RESEARCH METAHDOLOGY

NUMAN MAJEED
4TH YEAR MBBS
MUHAMMAD MEDICAL COLLEGE

Research

An investigation undertaken in order to discover new facts or to get additional information.

Research

Research is a systematic collection, analysis and interpretation of data to answer a specific question or solve a problem.

Types of Research

- **Basic Research**

  To generate new knowledge and technologies to deal with major unsolved health problems.

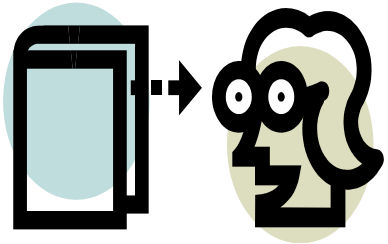
- **Applied Research**

  To identify priority problems and to evaluate polices and programs that will deliver the greatest health benefits.

Methods of Research

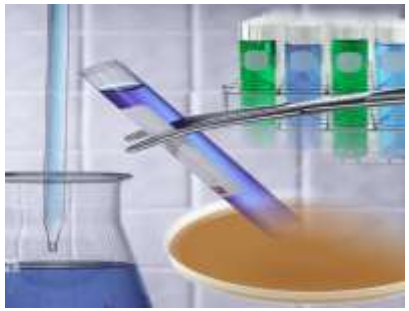
Description

- Patient's Profile
- Lab Parameters
- Case Reports
- Health System Research



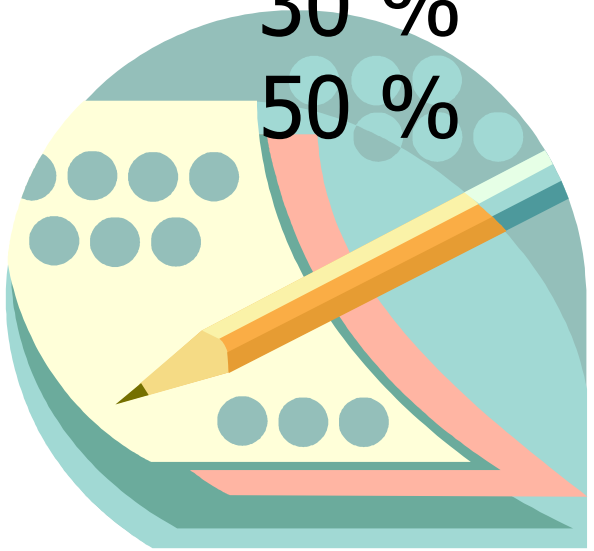
Comparison

- Two Drugs
- Two Methods
- Two Procedures
- Two Processes



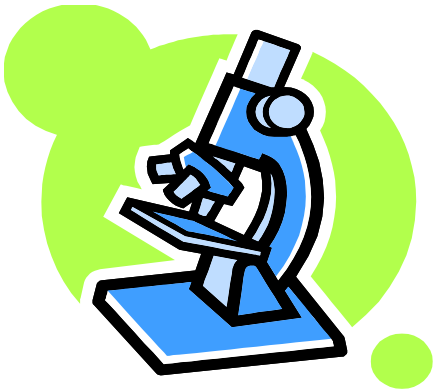
Essentials of Research

- Commitment 20 %
- Concentration 30 %
  Common Sense 50 %



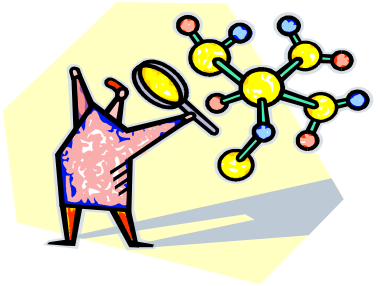
Scientific Facts

- ✓ Facts supported by substantial evidence.
- ✓ Never Final
- ✓ Never Absolute
- × Truth is not absolute
- ✓ Proof is relative to
  - Time
  - Method
  - Amount of Data
  - Interpretation



Characteristics of Research

- Research demands a clear understanding of the problem.
- Research requires a plan. Do not look for something in the hope that you will come across a solution.
- Research builds upon existing data using both positive and negative findings.
- Research collects new information to answer the original research question.



Study Types

Non-Intervention Study

Intervention Study

- **Non-Intervention Study**

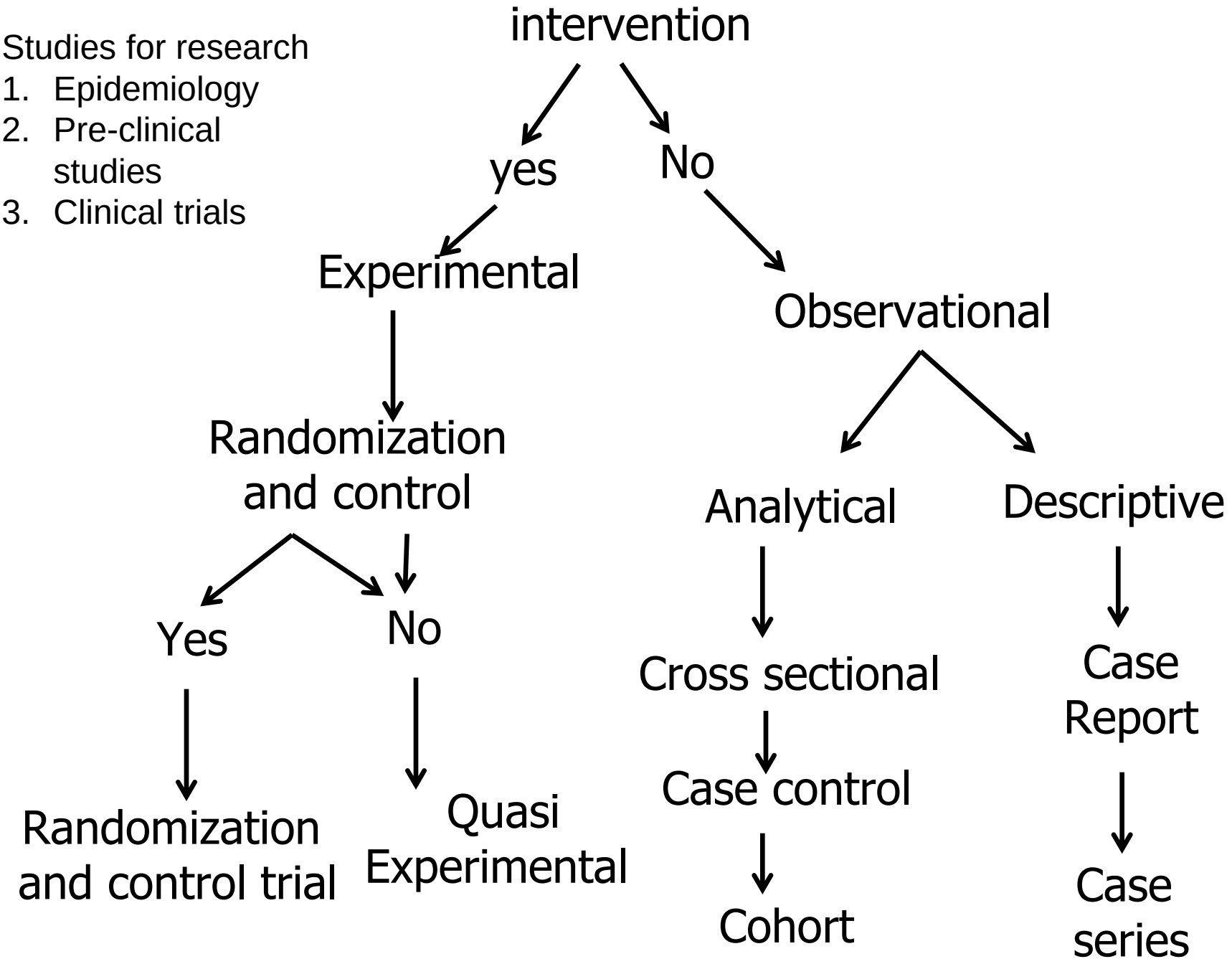
Researchers just describes an object or situation but does not intervene.

