CHAPTER TWO
RESEARCH DESIGN
2.1 INTRODUCTION

What is Research?

- Research in common manner of speaking refers to a search for knowledge. One can also define research as a scientific and systematic search for pertinent information on specific topic. In fact, research is an art of scientific investigation.
- The Advanced Learner's Dictionary of Current English lays down the meaning of research as "a careful investigation or inquiry especially through search for new facts in any branch of knowledge." Some people consider research as a movement, a movement from the known to the unknown.
- According to Clifford Woody, research comprises defining and redefining problems, formulating hypothesis or suggested solutions; collecting, organizing and evaluating data; making deductions and reaching conclusions; and at last carefully testing the conclusions to determine whether they fit the formulating hypothesis.
- The purpose of research is to discover answers to questions through the application of scientific procedures. The main aim of research is to find out the truth which is hidden and which has not been discovered as yet.

Types of Research

Some basic types of research are described as follows

Experimental Vs. Observational

- ***Experimental research:*** Studies preventions and treatments for diseases; investigator actively manipulates which groups receive the agent under study.
- ***Observational research:*** can be used to study the effects of a wider range of exposures than experimental studies, including preventions, treatments, and possible causes of disease. No intervention is done by investigators. Information are obtained by observation of events.

Descriptive vs. Analytical

- ***Descriptive research:*** includes surveys and fact-finding enquiries (investigation) of different kinds. The major purpose of descriptive research is description of the state of affairs as it exists at present. The main characteristic of this method is that the researcher has no control over the variables; he can only report what has happened or what is happening with respect to person, place & time.
- ***Analytical research:*** on the other hand, the researcher has to use facts or information already available, and analyze these to make a critical evaluation of the material.

Applied vs. Fundamental

Research can either be applied (or action) research or fundamental (basic or pure) research.

- ***Applied research:*** aims at finding a solution for an immediate problem facing a society or an industrial/business organization.
- ***Fundamental research:*** is mainly concerned with generalizations and with the formulation of a theory. Thus, the central aim of applied research is to discover a solution for some pressing practical problem, whereas basic research is directed towards finding information that has a broad base of applications and thus, adds to the already existing organized body of scientific knowledge.

Quantitative vs. Qualitative

- ***Quantitative research:*** is based on the measurement of quantity or amount. It is applicable to phenomena that can be expressed in terms of quantity.
- ***Qualitative research:*** on the other hand, is concerned with qualitative phenomenon, i.e., phenomena relating to or involving quality or kind. For instance, when we are interested in investigating the reasons for human behavior (i.e., why people think or do certain things),

Conceptual vs. Empirical:

- ***Conceptual research:*** is that related to some abstract idea(s) or theory. It is generally used by philosophers and thinkers to develop new concepts or to reinterpret existing ones.
- ***Empirical research:*** relies on experience or observation alone, often without due regard for system and theory. It is data-based research, coming up with conclusions which are capable of being verified by observation or experiment. We can also call it as experimental type of research.

What is Research Design?

- Design is a plan or drawing produced to show the look and function or workings of something before it is built or made.
- Then, research design is the conceptual structure within which research is conducted; it constitutes the blueprint (plan) for the collection, measurement and analysis of data. As such the design includes an outline of what the researcher will do from writing the hypothesis and its operational implications to the final analysis of data.
- More explicitly, the desing decisions happen to be in respect of:
  - What is the study about?
  - Why is the study being made?
  - Where will the study be carried out?
  - What type of data is required?
  - Where can the required data be found?
  - What periods of time will the study include?
  - What will be the sample design?
  - What techniques of data collection will be used?
  - How will the data be analysed? In what style will the report be prepared?

- Keeping in view the above stated design decisions; one may split the overall research design into the following parts:
  - ***The sampling design***: This deals with the method of selecting items to be observed for the given study.
  - ***The observational design:*** This relates to the conditions under which the observations are to be made;
  - ***The statistical design:*** which concerns with the question of how many items are to be observed and how the information and data gathered are to be analysed; and
  - ***The operational design:*** which deals with the techniques by which the procedures specified in the sampling, statistical and observational designs can be carried out
- From what has been stated above, we can state the important features of a research design as under:
  - ✓ It is a plan that specifies the sources and types of information relevant to the research problem.
  - ✓ It is a strategy specifying which approach will be used for gathering and analysing the data.
  - ✓ It also includes the time and cost budgets since most studies are done under these two constraints.
- In brief, research design must, at least, contain:
  - ❖ A clear statement of the research problem;
  - ❖ Procedures and techniques to be used for gathering information;
  - ❖ The population to be studied; and
  - ❖ Methods to be used in processing and analysing data.

Features of Good Design

A good design is often characterized by adjectives like flexible, appropriate, efficient, economical, and so on. Generally, the design which minimizes bias and maximizes the reliability of the data collected and analysed is considered a good design.

