • Analysis may be time consuming and access may be difficult

BIAS IN DATA COLLECTION

Bias in data collection is a distortion during collection of data with the result that it does not represent reality. Following are possible sources of bias during data collection:

Defective Instruments

- Questionnaires with fixed or closed questions on topics about which little is known (often asking the 'wrong things'); open-ended questions without guidelines on how to ask (or to answer) them; vaguely phrased questions; 'leading questions' that cause the respondent to believe one answer would be preferred over another; or questions placed in an illogical order.
- Weighing scales or other measuring equipment that are not standardized/calibrated.

  These sources of bias can be prevented by carefully planning the data collection process and by pre-testing the data collection tools.

Observer Bias

Observer bias can easily occur when conducting observations or utilizing loosely structured group or individual interviews. There is a risk that the data collector will only see or hear things in which (s)he is interested or will miss information that is critical to the research. Observation protocols and guidelines for conducting loosely structured interviews should be prepared, and training and practice should be provided to data collectors in using both these tools. Moreover, it is highly recommended that data collectors work in pairs when using flexible research techniques and discuss and interpret the data immediately after collecting it. Another possibility—commonly used by anthropologists—is using a tape recorder and transcribing the tape word by word.

Effect of the Interview on the Informant

This is a possible factor in all interview situations. The informant may mistrust the intention of the interview and avoid certain questions or give misleading answers. It is also important to be careful in the selection of interviewers. In a study soliciting the reasons for the low utilization of local health services, for example, one should not ask health workers from the health centers concerned to interview the population. Their use as interviewers would certainly influence the results of the study.

Information Bias

Sometimes the information itself has weaknesses. Medical records may have many blanks or be illegible. This affects the quality of the data collected.

For example, in a TB defaulter study, the percentage of defaulters with an incomplete or missing address should be calculated.

Another common information bias is due to gaps in people's memory; this is called memory or recall bias. A mother may not remember all details of her child's last diarrhea episode and of the treatment she gave two or three months afterwards. For such common diseases it is advisable to limit the period of recall, asking, for example, "Has your child had diarrhea over the past two weeks?"

ETHICAL CONSIDERATIONS

While developing the data collection techniques, one should consider whether the research procedures are likely to cause any physical or emotional harm. Harm may be caused, for example, by:

- violating informants' right to privacy by posing sensitive questions or by gaining access to records which may contain personal data;
- observing the behavior of informants without their being aware (concealed observation should therefore always be crosschecked or discussed with other researchers with respect to ethical admissibility);
- allowing personal information to be made public which informants would want to be kept private, and
- failing to observe/respect certain cultural values, traditions or taboos valued by the informants.

Several methods for dealing with these issues may be recommended:

Permission to Proceed

a. Informed consent to be obtained before the study or the interview begins; from the relevant authorities, individuals and the community in which the project is to be carried out. This may involve organizing meetings at national or provincial level, at district and at village level. For clinical studies this may also involve obtaining written informed consent.
b. Not exploring sensitive issues before a good relationship has been established with the informant.
c. Ensuring the confidentiality of the data obtained.
d. Learning enough about the culture of informants to ensure it is respected during the data collection process.

If sensitive questions are asked, for example, about family planning or sexual practices, or about opinions of patients on the health services provided, it may be advisable to omit names and addresses from the questionnaires.

To conclude, it is necessary to carefully prepare data collection tools, plan technique for obtaining data, understand bias and ethical issues, so as to generate high quality of information for better health care and development.

Chapter 15

DESIGNING RESEARCH INSTRUMENTS, INTERVIEW GUIDES AND SKILLS

The validity of results and quality of research depends to a large extent on the quality of the data collection instruments/tools/questionnaire. Much of the data in medical research is collected using Interviews and administering questionnaires. Therefore designing a good 'questionnaire' is an important part in the development of a research proposal. There are various types of questions used to collect the data; some of them are as follows:

Open Ended Questions

Open-ended questions give the respondent freedom to answer and the responses are recorded in the respondents' own words. Such questions are useful for obtaining in-depth information on:

- facts with which the researcher is not very familiar,
- opinions, attitudes and suggestions of informants, or
- sensitive issues.

Examples - What were the reasons to stop alcohol?

- What did you do when you came to know that you have HIV infection?
- What habits do you believe increase chances of coronary heart disease?
- What is your opinion on the Janani Suraksha Yojana (JSY)/Maternity Benefit Scheme in India?

Advantages, Disadvantages and Measures to Improve Open Ended Questions

Advantages	*Disadvantages*	*Measures to improve*
1. It allows probing more deeply into issues of interest being raised.	1. It requires skilled interviewers. A big risk is incomplete recording of all relevant issues covered in the discussion.	1. Thoroughly train and supervise the interviewers or select experienced persons.
2. Issues not previously planned but may provide valuable new insights on the problem.	2. Analysis is time-consuming.	2. Prepare a list of further questions to keep at hand using to 'probe' for answer(s) in a systematic way.

Contd...

Contd...

Advantages	*Disadvantages*	*Measures to improve*
3. Information provided in the respondents' own words might be useful as examples or illustrations, add interest to the final report.	3. It usually requires qualitative methods to improve the information.	3. Pre-test open-ended questions.

Closed Ended Questions

Some of the closed ended questions are as follows:

a. **Dichotomous questions:**
   Example: • Have you ever had an accident? 1. Yes 2. No
   • Do you eat an egg everyday? 1. Yes 2. NO

b. **Multiple-Choice Questions:**
   Example: How important is it to you to attend a lecture?
   i. Extremely important
   ii. Very important
   iii. Somewhat important
   iv. Not at all important

c. **Cafeteria questions:**
   Example: People have different opinions about the use of estrogen replacement therapy for women in menopause. Which of the following statements best represents your point of view?
   i. Estrogen replacement is dangerous and should be totally banned.
   ii. Estrogen replacement may have some undesirable side effects and needs caution in use.
   iii. I am undecided about the use of estrogen replacement.
   iv. Estrogen replacement has beneficial effect and needs to be promoted.
   v. Estrogen replacement therapy is wonder cure that should be administered routinely to menopausal women.

d. **Rank order Questions:**
   Example: Please indicate the priority of your life by putting the number in decreasing order (1 being the first, 2 being the next and so on.
   1. Wealth
   2. Health
   3. Friendship
   4. Family
   5. Relationship
   6. Success
   7. Promotions
   8. Religion

e. **Force Choice questions:**
Example: Which statement more closely represents your view point?
1. I am meticulous in my planning.
2. I think, I don't have good communication skills.

f. **Rating questions:**
Example: On 0–10 scale, measure your satisfaction level by encircling the number (0 being extremely dissatisfied and 10 being extremely satisfied).

0	1	2	3	4	5	6	7	8	9	10
extremely dissatisfied										extremely satisfied

g. **Likert scale:** It is named after Rensis Likert, a social psychologist. It consists of several declarative statements/ items that express the view point on a topic. Respondents are asked to indicate the degree to which they agree or disagree.

Topics/ Questions	*Strongly agree*	*Agree*	*Not decided*	*Disagree*	*Strongly Disagree*
1					
2					
3					
4					

h. **Visual analog questions (VAS):** It is type of psychosocial measurement rating question. These are more sensitive for subjective experience than rating based categorical adjectives. It helps the investigator to efficiently quantify subtle gradations in the strength or intensity of an individual characteristics. Here is the VAS for severity of pain (put x to mark your best response).
None .....× ..... Unbearable

Advantages, Disadvantages and Measure to Improve Closed Ended Questions

Advantages	*Disadvantages*	*Measures to improve*
1. Quicker and easier to answer	1. Set of answers may not be exhaustive	1. Develop picture codes which can be used for illiterates as well as literates (e.g., five, four, three, two and one stars indicating a 5-point scale).
2. Easier to tabulate and analyze	2. Answers may not be mutually exclusive	2. First present the extremes and then the values in between so that the respondent is straight away aware of the range of answers.

Contd...

Contd...

Advantages	*Disadvantages*	*Measures to improve*
3. Time saving	3. In case of illiterate respondents, the interviewer may be tempted to read the list of possible answers in the given sequence, thereby influencing the choice of response and introducing bias.	3. Ensure inclusion of follow up questions to elaborate on reasons for choosing a given rating.
4. Often helps to clarify the meaning of the question.	4. If there is no question to elaborate on the informant's reasons for choosing a certain rating, uniformity in rating may still be deceptive, as there may be considerable variation in reason for choosing the same ratings.	
5. Well-suited for use in multi-item scales designed to produce a single score.		
6. Comparing responses of different groups, or of the same group over time, becomes easier.		

Designing the Questionnaire/Interview Tool

The questions should be clear, specific, simple (use simple and common words that convey the idea and avoid technical terms) and neutral (avoid jargons, loaded words and stereotypes that suggest that there is most desirable answer). Following steps may be adopted to design the questionnaire/ interview tool:

- State objectives and variables of the research study.
- Formulate one or more questions that will provide the information needed for each variable.
- Check whether each question measures one thing at a time.
- Avoid leading questions.
- Use proper wordings.
- Ask sensitive questions in a socially acceptable way.
- Design your interview schedule or questionnaire to be 'informant friendly'.
- Translation is needed if interviews are to be conducted in one or more local languages. The questionnaire should be translated in order to standardize the way questions will be asked.
  After having it translated, it should be retranslated into the original language by a different person. One can then compare the two versions

for differences and make decisions concerning the final phrasing of difficult questions.

Avoid Pitfalls

- Double barreled questions:
  Each question should contain only one concept. Use of words like "and/or" sometimes lead to undesirable response.
  Example: How many cups of coffee or tea do you drink per day? (it is better to break this question in two, asking separately for coffee and tea).
- Hidden assumptions: There should not be any preconceived assumptions for getting the answer to a question.
- The question and answer options do not match. It is important that the question matches the options provided for the answer, a task that seems simple but is often done incorrectly.

When You Finalize the Questionnaire, be Sure that–

A separate, introductory page is attached to each questionnaire, explaining the purpose of the study, requesting the informant's consent to be interviewed and assuring confidentiality of the data obtained.

Each questionnaire has a heading and space to insert the number, date and location of the interview, and, if required, the name of the informant. You may add the name of the interviewer, to facilitate quality control.

Layout is such that questions belonging together appear together visually. If the questionnaire is long, you may use subheadings for groups of questions.

Sufficient space is provided for answers to open-ended questions, categories such as 'other' and for comments on pre-categorized questions.

Boxes for pre-categorized answers are placed in a consistent manner (e.g., on the right-half of the page).

Self-administered (Written) Questionnaires

All steps discussed above apply to written questionnaires as well as to guides/questionnaires used in interviews. For written questionnaires, however, clear guidelines will have to be added on how the answers to questions should be filled in.

Self-administered questionnaires are most commonly used in large-scale surveys using predominantly pre-categorized answers among literate study populations.

As a response rate of 50% or less to written questionnaires is not exceptional, these tools will rarely be used in small-scale studies. In exploratory studies which require intensive interaction with informants in

order to gain better insight in an issue, self-administered questionnaires would be inadequate tools. These are coupled with other qualitative methods like FGD, KII , in-depth interview, etc.

INTERVIEW SKILLS

Interview types and techniques are described in detail in Chapter 14, however, some of the important steps are given here.

Steps

- Meeting and informing the opinion leaders and key personnel the date and purpose of the study/ interview.
- Minimize the social distance between the interviewer and the informant. Interviewers should try to blend in the environment. Interviewer's cloths should be culturally acceptable and as simple as possible (no fancy dresses, high heels or tight jeans in rural areas).
- Sitting arrangements for interviewer(s) and informant(s) should preferably be at the same height (no straight chair when the informant is sitting on a mat on the floor) and beside each other, forming an angle of 90 degrees, rather than opposite each other.
- Gender relations have to be respected. When interviewer and informant are of opposite sex, more physical distance will usually be required than when they are of the same sex.
- Interviewer should show interest, make the informant feel at ease and never show any disapproval of the information received during the interview.
- Noting down answers should never go at the cost of the eye contact with the informant.
- Keeping control over the interview without imposing oneself is a skill each researcher has to learn.

Chapter 16

DATA MANAGEMENT, PROCESSING AND ANALYSIS

The data management system has to be set up before the study begins. This includes designing the forms for recording the measurements, choosing the software for data editing, dummy tabulations, etc.

Data represent the information that will ultimately allow investigator to describe phenomena, predict events, identify and quantify differences between conditions, and establish the effectiveness of interventions, because of their critical nature.

Data should be treated with the utmost respect and care. In addition to ensuring the confidentiality, the security of personal data is to be planned. The researcher should carefully plan how the data will be logged, entered, transformed and organized into a database that will facilitate accurate and efficient statistical analysis.

Data Quality Control and Management

Steps that Precede the Study

- Be parsimonious: collect only needed variables
- Select appropriate computer hardware and software
- Program the database to flag missing and out-of-range values
- Plan analysis and test with dummy tables
- Design forms that are self-explanatory, coherent, clearly formatted , pretested and validated

Steps During the Study

- Flag or check for omissions or major errors
- No errors in ID, name, date, etc.
- No missing entries or faulty skip pattern
- Legible entries
- Values of key variables are consistent and within permissible range.

Logging and Tracking Data

Any study that involves data collection will require some procedure to log the information as it comes in and track it until it is ready to be analyzed.

Research data can be obtained from number of sources, e.g., personal records, participant interviews, observations, laboratory reports, and pretest and post-test measures. Without a well-established procedure, data can easily become disorganized, un-interpretable, and ultimately unusable.

Computer database, e.g., Microsoft Access, Microsoft Excel, Claris FileMaker, Epi-info, LOTUS, SPSS, SAS, etc. will provide researchers with up-to-date information throughout the study, and it will save substantial time and effort when they are ready to analyze their data and report the findings.

The recruitment log is a comprehensive record of all individuals approached about participation in a study. The log can also serve to record the dates and times that potential participants were approached, whether they met eligibility criteria, and whether they agreed and provided informed consent to participate in the study. Importantly, for ethical reasons, no identifying information should be recorded for individuals who do not consent to participate in the research study. The primary purpose of the recruitment log is to keep track of participant enrollment and to determine how representative the resulting cohort of study participants is of the population that the researcher is attempting to examine.

Data Screening

Immediately following data collection, but prior to data entry, the researcher should carefully screen all data for accuracy. The promptness of these procedures is very important because research staff may still be able to re-contact study participants to address any omissions, errors, or inaccuracies. In some cases, the research staff may inadvertently have failed to record certain information (e.g., assessment date, study site) or perhaps recorded a response illegibly. In such instances, the research staff may be able to correct the data themselves if too much time has not elapsed. Because data collection and data entry are often done by different research staff, it may be more difficult and time consuming to make such clarifications once the information is passed onto data entry staff.

One way to simplify the data screening process and make it more time efficient is to collect data using computerized assessment instruments. Computerized assessments can be programmed to accept only responses within certain ranges, to check for blank fields or skipped items, and even to conduct cross-checks between certain items to identify potential inconsistencies between responses. Another major benefit of these programs is that the entered data can usually be electronically transferred into a permanent database, thereby automating the data entry procedure. Although this type of computerization may, at first glance, appear to be an impossible budgetary expense, it might be more economical than it seems when one considers the savings in staff time spent on data screening and entry.

Whether it is done manually or electronically, data screening is an essential process in ensuring that data are accurate and complete. Generally, the researcher should plan to screen the data to make certain that–

1. Responses are legible and understandable.
2. Responses are within an acceptable range.
3. Responses are complete, and
4. All of the necessary information has been included.

Constructing a Database

Once data are screened and all corrections made, the data should be entered into a well-structured database. When planning a study, the researcher should carefully consider the structure of the database and how it will be used. In many cases, it may be helpful to think backward and to begin by anticipating how the data will be analyzed. This will help the researcher to figure out exactly which variables need to be entered, how they should be ordered, and how they should be formatted. Moreover, the statistical analysis may also dictate what type of program you choose for your database. For example, certain advanced statistical analysis may require the use of specific statistical programs. While designing the general structure of the database, the researcher must carefully consider all the variables that will need to be entered. Forgetting to enter one or more variables, although not as problematic as failing to collect certain data elements, will add substantial effort and expense because the researcher must then go back to the hard data to find the missing data elements.