- **Intervention Study**

Researchers intervenes to manipulate the objects or situations and measures the outcome of his intervention.

Studies for research

1. Epidemiology
2. Pre-clinical studies
3. Clinical trials



Non- Interventional Study

1. Exploratory Study

A small study of relatively short duration, which is carried out when little is known about a situation.

2. Descriptive Study

Involves systematic collection and presentation of data to give a clear picture of a particular situation.

3. Analytical Study

An analytical study attempts to establish causes or risk factors for a certain problem. This is done by comparing two or more groups some of which have the problem and some do not.

Descriptive Study

- **Describe the pattern of disease in relation to**
  - **Person**
  - **Place**
  - **Time**
- **Use information from diverse sources like clinical records of hospital or private practices as well as national figures.**
- **Ability to test hypotheses.**
- **Describe the pattern of disease occurrence as well as formulate research questions.**

Descriptive Studies

Descriptive studies are the most frequently encountered study design in the medical literature.

The identification of descriptive characteristics frequently constitutes an important first step in the search for determinants or risk factors that can be altered or eliminated to reduce or prevent the disease.

Comparison

Comparison is a fundamental research strategy to identify variables that help explain why one group of persons or objects differs from other.

We could, for example, compare

- A new drug with an old drug
- A new treatment with placebo.

Analytical Studies

- An analytical study attempts to establish causes or risk factors for diseases (problems).
- This is done by comparing two or more groups, some of which have or develop disease (problem) and some of which do not.

Analytical Studies

- **Cross Sectional Studies**
- **Case Control Studies**
- **Cohort Studies**

Cross sectional studies

- Cross sectional studies describe as well as compare various groups.
- Cross sectional studies cover a sample of population
- Because all subjects represent existing cases, both the disease as well as risk factors are ascertained at the same time.
- Cross sectional studies determine the **Prevalence** of a disease and not the **Incidence**.

Retrospective

- Looking back at the past events.
- View of past events.

