

## Research Methodology Part 3

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## Review of Part 1 & Part 2

- Part 1 of the presentation dealt with the basic aspects of research methodology
- It included topics such as:
  - Meaning of research
  - Definition of research
  - General characteristics of research
  - Objectives of research
  - Motivation in research
  - Types of research
  - Introduction to research methodology
    - Research approaches
      - Quantitative approach
      - Qualitative approach
    - Sub-classification of quantitative approach
      - Inferential
      - Experimental
      - Simulation
  - Significance of research

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## Review (contd.)

- In part 2 of the presentation, the topics discussed were
  - The research process
  - These steps are:
    - Formulation of research problem
    - Formulation of researchable question
    - Literature survey
    - Development of working hypothesis
    - Research design

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## Topics of Part 3 of Presentation

- This part deals with study design
- Among the many types of study design, the one most suitable for the study to be chosen
- The study design should be able to answer the research question and should be feasible to undertake
- The major study designs discussed in this part are:
  - Cross sectional study
  - Longitudinal study
  - Before and after study design
  - Study based on nature of the investigation
  - Epidemiological research design

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## Study Design

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## Cross-sectional Study Design

- Cross-sectional studies
  - This type of studies are also known as one-shot or status studies
  - These are most commonly used design in the social sciences
  - Most suited to studies for
    - Finding out the prevalence of a phenomenon, situation, problem, attitude or issue
    - Done by taking a sample of cross-section of population
  - These studies are very simple in design

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## Cross-sectional Study Design

- Examples of cross-sectional studies that are most suitable for a study of the following topics:
  - The attitude of study population towards construction of nuclear power plant at Kudankulam Nuclear Power Plant in Tamil Nadu
  - The socio-economic characteristics of patients visiting medica superspecialty hospital
  - Employee engagement level at medica
  - Age distribution of nursing personnel in different hospital in Kolkata

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## The Before-and-After Study Design

- The advantage of this type of studies is that it can measure the change in a situation after an intervention
- Effectiveness of a programme can be very appropriately measured by this type of study
- In this, two sets of cross-sectional data are obtained from the same population to find out the changes
- Example:
  - The hypothesis that *May I Help You counter girls* work standing and the tiredness affects their behaviour in the later part of the day
    - The hypothesis can be proved or disproved by providing sitting and doing a before-and-after study

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## Longitudinal Study Design

- This type of study can determine the pattern of change in relation to time. For example,
  - Association of smoking with lung cancer
- Longitudinal studies are useful for collecting factual information over a period of time
- In this type of study, the study population is visited a number of times at regular intervals over a long period of time
  - Intervals may vary depending on type of study
- Data is collected from the same population but may or may not be the same respondents
- It can be seen as repeated cross sectional studies

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## Study based on Reference Period

- Reference period is the time-frame in which a study is exploring a phenomenon, situation, event or problem
- These types of studies are:
  - Retrospective
  - Prospective
  - Retrospective-prospective
- Retrospective study design
  - It investigates a phenomenon that has already happened
  - It can be studied by collecting past (historical) data from documents or respondents recall of the past event

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## Study based on Reference Period

- **Prospective study design**
  - Prospective studies refer to likely prevalence of a phenomenon, situation, problem, attitude or outcome in the future
  - This type of study design try to establish the outcome of an event or what is likely to happen
  - Examples:
    - To determine the impact of training on performance of nurses
    - To determine the effects of pulse polio programme
    - To determine the effects of bikers helmet wearing campaign on fatal head injuries in road traffic accidents

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## Study design based on Nature of the Investigation

- **Quantitative Research Study design can be classified as:**
  - Experimental
  - Non-experimental
  - Quasi or semi-experimental
- **Example:**
  - Say, you want to investigate the effect of new drug for curing a disease or impact of a teaching method on comprehension of students
    - It is assumed that there is a *cause-and-effect* relationship
  - There are two ways of studying the relationship

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## Study design based on Nature of the Investigation

- **First**
  - Involves the researcher to introduce the intervention (Cause)
  - Wait till the change is produced or given sufficient time to produce the change
- **Second**
  - Researcher observes the phenomenon and attempting to establish what caused it
  - In this case the investigator starts from the outcome and attempts to determine what caused the phenomenon
- If studied in the first way, it is called experimental study
- If the second method is followed it is non-experimental study
  - Example: Incidence of catheter associated urinary tract infection