The Data Codebook

In addition to developing a well-structured database, researchers should take the time to develop a data codebook. A data codebook is a written or computerized list that provides a clear and comprehensive description of the variables that will be included in the database.

A detailed codebook is essential when the researcher begins to analyze the data. Moreover, it serves as a permanent database guide, so that the researcher, when attempting to reanalyze certain data, will not be stuck trying to remember what certain variable names mean or what data were used for a certain analysis. Ultimately, the lack of a well-defined data codebook may render a database un-interpretable and useless. At a bare minimum, a data codebook should contain the following elements for each variable:

- Variable name
- Variable description
- Variable format (number, data, text)
- Instrument or method of collection
- Date collected
- Respondent or group
- Variable location (in database)
- Notes

Data Processing–Quantitative Data

Data can be processed manually (using data master sheets or manual compilation of the questionnaires) or by computer using a micro-computer and existing software/self-written programs for data analysis. It involves categorizing the data, coding, and summarizing the data in data master sheets, manual compilation without master sheets, or data entry and verification by computer.

Categorizing

Categorical variables and numerical variables are to be categorized separately; otherwise if it comes to notice during data analysis that the categories had been wrongly chosen, one cannot reclassify the data anymore.

Coding

If the data are to be entered in a computer for subsequent processing and analysis, it is essential to develop a coding system.

For computer analysis, each category of a variable can be coded with a letter, group of letters or word, or be given a number. For example, the answer 'yes' may be coded as 'Y' or 1; 'no' as 'N' or 2 and 'no response' or 'unknown' as 'U' or 9.

The codes should be entered on the questionnaire (or checklist) itself. When finalizing the questionnaire, for each question one should insert a box for the code in the right margin of the page. These boxes should not be used by the interviewer. They are only filled in afterwards during data processing. Take care that there are as many boxes as the number of digits in each code.

Summarizing the Data in Data Master Sheets, Manual Compilation, or Compilation by Computer

1. Data master sheets / data master table

If data are processed by hand, it is often most efficient to summarize the raw research data in a so-called data master sheet, to facilitate data analysis. On a data master sheet all the answers of individual respondents are entered by hand.

Master sheets can be made in different ways. For short simple questionnaires, one may put all possible answers for each question in headers at the top of the sheet and then list or tick the answers of the informants one by one in the appropriate columns.

For example, the straightforward answers of the smoking questionnaire for male smokers could be processed as follows: Master sheet for smokers (males):

No.	Q1 Sex	Q2 Age		Q6 No. of cig.		Q7 Age on set		Q9 Tried to				Q14 Cough > 2 wks		Q14 Cough/ chest pain	
								Reduce		Stop					
		Yrs	Cat	Yrs	Cat	Yrs	Cat	Yes	No	Yes	No	Yes	No	Yes	No
1	M	18	(1)	10	(2)	12	(2)	1x			√		√		√
2	M	35	(3)	30	(4)	20	(4)		NR	1x			√	√	
3	M	54	(4)	15	(2)	14	(2)	10x		3x		√		√	
Etc.															
Total	31	Av	35	Av	20	Av	18	26	4+ 1NR	19	12	5	26	11	20

Categories

Age	*No. of cigarettes/day*	*Age onset smoking*
15 – 24 = 1	<10 = 1	<10 = 1
25 – 34 = 2	10 – 19 = 2	10 – 14 = 2
35 – 44 = 3	20 – 29 = 3	15 – 19 = 3
45 – 54 = 4	30 – 39 = 4	20 – 24 = 4
55 + = 5	40 + = 5	25 + = 5

Some answers, however, require more elaborate coding and have more categories. For example, education and occupation could be summarized as follows:

No.	Education									Occupation															
	None	Highest level reached						Still in school	NR	Self							Head Household								
		Years	Type																						
			PS	SS	OT	UY	O	Yes	No		0	1	2	3	4	5	6	1	2	3	4	5	6	U	NR
1		5	√						√			√								√					
2		9		√					√						√					NA					
3	√								NA							√				NA					

Categories

Eduction

PS = Primary school
SS = Secondary school
OT = Occupational training
UY = University level
O = Other
U = No response/unknown
NA = Not applicable

Occupation/income

0 = No source of income
1 = Irregular income from petty trade, handicraft, farming on borrowed land (not enough to live on)
2 = Unskilled laborer
3 = Farmer (with land)
4 = Trader/beer brewer/coffee-shop or taxi owner, etc.
5 = Teacher, nurse, civil servant
6 = Doctor, lawyer, government administrator

2. Compilation by hand (without using master sheets):

When the sample is small (less than 30) and the collected data is limited, it might be more efficient to do the compilation manually. Certain procedures will help ensure accuracy and speed.

1	If only one person is doing the compilation use **manual sorting**. If a team of 2 persons work together, use either manual sorting or **tally counting.**
2	Manual sorting can be used only if data on each subject is on a different sheet of paper/entered in a separate questionnaire.
3	To do **manual sorting**, the basic procedure is to: Take one question at a time, sort the questionnaires into different piles representing the various responses to the question.
4.	To do **tally counting**, the basic procedure is: One member of the compiling team reads out the information while the other records it in the form of a tally (e.g., III representing 3 subjects, IIII representing 5 subjects who present a particular answer). Tally count for no more than two variables at one time (e.g., sex plus type of facility used). After tally counting, add the tallies and record the number of subjects in each group.

3. Computer compilation

Before we decide to use a computer, we have to be sure that it will save time or that the quality of the analysis will benefit from it. Note that feeding data into a computer costs time and money. The computer should not be used if the sample is small and the data is mainly generated by open questions (qualitative data), unless there is a resource person who is competent in using a program for qualitative data analysis such as Qualitan or SPSS. The larger the sample, the more beneficial in general the use of a computer will be.

Computer compilation consists of the following steps:

i. Choosing an appropriate computer program
ii. Data entry
iii. Verification or validation of the data
iv. Programming (if necessary)
v. Computer outputs/prints

i. **Choosing an appropriate computer program:** A number of computer programs are available in the market that can be used to process and analyze research data. The most widely used programs are:
   - Epi Info (version 6), a user-friendly program for data entry and analysis, which also has a word processing function for creating questionnaires (developed by the Centre for Disease Control, Atlanta, USA and World Health Organization, Geneva).
   - LOTUS 1-2-3, a spreadsheet program (from the Lotus Development Corporation), dBase (version III plus or IV), a data-management program (from Ashton-Tate), SPSS, which is a quite advanced Statistical Package for Social Sciences (SPSS Inc.).

ii. **Data entry:** To enter data into the computer you have to develop a data entry format, depending on the program you are using. However,

it is possible to enter data using dBase (which is relatively good for data entry) and do the analysis in LOTUS 1-2-3 or SPSS.

After deciding on a data entry format, the information on the data collection instrument will have to be coded (e.g., Male: M or 1, Female: F or 2). During data entry, the information relating to each subject in the study is keyed into the computer in the form of the relevant code (e.g., if the first subject (identified as 001) is a male (code 1) aged 25, the data could be keyed in as 001125).

Note that data entry can be done through the private sector, which may be fast and not too expensive. Health office staff who are not accustomed to this work tend to be slow and make many errors in entry.

iii. **Verification:** During data entry, mistakes will definitely creep in. The computer can print out the data exactly as it has been entered. So the printout can be checked visually for obvious errors, e.g., exceptionally long or short lines, blanks that should not be there, alphabetic codes where numbers are expected, obviously wrong codes, etc.

iv. **Programming:** If we use computer personnel to analyze the data, it is important to communicate effectively with them. Do not leave the analysis to the computer specialist. The researcher should tell the computer personnel:
   - the names of all the variables in the questionnaire;
   - the location of these variables in relation to the data for one subject, i.e., the data format;
   - how many subjects are to be analyzed and which groups are to be compared;
   - whether any variables are to be re-coded or calculated; and
   - for which variables we need straight tabulations and which variables we would like to cross-tabulate.

v. **Computer outputs:** The computer can do all kinds of analysis and the results can be printed. It is important to decide whether each of the tables, graphs, and statistical tests that can be produced makes sense and should be used in our report.

4. Data analysis (details are given in chapter no 12 and 13):

Quantitative Data

Analysis of quantitative data involves the production and interpretation of frequencies, tables, graphs, etc., that describe the data.

Qualitative Data

There are many methods of analyzing qualitative data. Some of them are described in the chapter on analyzing qualitative data. Some guidelines are as follows:

The Data can be Analyzed in Seven Steps

Step 1: Take a sample of questionnaires and list all answers for a particular question. Take care to include the source of each answer you list (in the case of questionnaires one can use the questionnaire number), so that one can place each answer in its original context, if required.

Step 2: To establish categories, first read carefully through the whole list of answers. Then start giving codes (A, B, C, for example or key words) for the answers that belong together in one category, and write these codes in the left margin. Use a pencil so that it is easy to change the categories if change mind.

Step 3: List the answers again, grouping those with the same code together.

Step 4: Then interpret each category of answers and try to give it a label that covers the content of all answers. In the case of data on opinions, for example, there may be only a limited number of possibilities, which may range from (very) positive, neutral, to (very) negative.

Step 5: Now try a next batch of 20 questionnaires and check if the labels work. Adjust the categories and labels, if necessary.

Step 6: Make a final list of labels for each category and give each label a code (keyword, letter or number).

Step 7: Code all data, including what has already been coded, and enter these codes in the master sheet or in the computer.

Note again that one may include a category 'others', but it should be as small as possible, preferably used for less than 5% of the total answers.
If one categorizes responses to open-ended questions in this way one can:

- Analyze the content of each answer given in particular categories, for example, in order to plan what actions should be taken (e.g., for health education). Gaining insight in a problem, or possible interventions for a problem, is the most important function of qualitative data.
- Report the number and percentage of respondents that fall into each category; so that one gains insight in the relative weight of different opinions or reasons.

Questions that ask for descriptions of procedures, practices, or beliefs usually do not provide quantifiable answers (though one may quantify certain aspects of them). The answers rather form part of a jigsaw puzzle that has to be put together in order to obtain insight in the problem/topic under study.

Quality Control Tables and Checklists for Conducting Clinical Trials

Tabulations for monitoring performance characteristics:

A. Clinic/community characteristics
   - Recruitment
     - Number of participants screened for enrollment, number rejected and reasons for rejections
     - Cumulative graph of number recruited compared with that required to achieve recruitment goals.
   - Follow-up
     - Number of completed follow-up examinations for each expected visit; number seen within specified time frame.
     - Number of drop-outs and participants who cannot be located for follow-up.
   - Data quantity and quality
     - Number of forms completed, number that generated edited messages and number unanswered edit queries.
     - Number of forms missing
   - Protocol adherence
     - Number of ineligible participants enrolled
     - Adherence to other measurement

B. Data center characteristics
   - Number of forms received and awaiting data entry
   - Cumulative list of coding and protocol change
   - Time table indicating completed and unfinished tasks

C. Laboratory characteristics
   - Number of samples received and number analyzed
   - Number of samples inadequately identified, lost or destroyed
   - Number of samples requiring re-analysis and tabulations of reasons

D. Site visit components - clinical center
   - Meeting with principal investigator, clinic staff
   - Inspection for record storage facility
   - Check for completeness and accuracy of data
   - Observation of clinic staff for conduction of specified procedures
   - Check for SOPs, manuals, forms, etc.

E. Site visit components - Data center
   - Review of methods for data management, verification and inventorying
   - Check for adequacy for storing data
   - Review of methods for randomization and data editing procedures
   - Review of program methods
   - Review of data analysis philosophy, data back-up and master file, etc.

Chapter 17

ETHICAL ISSUES IN HEALTH RESEARCH

Biomedical and social research is essential for the development of better interventions to prevent and treat illnesses.

Research with human participants raises ethical concerns because people accept risks and inconveniences primarily to advance scientific knowledge and to benefit others. For the public to be willing to participate in biomedical research and to provide public funding, it needs to trust that such research is conducted to strict ethical standards.

World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects: Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 (Annexure–II)

After The *Nuremberg Code in 1948* (Annexure – I), the next major development in the protection of research participants came in 1964 at the 18th World Medical Assembly in Helsinki, Finland. In the *Helsinki Declaration*, the World Medical Association adopted 12 principles to guide physicians on ethical considerations related to biomedical research. Among its many contributions, the declaration helped to clarify the very important distinction between medical treatment, which is provided to directly benefit the patient, and medical research, which may or may not provide a direct benefit.

The declaration also recommended that human biomedical research adheres to accepted scientific principles and be based on scientifically valid and rigorous laboratory and animal experimentation, as well as on a thorough knowledge of scientific literature. These guidelines were revised at subsequent meetings in 1975, 1983 and 1989.

In 1974, largely in response to the Tuskegee Syphilis Study, the US Congress passed the National Research Act, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Research Act led to the development of institutional review boards (IRBs). These review boards, which are described in detail later, are specific human-subjects committees that review and determine the ethicality of research. The National Research Act required IRB review and approval of all federally funded research involving human participants.

The Commission was responsible for (1) identifying the ethical principles that should govern research involving human participants and (2) recommending steps to improve the Regulations for the Protection of Human Subjects.

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research".

The ***Belmont Report*** established three principles that underlie the ethical conduct of all research conducted with human participants:

1. respect for persons,
2. beneficence, and
3. justice

It is generally agreed that these principles, which in the abstract have equal moral force, guide the conscientious preparation of proposals for scientific studies. In varying circumstances they may be expressed differently and given different moral weight, and their application may lead to different decisions or courses of action. The present guidelines are directed at the application of these principles to research involving human subjects.

Respect for persons incorporates at least two fundamental ethical considerations, namely:

a. Respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination.
b. Protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.

Beneficence refers to the ethical obligation to maximize benefits and to minimize harms and wrongs. This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the investigators be competent both to conduct the research and to safeguard the welfare of the research subjects. Beneficence further proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, *non-maleficence* (do no harm).

Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects the principle refers primarily to *distributive justice*, which requires the equitable distribution of both the burdens and the benefits of participation in research. Differences in distribution of burdens and benefits are justifiable only if they are based on morally relevant distinctions between persons; one such distinction is vulnerability. "Vulnerability" refers to a substantial

incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provisions must be made for the protection of the rights and welfare of vulnerable persons.

Federal Research Protections

There are two primary categories of federal research protections for human participants. The first is provided in the Federal Policy for the Protection of Human Subjects, also known as the *Common Rule*. The Common Rule is a set of regulations adopted independently by 17 federal agencies that support or conduct research with human research participants. The 17 agencies adopted regulations based on the language set forth in Title 45, Part 46, Subpart A, of the *Code of Federal Regulations (CFR)*. Thus, the Common Rule is, for most intents and purposes, Subpart A of the Department of Health and Human Services' regulations.

The second category of federal protections that relates to human research participants is the set of rules governing drug, device, and biologics research. These rules are administered by the US. Food and Drug Administration (FDA). Specifically, the FDA regulates research involving products regulated by the FDA, including research and marketing permits for drugs, biological products, and medical devices for human use, regardless of whether federal funds are used.

In general, the federal regulations focus on two main areas that are integral to the protection of human participants: informed consent and institutional review boards.

INFORMED CONSENT

The principle mechanism for describing the research study to potential participants and providing them with the opportunity to make autonomous and informed decisions regarding whether to participate or not, is *informed consent*. For this reason, informed consent has been characterized as the cornerstone of human rights protections.

The three basic elements of an informed consent are that it must be (1) competent, (2) knowing, and (3) voluntary. Notably, each of these three prongs may be conceptualized as having its own unique source of vulnerability. In the context of research, these potential vulnerabilities may be conceptualized as stemming from sources that may be intrinsic, extrinsic, or relational.