The design which gives the smallest experimental error is supposed to be the best design in many investigations. Similarly, a design which yields maximal information and provides an opportunity for considering many different aspects of a problem is considered most appropriate and efficient design in respect of many research problems.

- A research design appropriate for a particular research problem, usually involves the consideration of the following factors:
  - The means of obtaining information;
  - The availability and skills of the researcher and his staff, if any;
  - The objective of the problem to be studied;
  - The nature of the problem to be studied; and
  - The availability of time and money for the research work

2.2 CATEGORIES OF RESEARCH DESIGN

The two broad types of epidemiological study designs are, experimental (interventional) and observational.

An experimental study uses randomization to allocate subjects to different categories of the exposure. An observational study does not use randomization.

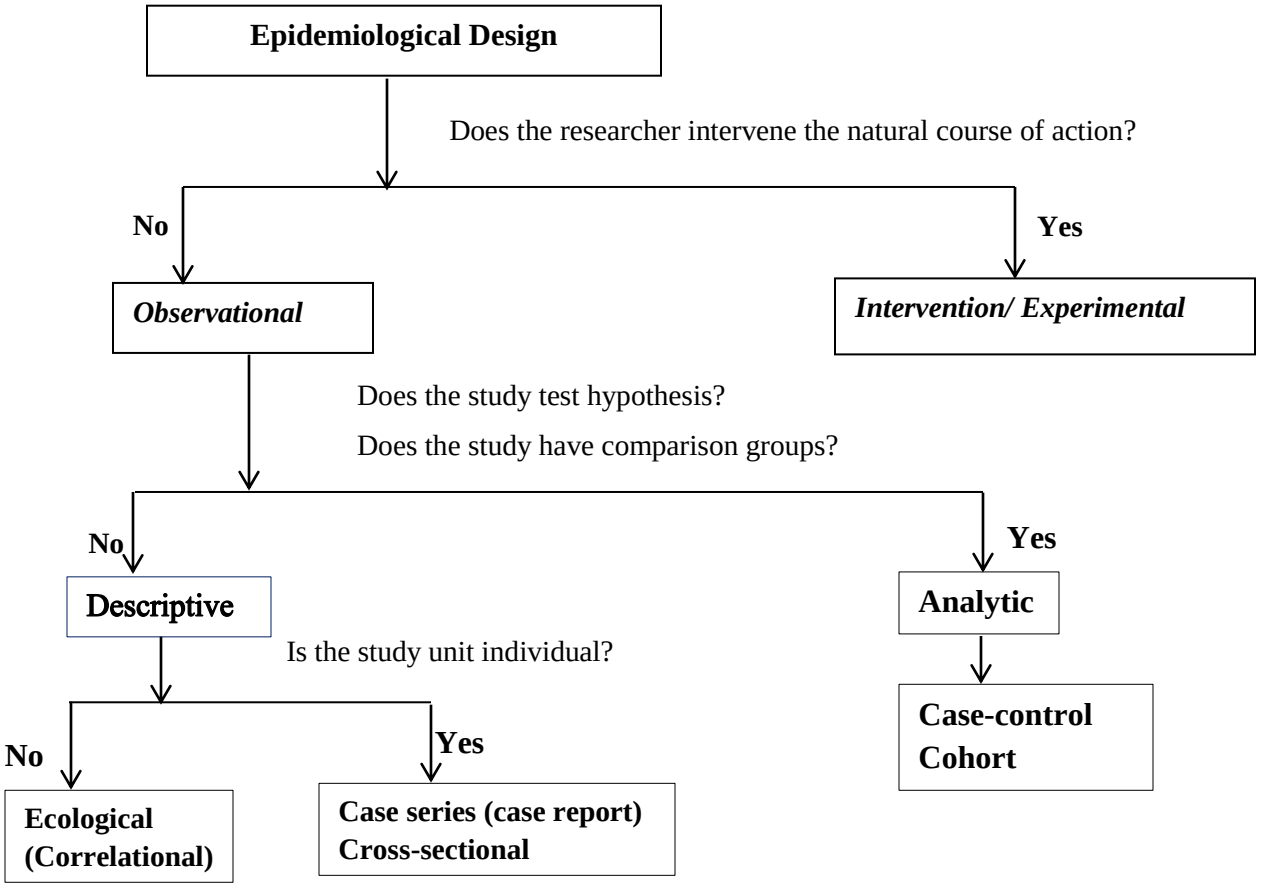
In experimental studies, the investigator, through randomization, actively determines (controls) the exposure status for each subject, and then follows them and documents subsequent disease outcome.

In an observational study, the subjects themselves, or perhaps their genetics, determine their exposure, for example, whether to smoke or not. The investigator is relegated to the role of simply observing exposure status and subsequent disease outcome.

Experimental studies in epidemiology usually take the form of clinical trials and community trials.

Observational studies are broadly identified as two types: called descriptive and analytic. Most epidemiologic studies are observational.