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## Study design based on Nature of the Investigation

- **Experimental Study Designs**
  - There are many types of experimental study design
- **Some of these are:**
  - **After-only experimental design**
    - In this type of design, the researcher knows that the population is being, or has been exposed to an intervention
    - S/He wishes to study the impact on the population
    - Baseline (pre-test) information is collected based either on recall by the respondents or by document study
    - The change in the dependent variable is measured by difference between the 'before' and 'after' data sets

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## Study design based on Nature of the Investigation

- **Before-and-after experimental design**
  - The main advantage of this type of study design is:
    - it can measure change in a situation, phenomenon, issue, problem or attitude
  - It is the most appropriate design for measuring the impact or effectiveness of a programme
  - It can be described as two sets of cross-sectional data collection points on the same population
    - This is to find out the change in the phenomenon or variable(s) between two points in time
  - It is carried out by adopting the same process as a cross-sectional study except that it comprises two cross-sectional data set

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## Study design based on Nature of the Investigation

- The following are examples of topics that can be studied using this design:
  - The impact of administrative restructuring on the quality of services provided by an organisation
  - The effectiveness of marriage counseling service
  - The impact of sex education on sexual behaviour among school children
  - The effect of a drug awareness programme on the knowledge about, and use of, drugs among young people
  - The impact of incentives on the productivity of employees in an organisation

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## Study design based on Nature of the Investigation

- **Longitudinal study design**
  - This study design is used to determine the pattern of change in relation to time
  - It is useful for collecting factual information on a continuing basis
  - Example:
    - Trends in the demand for labour, immigration, morbidity pattern, fertility pattern and so on
  - In this study, the study population a number of times at regular intervals
  - Type of information collected from same study population each time is identical. The respondents may vary

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## Study design based on Nature of the Investigation

- **The Control group design**
  - Two study groups are selected
    - A control group
    - Experimental group
  - The groups should be comparable except for the intervention
  - The experimental group either receives/ exposed to the intervention but not the control group
  - Firstly, 'before' observation is made on both groups
  - Experimental group is then exposed to the intervention

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## Study design based on Nature of the Investigation

- It is assumed that intervention had an effect on the experimental group
- Then 'after' observation is made on both the groups
- The difference observed between 'before' and 'after' observations in the dependent variable is considered to be due to intervention
- It is important to remember that the chief objective of the control group is to quantify the impact of extraneous variables
  - This helps in ascertaining the impact of the intervention only

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## Study design based on Nature of the Investigation

- **Double-Control Design**
  - In control design, the impact of intervention can be attributable to extraneous variables
  - But there can be other effects that may not be separable
  - These other effects may be due to research instrument or respondents
  - When there is a need to identify and separate out these effects, a double control study is required
  - In double-control studies, two control groups are required instead of one

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## Study design based on Nature of the Investigation

- **Cross-over Comparative Experimental Design**
  - When assessing effectiveness of drugs in treating a condition, the control group is not treated with the drug
  - This is considered unethical
  - In this, intervention is given to one group and after sometime the impact is measured
  - Then the control group becomes the experimental group and the experimental group becomes the control group, i.e., the interventions are crossed over
  - Sometimes, this alternation is repeated several times

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## Study design based on Nature of the Investigation

- **Trend studies**
  - For mapping changes over a period of time, the trend studies are most appropriate
  - Here, one determines what happened in the past, what is happening now and what is likely to happen in future in a population group
  - Trend studies are useful for forecasting
- **Cohort studies**
  - Cohorts are based upon the common characteristics such as year of birth, graduation or marriage within a subgroup of population
  - Say, to study the proficiency in conversational English for those born in 40's this type of study can be done

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## Study design based on Nature of the Investigation

- **Panel studies**
  - It is similar to trend and cohort studies
  - It is longitudinal and also prospective in nature
  - Information is collected from same respondents
  - Example:
    - To study the pattern of changes in household expenditure
    - A few families are chosen
    - Find out the amount they spend every fortnight on household items
    - Same information is collected from the same families over a period of time
    - Note the changes in their expenditure

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## Study design based on Nature of the Investigation