1. *Intrinsic vulnerabilities are personal characteristics* that may limit an individual's capacities or freedoms. For instance, an individual who is under the influence of a psychoactive substance or is actively

psychotic might have difficulty comprehending or attending to consent information. Such vulnerabilities relate to the first prong of informed consent, that of competence (also referred to in the literature as "decisional capacity"). Many theorists have broadly conceptualized competence to include such functions as understanding, appreciation, reasoning, and expressing a choice. However, these functions are directly related to the legal and ethical concept of competence only in so far as they refer to an individual's intrinsic capability to engage in these functions.

2. *Extrinsic vulnerabilities are situational factors* that may limit the capacities or freedoms of the individual. For example, an individual who has just been arrested or who is facing sentencing may be too anxious or confused, or may be subject to implicit or explicit coercion to provide voluntary and informed consent. Such extrinsic vulnerabilities may relate either to knowingness or to voluntariness to the degree that the situation, not the individual's capacity, prevents him or her from making an informed and autonomous decision.
3. *Relational vulnerabilities* occur as a result of a relationship with another individual or set of individuals. For example, a prisoner who is asked by the warden to participate in research is unlikely to feel free to decline.

   Similarly, a terminally-ill person recruited into a study by a caregiver may confuse the care giving and research roles. Relational vulnerabilities typically relate to the third prong of the informed consent process, voluntariness. Certain relationships may be implicitly coercive or manipulative because they may unduly influence the individual's decision.

Competence

The presence of cognitive impairment or limited understanding does not automatically disqualify individuals from consenting or assenting to research studies. As discussed, the principle of respect for persons asserts that these individuals should have every right to participate in research if they so choose. According to federal regulations (45 CFR § 46.111[b]), "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects." Therefore, the critical issue is not whether they should be allowed to participate, but whether their condition leads to an impaired decisional capacity.

Appelbaum and Grisso, (2001) have stated that to our knowledge, there has been only one instrument developed specifically for this purpose, the MacArthur Competence Assessment Tool for Clinical Research,

developed by two of the leading authorities in consent and research ethics, the instrument provides a semi-structured interview format that can be tailored to specific research protocols and used to assess and rate the abilities of potential research participants in four areas that represent part of the standard of competence to consent in many jurisdictions.

The instrument helps to determine the degree to which potential participants–

- understand the nature of the research and its procedures;
- appreciate the consequences of participation;
- Show the ability to consider alternatives, including the option not to participate; and
- show the ability to make a reasoned choice.

Although this instrument appears to be appropriate for assessing competence, researchers should make certain to carefully consult local and institutional regulations before relying solely on this type of instrument. Depending on the specific condition of the potential participants, researchers may want to engage the services of a specialist (e.g., a neurologist, child psychologist) when making competence determinations. Importantly, researchers should not mistakenly interpret potential participants' attentiveness and agreeable comments or behavior as evidence of their competence because many cognitively impaired persons retain attentiveness and social skills. Similarly, performance on brief mental status examination should not be considered sufficient to determine competence, although such information may be helpful in combination with other competence measures.

If the potential research participant is determined to be competent to provide consent, the researcher should obtain the participant's informed consent. If the potential participant is not sufficiently competent, informed consent should be obtained from his or her caregiver or surrogate and assent should be obtained from the participant.

Knowingness

It is still not clear whether many research participants actually participate knowledgeably in decision making about their research involvement.

In fact, evidence suggests that participants in clinical research often fail to understand or remember much of the information provided in consent documents, including information relevant to their autonomy, such as the voluntary nature of participation and their right to withdraw from the study at any time without negative repercussions.

Problems with the understanding of both research and treatment protocols have been widely reported. Studies indicate that research participants often lack awareness of being participants in a research study, have poor recall of study information, have inadequate recall of

important risks of the procedures or treatments, lack understanding of randomization procedures and placebo treatments, lack awareness of the ability to withdraw from the research study at any time, and are often confused about the dual roles of clinician versus researcher.

A number of client variables are associated with the understanding of consent information. Several studies found educational and vocabulary levels to be significantly and positively correlated with measures of understanding of consent information. Although age alone has not been consistently associated with diminished performance on consent quizzes, it does appear to interact with education in that older individuals with less education display decreased understanding of consent information.

Drug and alcohol abusers may present a unique set of difficulties in terms of their comprehension and retention of consent information, not only because of the mental and physical reactions to the psychoactive substances, but also because of the variety of conditions that are co-morbid with substance. Acute drug intoxication or withdrawal can impair attention, cognition, or retention of important information due to limited educational opportunities and chronic brain changes resulting from long-term drug or alcohol use.

INSTITUTIONAL ETHICS COMMITTEE (IEC)/INSTITUTIONAL REVIEW BOARD (IRB)

It is mandatory that all proposals on biomedical research involving human subjects should be cleared by an appropriately constituted Institutional Ethics Committee (IEC), also referred to as Institutional Review Board (IRB) in many countries, to safeguard the welfare and the rights of the participants. The Ethics Committees are entrusted not only with the initial review of the proposed research protocols prior to initiation of the projects but also have a continuing responsibility of regular monitoring for the compliance of the ethics of the approved programs till the same are completed. Such an ongoing review is in accordance with the Declaration of Helsinki and all the international guidelines for biomedical research.

The basic responsibility of an IEC is to ensure a competent review of all ethical aspects of the project proposals received and execute the same free from any bias and influence that could affect their objectivity. IECs should provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Scientific Review Committees.

In smaller institutions the Ethics Committee may take up the dual responsibility of Scientific and Ethical Review Committees. The responsibilities of an IEC can be defined as follows:

1. To protect the dignity, rights and well-being of the potential research participants.

2. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
3. To assist in the development and the education of a research community responsive to local health care requirements.

ELEMENTS OF THE REVIEW

The primary task of an IEC/IRB lies in the review of research proposals and their supporting documents, with special attention given to the informed consent process, documentation, and the suitability and feasibility of the protocol. IECs need to take into account prior scientific reviews, if any, and the requirements of applicable laws and regulations. The following should be considered as applicable:

1. **Scientific Design and Conduct of the Study:**
   - 1.1 the appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants.
   - 1.2 the justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
   - 1.3 the justification for the use of control arms.
   - 1.4 criteria for premature withdrawal of research participants.
   - 1.5 criteria for suspending or terminating the research as a whole.
   - 1.6 the adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety monitoring board (DSMB).
   - 1.7 the adequacy of the site, including the supporting staff, available facilities, and emergency procedures.
   - 1.8 the manner in which the results of the research will be reported and published.

2. **Recruitment of Research Participants:**
   - 2.1 the characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity).
   - 2.2 the means by which initial contact and recruitment is to be conducted.
   - 2.3 the means by which full information is to be conveyed to potential research participants or their representatives.
   - 2.4 inclusion criteria for research participants.
   - 2.5 exclusion criteria for research participants.

3. **Care and Protection of Research Participants:**
   - 3.1 the suitability of the investigator(s)'s qualifications and experience for the proposed study.
   - 3.2 any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action.
   - 3.3 the medical care to be provided to research participants during and after the course of the research.
   - 3.4 the adequacy of medical supervision and psycho-social support for the research participants.
   - 3.5 steps to be taken if research participants voluntarily withdraw during the course of the research.
   - 3.6 the criteria for extended access to, the emergency use of, and/or the compassionate use of study products.
   - 3.7 the arrangements, if appropriate, for informing the research participant's general practitioner, including procedures for seeking the participant's consent to do so.
   - 3.8 a description of any plans to make the study product available to the research participants following the research.
   - 3.9 a description of any financial costs to research participants.
   - 3.10 the rewards and compensations for research participants.
   - 3.11 the provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research.
   - 3.12 the insurance and indemnity arrangements.

4. **Protection of Research Participant Confidentiality:**
   - 4.1 a description of the persons who will have access to personal data of the research participants, including medical records and biological samples.
   - 4.2 the measures taken to ensure the confidentiality and security of personal information concerning research participants.

5. **Informed Consent Process:**
   - 5.1 a full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent.
   - 5.2 the adequacy, completeness, and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representative(s).
   - 5.3 clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.
   - 5.4 assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety, and well-being).

5.5 the provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

6. **Community Considerations:**
   6.1 the impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn.
   6.2 the steps taken to consult with the concerned communities during the course of designing the research.
   6.3 the influence of the community on the consent of individuals.
   6.4 proposed community consultation during the course of the research.
   6.5 the extent to which the research contributes to capacity building, such as the enhancement of local health care, research, and the ability to respond to public health needs.
   6.6 a description of the availability and affordability of any successful study product to the concerned communities following the research.
   6.7 the manner in which the results of the research will be made available to the research participants and the concerned communities.

SELECTION OF SPECIAL GROUPS AS RESEARCH SUBJECTS: (INDIAN COUNCIL OF MEDICAL RESEARCH)

1. Pregnant or Nursing Women

Pregnant or nursing women should in no circumstances be the subject of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the fetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be subjects of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable subjects.

a. The justification of participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Examples of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting fetal abnormalities and for conditions associated with or aggravated by pregnancy, etc. Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breastfeeding to the nursing child should be properly assessed except in those studies where breastfeeding is harmful to the infant.
b. Research related to termination of pregnancy: Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be

made subjects for such research as per The Medical Termination of Pregnancy Act, GOI,1971.

c. Research related to pre-natal diagnostic techniques: In pregnant women such research should be limited to detect the fetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, Govt. of India (GOI), 1994 and not for sex determination of the fetus.

2. Children

Before undertaking trial in children, the investigator must ensure that:

a. children will not be involved in research that could be carried out equally well with adults.
b. the purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug, the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children.
c. a parent or legal guardian of each child has given proxy consent.
d. the assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors, adolescents, etc.
e. research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support.
f. interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child subject must be justified in relation to the anticipated risks involved in the study and anticipated benefits to society.
g. the child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/tested, provided the consent has been obtained from parents/guardian.
h. interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child subject as any available alternative interventions; i.e. the risk presented by interventions not intended to benefit the individual child subject is low when compared to the importance of the knowledge that is to be gained.

3. Vulnerable Groups

Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

a. research on genetics should not lead to racial inequalities.
b. persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them.

c. rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected.
d. adequate justification is required for the involvement of subjects such as prisoners, students, subordinates, employees, service personnel etc. who have reduced autonomy as research subjects.

Data Safety Monitoring

Concerns about respect, beneficence and justice are not entirely put to rest by institutional review and informed consent. Although these processes ensure the appropriateness of the research protocol and allow potential participants to make autonomous informed decisions, they do not provide for ongoing oversight that may be necessary to maintain the safety and ethical protections of participants as they proceed through the research experience. To accomplish this may require the development of a data safety monitoring plan (DSMP).

Adverse and Serious Adverse Events

Researchers are required to report (to the governing IRBs) any untoward or adverse events involving research participants during the course of their research involvement. Although the specific reporting requirements differ by IRB and funding source, the definitions of adverse events (originating in the FDA's definitions of adverse events in medical trials) are generally the same.

An adverse event (AE) is defined as any untoward medical problem that occurs during a treatment or intervention, whether it is deemed to be related to the intervention or not. A serious adverse event (SAE) is defined as any occurrence that results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; or creates persistent or significant disability/incapacity, or a congenital anomaly/birth defects.

Detailed information on ethical considerations in research like Nuremberg Code, Helsinki declaration and Indian Council of Medical research (ICMR) is given as Annexures I-VI.

ANNEXURE–I

The *Nuremberg Code* (The Nuremberg Code was adopted by the United Nations General Assembly in 1948.)

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted, where there is a priority reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subjects against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care is required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.
10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

ANNEXURE–II

World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964

INTRODUCTION

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.
   The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.
2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.
3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.
4. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are under-represented in medical research should be provided appropriate access to participation in research.
6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.
7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
8. In medical practice and in medical research, most interventions involve risks and burdens.
9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.

10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.
12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.
13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.
14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.
15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.
16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications.

Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.

17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.
18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.
19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.
20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.
21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.
22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.
23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.
24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential

subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.
26. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.
27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.
28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.
29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.
30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of

their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
    - The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
    - where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.
33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.
34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.
35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

ANNEXURE–III

'Policy Statement on Ethical Considerations Involved in Research on Human Subjects' (The Indian Council of Medical Research (ICMR) February 1980)

GENERAL STATEMENT

Medical and related research using human beings as subjects must necessarily ensure that–

i. The *purpose* of such research is that it should be directed towards the increase of knowledge about the human condition in relation to its social and natural environment, mindful that the human species is one of the many species in a planet in which the well-being of all species is under threat, no less from the human species as any other, and that such research is for the betterment of all, especially the least advantaged.

ii. Such research is *conducted* under conditions that no person or persons become a mere means for the betterment of others and that human beings who are subject to any medical research or scientific experimentation are dealt with in a manner conducive to and consistent with their dignity and well-being, under conditions of professional fair treatment and transparency; and after ensuring that the subject is placed at no greater risk other than such risk commensurate with the well-being of the subject in question in the light of the object to the achieved.

iii. Such research must be subjected to a regime of *evaluation* at all stages of the proposal, i.e., research design and experimentation, declaration of results and use of the results thereof, and that each such evaluation shall bear in mind the objects to be achieved, the means by which they are sought to be achieved, the anticipated benefits and dangers, the potential uses and abuses of the experiment and its results, and above all, the premium that civilized society places on saving and ensuring the safety of each human life as an end in itself.

STATEMENT OF GENERAL PRINCIPLES

Any research using the human beings as subjects of medical or scientific research or experimentation shall bear in mind the following principles:

I. **Principles of essentiality** whereby, the research entailing the use of human subjects is considered to be absolutely essential after a due consideration of all alternatives in the light of the existing knowledge in the proposed area of research and after the proposed research has been duly vetted and considered by an appropriate and responsible body of persons who are external to the particular research and who,

after careful consideration, come to the conclusion that the said research is necessary for the advancement of knowledge and for the benefit of all members of the human species and for the ecological and environmental well-being of the planet.

II. **Principles of voluntariness, informed consent and community agreement** whereby, research subjects are fully apprised of the research and the impact and risk of such research on the research subject and others; and whereby the research subjects retain the right to abstain from further participation in the research irrespective of any legal or other obligation that may have been entered into by such human subjects or someone on their behalf, subject to only minimal restitutive obligations of any advance consideration received and outstanding.

Where any such research entails treating any community or group of persons as a research subject, these principles of voluntariness and informed consent shall apply, mutatis mutandis, to the community as a whole and to each individual member who is the subject of the research or experiment. Where the human subject is incapable of giving consent and it is considered essential that research or experimentation be conducted on such a person incompetent to give consent, the principle of voluntariness and informed consent shall continue to apply and such consent and voluntariness shall be obtained and exercised on behalf of such research subjects by someone who is empowered and under a duty to act on their behalf. The principles of informed consent and voluntariness are cardinal principles to be observed throughout the research and experiment, including its aftermath and applied use so that research subjects are continually kept informed of any and all developments in so far as they affect them and others. However, without in any way undermining the cardinal importance of obtaining informed consent from any human subject involved in any research, the nature and form of the consent and the evidentiary requirements to prove that such consent was taken, shall depend upon the degree and seriousness of the invasiveness into the concerned human subject's personal and privacy, health and life generally, and, the overall purpose and the importance of the research.

III. **Principles of non-exploitation** whereby as a general rule, research subjects are remunerated for their involvement in the research or experiment; and, irrespective of the social and economic condition or status, or literacy or educational levels attained by the research subjects kept fully apprised of all the dangers arising in and out of the research so that they can appreciate all the physical and psychological risks as well as moral implications of the research whether to themselves or others, including those yet to be born. Such human subjects should be selected so that the burdens and benefits of the research

are distributed without arbitrariness, discrimination or caprice. Each research shall include an in-built mechanism for compensation for the human subjects either through insurance cover or any other appropriate means to cover all foreseeable and unforeseeable risks by providing for remedial action and comprehensive aftercare, including treatment during and after the research or experiment, in respect of any effect that the conduct of research or experimentation may have on the human subject and to ensure that immediate recompense and rehabilitative measures are taken in respect of all affected, if and when necessary.