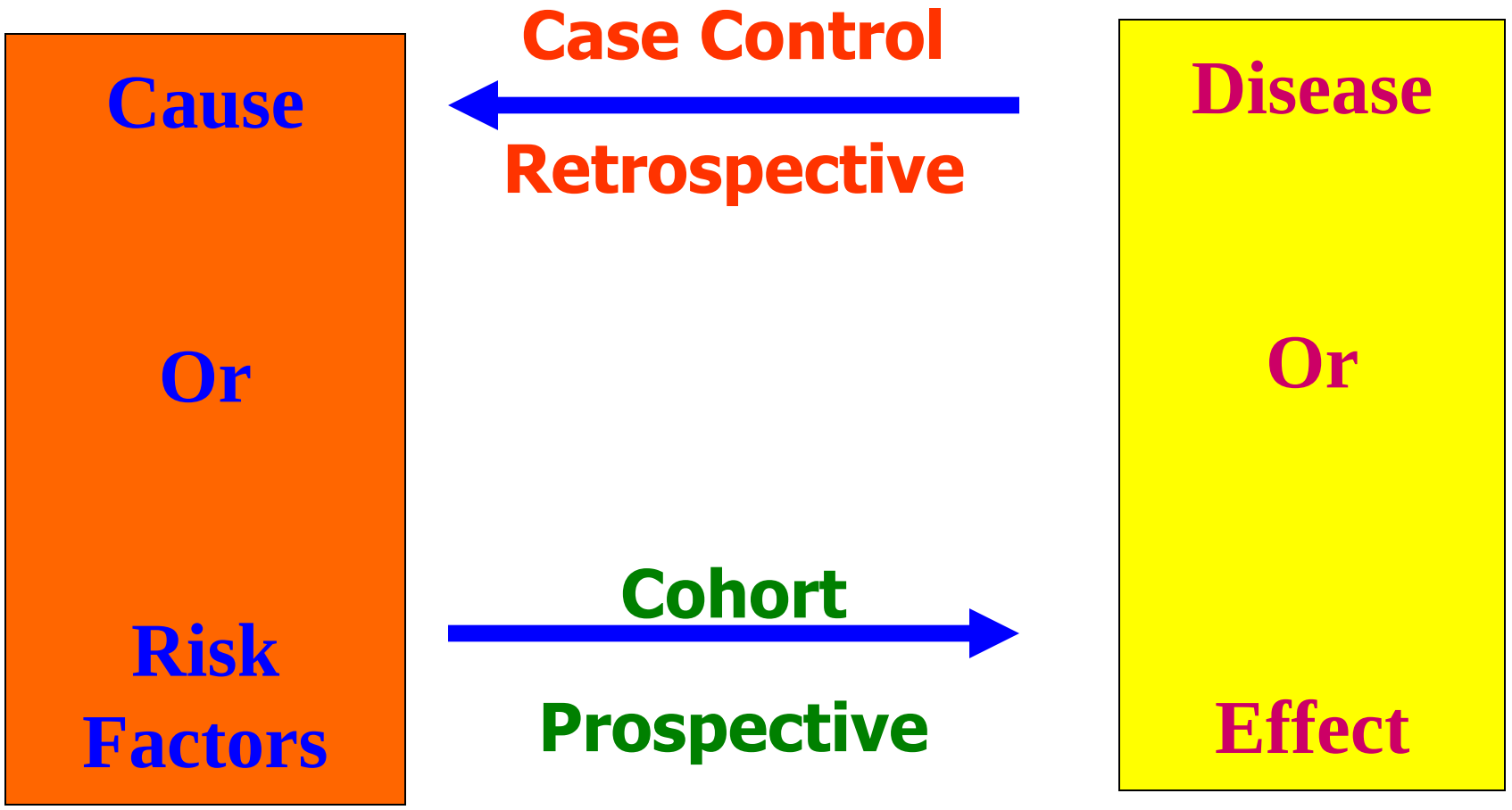
Cohort

A cohort is a group of people, who share some common characteristics or pass through the same experience.

- Born in the same year.
- Eating same type of food
- Exposed to a risk factor.

Comparison

Case Control	Cohort
Retrospective	Prospective/ Longitudinal
Hospital Based	Community based
Quick	Time consuming
Easy to conduct	Logistically difficult
Small sample size	Large sample size
Less expensive	Very expensive
Rare diseases	Common disease
None	Incidence

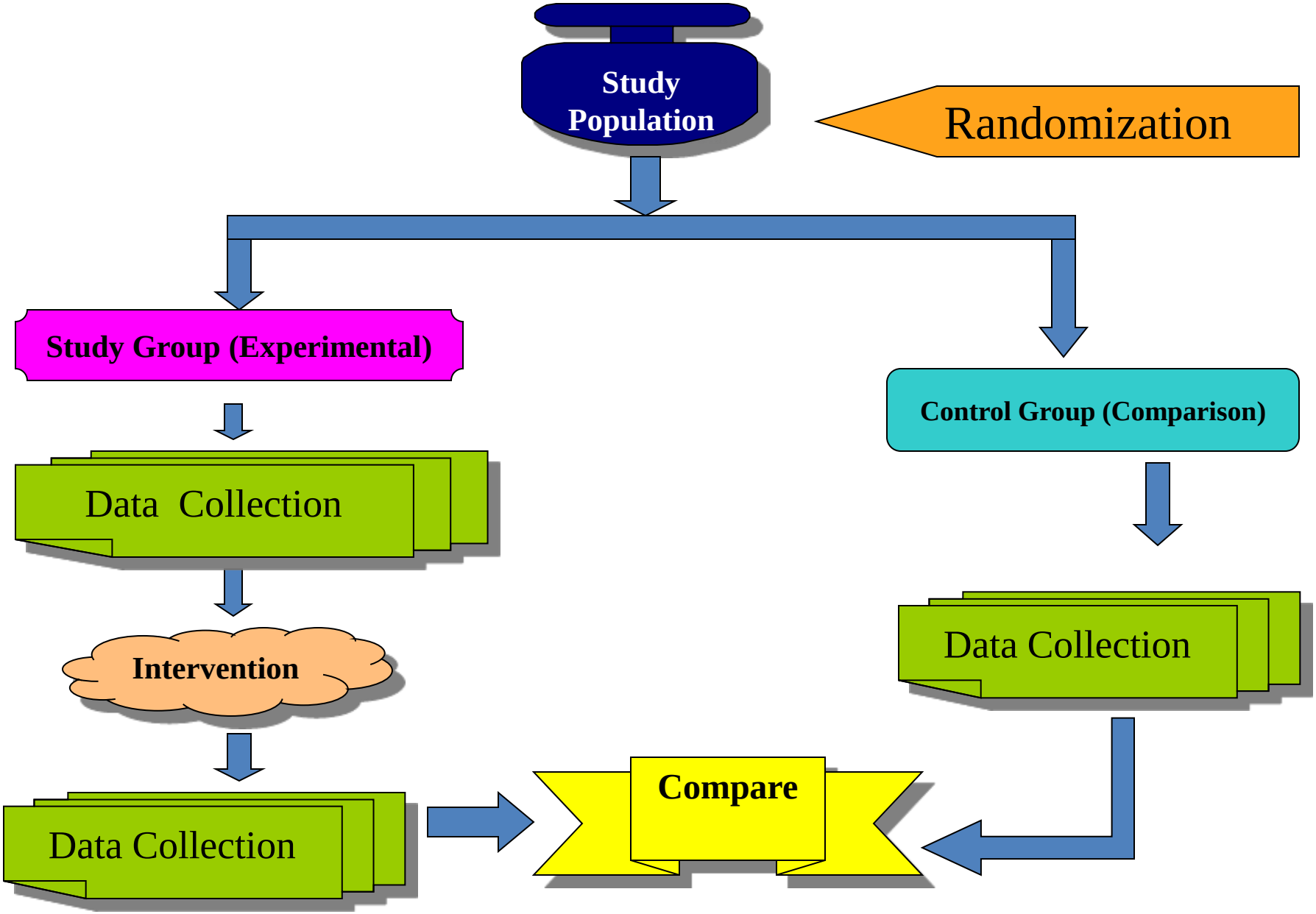

Cause
Or
Risk
Factors
Case Control
Retrospective
Cohort
Prospective
Disease
Or
Effect