- **Blind studies**
  - This concept of study can be used with comparable and placebo experimental design
  - This types of study is undertaken for assessing the effectiveness of drugs
  - The study population does not know whether it is getting real or placebo drug s
- **Double-blind studies**
  - Concept is similar as blind studies
  - In this, the researcher also does not know which of the drugs is placebo or real

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## Epidemiological Research

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## Epidemiological Research Design

- There are four major type of epidemiological research studies
  1. Cross-sectional
  2. Case-control
  3. Cohort
  4. Experimental
- **Cross Sectional Studies**
  - This type of study is a way of describing the frequency distributions of health characteristics in populations

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## Cross sectional Epidemiological Study

- **Contd.**
  - It also describes the associations of health characteristics with other health variables
  - This is a kind of snapshot studies
  - Cross sectional studies cannot answer 'why' but is useful in answering 'what' of differentials of health events that exists
  - Cannot determine actual cause(s) of a disease but can generate a hypothesis about the causes
  - This hypothesis can be a basis of future epidemiological research

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## Case Control Study

- **Case Control Study**
  - Cross sectional studies helps to develop hypothesis but do not say which came first — the cause or the effect
  - In this study, first cases are selected based on the condition we are interested to study
    - Enquire from the patients about their past to unveil the supposed causes
    - These are the "cases"
  - Next, we select another group of cases without the above condition
    - These are the "controls"
    - Then we ask them about the contact with or exposure to the supposed causes
  - These are called case control studies as cases are compared with controls in retrospective manner

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- Contd.
- **Selecting Cases and Controls**
  - To conduct a case control study, the cases with the disease (which we want to study) must be found
    - Obtain from them or about them the history of the assumed antecedent or cause (exposure)
  - Next, find persons with similar characteristics but without the disease
    - These are the control group or comparison group
    - Obtain from them or about them the history of exposure
  - Cases and controls must come from the same population

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- Contd.
- By observation, one tries to find the association of the causal factors with the disease
- Now, find the differences in the frequency of the supposed causes among both groups
- Example:
  - Let us do a case control study to determine whether cigarette smoking causes lung cancer
    - Select cases of lung cancer and persons without lung cancer but with other matching characteristics such as age, gender, race etc
    - Retrospectively, look into the history of smoking in both groups
    - Determine frequency and length of smoking in the disease and the control group
    - If these are significantly more in disease group we may conclude that smoking causes cancer

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- Contd.
- **In case control studies, both the groups must match**
  - If the controls are selected properly, then the differences in the antecedent are the cause of the disease
  - But there are certain confounding variables
  - In the lung cancer example, age is a factor which is related to increased prevalence of the disease
  - Age is also related to smoking history
  - This will pose difficulty in interpretation
  - This can be avoided by selecting cases and controls of the same age
  - In matching the controls with cases, the confounding variables are required to be controlled.

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- Contd.
- **Cohort Study**
  - This type of study is also known as prospective study or incidence study
  - This method fulfils the following need:
    - Can confirm the causal association
    - Certain missing relationship of cross sectional and case control study can be established. This is:
      - Definite time/entity relationship
    - It establishes presumed time (secular) relationship between presumed antecedents and presumed effects
      - Can establish between antecedents and effects, which came first
    - It is the preferred method for epidemiological predictions

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- **What is a cohort?**
  - A cohort is a group or aggregate of persons
  - They share similar antecedent characteristics
  - This group is followed to observe whether certain given health outcome is developed in them or not
- **Examples**
  - All new employees of the hospital in a certain year
  - All the PTCA cases during the last six months
- **The criteria to be considered for inclusion:**
  - Ability to define who can be included as cohort
  - Including a time frame for observation of the group
  - Are free from disease

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- Contd.
- In cohort studies, individuals are followed up over a period of time
- Incidence of disease occurrence in those with probable risk factors along with those without the risk factors can be observed
- Thus, possible association between disease and risk factors can be determined
- Incidence and prevalence rates of a disease can be related

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- **Experimental Studies**

- This is an extension of cohort study
- The group is exposed to an experimental antecedent
- The control group who are not exposed
- Then it is examined whether the expected outcome has occurred or not in comparison with the control group
- A natural experiment also can be conducted by follow up observation of a cohort who are exposed to a natural phenomenon
- This group is compared with those who are not so exposed to the phenomenon

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Thank you

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