IV. **Principles of privacy and confidentiality** whereby, the identity and records of the human subjects of the research or experiment are as far as possible kept confidential; and that no details about identity of said human subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions, without the specific consent in writing of the human subject concerned, or someone authorized on their behalf; and after ensuring that the said human subject does not suffer from any form of hardship, discrimination or stigmatization as a consequence of having participated in the research or experiment.

V. **Principles of precaution and risk minimization** whereby due care and caution is taken at all stages of the research and experiment (from its inception as a research idea, its subsequent research design, the conduct of the research or experiment and its applicative use) to ensure that the research subject and those affected by it are put to the minimum risk, suffer from no irreversible adverse effects and, generally, benefit from and by the research or experiment; and that requisite steps are taken to ensure that both professional and ethical reviews of the research are undertaken at appropriate stages so that further and specific guidelines are laid down, and necessary directions given, in respect of the conduct of the research or experiment.

VI. **Principles of professional competence** whereby the research is conducted at all times by competent and qualified persons who act with total integrity and impartiality and who have been made aware of, and are mindful of, the ethical considerations to be borne in mind in respect of such research or experiment.

VII. **Principles of accountability and transparency** whereby the research or experiment will be conducted in a fair, honest, impartial and transparent manner after full disclosure is made by those associated with the research or experiment of each aspect of their interest in the research, and any conflict of interest that may exist; and whereby, subject to the principles of privacy and confidentiality and the rights of the researcher, full and complete records of the research

inclusive of data and notes are retained for such reasonable period as may be prescribed or considered necessary for the purposes of post-research monitoring, evaluation of the research, conducting further research (whether by the initial researcher or otherwise) and in order to make such records available for scrutiny by the appropriate legal and administrative authority, if necessary.

VIII. **Principles of the maximization of the public interest and of distributive justice** whereby the research or experiment and its subsequent applicative use are conducted and used to benefit all human kind and not just those who are socially better off but also the least advantaged; and in particular, the research subject themselves.

IX. **Principles of institutional arrangements** whereby there shall be a duty on all persons connected with the research to ensure that all the procedures required to be complied with and all institutional arrangements required to be made in respect of the research and its subsequent use or application are duly made in a bonafide and transparent manner; and to take all appropriate steps to ensure that research reports, materials and data connected with the research are duly preserved and archived.

X. **Principles of public domain** whereby the research and any further research, experimentation or evaluation in response to, and emanating from such research is brought into the public domain so that its results are generally made known through scientific and other publications subject to such rights as are available to the researcher and those associated with the research under the law in force at that time.

XI. **Principles of totality of responsibility** whereby the professional and moral responsibility, for the due observance of all the principles, guidelines or prescriptions laid down generally or in respect of the research or experiment in question, devolves on all those directly or indirectly connected with the research or experiment including the researchers, those responsible for funding or contributing to the funding of the research, the institution or institutions where the research is conducted and the various persons, groups or undertakings who sponsor, use or derive benefit from the research, market the product (if any) or prescribe its use so that, inter alia, the effect of the research or experiment is duly monitored and constantly subject to review and remedial action at all stages of the research and experiment and its future use.

XII. **Principles of compliance** whereby there is a general and positive duty on all persons, conducting, associated or connected with any research entailing the use of a human subject to ensure that both the letter and the spirit of these guidelines, as well as any other norms, directions and guidelines which have been specifically laid down or prescribed and which are applicable for that area of research or experimentation, are scrupulously observed and duly complied with.

ANNEXURE–IV

Statement of Specific Principles for Clinical Evaluation of Drugs/Vaccines/Devices/Diagnostics/Herbal Remedies ETC. (As per Indian Council for Medical Research policy)

Human studies designed to evaluate the safety, effectiveness, or usefulness of an intervention include research on therapeutics, diagnostic procedures and preventive measures including vaccines. The type of experimental procedures that a patient is submitted to has become more complex and varied as the complexities of medical research have increased. It is clearly accepted that it is essential to carry out research on human subjects to discover better medical and therapeutic modalities for the benefit of mankind. It is equally clear that such research on normal subjects and patients is associated with some degree of risk to the individual concerned. These guidelines have been framed to carry out the evaluation of drugs, vaccines, devices and other diagnostic materials on human subjects including herbal remedies, in accordance with the basic ethical principles. These guidelines are important for the protection of research subjects against any avoidable risk and to guide the researchers in the preparation of research proposals/protocols.

For the clinical evaluation of proposed research intervention, the framework of guidelines is provided for the following areas:

1. Drug trials.
2. Vaccine trials.
3. Surgical procedures/medical devices.
4. Diagnostic agents—with special reference to use of radioactive materials and X-rays.
5. Trials with herbal remedies.

GENERAL PRINCIPLES

All the research involving human subjects should be conducted in accordance with the four basic ethical principles, namely Autonomy or respect for person/subject, Beneficence, Non-maleficence and Justice. The guidelines laid down are directed at application of these basic principles to research involving human subjects. An investigator is the person responsible for the research trial and for protection of the rights, health and welfare of the subjects recruited for the study. He/she should have qualification and competence in clinical trial research methods for proper conduct of the trial and should be aware of and comply with all requirements of the study protocol as enumerated under the General Principles and General Issues.

SPECIFIC PRINCIPLES

1. Drug Trials

Clinical trial of drugs is a randomized single or double blind controlled study in human subjects, designed to evaluate prospectively the safety and effectiveness of new drugs/new formulations. The new drug as defined under the Drugs and Cosmetic Rules 1945 (DCR), and subsequent amendments include:

a. a new chemical entity (NCE).
b. a drug which has been approved for a certain indication, by a certain route, in a certain dosage regimen, but which is now proposed to be used for another indication, by another route, or in another dosage regimen.
c. a combination of two or more drugs which, although approved individually, are proposed to be combined for the first time in a fixed dose combination (FDC).

The proposed trial should be carried out, only after approval of the Drugs Controller General of India (DCGI), as is necessary under The Schedule Y of Drugs and Cosmetics Act, 1940. The investigator should also get the approval of Ethical Committee of the Institution before submitting the proposal to DCGI. All the guiding principles should be followed irrespective of whether the drug has been developed in this country or abroad or whether clinical trials have been carried out outside India or not.

Phases of Clinical Trials

The first three of the following four phases of clinical trials of drug require ethical clearance:

Phase I: The objective of phase 1 of clinical trial is to determine the safety of the maximum tolerated dose in healthy adults of both sexes. Healthy female volunteers could be included provided they have completed their family or do not intend to have a child in the future. At least two subjects should be administered each dose to establish the safe dose range, pharmacokinetic, pharmaco-dynamic effects, and adverse reactions, if any, with their intensity and nature. Investigator trained in clinical pharmacology should preferably carry out these studies. The duration of time lapsing between two trials in the same volunteer should be a minimum of 3 months. The volunteers should preferably be covered under some insurance scheme.

Phase II: These are controlled studies conducted in a limited number of patients of both sexes to determine therapeutic uses, effective dose range and further evaluation of safety and pharmacokinetics when necessary.

Normally 20–25 patients should be studied for assessment of each dosage. These studies are usually limited to 3–4 centers.

Phase III: The purpose of these trials is to obtain adequate data about the efficacy and safety of drugs in a larger number of patients of both sexes in multiple centers usually in comparison with a standard drug and/or a placebo if a standard drug does not exist for the disease under study. On successful completion of phase III trials permission is granted for marketing of the drug.

Phase IV: After approval of the drug for marketing, phase IV study or post-marketing surveillance is undertaken to obtain additional information about the drug's risks, benefits and optimal use. Although this is outside the purview of the ethical committee, it is an important aspect of drug trial on the long-term effects of the drugs and the adverse reactions induced by drugs, if any, should be brought to the notice of the *Ethics Committee*.

Throughout the drug trials, the distinction between therapy and research should be maintained. A physician/investigator who participates in research by administering the new drug to consenting patients should ensure that the patients understand and remember that the drug is experimental and that its benefits for the condition under study are yet unproven. Use of a placebo in drug trials and sham surgery has come under severe scrutiny at the present age and requires careful consideration before approval. Denial of the available treatment to control (placebo) group of patients is unethical.

- Trials of drugs without the approval of the appropriate authority should be dealt according to the law of the land and the Guidelines formulated by the country's regulatory agencies. After the clinical trial is over, if need be, it should be made mandatory that the sponsoring agency should provide the drug to the patient till it is marketed in the country.
- The criteria for termination of a trial must be defined a priori in the proposal of the trial and plan of interim analysis must be clearly presented. This is important when on interim analysis the test drug is found to be clearly more effective or less effective than the standard drug. The trial can be discontinued thereafter and better drug should be given to patient receiving less effective drug.
- Issues of partner notification and discordant couples should be taken care of before initiating any HIV/AIDS related trial.
- Good Clinical Practices (GCP) provide operative guidelines for ethical and scientific standards for the designing of a trial protocol including conduct, recording and reporting procedures and should be strictly adhered to while carrying out a trial. Till such time that the Standard Operating Procedures (SOP) for Indian GCP are formulated, the international guidelines issued by World Health Organization (WHO) and International Committee on Harmonization (ICH) should be followed.

Special Concerns: Multicentric Trials

A multicentric trial is conducted simultaneously by several investigators at different centers following the same protocol and proformance. Ideally, these trials should be initiated at the same time at all the centers.

- All the Investigators should give a written acceptance of the protocol to be followed for the trial duly approved by the ethics committee of the host institutes.
- Meetings should be organized at the initial and intermediary stages of the trial to ensure uniform procedures at all centers.
- Training should be imparted to research staff at the participating centers to familiarize them with the uniform procedures.
- Standardization of methods for recruitment and evaluation/monitoring of laboratory procedures and conduct of trial should be carried out.
- There should be monitoring of adherence to protocol including measures to terminate the participation of some centers, if necessary.
- Specific role of coordinators and monitors should be defined.
- Centralized data management and analysis should be planned.
- Drafting of a common final report and publication procedure should be decided at the outset. No individual center should publish any data till appropriate authorities accept the combined report.
- The code of the administered drug could be broken in the event of a severe adverse reaction occurring during the conduct of a double blind trial necessitating such a step.

2. Contraceptives

- All procedures for clinical trials are applicable. Subjects should be clearly informed about the alternatives available.
- In women where implant has been used as a contraceptive for trial, a proper follow-up for removal of the implant should be done, whether the trial is over or the subject has withdrawn from the trial.
- Children born due to failure of contraceptives under study should be followed up for any abnormalities if the woman does not opt for medical termination of pregnancy.

Monitoring and Reporting Adverse Reactions or Events

Any serious adverse events occurring during the course of the trial should be immediately brought to the attention of ethics committee, sponsors and Drug Controller General of India. At the end of the trial, all adverse events whether related to trial or not are to be listed, evaluated and discussed in detail in the final report.

II. Vaccine Trials

The guidelines to conduct the clinical trial on investigational vaccines are similar to those governing a drug trial. The phases of these trials differ from drug trials as given below:

Phase I: This refers to the first introduction of a vaccine into a human population for determination of its safety and biological effects including immunogenicity. This phase includes study of dose and route of administration and should involve *low risk subjects*. For example, immunogenicity to hepatitis B vaccine should not be determined in high-risk subjects.

Phase II: This refers to the initial trials examining effectiveness (immunogenicity) in a limited number of volunteers. Vaccines can be prophylactic and therapeutic in nature. While prophylactic vaccines are given to normal subjects, therapeutic or curative vaccines may be given to patients suffering from particular disease.

Phase III: This focuses on assessment of safety and effectiveness in the prevention of disease, involving controlled study on a larger number of volunteers (in thousands) in multicenters.

Special Concerns

- Some vaccines that contain active or live-attenuated micro-organisms can possibly possess a small risk of producing that particular infection. The subject to be vaccinated should be informed of the same.
- The subjects in control groups or when subjected to ineffective vaccines run a risk of contracting the disease.
- The risks associated with vaccines produced by recombinant DNA techniques are not completely known. However, for all the recombinant vaccines/products the guidelines issued by the Department of Biotechnology should be strictly followed.

III. Clinical Trials with Surgical Procedures/Medical Devices

Of late, biomedical technology has made considerable progress in the conceptualization and designing of bio-equipments. Several medical devices and critical care equipments have been developed and many more are in various stages of development. However, only through good manufacturing practices (GMP) can the end products reach the stage of utilization by society. Most of these products are only evaluated by Central Excise testing for taxation purposes which discourages entrepreneurs to venture in this area with quality products especially when they do not come under the strict purview of the existing regulatory bodies like ISI, BSI and Drugs Controller General. This is evidenced by the very low number of patents or propriety medical equipments manufactured and produced

in the country. As the capacity of the country in this area is improving day by day, the need for a regulatory mechanism/authority is increasingly obvious. The concept of regulations governing investigations involving biomedical devices is, therefore, relatively new in India. At present, except for needles and syringes, these are not covered by the Drugs and Cosmetics Act, 1940. The Chief Executive of the Society of Biomedical Technology (SBMT) set up under the Defense Research Development Organisation (DRDO) has drafted a proposal for the setting up of a regulatory authority, tentatively named as the Indian Medical Devices Regulatory Authority (IMDRA). Until the guidelines are formulated and implemented by this Regulatory Authority clinical trials with biomedical devices should be approved on case to case basis by committees constituted for the specific purpose.

Definitions

Medical devices: A medical device is defined as an inert diagnostic or therapeutic article that does not achieve any of its principal intended purposes through chemical action, within or on the body unlike the medicated devices which contain pharmacologically active substances which are treated as drugs. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intra-ocular lenses, orthopedic pins and other orthopedic accessories. Depending upon risks involved, the devices could be classified as follows:

a. Non-critical devices–An investigational device that does not present significant risk to the patients, e.g. Thermometer, BP apparatus.
b. Critical devices–An investigational medical device that presents a potential serious risk to the health, safety or welfare of the subject for example, pacemarkers, implants, internal catheters.

All the general principles of clinical trials described for drug trials should also be considered for trials of medical devices. As for the drugs, safety evaluation and premarket efficacy of devices for 1–3 years with data on adverse reactions should be obtained before pre-market certification. The duration of the trial and extent of use may be decided in case to case basis by the appropriate authorities. However, the following important factors that are unique to medical devices should be taken into consideration while evaluating the related research projects:

- Safety data of the medical device in animals should be obtained and likely risks posed by the device should be considered.
- Clinical trial of medical devices is different from drug trials, as former cannot be done in healthy volunteers. Hence Phase I of drug trial is not necessary for trial on devices.
- Medical devices used within the body may have greater risk potential than those used on or outside the body, for example, orthopedic pins vs crutches.

- Medical devices not used regularly have less risk potential than those used regularly, for example, contact lens vs intraocular lenses.
- Safety procedures to introduce a medical device in the patient should also be followed as the procedure itself may cause harm to the patient.
- Informed consent procedures should be followed as in drug trials. The patient information sheet should contain information on following procedures to be adopted if the patient decides to withdraw from the trial.

IV. Diagnostic Agents–Use of Radioactive Materials and X-rays

In human beings, for investigation and treatment, different radiations—X-rays, gamma rays and beta rays, radiopaque contrast agents and radioactive materials are used. The relative risks and benefits of research proposal utilizing radioactive materials or X-rays should be evaluated. Radiation limits for the use of such materials and X-rays should be in accordance with the limits set forth by the regulatory authority (BARC) for such materials. (BARC - Bhabha Atomic Research Centre, Mumbai).

Special Concerns

- Informed consent should be obtained before any diagnostic procedures.
- Information to be gained should be gathered using methods that do not expose subjects to more radiation than exposed normally.
- Research should be performed on patients undergoing the procedures for diagnostic or therapeutic purposes.
- Safety measures should be taken to protect research subjects and others who may be exposed to radiation.
- The protocol should make adequate provisions for detecting pregnancies to avoid risks of exposure to the embryo.
- Information to subject about possible genetic damage to offspring should be given.
- Non-radioactive diagnostic agents are considered as drugs and the same guidelines should be followed when using them.
- Ultrasound to be substituted wherever feasible.