Descriptive studies are performed to describe the natural history of a disease, to determine the allocation of health care resources, and to suggest hypotheses about disease causation. The main types of descriptive studies are: correlational/ecological, case report or case series, cross-sectional.



Analytic studies are performed to test hypotheses about the determinants of a disease or other health condition, with the ideal goal of assessing causation. The use of control group is the main distinguishing feature of analytic studies. The main categories of analytic study are cohort and case-control studies.

2.3 DESIGN OF EXPERIMENT (EXPERIMENTAL/ INTERVENTIONAL STUDY)

Experiment is a test or series of tests by made change in the input to see or observe the effect on the outcome. Design is a complete specification of experimental tests (procedure of experiment). So, designed of experiment refers to the process of planning the experiment how to collect, appropriate data, analyzed by statistical methods to get valid conclusion.

Experimental study is defined as an epidemiological study investigates the role of some preventive or therapeutic treatments. Individuals are allocated in to two or more groups by the active manipulation of investigators through randomization. The main distinction of experimental study from other epidemiological studies is the intervention of investigator through randomization.

2.3.1 Classification of Experimental Studies

Experimental study designs are classified in different base line (characteristics)

- Based on the **objective** (purpose) experimental studies are classified as:
  - **Prevention Trial:** Interventions are to be preventing disease occurrence and the study participants are persons without disease. The main objective is preventing disease. Example: Vaccination, Diet modification, Smoking cessation
  - **Clinical Trial**: Interventions are treatment based on drugs and study participants are persons with disease. The main objective is cure or control of disability and death. Eg. Surgery, drug, radiation
- Based on population (**study units**) experimental studies are classified as
  - **Clinical Trial**: Usually performed in clinical setting and the subjects are patients.
  - **Field Trial:** Used in testing medicine for preventive purpose and the subjects are healthy people. Eg. Vaccine trial.
  - **Community Trial**: Unit of the study is group of people/community. Eg. Fluoridation of water to prevent dental caries of people living around rift valley.
- Based on **design**, experimental studies are classified as
  - ***Uncontrolled Trial*:** No control group. Control will be past experience (history).
  - ***Non-Randomized Controlled***: There is control group but allocation into either group is not randomized.
  - ***Randomized Controlled***: There is control group and allocation into either group is randomized.

2.3.2 Selection of Study Population

The study population in experimental studies is allocated on the basis of eligibility criteria and consent process that reflect the purpose of experiment or trial, safety, and practical consideration.

Eg. Health people enrolled in preventive trial whereas diseases individual enrolled in therapeutic trial.

A. Eligibility = Inclusion + Exclusion criteria, based on benefits, objective, recognition……., by age, gender,…

☞ Consider women with breast cancer study

- ✓ Inclusion
  - Hospitalized patients 18 years-of-age or older
  - Oral temperature >38.5º C
- ✓ Exclusion
  - History of hypersensitivity to new treatment (and control)
  - Pregnant or breastfeeding
  - Hospitalized for CHD or for treatment of diabetes

B. Consent Process: - The process of gaining their agreement is known as informed consent. All eligible and willing individuals must give consent (agreement) to participate in an experimental study. During this process, the investigator describes the nature and objectives of the study, the tasks required of the participants, and the benefits and risks of participating. The process also includes obtaining the participant's oral or written consent.

2.3.3 Treatment Allocation (Assignment)

One of the most important aspects of the design of an experiment is the question of how patients should be allocated to the various treatments under investigation. Individuals who, give consent to participate, are assigned to receive one of the two or more treatments being compared through randomization.

Randomization is an allocation procedure that assigns subjects into one of the exposure or treatment groups being compared by randomization principle. Under the principles of randomization:

- ✓ Treatment assignment is based on chance alone.
- ✓ All subjects are equally likely to be assigned to any group (treated or control group)

Randomization tends to make demographic, behavioral, genetic and other characteristics of the comparison groups similar except for their exposure status or treatment type. The main advantage of randomization, are eliminating intentional or non-intentional **selection bias** and remove the effect of any **extraneous variables**.

There are different types of or treatment allocation methods which listed as follow.

I. **Simple (Complete) Randomization:** In simple randomization:

- ✓ The chance that a subject receives either treatment or control is 50%.
- ✓ Randomization assignment is performed independently of each subject.

Simple randomization may be done by:

- ✓ Tossing a Coin: Head (Treatment A) and Tail (Treatment B)
- ✓ Roll a six-sided die (from a pair of dice), *Even number(A)* and *Odd number(B)*
- ✓ Table of Random numbers

Potential problems of simple randomization, is possible imbalance of patient numbers in the two groups for very small study subjects.

II. Blocked Randomization (Permutated Block Randomization)

- ✓ Blocks of a particular number of patients are considered.
- ✓ Different random ordering of treatments assigned in each block; the process is repeated for consecutive blocks of patients until all have been randomized.
- ✓ Used to balance in the number of subjects.

