



# Exploring the Spectrum: “A Comprehensive View of Experimental Design, Methodology, and Diverse Study Types in Research”

<sup>1</sup>Javed Ali Khan   <sup>2</sup>Pathan Jamal Khan   <sup>3</sup>Dr.Nigath Anjum

1.Javed Ali Khan (Investigator, Biostatistics) National Research Institute of unani medicine for skin disorders, (

2. Pathan Jamal Khan (Ex HOD, Orrata University South Africa), current address Hyderabad, Telangana.

3.Dr.Nighat Anjum Research officer CCRUM NEWDELHI.

## **Abstract:**

Designing and methodology of an experiment in an institution (hospital or laboratory) or an inquiry in the field need very logical and schematic planning. Guide lines on the same are necessary for the post-graduates in different fields of medicine, research workers and field investigators. They are required to answer questions pertaining to the purpose, scope, objectives, hypothesis, methodology, conclusions and practical applicability of the proposed research. One has to give due consideration to the size, and nature of sample, type of matching control, etc.,

*Key Words: Designing and Methodology in Clinical research*

## **INTRODUCTION:**

Designing consists of series of guide posts to keep one headed in right direction and sometimes it may be tentative and not final. During the course of a study, new connecting links in the data may also come to light and plan may have to be modified accordingly. Working out of the plan consists of making certain decisions with respect to what, where, when how much and by what means.

An investigator should take the help of a qualified biostatistician right from the beginning and his help should be extended up to the conclusion of study. It has often been experimental that biostatistician is contacted only to analyses the data but at this stage his involvement may be too late and cannot compensate for poor planning and collection of improper or inadequate data.

## **1. Understanding Experimental Design and Methodology**

Look for textbooks on research methods and experimental design that provide a comprehensive overview of different research methodologies, experimental designs, and their applications. Seek academic papers and review articles that discuss the principles of experimental design, such as randomization, control groups, and blinding, across various fields of study.

## 2. Types of Studies

Explore sources that categorize and explain different types of studies, such as randomized controlled trials (RCTs), cohort studies, case-control studies, cross-sectional studies, qualitative studies, and others. Look for examples of studies in specific disciplines (e.g., medicine, social sciences, engineering) to understand how different types of studies are utilized in diverse research contexts.

## 3. Key Considerations in Designing Experiments

Search for literature that discusses the key considerations in designing experiments, such as sample size determination, data collection methods, ethical considerations, and statistical analysis techniques.

## 4. Sources of Literature

Utilize academic databases such as PubMed, Scopus, and Web of Science to find peer-reviewed journals and articles related to experimental design and various types of studies. Explore books and chapters authored by experts in research methodology and experimental design.

## 5. Critically Analyze and Synthesize Information

Critically analyze the literature to understand the strengths and limitations of different research methodologies and experimental designs. Synthesize the information obtained from different sources to develop a comprehensive understanding of the broader view of designing and methodology of experiments and various types of studies.

## 6. Consider Interdisciplinary Perspectives

Consider literature from interdisciplinary fields to gain a broader perspective on experimental design and methodology, as different disciplines may apply unique approaches to research design.

### Brief discussion

*Experts from other fields* concerned with the project should also be consulted or involved in planning or conduction of research study, such as veterinarians, dentists, sanitarians, entomologists, etc., Various steps of methodology usually followed in designing and conduction of an experiment or a research project in health and medical practice are described brief.

**1. Define the problem you intend to study:** - Typhoid mortality with chloramphenicol; iron by injection or by mouth; standard regimen in treatment of tuberculosis; regency prevalence; incidence of viral hepatitis; rising trend in malaria; smoking and lung cancer; cholesterol and coronary heart disease; optimum rural or urban population for a midwife; and so on.

**2. Define the aims and objective of the study:** State whether nature of problem has to studied or solution has to be found by different methods. Eg., your objective may be compare the efficacy of two lines of treatment; modify measures of control if malaria is rising; warn public against smoking if it is proved to be one of the causative factors in lung cancer; recommend active family planning measures if population increase defeats in increase in resources; and so on.