V. Clinical Evaluation of Herbal Remedies and Medicinal Plants

For the herbal remedies and medicinal plants that are to be clinically evaluated for use in the Allopathic System and which may later be used in allopathic hospitals, the procedures laid down by the office of the Drugs Controller General of India for allopathic drugs should be followed. This does not pertain to guidelines issued for clinical evaluation of Ayurveda, Siddha or Unani drugs by experts in those systems of medicine which may be used later in their own hospitals and clinics. All the general principles of clinical trials described earlier pertain also to herbal remedies.

However, when clinical trials of herbal drugs used in recognized Indian Systems of Medicine and Homeopathy are to be undertaken in Allopathic Hospitals, association of physicians from the concerned system as co-investigators/collaborators/members of the expert group is desirable for designing and evaluating the study.

Special Concerns

The herbal products can belong to either of the three categories given below:

1. A lot is known about the use of a plant or its extract in the ancient Ayurveda, Siddha or Unani literature or the plant may actually be regularly used by physicians of the traditional systems of medicine for a number of years. The substance is being clinically evaluated for same indication for which it is being used or as has been described in the texts.
2. When an extract of a plant or a compound isolated from the plant has to be clinically evaluated for a therapeutic effect not originally described in the texts of traditional systems or, the method of preparation is different, it has to be treated as a new substance or new chemical entity (NCE) and the same type of acute, sub-acute and chronic toxicity data will have to be generated as required by the regulatory authority before it is cleared for clinical evaluation.
3. An extract or a compound isolated from a plant which has never been in use before and has not ever been mentioned in ancient literature, should be treated as a new drug, and, therefore, should undergo all regulatory requirements before being evaluated clinically.

It is important that plants and herbal remedies currently in use or mentioned in literature of recognized Traditional System of Medicine is prepared strictly in the same way as described in the literature while incorporating GMP norms for standardization. It may not be necessary to undertake phase I studies. However, it needs to be emphasized that since the substance to be tested is already in use in Indian Systems of Medicine or has been described in their texts, the need for testing its toxicity in animals has been considerably reduced. Neither would any toxicity study be needed for phase II trial unless there are reports suggesting toxicity or when the herbal preparation is to be used for more than 3 months. It should be necessary to undertake 4–6 weeks toxicity study in 2 species of animals in the circumstances pointed out in the preceding sentence or when a larger multicentric phase III trial is subsequently planned based on results of phase II study.

Clinical trials with herbal preparations should be carried out only after these have been standardized and markers identified to ensure that the substances being evaluated are always the same. The recommendations made earlier regarding informed consent, inducements for participation, information to be provided to the subject, withdrawal from study and research involving children or persons with diminished autonomy.

ANNEXURE–V

Statement of Specific Principles for Epidemiological Studies: (As per Indian Council for Medical Research Policy)

INTRODUCTION

Epidemiology is defined as the study of the distribution and determinants of health related states or events in specified populations and the application of this study to control health problems. Epidemiological studies are of primary importance in a large developing country like ours where the natural history, incidence, prevalence and impact on morbidity and mortality of a variety of diseases are not known. It has usually been considered that epidemiology of infectious diseases is of prime importance in our country. However, the evolving pattern of change in the society with upward economic mobility and increasing number of middle classes would mean that a significant number of life-style related diseases such as Ischemic Heart Disease are increasing. There is very little information about this and it would be useful to undertake long-term cohort studies in different population groups. Epidemiological studies are generally considered in two categories.

Observational and Experimental

Designs of these studies are based on cross-sectional, case-control or cohort approaches. Epidemiological studies cover research, program evaluation and surveillance. Scope of ethical guidelines for epidemiological studies is concerned with epidemiological research. Ethics in epidemiological studies is multidimensional covering clinical medicine, public health and the social milieu.

Perhaps the code of ethics is much better understood for clinical research, where the interaction between a patient and a clinical researcher is of supreme importance. In epidemiological research the researcher is dealing with a group of individuals and the questions faced by an epidemiologist are more of a professional nature. These questions would pertain to interactions with individual subjects, sources of funding or employer, fellow epidemiologist and the society at large. Need for a code of ethics for epidemiologists is being recognized globally and the issues for such a code in the context of epidemiological research in India deserve attention.

Epidemiological research differs from clinical research in the context of the large number of study subjects and generally a long time frame. If some mistakes or aberrations get detected during the course of conduct of such studies, repeating the whole exercise will be expensive, time consuming and may not even be feasible. Hence utmost care needs to be taken for various aspects—technical, practical and ethical.

DEFINITIONS

Observational Epidemiology: This includes the following types:

a. **Cross-sectional studies (Surveys):** This is primarily population based and involves selecting random samples of the population to be representative based on census data and then applying questionnaires to understand the prevalence of various diseases. Its aim is to assess aspects of the health of a population or to test hypotheses about possible cause of disease or suspected risk factors.

b. **Case-control studies:** This usually compares the past history of exposure to risks among patients who have a specified condition/disease (cases) with the past history of exposure to this among persons who resemble the cases in such respects as age, sex socioeconomic status, geographic location, but who do not have the disease. Case control studies can be done by following up available records, usually records in a hospital, but in the context of a country like ours, it may require direct contact between research workers and study subjects and informed consent to participation in the study is necessary.
However, if it entails only a review of medical records, informed consent may not be required and indeed may not be feasible.

c. **Cohort studies:** These are longitudinal or prospective studies of a group of individuals with differing exposure levels to suspected risk factors. They are observed over a long period usually several years. The rate of occurrence of the condition of interest is measured and compared in relation to identified risk factors. It requires a study of large number of subjects for a long time and involves asking questions, usually routine medical examination and sometimes laboratory investigations. Individuals are being followed up as the cohort and it is essential to identify precisely every individual to be studied.

Experimental Epidemiology: In experimental epidemiology the investigators alter one or more parameters under controlled conditions to study the effects of the intervention. These are usually randomized controlled trials done to test a preventive or therapeutic regimen or the efficacy of a diagnostic procedure. Although these are strictly speaking epidemiological studies they come under the purview of clinical evaluation of drugs/devices/products/vaccines, etc. The possibility of use of placebo as one of the arms of the trial should be explained and informed consent taken in such studies.

GENERAL PRINCIPLES

General ethical principles of respect for persons, duty to maximize possible benefits and minimize possible harm are important considerations in ethical guidelines. At the same time it is essential that all individuals in an epidemiological research are treated alike keeping in mind the rules

of distributive justice. The welfare of the individual has to be balanced against the welfare of the community and society at large.

The CIOMS/WHO Guidelines for Epidemiological Research assumes that the individuals or population being studied are capable of giving informed consent understanding the implications of the study. With large segments of our population, given their level of education, the full understanding in the sense of industrialized countries may not be achievable. How the principle of "do no harm" is ensured under such circumstances without being paternalistic is a major issue that has to be taken into consideration in ethical guidelines.

In cohort or survey techniques for incidence and prevalence of various diseases, a major issue that has to be considered is how much of intervention is justified and whether one is justified in withholding interventions. For example, if you are looking at longitudinal morbidity in a population group, should you give them health education that is well established with regard to preventive aspects, or should you leave them alone so that the natural evolution of the disease can be studied? Health education or other interventions including non-health interventions can be quite expensive. An alternate strategy that may be followed is to make curative therapy available to the population at their own request. This usually involves running a clinic, which is readily accessible to the population without any other intervention. However, it is generally considered unethical to withhold intervention or services.

SPECIFIC PRINCIPLES

1. **Informed consent:** When individuals are to be the subject of any epidemiological studies, the purpose and general objectives of the study has to be explained to them keeping in mind their level of understanding. It needs to be ensured that privacy will be maintained. In the context of developing countries, obtaining informed consent has been considered many times as difficult/impractical/not meeting the purpose on various grounds such as incompetence to comprehend the meaning or relevance of the consent and culturally being dependent on the decision of the head of the family or village/community head. However, there is no alternative to obtaining individual's informed consent but what should be the content of the informed consent is also a crucial issue.

   In spite of obtaining informed individual consent, it is quite likely that the subjects/patients may not be fully aware of their rights. In this context, the role of investigator is crucial and he/she should remain vigilant and conscious of his/her obligations towards the subjects/patients, all through the course of the studies.
2. In most epidemiological research it would be necessary to have the consent of the community which can be done through the village leaders, the panchayat head, the tribal leaders, etc.

3. In obtaining the consent of individuals or communities it is important to keep in mind that working through peer groups or through panchayat etc. may mean that the individuals or community would feel reluctant to agree and refuse to give consent because of societal pressures. This is something that has to be carefully avoided.
4. Particularly in a country like India, with the level of poverty that is prevalent it is easy to use inducements, especially financial inducements, to get individuals and communities to consent. Such inducements are not permissible. However, it is necessary to provide for adequate compensation for loss of wages and travel/other expenses incurred for participating in the study.
5. All risks involved including the risk of loss of privacy must be explained to the participants in an epidemiological study.
6. The design of the study should ensure that the benefits of the study are maximised for the individuals and communities taking part in the study. This means that at the onset itself the investigators should design the way in which the results of the study are going to be communicated and also decide whether individuals identified at particular risk during the course of the studies would be informed. It may also be necessary in some instances to inform the concerned family members about the results. For example, as in AIDS, STD, etc. It may not always be possible to communicate study results to individuals but research findings and advice should be publicized by appropriate available means. It is also important that the beneficial results of epidemiological studies are fed into the health system and necessary training modules should be developed as part of the epidemiological project.
7. All attempts should be made to minimize harm to the individuals and society at large. Special consideration for the cultural characteristics of the communities that are being studied is essential to prevent any disturbance to cultural sensitivities because of the investigation.
8. Maintaining confidentiality of epidemiological data is absolutely essential. A particular concern is the fact that some population based data may also have implications to issues like national security and these need to be carefully evaluated at the beginning.
9. In all situations where there is likely to be conflicts of interest it must be ensured that the interest of the individuals involved in the study are protected at all cost.
10. Scientific objectivity should be maintained with honesty and impartiality, both in the design and conduct of the study and in presenting and interpreting findings. Selective withholding of data and similar practices are unethical.
11. Ethical Review Procedures: In all Ethical Committees at least one or two individuals with an understanding of the principles of epidemiological ethics should review the proposal.

ANNEXURE–VI

INFORMED CONSENT PROCESS

1. Informed Consent of Subject

For all biomedical research involving human subjects, the investigator must obtain the informed consent of the prospective subject or in the case of an individual who is not capable of giving informed consent, the consent of a legal guardian. Informed consent is based on the principle that competent individuals are entitled to choose freely whether to participate in research or not. Informed consent protects the individual's freedom of choice and respect for individual's autonomy.

When research design involves not more than minimal risk (for example, where the research involves only collecting data from subject's records) the Institutional Ethics Committee may waive off some of the elements of informed consent. Waiver of informed consent could also be considered during conditions of emergency. However, this would be permissible only if Ethical Committee has already approved the study or use of drug. However, the patient or the legal guardian should be informed after she/he regains consciousness or is able to understand the study.

2. Obligations of Investigators Regarding Informed Consent

The investigator has the duty to–

i. Communicate to prospective subjects all the information necessary for informed consent. There should not be any restriction on subject's right to ask any questions related to the study as any restriction on this undermines the validity of informed consent.
ii. Exclude the possibility of unjustified deception, undue influence and intimidation. Deception of the subject is not permissible. However, sometimes information can be withheld till the completion of study, if such information would jeopardize the validity of research.
iii. Seek consent only after the prospective subject is adequately informed. Investigator should not give any unjustifiable assurances to prospective subject, which may influence the subject's decision to participate in the study.
iv. As a general rule, obtain from each prospective subject a signed form as an evidence of informed consent (written informed consent) preferably witnessed by a person not related to the trial, and in case of incompetence to do so, a legal guardian or other duly authorized representative.
v. Renew the informed consent of each subject, if there are material changes in the conditions or procedures of the research or new information becomes available during the ongoing trial.

vi. Not use intimidation in any form which invalidates informed consent. The investigator must assure prospective subjects that their decision to participate or not will not affect the patient-clinician relationship or any other benefits to which they are entitled.

3. Essential Information for Prospective Research Subjects

Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information in the language he or she is able to understand which should not only be scientifically accurate but should also be sensitive to their social and cultural context:

i. the aims and methods of the research.
ii. the expected duration of the subject participation.
iii. the benefits that might reasonably be expected as an outcome of research to the subject or to others.
iv. any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment to which she/he is being subjected.
v. any foreseeable risk or discomfort to the subject resulting from participation in the study.
vi. right to prevent use of his/her biological sample (DNA, cell-line, etc.) at any time during the conduct of the research.
vii. the extent to which confidentiality of records could be maintained, i.e., the limits to which the investigator would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality.
viii. responsibility of investigators.
ix. free treatment for research related injury by the investigator / institution.
x. compensation of subjects for disability or death resulting from such injury.
xi. freedom of individual/family to participate and to withdraw from research any time without penalty or loss of benefits which the subject would otherwise be entitled to.
xii. the identity of the research teams and contact persons with address and phone numbers.
xiii. foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same.
xiv. risk of discovery of biologically sensitive information.
xv. publication, if any, including photographs and pedigree charts.

The quality of the consent of certain social groups requires careful consideration as their agreement to volunteer may be unduly influenced by the Investigator.

Chapter 18

WRITING A RESEARCH PROPOSAL

The protocol is a detailed work plan of the study. Writing the protocol helps the investigator to organize, clarify and refine all the elements of the study.

A proposal is a written document for the purpose of obtaining fund from granting/funding agencies. It includes the study protocol, the budget and other administrative and supporting information that is required by the specific funding agency.

A good proposal is direct, straightforward with high scientific quality and communicates well. It is also well-organized having various sections with headings and paragraphing and able to anticipate potential flaws and address them.

BASIC OUTLINE OF A RESEARCH PROPOSAL/PROJECT
TITLE OF THE RESEARCH PROJECT
PROJECT SUMMARY
STATEMENT OF THE PROBLEM (Scientific Justification)
JUSTIFICATION AND USE OF THE RESULTS (Final Objectives, Applicability)
BACKGROUND (Argumentation, Possible Answers, and Hypothesis)
RESEARCH OBJECTIVES (General and Specific)
METHODOLOGY
• Operational Definitions (Operationalization)
• Study Settings and Duration
• Type of Study and General Design
• Universe of Study, Sample Selection and Size, Unit of Analysis and Observation, Selection Criteria, Plan for Recruitment
• Proposed Intervention (if applicable)
• Data Collection Procedures, Instruments Used, and Methods for Data Quality Control
• Procedures to Ensure Ethical Considerations in Research with Human Subjects
PLAN FOR ANALYSIS OF RESULTS
Methods and Models of Data Analysis According to Types of Variables; Programs to be Used for Data Analysis, Methods of Statistical Analysis
TIMETABLE AND GANTT CHART
BUDGET
LIMITATIONS AND ISSUES
BIBLIOGRAPHIC REFERENCES
ANNEXES (Data Collection Instruments, Elaboration on Methods and Procedures to be Used, etc.)

Title of the Research Project

A good title should be short, accurate, and concise. It should make the central objectives and variables of the study clear to the reader (reviewer). The title provides the "keywords" for the classification and indexing of the project. If it is possible without undue length, the title can give a preview of the protocol. It is important to specify what population or universe will be investigated. For example: Effects of the exercise on reduction of complications due to obesity: a cohort study at an obesity clinic in 'X' City.

Project Summary/Abstract

The abstract should give a clear idea to the reader of the central question that the research is intended to answer and its justification. It should specify the hypotheses and the research objectives. In addition, the abstract should briefly describe the methods and procedures.