Example: Suppose an experiment is conducted to investigate the effectiveness and safety of a test drug (T) with placebo (P) on 24 patients. Suppose permuted block randomization with block size of 4 patients. Since there are 2 treatments within block size 4, we have 6 possible permutations for random assignment as: **TTPP TPTP TPPT PTPT PTTP PPTT**. This implies there are six blocks with four patients in each block. Let us role a fair die and get a number "3". It is corresponds to the third block (**TPPT**). Then, the assignments for the first four patients are:

Patient # 1 ⟶ Treatment
Patient # 2 ⟶ Placebo
Patient # 3 ⟶ Placebo
Patient # 4 ⟶ Treatment

Exercise: Conduct the blocked randomization assignment for the left 20 patients

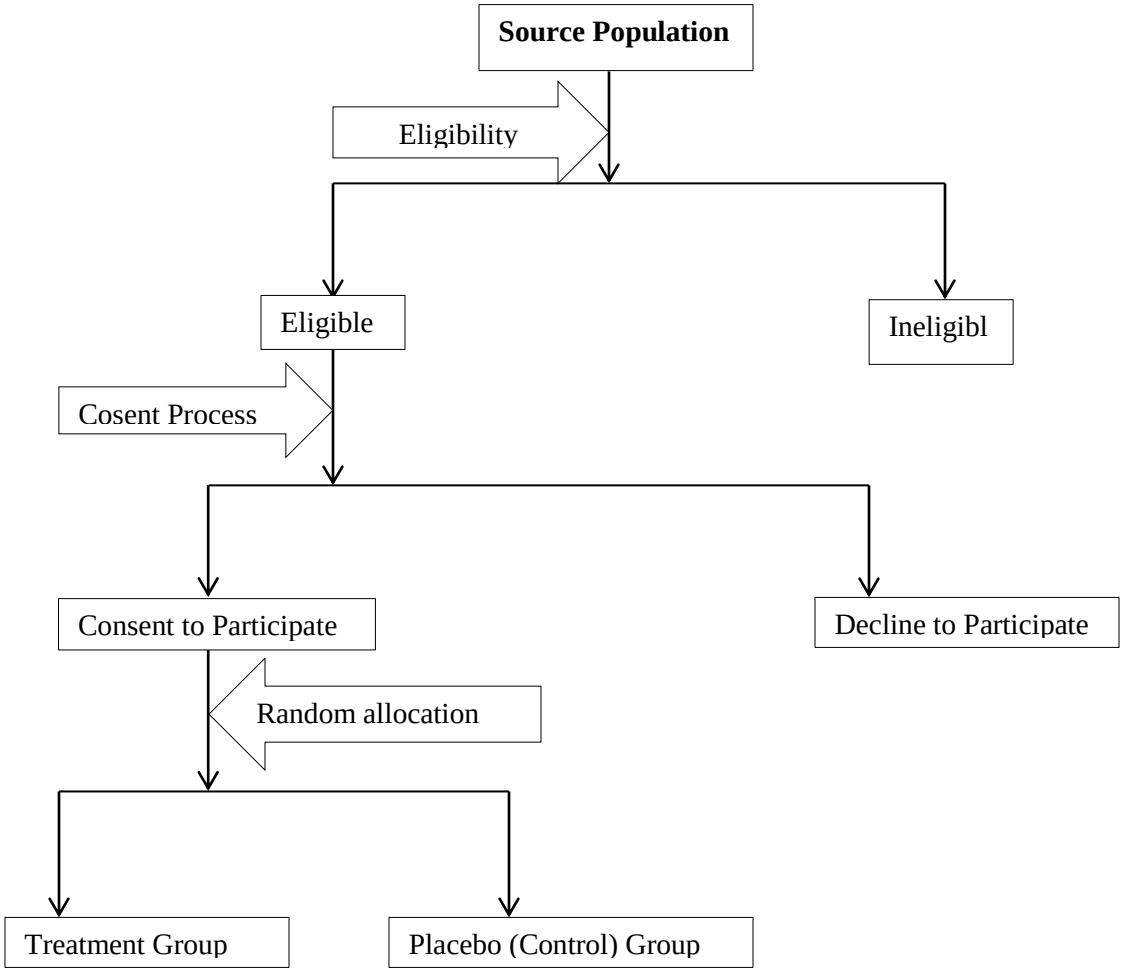
III. Minimization

An approach to achieving balance between treatment groups on selected prognostic factors is to use minimization (adaptive randomization) procedure in which the chance of allocating a new patient to a particular treatment is adjusted according to any existing imbalances in the baseline characteristics of the groups.

For example, if sex is a prognostic factor and one treatment group has more women than men, the allocation scheme is such that the next few male patients are more likely to be randomized into the group that currently has fewer men.

In general, the method is applied in situations involving several prognostic factors and patient allocation is then based on the aim of balancing the marginal treatment totals for each level of each factor.

The following scheme shows design lay out for randomized controlled experiment.