Intervention Studies

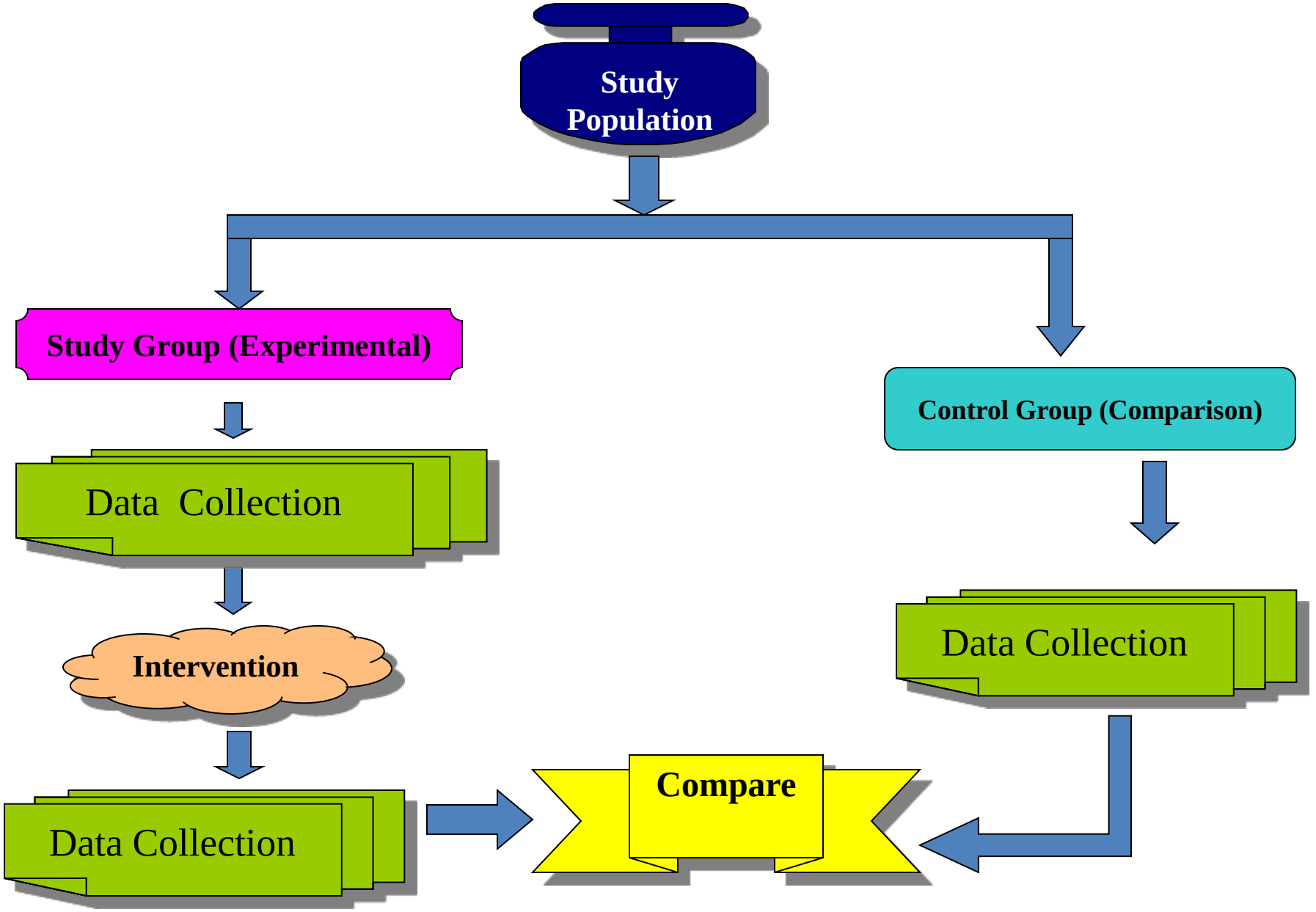
In intervention studies, the researches always manipulates the situation by introducing an intervention and measures the effects of his manipulation.

Usually (but not always), two groups are compared; one in which the intervention (e.g. treatment with a drug) takes place and another group that remains untouched (e.g. treatment with a placebo).

- Experimental studies
- Quasi experimental studies


Study Population
Randomization
Study Group (Experimental)
Control Group (Comparison)
Data Collection
Intervention
Data Collection
Data Collection
Compare

Quasi – experimental study



Clinical Trials

- A clinical trial is a research study to answer specific questions about new therapies or vaccines or new ways of using known treatment.
- Clinical trials are used to determine whether new drugs or treatment are both safe and effective.
- Carefully conducted clinical trials are the fastest and safest way to find treatments that work

Phases of Clinical Trials

- **Phase – I**
- **Phase – II**
- **Phase – III**
- **Phase – IV**

Phase – I Trials

In phase I clinical trials, researchers test a new drug or treatment in a small group of people (20 – 80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

Phase – II Trials

In phase II clinical trials, the study drug or treatment is given to large groups of people (100 – 300) to see if it is effective, and to further evaluate its safety.

Phase – III Trials

In phase III studies the study drug or treatment is given to large groups of people (1,000 – 3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

Phase – IV Trials

Phase – IV studies are done after the drug or treatment has been marketed. These studies continue testing the study drug or treatment to collect information about their effect I various populations and any side effects associated with long – term use.

Protocol

All clinical trials are based on a set of rules called a protocol. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

Randomization

- The major difference between a clinical trial and a prospective study is the randomized nature of the clinical trial.
- The experimental and control groups must be comparable in all factors except the one being studied i.e. the drug.
- One can achieve comparability on factors that are known to have an influence on the outcome, such as age, sex, race, or severity of disease, by matching for these factors. But one cannot match individuals for factors whose influence is not known or cannot be measured.
- This problem can be resolved by the random allocation of individuals to the experimental and control groups, which assures the comparability of these groups with respect to all factors – known and unknown, measurable and not measurable – except one being studied.
- Randomization is the means by which the investigator avoids introducing bias into the process of allocating individuals to the experimental or study groups.

Types of Blinding

	Single	Double	Triple
Subject	X	X	X
Researcher	--------	X	X
Data Analyst	--------	--------	X

X = Blind with respect to subject's allocation

---- = May be aware of subject's allocation

Odds Ratio

Used OC	No OC	Disease
40	10	DVT
20	30	No DVT

No. developing DVT among OC users/ No. NOT developing DVT among OC users

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No. developing DVT among Non users/ No. NOT developing DVT among Non users

Odds Ratio = 40/10 ÷ 20/30 = 4/0.67 = 5.97 or 6

Those who developed DVT were
6 times more likely to be using OC

Relative Risk

Risk	Total	Ca. Lung	Healthy
Smokers (Risk Present)	500	325	175
Non-Smokers (Risk Absent)	500	85	415