Statement of the Problem

This constitutes the scientific justification for the study; i.e., the basis of the need for research to generate further knowledge that will contribute to existing knowledge. The statement must be written in a way that gives empirical references to describe the situation and also clearly specifies the gaps in existing knowledge of the problem and/or the existing controversy and the non-conclusive evidence. Moreover, there may be very conclusive evidence for knowledge considered to be established, but the investigator questions the accumulated knowledge because of certain events that he or she intends to subject to verification. It is at this point where the investigator defines the object of study and conveys the questions or broader issues motivating the research. A logical sequence for presenting the statement would be :

- Magnitude, frequency, and distribution. Affected population groups and geographical areas.
  Ethnic and gender considerations.
- Probable causes of the problem: What is the current knowledge of the problem and its causes? Is there consensus? Is there controversy? Is there conclusive evidence?
- Possible solutions: In what ways have solutions/strategies to the problem been attempted? What has been proposed? What are the results?
- Unanswered questions: What remains to be answered? What areas have not been understood, determined, verified, or tested?

The problem statement should make a convincing argument that there is not sufficient knowledge available to explain the problem and its possible alternative solutions, or it should make a convincing argument

for the need to test what is known and taken as fact, if it is called into question by new findings or conditions.

The discussion in this section should show that the investigator has documented this problem and performed an exhaustive bibliographic review of the subject.

Justification and Use of the Results

This section describes the type of knowledge expected to be obtained and the intended purpose of its application. It should indicate the strategy for disseminating and using the research findings according to the potential users of the knowledge generated. The justification should answer the following:

- How does the research relate to the priorities of the region and the country?
- What knowledge and information will be obtained?
- What is the ultimate purpose that the knowledge obtained from the study will serve?
- How will the results be disseminated?
- How will the results be used, and who will be the beneficiaries?

The justification, which can be included as part of the statement of the problem or in a separate section, should make a convincing argument that the knowledge generated will be useful and generally applicable within the regional context.

Background Information

This is derived from the statement of the problem (presentation of empirical evidence and central question) and is the argumentation and demonstration that the "question" has a basis for probable answer(s) and/or working hypotheses. It also requires an exhaustive bibliographic review.

- Identification of the relationships between the independent variable and the response variables. What is known, and how has it been explained? Are the results conclusive? What is the basis of the question?
- How are the possible answers to the question explained and defended? What are the assumptions? What are the relationships? What are the working hypotheses?

Research Objectives (General and Specific)

These should be defined after the theoretical framework has been developed in a logical sequence, and the sequence is clear between the central question and possible responses to the questions and/or working hypotheses. This is recommended because the definition of the objectives is simply the operationalization of the answers and/or hypothesis formulated by the investigator.

General Objective/Aim

This should specify what kind of knowledge the study is expected to obtain. It should give a clear notion of what is to be described, determined, identified, compared, and, in case of studies with working hypotheses, confirmed.

Example: General Objective/Aim

Assessment of prevalence of IUGR among teenage and elderly pregnancies and to find out factors associated with IUGR.

Specific objectives:

1. To assess prevalence of IUGR among teenage (15–19 years) and elderly (30–40 years) pregnancies.
2. To assess factors associated with IUGR among teenage and elderly pregnancies.
3. To assess final outcome of pregnancy with regards to birth weight of babies.

Methodology

It should be written clearly with all relevant details. The methodology explains the procedures that will be used to achieve the objectives. In this section the operational definition for the variables, type of variables and the methods to measure them should be included. The methodology should consider the study design, the techniques and procedures used to achieve the proposed objectives. A description is given below of different components to be specified in the methodology:

i. Operational definition of variables

Operationalization is a process that will vary in accordance with the type of research and research design. However, the variables should be clearly defined and appropriately operationalized

The investigator should clearly describe what is understood by each variable, what type of variable is being considered, and the way its values are to be measured and reported (quantitatively, when the variable is numerical, and qualitatively, when the variables do not have numerical values).

Protocols will be considered incomplete if their operational aspects are vaguely formulated.

ii. Study setting and duration

The investigator should mention the place of study (hospital, clinic, or community (urban/rural/tribal) and also the total duration of the study in year/months depending on the type of research question/problem being researched.

iii. Type of study and general design

The investigator should clearly state the type of study that will be conducted and provide a detailed explanation of its design in addition to ethical considerations. On this point, the investigator should also state the strategies and mechanisms that will be used to reduce or eliminate threats to the validity of the results, i.e. the so-called confounding factors (in the selection and assignment of subjects, the loss of cases, and the control of instruments and observers, etc.).

Example: An experimental controlled study will be conducted with two groups of women; those who used oral contraceptive pills (OCP), and those who did not. Selection will be made of multi-parous women who have attended in the maternal and child hospital to find out the incidence of myocardial ischemia.

iv. Universe of study, sample selection and size, unit of analysis and observation, selection criteria

In this section the investigator should describe the universe of study/ reference population and all aspects of the selection procedures and techniques and the sample size. For both probability and non-probability samples, the investigator should indicate the procedure and criteria used and justify the selection and size.

In the case of qualitative or other studies using non-probability samples, in which subjects are selected for focus groups or as key informants, etc., the investigator should specify the selection criteria, the type of group and its size, and the procedures used to establish the group.

v. Proposed intervention (if applicable)

This section should be prepared when the research objectives and design provide for an evaluation of the results of an intervention (educational program, vaccine, treatment, procedures, etc.). Generally, these are comparative studies with experimental or quasi-experimental designs, before and after, where assessment is made of results attributable to the intervention. There should be a full description provided of the intervention and an explanation given of the activities in their order of occurrence. It is essential that the description of the intervention answers three fundamental questions: Who will be responsible for the intervention? Where will it take place? What activities will be performed, and with what frequency and intensity? Interventions involving human subjects require an ethical review.

vi. Data collection procedures, instruments used, and methods for data quality control

This section must describe in detail the procedures to be used to control the factors that undermine the validity or reliability of the results (controls

for observers or persons responsible for compiling the information, and controls for the instruments).

The investigator should write the procedures that will be used (population survey, in-depth interviews, focus group discussions, content analysis, social mapping, etc.), how and when the procedures will be used, and the instruments/tools that will be used to collect information (questionnaire, interview guide, observation recording form, guide for a focus group moderator, content analysis guide, etc.). Procedures or techniques, e.g. laboratory tests, radiological investigations that are standardized and/or documented in the literature should be described briefly, and bibliographic references should be given to sources where the details of these procedures and techniques can be found.

For collection of secondary data, the investigator should describe their sources, content, and quality.

vii. Procedures to ensure ethical considerations in research with human subjects

When the research involves human subjects, this section should explicitly provide for the following aspects:

- The known benefits and risks or disadvantages for the subjects in the study.
- Exact description of the information to be delivered to the subjects of the study and then it will be communicated orally or in writing. Examples of this information include: the objectives and purposes of the study, any experimental procedures, any known short- or long-term risks, possible discomforts, expected benefits of the procedures used, duration of the studies, alternative methods for treatment if the study is a clinical trial, suspension of the study if a finding is made of negative effects or if there is sufficient evidence of positive effects that do not justify continuing with the study, and the freedom of subjects to withdraw from the study whenever they want.
- When appropriate, indicate any special incentive or treatment that subjects will receive through their participation in the study. If there is any type of remuneration, specify the amount, method of delivery, time, and reason why payment is required.
- Indicate how the information obtained from participants in the study will be kept confidential.
- List the drugs, vaccines, diagnoses, procedures, or instruments to be used, whether they are registered, unregistered, new, or currently in use in the country.

Moreover, responses are required for other ethical aspects, such as:

- How the confidentiality of personal information will be maintained?

- Information should be provided on the free and informed consent of the participants and the strategy that will be used to obtain it specially in case of experimental studies.
- Brief synopsis of how the research findings will be reported and shared with participants or to other interested parties.
- Indicate and justify the inclusion, as appropriate, of children, the elderly, physically challenged and pregnant women. Justify the non-inclusion in the study group, if appropriate, of women (of any age), an ethnic minority, racial group, etc.
- When appropriate, indicate how the appropriate balance of the two sexes will be ensured in the study groups.

When studies involve human subjects, an institutional ethics committee in the country /region/organization where the research will be conducted should evaluate and endorse the research, preferably before it is submitted to the funding agencies/starting of the project.

viii. Plan for the analysis of results

Although this item is considered under the methodology, it is suggested that the investigator treats it as a separate section. Indications are given below of what is expected from a plan of analysis.

Methods and Models of Data Analysis According to Types of Variables

In accordance with the proposed objectives and based on the types of variables, the investigator should specify how the variables will be measured and how they will be presented (quantitative and/or qualitative), indicating the analytical models and techniques (statistical, non-statistical, or analytical techniques for non-numeric data, etc.). The investigator should provide a preliminary scheme for tabulating the data (especially for variables that are presented numerically). It is recommended that special attention be given to the key variables that will be used in the statistical models.

Programs to be Used for Data Analysis

Briefly describe the software packages that will be used and their anticipated applications.

Gantt chart: A Gantt chart is a graphical representation of the task and duration against the progression of time. It is a useful tool for planning, scheduling and monitoring the progress of projects.

Example: A study on infant mortality:

Task to be Performed	*First Year-2010*				*Second Year -2011*		
	1ST Qu	*2nd Qu*	*3rd Qu*	*4th Qu*	*1st Qu*	*2nd Qu*	*2nd Qu*
Finalize research proposal and submit for clearance							
Translate questionnaire, type and multiply							
Recruit research assistants and train							
Pretesting							
Data collection							
Process data							
Analysis of data and report writing							
Sharing and dissemination of findings							

SCHEDULE/WORK PLAN

Task to be performed	*Dates*	*Personnel responsible*
Finalize research proposal and submit for clearance	15 -25 Feb. 2010	Team and team leader (TL)
Translate questionnaire, type and multiply	26 Feb-10 Mar 2010	Team secretary
Recruit research assistants and train	10 Mar-10 June 2010	TL
Pretesting	10-30 Jun. 2010	Team + Assistants + Facilitator + Driver
Data collection	1 July 2010-15 Feb 2011	Team + Assistants + 2 Drivers
Process data	16 Feb-25 Mar 2011	Team + Facilitator
Analysis of data and report writing	26 Mar-June 2011	Team + Facilitator + Secretary
Sharing and dissemination of findings	July-Aug 2011	Team

BUDGET

Optimal resource utilization is the key for success of a program especially in resource constrained countries; therefore budget plan is necessary to:

1. Identify locally available resources and additional resources required.
2. Allocate resources based on priorities of activities.
3. Activitywise tracking of resources.

Always plan an estimated budget as actual budget may not be possible at the beginning of the project/program. The budget is to be prepared on the basis of type, frequency, period, unit cost and place of activities. Always add budget for unforeseen conditions/overheads (should not be more than 10% of total budget). The following points may be considered while planning for the estimated budget.

Estimated Budget

a. Non-recurring: This head may include building, instruments/equipment, vehicle, etc.
b. Recurring:
   i. Staff Salaries–Full time/Part time/Honorary
   ii. Operational expenditure–Baseline Survey, Training/Workshops/Guest Lectures, Medical Camps/Health Check-ups, IEC activities/material, POL expenditure, Others (specify)
   iii. Office expenditure–Printing and Stationery, Meetings, Rent, Others (specify)
   iv. Overheads (not more than 10% of total budget)

   Total Budget = Non-recurring + Recurring

Example: This is an imaginary budget for a health education drive for population of 100,000. All the items are not included as this is the only guideline.

	Budget Category	*Unit Cost (Rs)*	*Quantity*	*No./ Year*	*Funding Agencies' Contribution*	*Institutional Contribution (if any)*	*Total (Rs.)*
A.	**Non-recurring**						
1.	**Vehicle-Tata Sumo-10 seater**	7,00,000	1		7,00,000		7,00,000
2.	**Equipment** Computer with modem and printer	40,000	1	1	40,000		40,000
B.	**Recurring**						
1.	**Salaries**-Project Coordinator	8,000	1	11	88,000		88,000
2.	**Honoraria**-Peer Educator	1,000	9	11	99,000		99,000
3.	**General Administration**						
	Rent	6000/m		12 m	72,000		72,000
	Water and Electricity	5000/m		12 m	60,000		60,000
	Communication -Internet	500	1	11	5,500		5,500
4.	**Administrative**						
	Meeting expenses	2,000	1	1	2,000		2,000
	Office Stationery	1,000	1	12	12,000		12,000
5.	**Overhead**						24,650
	Total Budget (A+B)						**11,03,150**

Chapter 19

STEPS IN THESIS WRITING

(The Art and Science of Writing Postgraduate Thesis/Dissertation)

Introduction: Submission of thesis/dissertation is a pre-requisite for the postgraduate (PG) medical degrees by most of the universities. As such, there are no comprehensive guidelines for the preparation of the dissertation either to the PG students or their guides. Writing the dissertation in an acceptable format will not only ensure its approval by examiners but will also help the young scientist in writing a good scientific paper. This chapter will provide essential guidelines to write a thesis/dissertation.

Definition

Dissertation is a treatise or a written composition that deals with a subject formally and systematically.

Thesis is a proposition stated especially as a theme to be discussed or proved or maintained against attack or an essay based on research.

Dissertation/Thesis are a proof that one cannot only do science, but also write science.

"The average dissertation is nothing but transference of bones form one graveyard to another" said Frank Dobie.

Scientific Structure (Anatomy) of Dissertation

When one think of the structure of thesis/dissertation, one is reminded of the following verse written by 'Rudyard Kipling' and quoted by 'Richard Asher' a famous medical writer in his essay "SIX HONEST MEN FOR MEDICAL WRITERS".

I keep six honest serving men
They taught me all I know
Their names are what, why, when
How, where and who.

Thus while writing a dissertation the questions what, why, when, how, where and who should be answered.

Dissertation/Thesis proposals are designed to:

- Justify and plan (or contract for) a research project.
- Show how your project contributes to existing research.

- Demonstrate to your advisor and committee that you understand how to conduct discipline-specific research within an acceptable time-frame.

Tips to Start Thesis/Dissertation Writing

General Advice

- Establish a writing schedule, preferably writing at the same time and place each day.
- Begin by free-writing. Remember that no one but you have to see the initial draft.
- Keep a small notebook with you throughout the day to write down relevant thoughts.
- Say parts of your writing into a recording device and then play it back to yourself (if possible).
- Compose different parts of the proposal in different computer files or on different index cards to help with arranging and rearranging.
- Start with more "clear cut" sections first, rather than with the Introduction, since it may be the most difficult part to write.

Proposal-Specific Advice

- Understand that the proposal will be a negotiated document, so be prepared to draft, redraft, and resubmit it.
- Think of the proposal as an introduction to your thesis—not a chapter, not an extensive literature review, not an opportunity to rehearse the major conflicts in your field. You are "bridging the gap" between existing work and your work.
- Remember that the proposal is not a contract that determines what your thesis will demonstrate. You will likely modify and refine your scope, argument, and methods.
- Remember that your proposal is not meant to limit your ideas, but to help you think in practical terms about how you intend to research and write your dissertation.
- Ask colleagues to form a writing group that you can use to exchange ideas, drafts, and experiences. As lonely as it may seem sometimes, writing is a social activity.

Bradford Hill in 1965 evolved the ***IMRAD structure*** (Introduction, Methods, Results, and Discussion,), however, for our purposes we shall adopt the following structure:

a. Title
b. Introduction: Why you want to do study?
c. Aims and objectives: What will you achieve?
d. Review of Literature: What are the other studies available on same topic/subject?

e. Material and Methods: How will you do the study?
f. Observations/ Results: What are the findings?
g. Discussion: What do the findings mean?
h. Summary (including Conclusion)
i. Recommendations (based on study findings)
j. References (Bibliography)
k. Annexure

Title

The title should describe the content in the fewest possible words. The title is what catches the reader's eye and deserves careful thought. The title needs to be accurate, specific, retrievable short yet sufficiently descriptive and as informative as possible. Abbreviations should not be used in the title. Paradoxical obscure or misleading titles should not be used. Do not produce long incomprehensible strings and adjectives as seen in this example: "Cytological changes in the conjunctiva in the patients with vitamin A deficiency with or without protein calorie malnutrition". At the same time the title should not be made meaningless for the sake of brevity as seen in this example "Cell block study".