2.3.4 Analysis

The main objective of experiment is to test effectiveness and safety of treatment and inference about the target population. The classic analytic approach for an experimental study is known as **intent-to-treat** or treatment assignment analysis. All individuals who were randomly allocated to a treatment are analyzed regardless of whether they completed the regimen or received the treatment.

2.3.5 Problems in Experimental Studies

Ethical Considerations: Some of the ethical issues are:

- Practices or substances already known to be harmful should not be used in this study.
- Therapies known to be beneficial should not be withheld from any affected individuals in the study population.
- Investigators have to have a complete knowledge of the subject under study.

- The researcher must have at least informed consent from each study participant and subjects should be left free to withdraw from the study at any time.
- A written research protocol is a must.

Feasibility/ practical issues

- Subject recruitment, getting adequate individuals to enroll into a study is not easy.
- Difficulty in getting sufficiently large population who are willing to undergo to participate
- Difficult to find equivalent control group.

Cost: Experimental studies are often very **expensive** because of the long follow-up period.

2.4 OBSERVATIONAL STUDIES

Under observational studies

- Information is obtained by observation of events.
- No intervention is done, no deliberate interference with natural course of disease.
- Used to study the effects of a wider range of exposures than experimental studies

The two major categories of observational studies are classified as descriptive studies and analytic studies based on focus of investigation.

2.4.1 DESCRIPTIVE STUDIES

Descriptive studies are mainly concerned with the distribution of health and health related events with respect to person (Who), place (Where) and time (When) in a population.

Person: Describing disease occurrence by personal characteristics

- Important to identify some modifiable factors in order to prevent or control the disease.

Place: This provides information on geographic distribution of the disease.

- Provides clue in identifying factors influencing the occurrence of the disease either in the host or environment.

Time: Information organized by time

- Easily shows the trend of the disease over time and establishes the usual occurrence of the disease in the population which is essential in identifying excess occurrence (epidemics).
- It can also be used to predict seasonal and secular (long-term) trends.

The main important feature of descriptive studies is used to improving health service & promoting health.

These, descriptive studies are:

- ✓ Mainly concerned with the distribution of diseases with respect to time, place and person.
- ✓ Provide useful information for health managers to allocate resource and to plan effective prevention programs.
- ✓ Generate epidemiological hypothesis: an important first step in the search for disease determinants or risk factors.

- ✓ Can use information collected routinely which are readily available in many places. (less expensive and less time-consuming than analytic studies)
- ✓ The most common type of epidemiological design strategies in medical literature.

The main types of descriptive epidemiologic studies are:

- ❖ Correlational/ecological
- ❖ Case report or case series
- ❖ Cross-sectional (sometimes analytic if comparison group exist)

2.4.1A CORRELATIONAL/ECOLOGICAL STUDIES

- ☞ Uses data from entire population to compare disease frequencies:
  - ➢ Between different groups during the same period of time, or
  - ➢ In the same population at different points in time.
- ☞ Does not provide individual data, rather presents average exposure level in the community.
- ☞ Cause could not be ascertained.
- ☞ Correlation coefficient (r) is the measure of association in Correlational studies.

Example:

- ❖ Average per capita fat consumption and breast cancer rates compared between countries.
- ❖ Comparing incidence of dental cares in relation to fluoride content of the water among towns in the rift valley.
- ❖ Mortality from CHD in relation to per capita cigarette sales among the regions of Ethiopia.

Strength

- ➢ Can be done quickly, inexpensively, and often using available data (routine records and reports-- for example, death rates, per capita income, national food consumption…)

Limitation

- ➢ Inability to link exposure with disease.
- ➢ Data on exposure and outcome are not linked at the individual level; association found with aggregate data (average values) may not apply to individuals (Prone to **ecological fallacy**)
- ➢ Lack of ability to control for effects of potential confounding factors.

2.4.1B CASE REPORT AND CASE SERIES

Describes the experience of a single or a group of patients with similar diagnosis or health problem derived from either the practice of one or more health care professionals or a defined health care setting such as hospital, health center or specialized The following information/data are important inputs in making better use of the case series study,

- ✓ Defining the disease or health problem clearly
- ✓ Recording the date when the disease/death occurred (Time)
- ✓ Recording where the person lived, worked,…

- ✓ Recording personal characteristics of the person such as age and sex (Person) clinic.
- ✓ Explore the opportunities for collecting additional data from records or the person directly.
- ✓ Estimating the size and the characteristics of the population at risk.

Strength:

- ➢ Useful for studying signs and symptoms and creating case definitions for epidemiological studies. Example: AIDS
- ➢ Case-series that include cases at various stages of an illness from mild cases to dead supplemented by investigation of the past medical history of these cases and observing them to death (doing autopsy as appropriate) can help build up a picture of the natural history of a disease.
- ➢ Very useful in providing critical information, for hypothesis generation, for sound analytical studies.