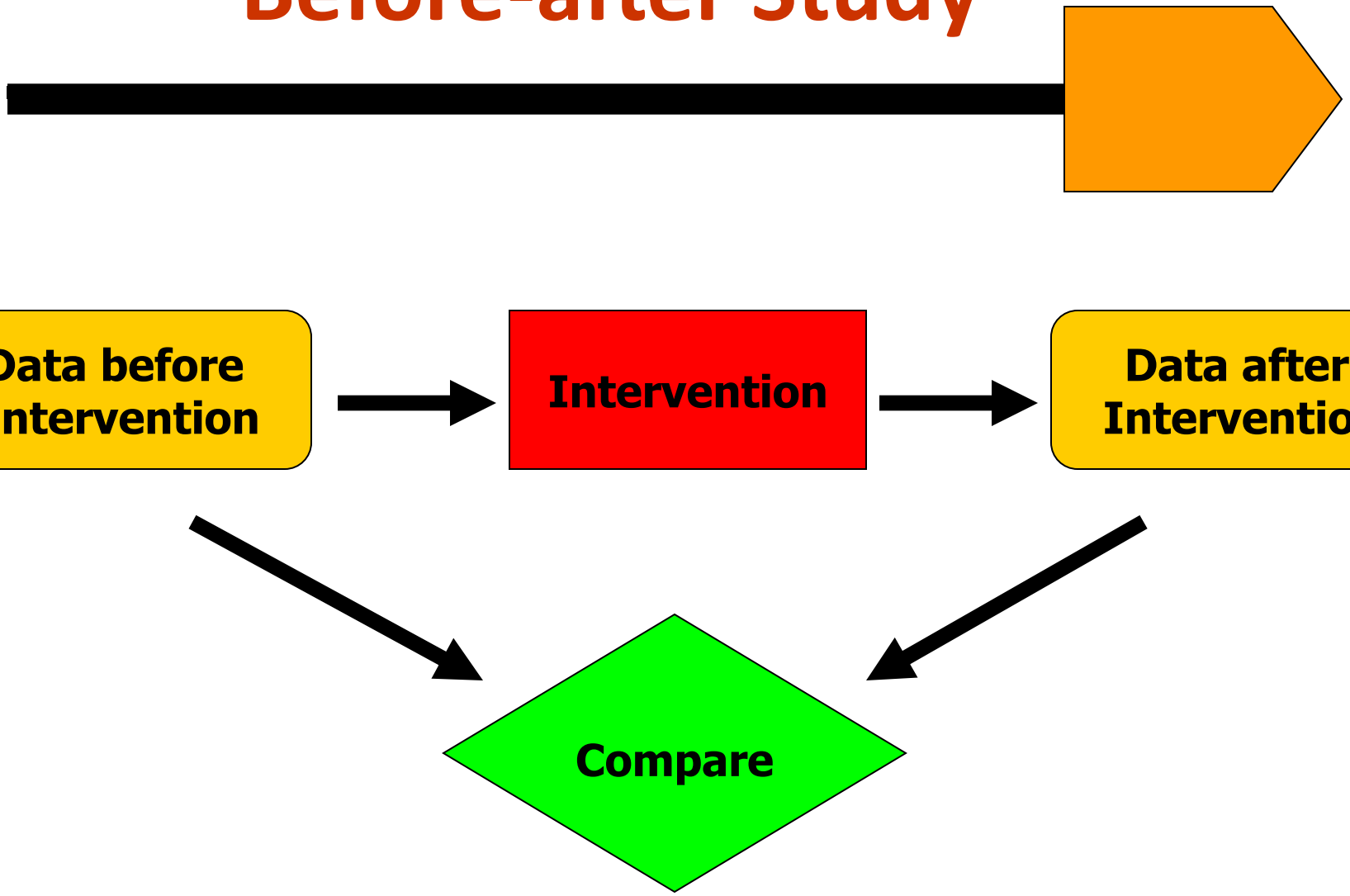
Incidence of Ca. Lung among smokers = 325 ÷ 500 = 65 %

Incidence of Ca. Lung in non - smokers = 85 ÷ 500 = 17 %

Relative Risk = 65 ÷ 17 = 3.8 %

Smokers had 3.8 times higher risk of developing Lung Cancer as compared to non - smokers

Before-after Study



Sampling

- **The procedure of selecting certain number of study units from a defined population is called Sampling.**

- **A representative sample has all important characteristics of the population from which it is drawn.**

Universe

A specified group (usually very large) of the persons, objects, measurements or values.

- Study Population
- Target Population
- Reference Population

Study Unit

The unit of selection in study population can be a

- **Person**
- **Household**
- **Family**
- **School**
- **Patient with a particular disease**
- **Patient undergoing a particular surgical procedure**
- **Patient receiving a particular medicine.**

Types of Sampling

1. **Probability Sampling**
2. **Non Probability Sampling**

- **Probability Sampling**

  When each sampling unit has an equal and known chance of being included in sample.

- **Non Probability Sampling**

  When sampling units do not have an equal chance of being included in the sample.

Non Probability Sampling

- Convenience Sampling
- Quota Sampling
- Snow- ball Sampling
- Temporal Sampling

Convenience Sampling

In this method, the study units that happen to be available at the time of data collection, are selected in the sample.

Quota Sampling

This method ensure that a certain number of study units from different categories with specific characteristics appear in the sample so that all these characteristics are represented.

Snow – ball Sampling

When individuals with certain characteristics are asked to identify similar individuals for inclusion in the study.

Temporal Sampling

When all cases occurring in a specified period of time are included in the study.

Probability Sampling

Probability sampling involves selecting procedures to ensure that all study units have an equal and / or known chance of being included in the study.

- **Simple Random Sampling**
- **Systematic Random Sampling**
- **Stratified Sampling**
- **Cluster Sampling**
- **Multi- Stage Sampling**

Simple Random Sampling

For selecting a simple random sample we need:

1. **To make a numbered list of all the study units in the population from which you want to draw a sample.**
2. **To select the required number of sampling units using a *lottery method* or *Random Number Tables.***

Systematic Random Sampling

- **In systematic random sampling, the sampling units are selected at regular intervals (e.g. every 5th, 15th, 34th) from the sampling frame.**
- **Ideally, we randomly select a number to tell us where to start selecting individuals from the list.**

Stratified Sampling

If it is important that the sample includes the representative groups of study units with specific characteristics e.g. residents from urban and rural areas of different age groups, then:

- **The sampling frame must be divided into groups or STRATA according to these characteristics.**
- **Random or systematic random samples of predetermined size will then be obtained from each group (Stratum).**

Cluster Sampling

- **In Cluster Sampling, a simple random sample is selected not of individual subjects but of groups or clusters of individuals. The clusters may be villages, apartments, classes, housing units, families etc.**
- **This is often a convenient method, especially when there is no sampling frame showing all individual subjects.**
- **The clusters are often geographic unit (villages) or organizational units (clinics, factories, schools).**

Multi-stage Sampling

- In very large and diverse populations, sampling may be done in two or more stages. This is often the case in the community based studies, where the people are to be contacted in different villages and villages are to be chosen from different areas.
- The sampling procedure is carried out in phases.

Multi-stage : Example

A study of health care utilization is to be carried out in a district and 150 households are to be interviewed. The district has 6 Tehsils and each Tehsil has 10 to 15 villages.