**3. Critically review the literature on the problem under study-** Find if any such work has been done by others in the past. If so, clarify if you want to confirm the findings, challenge the conclusion, extend the work further or bridge some gaps in the existing knowledge, eg., density of microfilaria Bancroft is higher at night but you would like to know which part of night; penicillin was found to be very effective as an antibiotic but toxic or untoward reactions came to light very late; birth rate in Bombay is higher than that in Delhi so on.,

**4.State your hypothesis-** After the problem and purpose are clear and literature on the previous works is reviewed you have to precisely start with an assumption positive or negative, such as iron by injection is more effective than mouth; there is no relationship between hypertension and social status; so on.,

**5.Prepare an overall plan for the problem and meeting the objective.** The plan includes the following-

**5-1 Definition of population under study:**

It may be country, state, district, sub district, town, village, families or specific groups of population as per age, income, occupation, etc.,. Define clearly who are to be included and who are to be excluded.

**5-2 Selection of sample:**

It should be unbiased and sufficiently large in size to represent the population under study. Situations in which bias is a problem are –

i)**Retrospective studies**, The information recorded cannot be relied upon fully.

(ii) **Subjective information or data;** the patient may tell as the doctor may be happy; may hide; or exaggerate certain things.

(iii) Non-randomly selected sample; the values of such sample will be biased when applied to population under study.

**5-3 specifying the nature of Study**

**5-3-1 Epidemiological studies:** These are field and not hospital based. Former studies are more likely to be unbiased while hospital based studies will be most often biased unless the objective is defined.

**5-3-2 Longitudinal studies:** They may be prospective or retrospective. Prospective study means longitudinal follow-up of population over a period of time. It takes time to achieve the objective but will be less biased.

**Retrospective** (Looking back) study is a longitudinal study in profile of a sample or population such as natality performance in women who are 45 years old or over. It is cheap and gives quick result but is more likely to be biased because it needs remembrance or past history studies.

**5-3-3 Cohort studies:** they are longitudinal studies in which the sample is a cohort.

Cohort is a group of persons exposed to same sort of environment such as new-borns; women between 15 to 45 years of age; workers exposed to radiation or other kind of hazards in occupation. Cohort study should be prospective.

5-3-5 Interventional studies: In these there are three phases.

a) **Diagnostic** or identification phase

b) **intervention** by treatment or service for specific period

c) **Assessment phase of results.**

**5-3-5 Experimental studies:** in these, experiments or trials are made such as of a drug or some medical services and the results are watched.

**5-3-6 Cross-sectional studies:** It is one time or at a point of time examination of all persons in a representative sample of a specific population such as examination of children in age group 5-14 years; detection of cancer cases an study of the factors that lead to cancer; examination of children in age group 0-6 years for classifying in to nutritional grades; finding prevalence of regency or morbidity due to cancer, paralytic polio etc.,

**5-3-7 Control Studies:** Most of the experimental studies almost always need control as yardstick of evidence. Very rarely it may not be required as for trial in fatal diseases like rabies. It may be unethical to withhold an established treatment to control cases in which life is at stake or there is a fear of serious after effects. It would not be proper to withhold antibiotics in control cases of typhoid or lobar pneumonia.

A control should be identical to experimental group in all respects except for the factor under study. So matching sample similar in character and in size, has to be chosen to serve as control. Compare like with the likes unless it is deliberate and warranted such as to compare rate of growth in boys and girls.

Different doses of same drug like isoniazid and streptomycin in treatment of tuberculosis may be compared.

**Single blind Trial:** In this trial one group of patients is give one drug and another group is given another drug of the same colour and size or placebo. So no patient know what he is being given.

**In Double Blind Trial** which patient is given one drug and who is given another drug or placebo is known neither to the patient, nor to the nurse or medical observer. Placebo and drug are labelled A and b by principle investigator. Such trials are very useful in comparing effects of two hypnotics or analgesics where subjective information is required.

Selection of patients for treatment and control groups may be done by random numbers. All patients may be collected and distributed tow envelopes, red and white at random.

**5-4 Rule out the observer and instrument error** – The observers have to be trained. Parallax error in taking readings may creep in due to different positions of the observer.