Limitations:

- ➢ Report is based on single or few patients, which could happen just by coincidence.
- ➢ Lack of an appropriate comparison group.
- ➢ Rates cannot be calculated since the population corresponding to the source of cases cannot be defined well.
- ➢ Detailed and complete risk factor information is difficult to obtain for all cases from records.
- ➢ Studies are prone to atomistic fallacy (the opposite of ecological fallacy); the forces that cause or prevent disease at an individual level are different from those that work at societal level

2.4.1C CROSS-SECTIONAL STUDIES

Cross sectional studies or prevalence survey: measure disease and exposure status simultaneously among individuals in a well-defined population at a point in time.

Characteristics of cross-sectional studies:

- ❖ Assess both exposure and outcome simultaneously
- ❖ Are based on point prevalence rates with only few exceptions
- ❖ Are frequently made on total population samples
- ❖ Subdivision of the total population takes place after data collection unlike in cohort & case- control studies
- ❖ Are cheaper, easier & useful for studies of exposures that are unalterable over time or relatively permanent features for individuals E.g.-blood group, ethnicity, sex, etc.

Advantages of Cross-Sectional Studies

- ✓ Less expensive: a one-step, one-time collection of data
- ✓ It starts with reference population, thus making possible generalization
- ✓ Provide much information useful for planning health services & medical programs

- ✓ Show relative distribution of conditions, diseases, injury & disability in groups & populations
- ✓ Are based on a sample of a major population & do not relay on individuals that present themselves for medical treatment.

Disadvantages

- ➢ It is difficult to know which occurred first, the exposure or the outcome, this is known as **'chicken or egg dilemma'.**

E.g. In the study of knowledge of modern contraceptive, and use of contraception, you may show that women who know about modern contraception are more likely to use it. So you may want to educate women about it, believing that this will lead to higher rate of use.

The problem is, did the women know about it and then start to use it, or did they learn about it because they were using it?

- ➢ It may not show strong cause-effect relationship if sample size is small.
- ➢ Survivor bias- people who died of the disease are missed in cross-sectional study.

2.4.2 ANALYTIC STUDIES

Focuses on the determinants of a disease by testing the hypothesis formulated from descriptive studies, with the ultimate goal of judging whether a particular exposure causes or prevents disease.

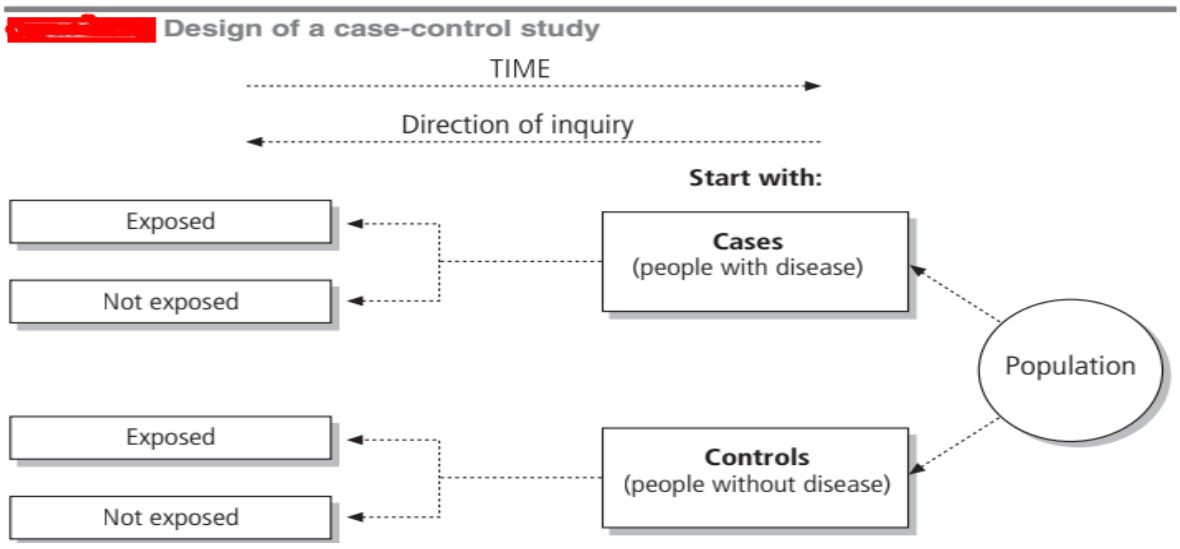
The common types of analytic studies are case-control and cohort studies

2.4.2A CASE-CONTROL STUDIES

Case-control studies are a retrospective (back ward) study designs since the investigator is looking backward from the disease to a possible cause. It starts after onset of disease and asses the postulated exposure or risk factor history. Therefore case-control studies are **backward** in directionality.

Subjects are selected based on their **diseases** status. Subjects with disease are termed as cases and without disease are termed as controls.

The following diagram shows the design lay out of case-control study.



Selection of Cases

The first step in the selection of cases for a case–control study is the formulation of a disease or case definition. A case definition is usually based on a combination of signs and symptoms, physical and pathological examinations, and results of diagnostic tests.