- **Select 3 Tehsils out of 6 by simple random sampling**
- **From each Tehsil, select 5 villages by simple random sampling**
- **From each village select 10 households by systematic random sampling.**

Sampling Procedure - 1

- An important issue influencing the choice of the most appropriate sample is whether a **Sampling Frame is available or not.**
- **Sampling Frame** is the listing of all the units that form the study population.

Sampling Procedure – 2

- **If a sampling frame is not available, it is not possible to sample the study units in such a way that the probability for the different units to be selected in the sample is known. In such cases, use Non Probability Sampling.**
- **If the sampling frame exists or can be compiled, each study unit has a known probability of being selected in the sample. Therefore, Probability Sampling should be used.**

Sample Size

Single Mean

Standard Deviation ^{2} ÷ Standard Error ^{2}

We wish to determine the mean birth weight of the infants. The mean weight is expected to be 3000 G ± SD 500. Standard Error will be 25 G

500 ^{2} ÷ 25 ^{2} = 250,000 ÷ 625 = 400 Infants

Single Rate

Rate ÷ Standard Error ^{2}

The maternal mortality in the country is expected to be 70 per 10,000 live births. The permissible SE is 5 /10,000.

(70/ 10,000) ÷ 5/10,000 = 28,000 live births

Sample Size:

Single Proportion

Proportion – (100 – Proportion) ÷ Standard Error ^{2}

Difference between two Means

(SD1 2 + SD2 2) ÷ Standard Error ^{2}

Difference between two Rates

(Rate1 + Rate2) ÷ Standard Error ^{2}

Sample Size

Study Design
Prevalence
Confidence Level
Margin of Error

Sample Size for Surveys

$$\text{Sample Size} = \frac{\text{Confidence Limits}^2}{\text{Margin of Error}^2} \times \frac{\text{Proportion without disease}}{\text{Proportion with disease}}$$

Prevalence 5 % **Confidence Limit 95 %** **Margin of Error 7 %**

$$\frac{1.96^2}{0.7^2} \times \frac{0.95}{0.05} \quad (1 - 0.05)$$

$$784 \times 19 = 14{,}896$$

DATA

Something assumed as facts and made the basis of reasoning or calculation.

1. **Qualitative or Categorical**

   Sex, Color, Race

2. **Quantitative or Numerical**

   Age, Height, Parity

Categorical Data

- **Nominal:** categories of data cannot be ordered one above the other.

  Sex: Male, Female

  Marital Status: Single, Married, Divorced,

- **Ordinal:** Categories of the data can be ordered one above the other or voice versa.

  Level of knowledge: Good, Average, Poor

  Opinion: Fully Agree, Agree, Disagree

Variable

An item of data that can be observed or measured.

Quantitative Variable

A variable that has a numerical value

e.g. Age, No. of Children

Qualitative Variable

A variable that is not characterized by a numerical value.

e.g. Sex, Category of Diseases

Quantitative Variables

Discrete Variable

A quantitative variable, whose possible values are in whole numbers.

Example: No of visits to a GP.

No. of Children

Continuous Variable

A quantitative variable that has an un interrupted range of values

Example: Blood Pressure, Weight

Types of Variables

- **Independent Variable**

  A variable, whose effect is being measured. (Cause)

- **Dependent Variable**

  The variable, on whom the effect is being observed. (Effect)

- **Confounding Variable**

  A variable, which affects both independent as well as dependent variable (Cause as well as Effect)

Data Collection Techniques

- Using available information
- Observing
- Interviewing
- Administering questionnaire
- Focus Group Discussion (FGD)
- Nominal Group Technique (NGT)
- The Delphi Technique

Types of Questions

- **Open – ended**
- **Closed**

Open – ended Questions

Permits free response that should be recorded in the respondent's own words.

Close ended Questions

Close-ended questions offer a list of possible options or answer from which the respondent must choose.

Designing a Questionnaire

- Content
- Formulating questions
- Sequencing questions
- Formatting the questionnaire
- Translation

Designing a Questionnaire

- Take objective and variables as starting point.
- Formulate one or more questions that will provide the needed information for each variable
- Design your questionnaire to be users friendly.
- Format the questionnaire so that questions belonging together appear together
- Use simple every day language

Focus Group Discussion

1. Focus Group Discussion (FGD) is a discussion of 6 – 12 persons guided by a facilitator, during which group members talk freely and spontaneously about a certain topic.
2. The purpose of FGD is to obtain in-depth information on concepts, perceptions, and ideas of the group. An FGD aims to be more than a question answer interaction. The idea is that group members discuss the topic among themselves.

Focus Group Discussion

1. Helps to develop research hypotheses by exploring in greater depth the problem to be investigated and its possible causes.
2. Formulate appropriate questions for more structured, larger-scale surveys.
3. Supplement information on community knowledge, beliefs, attitude and behavior already available but incomplete of unclear.
4. Develop appropriate messages for health education programs.
5. Explore controversial topics.

Nominal Group Technique

- **The Nominal Group Technique (NGT) is a technique that is useful when one wants to obtain a consensus on a topic where decision- making can be usefully guided by the perceptions and opinion of the various group members.**
- **The sequences of the group discussion is usually individual expression followed "Voting" followed by further discussion and another round of voting.**
- **The group discussion comes to an end when the results of the last vote are not appreciably different from the last- but- one vote.**

Delphi Technique

The Delphi Technique and the Nominal Group Technique are used in a situation where a group needs censuses over an issue that is highly value-laden. The major difference is that in the Delphi Technique, groups do not (usually) meet for discussion, they communicate by means of questionnaires.

Each time a questionnaire circulates, the number of permissible answer is reduced based on the answer in the previous questionnaire. The technique needs ample time and participants must have good written communication skills.

Statistics

- Greece 1787
- A branch of political science dealing with the collection, classification and discussion of facts bearing on the condition of a state or community.
- The science dealing with collection and arrangement of numerical facts or data relating to human affairs or natural phenomena.

Definitions

Percentage

$$\frac{\text{Units with specific characteristics}}{\text{Total number of units}}$$

% of men will be 50 ÷ 200 x 100 = 25 %

Proportion

Relationship of one part of the population to the total population

$$\frac{\text{One part of population}}{\text{Total population}}$$

Proportion of men : 50 ÷ 200 = ¼

Proportion x 100 = Percentage

Percentile

$$\frac{\text{Highest Value} - \text{Lower Value}}{100}$$

Ratio

Relationship of two parts of a population.