Thus it is worth analyzing the title and to make sure that it contains elements of the dissertation that it is intended to convey. For example: "Conjunctival Cytology in Xerophthalmia", "Cell Block Study of Body Fluids". "Fine Needle Aspiration Cytological Study of Salivary Gland Tumors".

A good title should:

- Orient your readers to the topic you will research.
- Indicate the type of study you will conduct.

Introduction

The introduction should answer the question "why you want to do the study"? That is, why should you actually do the work? In just 500–1000 words the introduction should state:

a. The nature and the scope of the problem.
b. The rationale for the study.

The introduction should be intelligible and not long and pompous. It should introduce the state of knowledge before the work was started, define the gaps in knowledge which the work will fill and state what works set out to do?

A good introduction should:

- Establish the general territory (real world or research) in which the research is placed.

- Describe the broad foundations of your study, including some references to existing literature and/or empirically observable situations. In other words, the introduction needs to provide sufficient background for readers to understand where from your study is coming.
- Indicate the general scope of your project, but do not go into so much detail that later sections (purpose/literature review) become irrelevant.
- Provide an overview of the sections that will appear in your proposal (optional).
- Engage the readers.

Aims and Objectives

The objectives of the research project should summarize what is to be achieved by the study. Aim or the General Objective of a study states what is expected to be achieved by the study in general terms.

It is possible (and advisable) to break down a general objective into smaller, logically connected parts. These are usually referred to as Specific Objectives.

Objectives answer the questions like what, where, when about the study.

Objectives must be SMART:

S – Specific
M – Measurable
A – Achievable
R – Relevant
T – Time bound

Review of Literature

This pertains to searching and recording salient and pertinent points from articles written by earlier workers/researchers on the subject that you have chosen. Record the information in chronological order. The articles reviewed should be retrievable. It is not necessary to review the entire story of the subject from Pythagoras to the present day but only relevant articles should be reviewed.

Literature Searching

"Knowledge is of two kinds. We know a subject ourselves or we know where we can find the information about it", said Dr Samuel Johnson.

The literature review is a critical look at the existing research that is significant to the work that you are carrying out. Obviously, at this point you are not likely to have read everything related to your research questions, but you should still be able to identify the key texts with which

you will be in conversation as you write your dissertation/thesis. Literature reviews often include both the theoretical approaches to your topic and research (empirical or analytical) on your topic.

Writing the Literature Review Allows Understanding

- How other researchers/scholars have written about the topic?
- The range of theories researchers/scholars use to analyze their primary materials or data
- How other researchers/scholars connect their specific research topics to larger issues, questions, or practices within the field?
- The best methodologies and research techniques for your particular topic.

The literature review has four major functions that you should keep in mind as you write:

- It situates the current study within a wider disciplinary conversation.
- It illustrates the uniqueness, importance of and need for your particular project by explaining how your research questions and approach are different from those of other researchers/scholars.
- It justifies methodological choices.
- It demonstrates your familiarity with the topic and appropriate approaches to studying it.

Effective Literature Reviews Should–

- Take out the Introduction's brief description of the background of your study.
- Critically assess important research trends or areas of interest relevant to your study.
- Identify potential gaps in knowledge.
- Establish a need for current and/or future research projects.

Tips on Drafting Your Literature Review

- Categorize the literature into recognizable topic clusters and begin each with a sub-heading. Look for trends and themes and then synthesize related information. You should–
  1. Take out the various positions that are relevant to your project.
  2. Build on conclusions that lead to your project, or
  3. Demonstrate the places where the literature is lacking, whether due to a methodology you think is incomplete or to assumptions you think are flawed.
- Avoid "Pathak et al says that", "Smith says X, Jones says Y" in literature review. You should be tying the literature you review to specific facets of your problem, not to review for the sake of reviewing.

- Avoid including all the studies on the subject or the vast array of scholarship that brought you to the subject. As tempting as it might be to throw in everything you know, the literature review is not the place for such demonstration. Stick to those pieces of the literature directly relevant to your narrowed subject (question or statement of a problem).
- Avoid polemics, praise, and blame. You should fight the temptation to strongly express your opinions about the previous literature. Your task is to justify your project given the known scholarship, so polemics, praise, and blame are unnecessary and possibly distracting.

Key Points: After assessing the literature in your field, you should be able to answer the following questions:

- Why should we study (further) this research topic/problem?
- What contributions will my study make to the existing literature?

Detailed literature search has been dealt in chapter 3. Please read carefully.

Materials and Methods

This section is essential and important to most good research proposals. How you study a problem is often as important as the results you collect. This section includes a description of the general means through which the goals of the study will be achieved: Methods, materials, procedures, tasks, etc.

An effective methodology section should:

- Introduce the overall methodological approach for each problem or question. Is your study qualitative or quantitative? Are you going to take a special approach, such as action research, or use case studies? Is it observational or experimental?
- Reference population, study population, study subjects, sample size and sampling methods to be decided at the beginning of the study.
- Indicate how the approach fits the overall research design. Your methods should have a clear connection with your research questions and/or hypotheses. In other words, make sure that your methods will actually answer your questions or stated objectives, i.e. write in detail about "the proposed tests, or methods, or scientific procedures, etc. One should also include inclusion, exclusion, eligibility and diagnostic criteria especially in medical and health research.
- It is necessary to mention independent and dependent variables.
- Describe the specific methods of data collection you are going to use—e.g. surveys, interviews, questionnaires, observation, archival or traditional library research.
- Methods for Data Quality Control to be described.

- Various procedures to ensure ethical considerations in your research with human subjects.
- Explain how you intend to analyze and interpret your results. Will you use statistical analysis? Will you use specific theoretical perspectives to help you analyze a text or explain observed behaviors?
- If necessary, provide background and rationale for methodologies that are unfamiliar for your readers. (Typically, the social sciences and humanities require more explanation/rationale of methods than the hard sciences).
- If applicable, you may also need to provide a rationale for subject selection (particularly if you have not already provided one). For instance, if you propose to conduct interviews and use questionnaires, how do you intend to select the sample population? If you are analyzing literary texts, which texts have you chosen, and why?
- It is necessary to explain various terminologies and standards which will be used in your research.
- Whether preliminary test run/poilet study will be done, if so how?
- Address potential limitations. Are there any practical limitations that could affect your data collection? How will you attempt to control for potential confounding variables and errors?

Results: This section must answer the question "What did you find"?

The description of the results of your work is the heart of your thesis/dissertation. It is the communication of facts, measurements and observations in your work. In this section you might like to include illustrations, like photograph, sector graphs histograms, pie charts, tables and so on. Remember that illustrations should not be used as ornaments but should support the text and aid in clear description and concise explanations, use them to help convey the information accurately and succinctly.

All photographs should have a figure number written in Arabic numerals a short caption or legend and in case of photomicrographs the stain used and magnification should be written, e.g. Fig. 1 Mast cell with dense granules obscuring the nucleus. Toluidine blue x 100.

Tables should be numbered in Roman numeral, e.g. Table I.

Clear writing is an expression of clear active voice that should be used. By changing the passive verb, e.g. "was achieved" to active verb "improved". As far as possible, write in past tense. Punctuators particularly commas, full stops and quotation marks should be used carefully as wrong usage can alter the meaning totally for example–

Go, slow work in progress.

Go slow, work in progress.

"The Managing Director" said the Chairman, "is a fool"

The Managing Director Said, "the Chairman is a fool".

Discussion: Answer the question "what do the results mean?"

This is the most difficult aspect of dissertation/thesis writing. It should include the following:

a. Present principles, relationships and generalization shown by the results.
b. Point out exceptions and lack of correlations.
c. Indicate agreement or contrast with previously published work.
d. State the implications of your results.
e. Give reasons for your conclusions.
f. Mention the limitations of your work.
g. Indicate scope for further work.

It is in the discussion that the author incorporates his contribution into existing knowledge. At its fullest, the discussion will want to do lots of things; it should recapitulate the main findings, discuss the methods you used if there is something interesting or unusual about them, discuss the results of other people those that conflict with yours and those that confirm them and argue the case of your results against those that conflict saying why yours are more convincing. Do not simply say that they disagree and other agree; there has to be some argument. And finally say what the implications of your study are or that more research is needed.

When discussing the conclusions of other workers, one should clearly state their origins and quote them correctly bearing in mind that unfavorable comparisons with previous work do not increase the merit of one's own work. It is better to show how one's results correct a false impression or lend themselves to a different interpretation.

Summary and Conclusions

The summary should concisely describe–

a. The problem
b. The solution
c. The principal conclusion(s)

In the summary, avoid experimental details and references to previous work. Do not draw wrong conclusions.

References

Under this there are two aspects, viz. citing of references in the text and listing of references in the list of references.

There are two styles for citing and listing: Harvard style and Vancouver style.

Citing of References

Harvard style: When there are three or less authors : Write all with their surnames and the year of publication, e.g. The occurrence of prostatic

tissue in a retroperitoneal teratoma has been observed by earlier workers (Kini, Raghuveer and Pai 1991).

When there are more than three authors, write the surname of only the first author, et al and year, e.g. the presence of psammoma bodies in papillary carcinoma has been observed by many workers in the past.

Vancouver style: Irrespective of the number of authors, write only the reference number as shown in this example:

Earlier workers have observed that endometrial hyperplasia is a pre-cancerous condition.[1]

Listing of References

Harvard Style

References are listed in alphabetical order irrespective of the order of their appearance in the text.

Vancouver Style

References are numbered according to their appearances in the text and listed accordingly. As per International Committee of Medical Journal Editors, uniform requirements for manuscripts submitted to biomedical journal are available in the following articles:

- Br. Med J 1988; 296: 401-405.
- Ann Intern Med 1988; 108: 258-265

Some Examples of Writing the References

1. **Standard Journal Article:**
   (List all authors when six or less; when seven or more, list only first three and add et al) Savitha Sodhi, Harsh Mohan, TS Jaiswal, Praveen S Mohan, Susheela Rathee.

   Should be written as

   Sodihi S, Mohan H, Jaiswal TS, Mohan PS, Rathee S. Placental pathology in pre-eclampsia syndrome.Indian J Patho Microbiol, 1990; 33:11-16.
2. **Book: Personal Author(s)**
   Eisen HN. Immunology: An introduction to molecular and cellular principles of immune response. 5th edn. New York : Harper and Row, 1974: 406-408.
   Rosai J Breast. In: Ackernman's surgical pathology. 8th edn. St Louis Baltimore: Mosby 1996:1565-1568.

3. **Book: Chapter in a book**
   Kobzik L, Schoen F. The lung In: Cotran RS, Kumar V, Robbins SL. Robbins Pathologic basis of disease. 5th edn Philadelphla: WB Saunders Co. 1994: 673-734.
4. **No author given**
   Anonymous. Cofee drinking and cancer of the pancreas (Editorial). Br. Med J: 1981;283:628.
5. **Agency Publication**
   AFIP publication:

   Scully RE. Tumors of the ovary and mal-developed gonads. In: Atlas of tumor pathology second serried Fasc. 16 .Washington, DC, 1979, Armed Forces Institute of Pathology.

WHO Publications

Enzinger FM. Lattes R, Torloni H: 1969. Histological typing of soft tissue tumors. Geneva, World Health Organization (International Histological Classification of Tumors, no. 3).

Epilogue	
DO- please - Spare me packets tattered,	Photographs all bent and battered
References in random order,	Obscure words typed off the border
Figures roughly drawn free hand,	Jargon none can understand
Flimsy paper, just one copy;	
Write instead such splendid text	That no guide is vexed
clearly typed with margins wide,	Room for comments at the side
English that is clear and concise	Lacking jargon, quite precise
Figures cleanly drawn and lettered	Photographs that cannot be battered
So that I can say quickly-	
'APPROVE THIS DISSERTATION WITHOUT HESITATION.'	

Chapter 20

HOW TO WRITE AN ARTICLE FOR PUBLICATION?

The craftsman is proud and careful of his tools.
The surgeon does not operate with an old razor blade.
The sportsman fusses happily and long over
the choices of rod, gun, club or racquet.
But the man that is working in words,
unless he/she is a professional writer (and not always then),
is singularly neglectful of his/her instruments.

–Ivor Brown

(Quoted in the Complete Plain Words by Sir Ernest Growers, Pelican,1963)

Not all who look at a journal are going to read,
Even one of the articles in it.
Writers must know, therefore,
What turns a looker into a reader?

–JW Howie

A naturalist's life would be a happy one if he had only to observe and never to write.

–Charles Darwin

In science, no matter how spectacular the results are, the work is not completed until the results are published

Many journal editors have agreed to use a set of uniform guidelines for manuscripts submitted to their journals. These guidelines are frequently updated and are known as the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

You must keep in mind before you start writing:
• LOGIC, LOGIC, LOGIC
• Your paper should represent a critical argument.
• Clear writing results from clear thinking.
• Clear thinking results from clear writing.
• Should be complete, accurate and convincing.
• Write with vigor and passion.

Bradford Hill questions will help author to think analytically while writing an original paper.

I	–	Introduction	Why did they start?
M	–	Methods	What did they start?
R	–	Result	What did they find?
A	–	And	
D	–	Discussion	What do the result mean?

CHECK-LIST FOR WRITING AN ORIGINAL PAPER

1. What is the message?
2. Why is the paper worth writing?
3. Who will read the paper?
4. Who will the authors be?
5. Which journal?
   - Read its instructions to the authors.
   - Note how the references are quoted in the text.
   - Is the reference list Harvard or numerical (sequential or alphabetical)?
   - Does it accept the Vancouver style?
   - How many copies are required?
6. Write the first draft?
   - of the introduction—why did we start?
   - of the methods—what did we do?
   - of result—what did we find?
   - Of the discussion—what do the result mean?
   - In whatever order suits you,
   - With references in Harvard or Vancouver style
   - Make file card and file them sequentially.
7. Draft tables.
8. Draft figure and figure legends.
9. Check the article to ensure that the material is in the right sections and that the meaning is clear. Amend where necessary.
10. Draft the remaining part—abstract, running title, key words, acknowledgements
11. Give it to the critical colleague to read for its correctness.
12. Discuss critically colleague's suggestions with them.
13. Amend the paper in the light of the suggestions.
14. Check the references against the originals.
15. Check all numerical material—in text, tables, and figures.
16. Write a covering letter to introduce the article to the editor.
17. Send it off to the journal.

Sections of the Manuscript/Article

Title Page

- The title is what catches the reader's eyes and deserves careful thought. It should be concise and descriptive, not a declarative sentence.
- Paradoxical, obscure or misleading title neither helps the reader nor the cataloguer.
- At bottom of page, include a "running head" version of the title (fewer than 40 characters.

- The title page should have names of authors, with first name and middle initial, name of department and institution where work was done (not where author currently is), institutional affiliation of each author (either indicated with asterisk or other marking, or done as a footnote).
- Name and address of corresponding author, including phone and Fax numbers and e-mail address.
- Acknowledgment of grant support (funding agency, grant number)
- Any disclaimers, if necessary and conflicts of interests.

Authorship: The Uniform Requirements and most journals address this issue.

- To be an author, the investigator should:
  1. Have contributed significant ideas and experimental design to the project.
  2. Have taken part in significant aspects of the experimentation, data analysis, or interpretation.
  3. Have participated in the writing (either draft form or critical revision) of the article.
- Each author should see the final version of the manuscript and give consent to co-authorship.
- The order of authorship on the by-line should be a joint decision of the co-authors.

Abstract page

Abstract should be less than 250 words although Vancouver style suggest a maximum of 150 words for unstructured and 250 in structured abstracts. It should be a single paragraph and should summarize the problem being addressed/purpose of the study, the methods used, the results, and the important conclusions.