The main sources of cases are

Hospital-based: easy and inexpensive to conduct but it is prone for selection bias.

Population-based: avoids selection bias, allows the description of a disease in the entire population and the direct computation of rates of disease in exposed and non-exposed persons.

Selection of Controls

There is no control group that is optimal for all situations. Selection of controls should consider besides comparability, practicability and economic impact. The ideal control should be selected from the source population of cases.

General population controls: Selected from defined population for cases.

Advantages:

- ✓ Generalizability & comparability is possible

Disadvantages:

- ✓ Expensive in cost and time
- ✓ **Recall bias**: Controls do not recall exposures with the same level of accuracy as cases since they may not be seriously concerned about their illness.
- ✓ **Selection bias**: People might be less motivated to participate for the same reason given above, which increases non-response rate.

Hospital Controls: Controls are selected from hospital patients with illness rather than disease of interest.

Advantages:

- ✓ Easily accessible, less expensive, and more cooperative than population based controls. Anticipate benefits.
- ✓ Minimize recall bias, selection bias and non-response bias

Disadvantages:

- ✓ Not representative of the source population (come from different population).
- ✓ Danger of altering the direction of association or masking a true association. The exposure of interest may be determinant factor of the control illness as well as the disease of interest.

Eg: Consider cigarette smoking and lung cancer. Other respiratory ill individuals cannot be a control because smoking is causes of other respiratory disease.

Control-case ratio:

The optimal control-case ratio is 4:1. As the number of controls per case increases, the power of the study also increases.

But, beyond 4:1, there is only a small increase in statistical power, which cannot justify the expenditure of additional resources

Analysis

Comparison is made primarily by estimating the relative risk as computed by the odds ratio approximation. Calculate the odds of being a case among the exposed compared to the odds of being a case among the non-exposed. The ratio of these two odds is expressed odds ratio.

Eg. An investigator wants to the relationship between laryngeal cancer and alcohol consumption. He selects 200 cases and 200 control and studies the histories of alcohol consumptions; found the following results. Calculate and interpret the results

	Laryngeal Cases	Non laryngeal (Controls)
Alcohol users	160	90
Nonusers	40	110

Odds ratio of a laryngeal cancer among alcohol consumer compared non-alcohol users is calculated as:

$$\boldsymbol{OR = \frac{ad}{bc} = \frac{160 * 110}{40 * 90} = 4.89}$$

Therefore the odds of laryngeal cancer among alcohol consuming individuals is around five times higher than non-alcohol consumer ones.

❖ Advantage and limitations of Case-Control Studies

Advantages:

- Optimal for evaluation of **rare** disease and disease **long latency period**
- Quick & inexpensive (cheaper)
- Can examine multiple etiologic factors or exposures for a single disease
- Tend to require a smaller sample size than other designs
- Relatively simple to carry out
- Feasible for obtaining sufficient cases

Disadvantages

- ☞ They do not allow to be evaluated several diseases, in contrast to cohort studies.
- ☞ They do not allow disease risk to be estimated directly because they work backwards from disease to exposure
- ☞ They are more susceptible to selection bias than other designs since the exposure has already occurred before cases and controls are selected.
- ☞ They are more susceptible to information bias than cohort studies because they are always backward in directionality.
- ☞ They are not efficient for studying rare exposures

2.4.2B COHORT STUDIES

A cohort is defined as a group of people with a common characteristic or experience. Cohort studies, also called concurrent, follow-up, incidence, longitudinal, prospective study, begin with a group of people who are free of disease, and who are classified into subgroups according to exposure to a potential cause of disease or outcome.

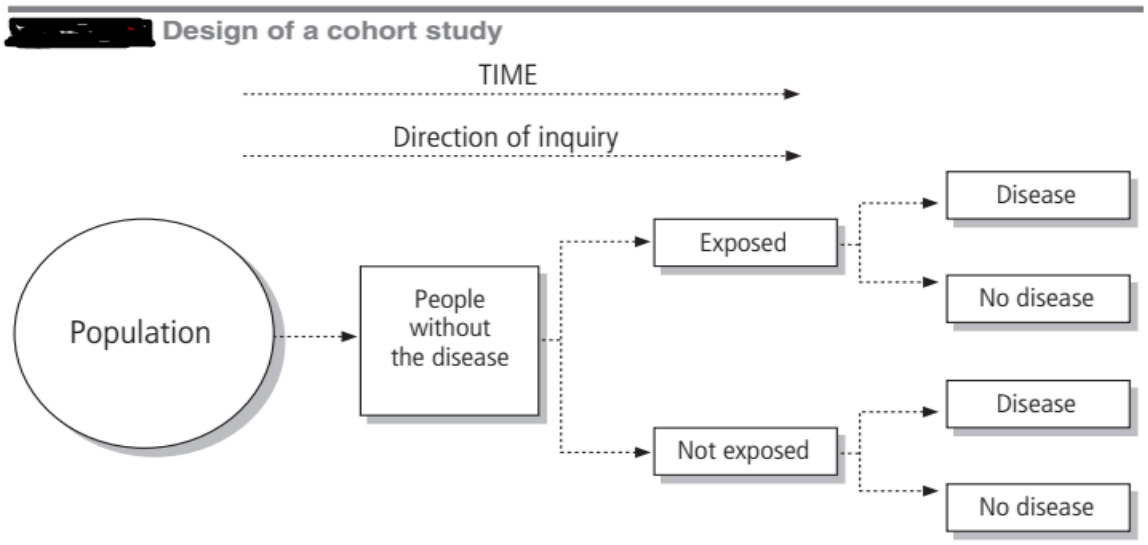
In cohort studies healthy subjects are defined according to their exposure status and followed over time to determine the incidence of disease or outcome. There are two types of cohort studies, **prospective** and **retrospective**, depending on the temporal relationship between the initiation of the study and the occurrence of the disease.