Male (a) to Female (b) = (a ÷ b)

50 ÷ 150 = 1 : 3

Numerator is not part of denominator

Rate

Relationship of one part of the study with the whole population multiplied with a constant over a specific period of time

Numerator is always a part of denominator

a ÷ (a + b) x K

K = Constant (100, 1000, 10000)

Infant Mortality Rate	IMR
Crude Birth Rate	CBR
Crude Death Rate	CDR
Maternal Mortality Rate	**MMR**

Components of Data

- **Measure of Central Tendency**

  Mean

  Median

  Mode

- **Modes of Dispersion**

  Standard Deviation

  Variance

  Coefficient of Variation

Mean

Sum of all values (Σ) divided by number of observations. It is denoted by $\bar{x}$.

- **Advantages**
  - Easy to calculate
  - Gives an idea of central tendency
- **Disadvantages**
  - Influenced by extreme values
  - May not convey proper sense e.g. Mean No. of children may turn out to be 5.77

Calculation of Mean

1. 10,000
2. 20,000
3. 15,000
4. 11,000
5. 16,000
6. 17,000
7. 23,000
8. 24,000
9. 13,000
10. 9,000

158,000 / 10 = 15,800

Median

When the data is arranged in ascending or descending order, the median is the value that divides the data in two equal parts.

- **Advantages**

  It is not influenced by extreme values

- **Disadvantages**
  - Not very precise measure
  - Not amenable to further statistical evaluation

Calculation of Median

1. Arrange all values in Ascending or Descending order.
2. Add 1 to the number of observations.
3. Divide by 2.
4. The answer will be the number of observation, which constitutes Median.

Standard Deviation

- It is a measure, which describes how much individual measures differ, on average, from the mean
- It is denoted by δ or SD
- It is the most important measure of dispersion around the mean and forms the basis of most statistical analysis.

Calculation of Standard Deviation

1. Add all Observations
2. Calculate mean
3. Find deviation of each Observation from Mean
4. Square each deviation and add them
5. Divide this sum by number of observation – 1
6. Take square root

Mean of Systolic Blood Pressure in 5 individuals

Observed Value (mm Hg)	Mean (mm Hg)	Deviation from mean (d)	Square of deviation $(d)^2$
110	124	-14	196
116	124	-8	64
120	124	-4	16
130	124	+6	36
144	124	+20	400

$\Sigma (d)^2 = 712$

$$S.D. = \sqrt{\frac{\Sigma (d)^2}{n-1}}, \sqrt{\frac{712}{5-1}}, \sqrt{178} = 13.3$$

Normal Distribution

Most common distribution

Two main features

- **Symmetrical about its mean**
- **Bell shaped**

Majority of continuous variables have this distribution

Based on Central Limit Theorem, which states that if a random sample is taken from a normal distribution, the sample mean will be an estimate of the population mean

A normal distribution can be summarized by its mean and variance

Use of Standard Deviation

Mean ± 1 SD = 68.2 % 68 %

Mean ± 2 SD = 95.4 % 95 %

Mean ± 3 SD = 99.7 % 99 %

- **Hypothesis**

  Idea/ suggestion put forward as a starting point for reasoning or explanation.

- **Hypothetical**

  Not based on certain knowledge

Hypothesis

Hypothesis is a supposition, which is tested by collecting facts. The analysis of these facts leads to its acceptance or rejection.

A researcher wants to compare the Infant Mortality Rates (IMR) in two regions. There can be two hypotheses.

- There is no difference between IMR of the two areas being studies **(Null Hypothesis)**
- There is difference between IMR of two areas **(Alternative Hypothesis)**

Hypothesis Testing

Experimental, Case-control, Cohort and Cross-sectional studies are carried out to provide data to answer a specific scientific question i.e. to test the hypothesis.

- Do workers in cotton mills have reduced lung function compared with a control group?
- Is a course of exercises beneficial to men suffering from chronic lung disease?

Tests of Significance : 2

- **Student's "t" Test**

  Student's "t" test, also referred to as "t" test, is used for numerical data to determine whether an observed difference between means of two groups can be considered significant.

- **Chi – Square Test**

  If we have categorical data, the Chi- square is used to find out whether the observed difference between proportion of events may be considered significant

P - Value

Probability of a result occurring by chance.

Student's "t" Test

1. Calculate the "t" Value
2. Use a "t" table
3. Interpret the results

Type of Delivery	No. of women	Mean Height (cm)	Standard deviation
Normal Delivery	**60** n_1	**156** $Mean_1$	**3.1** SD_1
Caesarean Section	**52** n_2	**154** $Mean_2$	**2.8** SD_2

$$\text{"t" value} = \frac{Mean_1 - Mean_2}{SD_1 + SD_2}$$

$$\text{"t"} = \sqrt{\frac{\frac{n_1}{156} - \frac{n_2}{154}}{\frac{3.1}{60}}}$$

Chi Square Test

- The Chi Square statistic compares the counts of categorical responses between two or more independent groups.
- There are several types of chi square tests depending on the way the data was collected and the hypothesis being tested.
- $X2 = \frac{(O-E\}2}{E}$

Other Tests of Significance

- ✓ McNemar's Test
- ✓ Fisher Exact Test
- ✓ Mantel Haenszel Test
- ✓ Wilcoxon Rank/Sum Test
- ✓ Mann Whitney U test
- ✓ Kruskal – Wallis Test
- ✓ Anova
- ✓ F - Test

Medical Ethics

- Historically, Western medical ethics may be traced to guidelines on the duty of physicians in antiquity, such as the Hippocratic Oath, and early rabbinic and Christian teachings.
- In the medieval and early modern period, the field is indebted to Muslim physicians such as Ishaq bin Ali Rahawi (who wrote the Conduct of a Physician, the first book dedicated to medical ethics) and Muhammad ibn Zakariya ar-Razi (known as Rhazes in the West), Jewish thinkers such as Maimonides, Roman Catholic scholastic thinkers such as Thomas Aquinas.