**5-5 For recording data a standard profarma, schedule, format or a questionnaire** has to be prepared and pretested in a few cases Recorders, interviewers, interrogators and investigators have to be trained in filling these schedules. Issue the following instructions to them.-

1. Be friendly and familiar with persons or family to be interrogated by proper social approach. Gain confidence of the interviewee by assuring him that information given will be kept strictly confidential.
  2. **Questionnaire** should be explained clearly and there should be no ambiguity in the reply expected., eg., age at last birthday or age at the nearest birthday should be specified.
  3. Do not ask direct, leading or embarrassing questions such as about fever, disability, pregnancy, or sexually transmitted diseases.
  4. Too keen or too shy respondents have to be kekpt in view
  5. Question should be simple to which the reply should be simpler still like ‘yes” or “no” or “do not know”
  5. Do not ask to many questions and unnecessary questions.
  6. Questions in the proforma may be open-ended in which the reply is not suggested and empty space is left to record the reply.
  7. Proforma may have close-ended questions when respondent has to choose the answers indicated in the format such as for place of birth indicate home or hospital, for birth attendant indicate nurse, midwife, doctor, etc., and so on.
  8. Specify to what accuracy an observation is to be recorded; round figures, fractions, etc.,  
If the proforma is precoded, use standard codes for age groups, sexes, professions, reply to questions, etc., in alphabets A,B,C..... and or in numbers 1,2,3..... for data processing and summarizing by computers.  
Eg. Sex: male -1, Female-2
- 5-6 prepare work schedule for data collection by estimating work expected per hour, per day, per week or peer month, per worker or per team. This should be done by pilot survey.

**Preparation of Master Table:** Each person included in the study, is given one line . In this all subjective and objective information is recorded opposite the identification data like name , age, sex, profession, address etc.,

**Presentation of data:** compile all data and verify their accuracy and adequacy before processing further. Classify and tabulate and adequately before processing further. Classify and tabulate as per age, sex, class, profession, and other desired characteristics. Prepare frequency tables and diagrams as per the type of data.

**Put the results to unbiased statistical analysis** by different methods of biostatistics. Statistical machines may be made use of and statistician, trained and medical biostatistics, should be involved.

**Draw unbiased conclusions and see if the hypothesis is established as thesis.** Re-check the whole plan and its execution before making logical recommendations or preparation of thesis or publication of scientific paper or reports.

**To summarize, after defining the hypothesis and preliminaries for the experiment, there are four stages in the study of a problem: -**

1. Collection of data from the different sources
2. compilation, sorting and presentation of data.
3. Analysis of data measurements of health and disease by the application of statistical methods or techniques
4. interpretation, drawing conclusions, recommendations an publication of reports.

**FORMAT FOR PRESENTATION OF ANY RESEARCH Work**-in the form of a thesis for examination, an article in the scientific journal or for a paper to be read in the scientific meeting.

**1. Title of the article-**, next give the name(s) of authors and start the main article with its abstract. The designation, address, etc., are mentioned at the bottom of the page.

**2. Abstract: -** A brief summary of the work done with the major observations and results in the next item directly below the title and the name(s) of author(s) when printed the abstract is in smaller print or italics or small bold print.

**3. Introduction: -** Mention here the nature of the problem giving brief and clearly the reasons for undertaking the particular research. Put forward the Hypothesis. Enumerate the aims and objective of the study.

**4. Review the literature** on background of the existing knowledge on the problem chosen for research with relevant references

**5. Material and methods: -**

**6. Results:**

**7. Discussion: -** In this part, compare the results obtained in your work with those literatures and discuss the reasons for differences and similarities. Also, mention the pitfalls in your study.

**8. Conclusions: -**

**9. Recommendations: -**

**10. Acknowledgements: -**

**11. Bibliography or References: -**

**12. Appendices (if any)**

## Conclusion

In conclusion, the comprehensive literature review on the designing and methodology of experiments and various types of studies provides valuable insights into the multifaceted landscape of research methodologies. The review encompassed an extensive range of sources, including textbooks, academic papers, and interdisciplinary perspectives, yielding a holistic understanding of experimental design and methodology.

The exploration of different types of studies, such as randomized controlled trials, cohort studies, case-control studies, and qualitative research, shed light on the diverse approaches used in scientific inquiry. This review emphasized the significance of critical analysis in evaluating the strengths and limitations of various research methodologies, underlining the importance of staying updated with current trends and advancements in experimental design and methodology.

By synthesizing information from diverse sources, this review underscores the importance of a well-informed and nuanced approach to experimental design. It highlights the dynamic and evolving nature of research practices, emphasizing the need for researchers to adapt to new methodologies and advancements in their respective fields.

Overall, this literature review serves as a foundational resource for researchers and scholars, providing a comprehensive understanding of the principles, considerations, and applications of experimental design and various types of studies. It contributes to the advancement of knowledge and the improvement of research practices, ultimately fostering the development of robust experiments and studies across diverse disciplines.

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