Prospective: The outcome has not occurred at the beginning of the study.

Retrospective: Both exposure and outcome have occurred before the beginning of the study.

In both cohorts the study starts at the exposure level and followed the incidence of outcomes. This means cohort studies are **forward** in directionality.

The following figure shows the design layout of cohort studies.



Selection of Subjects

Selection of exposed group in cohort studies should consider **scientific** and **feasibility** issues which include:

- ✓ The frequency of the exposure of interest in the study population
- ✓ The need to obtain complete and accurate exposure and outcome information on all study subjects. Example: the use of physicians or nurses permits longer and fairly complete follow up.
- ✓ The ability of obtaining sufficient exposed individuals in a reasonable period of time - identify high risk population (special group) to the exposure of interest. Selection of high risk group also allows the evaluation of a rare disease.

- ✓ Although cohort studies are in general not optimal for the evaluation of rare diseases, if the outcome of interest is relatively common among those exposed; i.e., if the attributable risk percent is high the design can be used efficiently.
- ✓ The cease to collect relevant information and to follow-up.

Remark: selection of control group should be comparable with characteristics of exposed group except exposure of interest.

Analysis

The basic analysis in cohort studies are: calculation and comparison of rates of the incidence of the outcome for exposed and non-exposed.

Eg. An investigator wants to study the risk of hip fracture among those with low and normal bone mineral density (BMD) and found the following summary result from 5 years follow up.

Bone mineral density (BMD)	Hip fracture	
	Positive	Negative
Low	230	400
Normal	110	369

The optimal analysis of this study is risk ratio or relative risk (RR) and calculated as:

$$\boldsymbol{RR = \frac{a(c+d)}{c(a+b)} = \frac{230 * 479}{110 * 630} = 1.59}$$

Interpretation: The risk of developing hip fracture was approximately 1.6 times higher in those with low bone mineral density compared with that normal bone mineral density.

❖ Advantage and disadvantages of cohort studies

Advantages

- ✓ Valuable when the exposure is rare and for high incidence disease
- ✓ Can examine multiple effects of a single exposure
- ✓ Can elucidate sequential relationship of exposure and outcome
- ✓ Allows direct measurement of risk
- ✓ Minimize selection information bias

Limitations

- ☞ Inefficient in evaluation of rare diseases and disease with long latency period
- ☞ Quit cost and time consuming (expensive)
- ☞ Loss to follow is a potential source of bias

2.5 Choosing Study Designs

Epidemiologists use both experimental and observational study designs to answer research questions. Each type of design represents a different way of harvesting the necessary information.

The selection of one design over another is depends on the **research question** and takes into account **validity**, **efficiency**, and **ethical** concerns.

For ethical reasons, **experimental** studies can only be used to investigate preventions and treatments for diseases. The hallmark of an experimental study is the investigator's active manipulation of the agent under study. Here, the investigator assigns subjects (usually at random) to two or more groups that either receive or do not receive the preventive or therapeutic agent. Investigators select this study design when they need data with a high degree of validity that is simply not possible in an observational study.

However, experimental studies are expensive and often infeasible and unethical, and so most epidemiologic research consists of observational studies.

Observational studies can be used to investigate a broader range of exposures including causes, preventions, and treatments for diseases. The two most important types of observational studies are the cohort study and the case–control study.

Epidemiologists use a **cohort** study when little is known about an exposure, because this type of study allows investigators to examine many health effects in relation to an exposure. In a cohort study, subjects are defined according to their exposure levels and are followed for disease occurrence.

In contrast, investigators use a **case–control** study when little is known about a disease, because this type of study allows researchers to examine many exposures in relation to a disease. In a case–control study, cases with the disease and controls are defined and their exposure histories are collected and compared.

Cross-sectional and ecologic studies are two other popular types of observational studies. One can use **cross-sectional** studies when the main objective is to examine exposure prevalence in relation to disease prevalence in a defined population at a single point in time. **Ecologic** studies used to investigate disease rates in relation to a population level factor.