Oath of Hippocrates

I SWEAR by Apollo the physician and Æsculapius, and Health, and All-heal, and all the gods and goddesses, that, according to my ability and judgment,

- **I will keep this Oath and this stipulation — to reckon him who taught me this Art equally dear to me as my parents, to share my substance with him, and relieve his necessities if required; to look upon his offspring in the same footing as my own brothers, and to teach them this art, if they shall wish to learn it, without fee or stipulation; and that by precept, lecture, and every other mode of instruction,**
- **I will impart a knowledge of the Art to my own sons, and those of my teachers, and to disciples bound by a stipulation and oath according to the law of medicine, but to none others.**
- **I will follow that system of regimen which, according to my ability and judgement, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous.**
- **I will give no deadly medicine to any one if asked, nor suggest any such counsel; and in like manner I will not give to a woman a pessary to produce abortion. With purity and with holiness I will pass my life and practice my Art.**

- **I will not cut persons laboring under the stone, but will leave this to be done by men who are practitioners of this work. Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption; and, further, from the seduction of females or males, of freemen and slaves. Whatever, in connection with my professional service, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad,**
- **I will not divulge, as reckoning that all such should be kept secret.**

While I continue to keep this Oath unviolated, may it be granted to me to enjoy life and the practice of the art, respected by all men, in all times. But should I trespass and violate this Oath, may the reverse be my lot.

Physician's Oath

At the time of being admitted as a member of the medical profession:

- I solemnly pledge myself to consecrate my life to the service of humanity;
- I will give to my teachers the respect and gratitude which is their due;
- I will practice my profession with conscience and dignity; the health of my patient will be my first consideration;
- I will maintain by all the means in my power, the honor and the noble traditions of the medical profession; my colleagues will be my brothers;
- I will not permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient;
- I will maintain the utmost respect for human life from the time of conception, even under threat, I will not use my medical knowledge contrary to the laws of humanity;
- I make these promises solemnly, freely and upon my honor.

The World Medical Association Declaration of Geneva (1948)

Declaration of Helsinki

The Declaration of Helsinki was created by the World Medical Association in 1960 to set a standard for the way human subjects are to be treated in experimentation.

The basic principles of the Declaration of Helsinki are:

- Respect for the individual
- Respect for the individual's right to make determinations and make informed decisions regarding participation in the research both before and during the research
- The individual's welfare always takes precedence over society or scientific needs
- Ethical considerations must always take precedence over laws and regulations
- If an individual is not able to grant consent or is a minor, than consent for participation should be sought from the guardian who is acting in the individuals best interest.

Basic Principles regarding Research in General:

- Research should be based on a thorough knowledge of the scientific background
- Research should offer a reasonable benefit to the population involved in the research
- Risks and benefits of the research should be carefully analyzed and should not cause further harm
- Research should be conducted by suitably trained investigators
- Research findings should be shared and made publicly accessible

Sherlock Holmes and **Dr. Watson** go on a camping trip. Set up their tent, and fall asleep.

Some hours later, Holmes wakes his faithful friend.

“Watson, look up at the sky and tell me what you see”

Watson replies “I see million of stars.”

“What does that tell you?”

Astronomically speaking, it tells me that there are million of galaxies and potentially billions of planets. **Astrologically,** it tells me that Saturn is in Leo. **Time wise,** it appears to be approximately a quarter past three. **Theologically**, its evident the Lord is all powerful and we are small and insignificant. **Meteorologically,** it seems we will have a beautiful day tomorrow. **What does it tell you?”**

Holmes is silent for a moment, then speaks,

“Watson, you idiot, someone has stolen our tent!”

Types of Medical Writing

1. Original Article
2. Review Article
3. Case Report
4. Case Series
5. Editorial
6. Letter to Editor
7. Book Review
8. Dissertation
9. Technical Report
10. Conference Report

PUBLISH OR PERISH

"Surely you were aware when you accepted the position, Professor, that it was publish or perish."

BUT

OR MAY CHANGE TO **AND** GIVING A KNOCKOUT BLOW TO YOUR PUBLICATIONS.

SO ALWAYS KEEP IN MIND TO AVOID FOLLOWING THINGS

Publish and perish

"The Seven Deadly Sins"

1. Data manipulation, falsification
2. Duplicate manuscripts
3. Redundant publication
4. Plagiarism
5. Author conflicts of interest
6. Animal use concerns
7. Humans use concerns

Structure of the Study

- **I** Introduction
- **M** Methods
- **R** Results
- **D** Discussion

Introduction

- What do you want to study?

  (Statement of Problem)
- What has already been studied?
- What is lacking?
- What contribution will your study make?

Materials (Subjects) & Methods

- When was the study conducted?
- Where was the study conducted?
- Inclusion & Exclusion Criteria.
- Informed Consent Procedures.
- Exact technical specifications.
- Genus, species and strain of animals, plants.
- Details of Statistical Methods.
- Include sufficient details to permit others in the field to replicate your work.

Materials (Subjects) & Methods

1. Study Design
2. Settings
3. Duration
4. Sample Size
5. Sampling Techniques
6. Inclusion Criteria
7. Exclusion Criteria
8. Data Collection Procedures
9. Data Analysis

Results

- Present your findings in a logical sequences.
- Use tables and graphs to summarize data.
- Mention negative results of interest.
- Give statistical significance.
- Estimate accuracy and precision of results.
- Avoid vague statements.

Results

- Present the findings in simple, standard, scientific language.
- Avoid abbreviations where ever possible.
- Tables should be self contained.
- The findings presented in tables should not differ from those given in the text.
- As far as possible, do not repeat in the text, what has been given in the tables.

Presentation of Data

1. Tables
2. Graphs
   - Bar
     - Vertical
     - Horizontal
   - Histogram
   - Line Graph
   - Scatter
   - Pie Chart
   - Column

Discussion

- ✓ How are the findings different from other studies?
- ✓ What is the statistical significance of these differences?
- ✓ What are the probable reasons for these differences?
- ✓ What are the policy implications of these findings?

Medical Journals

1. **Non Specialty Journals**
2. **Specialty Journals**
3. **Sub- Specialty Journals**

- **Non Specialty Journals**

  Lancet, BMJ, NEJM

- **Specialty Journals**
  - Annals of Internal Medicine
  - British Journal of Obstetrics & Gynecology
  - American Journal of Surgery
- **Sub- Specialty Journals**
  - Dialectology
  - Fertility & Sterility
  - Journal of Endocrinology

Reasons for Rejection of Papers

- Plagiarism
- The study did not examine an important scientific issue
- The study was not original.
- The study did not actually test the author's hypothesis.
- A different type of study should have been done.
- Practical difficulties (e.g. in recruiting subjects) led the authors to compromise on the original protocol.
- The sample size was too small.
- The study was uncontrolled or inadequately controlled.
- The authors have drawn unjustified conclusion.
- There is considerable conflict of interest (e.g. one of the authors or a sponsor might benefit financially from the publication of the paper.
- The paper is so badly written that it is incomprehensible.