- **Note:** In clinical biomedical journals, the abstract is broken into 4 paragraphs (background, methods, results, and conclusion).
- The abstract should be self-explanatory without reference to the text. Avoid abbreviations and references.
- List about 5–10 key words at bottom of page. The choice of these words is important because they will be used for indexing the article, not only for the journal, but on the web. Use Medical Subject Headings from Index Medicus.

Introduction

- It is short and states the purpose of the paper. What problem are you addressing? What is the relevance? Why should people care about this problem?
- Gives background information of the problem. Why is this problem important? What other experiments have been done to address the problem?

- What is the gap in knowledge presently? How will you expand (or challenge) the findings of others? You need to summarize other relevant papers, but do it in an orderly fashion.
- It does not review the history.
- A common problem for beginners, and even experienced writers, is to randomly summarize all papers on the subject, without focusing on the specific problem. Your presentation of the background should flow in a logical manner. Remember, logic is a key word in writing any scientific article/manuscript.
- Always quote references.

Materials and Methods: (What and how did they do?) This section should have the following details:

- Organize the Materials and Methods section in chronological order with a logical sequence.
- Start with materials, continue with protocols as they were used, and end with data analysis.
- Do not just randomly throw in the components of this section as you remember them.
- Describe how each experiment was done in enough detail so that another investigator can repeat the experiment without contacting the authors.
- When using an established method, give the reference, but include any modifications that you might have made.
- For methods that have been published but are not widely known, include a brief description. Identify chemicals and pharmaceuticals precisely, and give name of manufacturer and city and state in parentheses. However, for common, generic instruments, e.g., micro centrifuge, electrophoresis apparatus, you need not provide this information unless the brand has a bearing on your results.
- For chemicals, give concentration in conventional units (molarity, mg/ml).
- For biochemical assays or experiments, give final concentration of the solution, not only how much you added.
- Be careful that your protocols do not sound like a lab manual.
- Provide details of statistical methods used. Give numbers of observations and report subject losses. Specify computer programs used.
- When animal studies are involved, indicate whether procedures were in accordance with the institutional guide for Animal Care and Use Committee.
- Include exclusionary criteria and descriptions of controls.
- When human subjects are involved, indicate whether the procedures followed were in accordance with the Institutional Review Board and Declaration of Helsinki - revised in 1983 (World Medical Association 1964).
- Indicate if informed consent was obtained.

- Do not use patient names, initials, or hospital numbers in the manuscript. Rather, use unique identifiers that allow only the investigator to link the data to the patient.
- Failures to fulfill ethical requirements will be a reason for rejection of your article/manuscript.

Results: What did they find?

The description of the results obtained throughout the development of a research study is the heart and soul of the article/manuscript.

- The Results section should flow in a linear fashion with a proper logic
- The study should be presented as follows:
  - Relevance of data (why you did the experiment?)
  - Details of methods used (how you did it?)
  - Presentation of data
  - Conclusions from data
  - But not the interpretation (leave that for the Discussion section).
- Topic or introductory sentences are very important in the Results section. You must tell the reader why you did the experiment, and what is your thinking (rationale).
- In describing the experiment, refer to the Materials and Methods section.
- Data should be organized clearly and concisely in text, table(s), figure(s), graph(s) forms.
- The Table should be self-explanatory, numbered, each table for a specific problem with horizontal and vertical lines. It should also have statistical method (if used) below the table as footnote.
- **Figure legends:**
  - The reader should be able to look at the figure and its legend and be able to understand how the study was done as well as see the results.
  - The first statement in the legend should be the title of the figure. This does not have to be a complete sentence. There are two ways to approach the title for the figure. Some investigators (and journals) prefer to state what the figure represents, others give the conclusion of the figure.
  - Many journals like figure legends to be written in a brief, clipped style. This means that you can delete "a/an/the" as well as other extra words.
  - Check several times to be sure that graph symbols, and other notations in the figure correspond to the legend and to the text. This is one of the biggest problems with which journal editors (and reviewers) have to contend.

Discussion: What do the Results Mean?

In discussion, the author includes his contribution into existing knowledge. The discussion should answer the question and gap in the knowledge remained unfilled.

- State your conclusions and explain why they are novel and important. Do not reiterate the actual data (numbers, for example) presented in the Results section.
- Discuss the implications of your work in reference to studies by others. Do not repeat what is in the Introduction, but relate your work to what you presented earlier. If your experiments are in conflict with other reports, discuss possible reasons for this, e.g., different study methods/ study area, different chemicals, different procedure used.
- It is acceptable to suggest new studies/experiments, which would be a continuation of the work reported, or to refer to new experiments in progress.
- Highlight shortcomings/limitations of the study/methods.
- Make every word count in your Discussion. Do not be verbose.

Acknowledgments

- Always remember to acknowledge and thank colleagues who contributed to the work but do not meet the criteria for authorship (see above).
- This includes individuals who provided, referred patients to you, provided technical help, suggested an experiment, discussed your results with you, or critically read the manuscript. Also acknowledge financial support: who supported (e.g., ICMR, WHO, UNICEF, Glaxo etc.).
- Some journals may require written permission from individuals to be acknowledged, although this is rare.
- Write "We thank....," not "We would like to thank....," or "The authors thank.....".

References

The term reference is generally used in preference to bibliography which truly means a complete list of everything that has been published on a subject, but in practice, is often used as rather imprecisely to mean Further Reading.

References are provided to indicate sources from which the author has obtained information, but the value of an article/manuscript is not measured by the number of the references and they should not be merely to show erudition.

There are two aspects of the references:

1. **Citing of the references:** As per Harvard style, reference should be made in the text by giving name of the author and the year of study/ publication in parenthesis.
   e.g.(Goyal 2003) or author's name can be written as a part of sentence, e.g. Goyal(2003) reported that..... . If only two authors

had written an article , both the names should be given and for more than two, all names should be given for the first appearance in the text later on only first author's name adding et al.

As per Vancouver style, the references are cited in the text using superscripts or brackets in the order in which they appear in the text. They are identified by numerical numbers.

2. **Listing of the references:** The references are listed at the end of the article on a separate page. In Harvard system, they are arranged in alphabetical order irrespective of appearance/order in the text while in Vancouver system, references are listed consecutively in the order they appear in the text.

   Format of the reference for an article is as follows: Surname and initials of all authors followed by full title of the paper, full title/name of the journal, year of publication, volume and number of the journal and first and last page number of the article/paper.

   Format of the reference for a book/monogram is as follows: Surname and initials of all authors followed by full title of the book, number of the edition, place of publication, publisher and year of publication.

   Format of the reference for chapter in a book is as follows: Chapter author(s) surname and initials followed by full title of the chapter, book authors/editors name(s) and initials, full title of the book, place of publication, publisher and year of publication first and last page number of the chapter.

Submission to the Journal

- Many, if not most, journals now require electronic submission. Consequently, this requires certain dramatic changes in how you prepare your manuscript.
- Graphics must be in electronic form, so avoid hand-drawn figures and graphs. Common formats used are TIFF or EPS.
- The requirements for individual journals vary considerably, so be sure to consult the journal's Instructions to Authors.
- In all cases, whether submission is electronic or hard-copy, a covering letter should be sent explaining the important points of your paper and why it should be published in that particular journal.

Writing Style

- Make every word count!
- Sentences
  - Every sentence should make a single point.
  - The new information ("stress point") that each sentence provides should be at the end of the sentence.

  - Old information, which links the reader to the previous sentence, should be at the beginning of the sentence.
  - Word order should be subject—verb—object. Keep your subject and verb as close together as possible.
  - Use the active voice, e.g., "We measured." Passive voice is useful when there are two or more actions in a sentence.
  - Sentences should contain no more than 20–22 words.
- Paragraphs
  - Every paragraph should have a topic sentence that says what you are going to tell the reader about in that paragraph. [Analogy: Don't jump into the lake without telling bystanders why you are doing it. Are you going swimming? Are you going to rescue someone? Are you just fooling around, and perhaps endangering yourself?]
  - Use transition sentences to link paragraphs and sections. Why are you jumping from one experiment to another?
- As you write each sentence or paragraph, ask yourself: What am I trying to say? What is my question and why did I ask it?
- Always keep in mind who your reader is. How you write depends on the audience. Will the reader understand your jargon? Usually the reader does not know as much about the topic as you do (otherwise, you wouldn't be writing this), so keep in mind that you need to explain things as you go along.

TYPES OF DISTRACTIONS WHILE WRITING A PAPER

1. Pompous verbiage (extra words to show importance of the findings)—delete, simplify or make active voice.
2. Technical words used out of its field.
3. Abbreviation—irritating to the reader.
4. Wrong grammar.
5. Inaccurate or misleading use of words.
6. Redundant words.
7. Factually imprecise.
8. Technically imprecise.
9. Is it an "elegant variation" or not?
10. Unnecessary neologism.

Points of Grammar to be Kept in Mind

- Subject/verb agreement: Singular subject takes singular verb; plural subject takes plural verb. Remember that the noun closest to the verb might not be the subject.
- Common mistake: 'Data' is plural and takes a plural verb; the singular form is datum.

- a/an/the: a common problem for non-native English speakers
- which/that:
  - Use "that" without commas for essential (restrictive) material that cannot be omitted without changing the meaning of the sentence.
  - Use "which", with commas setting off the clause, for nonrestrictive, extra information.
- and/vs/or: use them correctly. "and/or" should never be used, except in legal matters.
  - dangling modifiers
  - present/past/perfect tense:
    - use present tense for established, general knowledge.
    - use past tense for particular results and for what you are reporting in this manuscript.
    - use present tense when referring to your figures and graphs.
    - use present perfect (have/has been) for observations that have been repeated or are ongoing.
- use parallel construction in clauses and verb forms.

Other Useful Suggestions

- Write for an extended period of time, e.g., all afternoon, or even all day. Don't try to write for just an hour at a time—it doesn't work!
- Once you finish your first draft, let it lie dormant for a while. Re-read your key references. When you return to your manuscript, look for the following:
  - Flaws in logic
  - Misquoted or misremembered facts
  - Excess verbiage
- When you do your re-write, polish up your prose and style.
  - Check meaning of every word.
  - Check relationships between words.
  - Make every word count.
  - Check requirements of your journal. Are there word, page, or figure limits?

Very important advice: Don't get discouraged. Remember No book, journal article, or masterpiece was ever written in a day!

Visit for details: (http://www.icmje.org).
http://www.mcg.edu/research/policy/guidelines.htm).

Chapter

21

CRITICAL APPRAISAL OF JOURNAL ARTICLE

(Critical Review and Evaluation of Scientific Research Publications)

(You need to study chapter 20 before starting this chapter)

NEED FOR THE CRITICAL REVIEW OF SCIENTIFIC RESEARCH PUBLICATION

Communication in medicine is a skill and to make it effective is a demanding task. It is not easy to clearly express in words that might have been well understood. Clarity in reporting of how and what is obtained as result of research is important for both researchers and the community. Clear report enables the practitioners to apply the result of the research in their practice.

Thus critically evaluated scientific research writing creates a healthy and productive cycle between theory and practice in medical education.

Following are 40 points/factors under nine headings for evaluating the article:

1. Title
2. Author(s)
3. Abstract
4. Introduction and review of literature
5. Materials and Methods
6. Results
7. Discussion and conclusion
8. References
9. General considerations and implications

Checklists for each of these nine headings will be discussed in detail. The number of points assigned to each element will be critically evaluated.

Who Should Evaluate?

A. Self-evaluation and an expert committee before submission.
B. Panel of peer reviewer
C. An expert reviewer

METHOD OF EVALUATION

A research paper evaluation can be done qualitatively or quantitatively. Reporting of Qualitative critique is sometimes controversial, subjective

and difficult to understand. Therefore Quantitative assessment by awarding points for all the elements proportional to their importance is more objective. A check list can be prepared to assign points for each element of the research paper. Following is one such check list:

Critiquing a research paper: Elements with their weightage for evaluation are as follows:

Sr. No.	*Elements*	*Weightage for the element*
1	Tiltle	0.67
2	Author(s)	0.33
3	Abstract	1.00
4	Introduction and review of literature	2.00
5	Materials and Methods	5.00
6	Results	2.00
7	Discussion and conclusion	2.00
8	References	1.00
9	General considerations and implications	1.00
	Total	**15.00**

Evaluate each of the 40 items given below by using one of the following options. Assign marks only up to item 37.

Assign: Y = Yes
N = No (If response does not provide correct answer or suggestions)

Title

1. (0.34) Does title correctly represent the content and breath of the study reported?
2. (0.33) Is title clear, concise and does it give importance to the study?

Author(s)

3. (0.33) Are titles (diploma/degree/appointment) and address of the author(s) clearly indicated?

Abstract

4. (0.34) Does abstract cover each and every component of the study and not only selected aspects?
   - Objectives
   - Design
   - Subjects
   - Setting

- Outcomes
- Materials
- Results
- Conclusion

5. (0.33) Does abstract contain precise information, actual data and the main results?
6. (0.33) Are the implications and benefits reported commensurate with the results obtained, i.e. generalizations in the abstract do not exceed the limits of the study?

Introduction and Review of Literature

7. (0.29) Is the goal of the study, compared to the goal of the paper, clearly stated that is either a research question or research hypothesis. If not, suggest a question statement.
8. (0.29) Are the key references reported? Is there a clear relationship between the literature and the problem being studied?
9. (0.28) Does review of the literature provide a theoretical and methodological framework for the problem under study?
10. (0.29) Are the references to previous finding accompanied by proper literature citations? (Due recognition of ownership of ideas is attributed).
11. (0.29) Are the important concepts and variables (both independent and dependent) defined clearly?
12. (0.28) Is the pertinence of the study presented both in relation to the problem as reported in the literature and in relation to the setting?
13. (0.28) Is the general overview of the study (big picture) presented? (If not, suggest an outline).

Materials and Methods

14. (0.50) Are independent and dependent variables selected for the study described clearly in relation to the nature of the question asked?
15. (0.75) Is research design described in detail either directly or by referring to the literature?
16. (0.50) Is research design appropriate in relation to confounding variables or presence of biases?
17. (0.50) Are procedure, measurement, etc. described in detail?
18. (0.75) Are the population of interest, the subjects (sample) and the sampling procedure clearly described? Is the sample size appropriate?

19. (0.50) Is the data collection procedure clearly described?
20. (0.50) Is the setting in which the study took place described?
21. (0.50) Are data analysis procedures (statistical tests) listed in precise terms?
22. (0.50) Are data analysis procedures (statistical tests) appropriate?

Results

23. (0.50) Do the specific data accompany the result statements?
24. (0.50) Are tables and figures used efficiently (neither too few nor too many)?
25. (0.50) Are the contents of the tables and figures clear and accurate: (long lists of raw data are not presented)?
26. (0.50) Does the results section contain actual results only? (Should not contain opinions or discussion).

Discussion and Conclusion

27. (0.50) Does the discussion cover all the debatable aspects of the study(pluses and minuses) ?
28. (0.50) Is discussion related directly to the study reported and not to other topics?
29. (0.50) Are current and past findings brought together in the discussion or conclusion?
30. (0.50) Are conclusion and practical outcomes of the study commensurate with the design used and the results obtained? (Do not go beyond the limits of the study conducted such as over generalizing given the design, the instruments and the sample used).

References

31. (0.34) Are number of references reasonable (Neither too few nor too many) and each reference brings a unique contribution?.
32. (0.33) Do contents of the paper clearly show that the references quoted were carefully read and well understood?.
33. (0.33) Are references presented according to standard rules of publication?.

General Considerations and Implications

General Considerations

34. (0.25) Are various sections of the paper clearly identified and the contents appropriate?.

35. (0.25) Is terminology uniform throughout the paper (including abbreviations and units of measurement)?
36. (0.25) Does the tone of the paper denote a rigorous approach on the part of the author, the level of sophistication of the paper appropriate for the readership?
37. (0.25) Is writing style clear, pleasant, and no spelling mistakes?

Implications

38. How will you use the results presented in this paper in building your argumentation for change in your own setting?
39. What are two suggestions to pass onto the author? (Mention them).

Conclusion

40. The critique should be objective and unbiased with elaborate suggestions.

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