Marwa Rashad Salem
Lecturer of Public Health and Community Medicine
Faculty of Medicine , Cairo University

Course Details

Course	Research Methods and Ethics
Term	Semester Two
Year	Second Year
Level	Undergraduate
Course Description	This course provides an introduction to a range of methodologies used in health research. With direction and using a structured template students are encouraged to begin the critique of the research protocol. The place of ethics in research will be complimented with the discussion of research in practice.

CONTENTS

LIST OF FIGURES

Glossary of key terms

Applied research

Research carried out for practical applications and problem-solving functions.

Basic research

Research carried out to discover something simply for the sake of knowledge to improve our understanding of the world.

Cohort studies

Examines different samples of a specific sub-population or cohort across time to examine how they may have changed during that period.

Content analysis

A quantitative research method used to analyse the content of messages in a systematic and objective manner to measure and compare their various characteristics.

Convenience sample

A sample made up of readily available subjects used in a research study.

Cross-sectional study

It provides a snapshot of the present with findings that are limited in scope.

In-Depth interviews

A method of qualitative data collection used when the phenomenon under study cannot be directly observed or measured. Interviewers will ask people for their opinions, views, experiences, feelings etc. on the topic, issue or phenomenon under study.

Longitudinal study

A study that collects data from the same population (but different samples) at different points in time.

Mean

Also known as the 'average', it is the median of a set of values.

Median

The mid-point of a set of values, when they are arranged in ascending or descending order.

Methods

The various data collection and analysis techniques, and practices followed in research, e.g. survey questionnaires, focus groups.

Non-participant observation

A field study where the researcher does not take part in the activities of the setting being observed or studied.

Non-representative sample

A sample that does not include cases or individuals from all subgroups of the targeted population. Findings of such as study are not generalizable to the population.

Population

All members of a group, case or class of subjects, variables or phenomena under study.

Probability sampling

A sample where each member or unit in the study population has an equal chance of being selected.

Process evaluation

A research method that determines if a program or campaign was implemented as designed.

Purposive sample

A sample made up of cases or individuals who meet the requirements of the study's design and possess the required characteristics.

Qualitative

Data that is non-numerical e.g. responses to open ended questions in a survey; opinions of people.

Quantitative

Data that is numerical and can be 'counted'. E.g. responses to close-ended questions in a survey.

Quota sample

A sample that selects subjects to include known or pre-determined percentages (quotas) of people from various groups, based on their actual distribution in the population.

Rationale

The researcher's explanation as to why the study is important, what purpose it serves and what will be its outcome to society or the academic field.

Reference list

A list of all sources of information used in writing-up the research findings and cited within the body of the publication.

Representative sample

A sample that includes cases or individuals from all subgroups of the targeted population.

Research questions

Used when the researcher is not sure what to look for. It indicates the general areas of the phenomenon under study. Data is then collected to examine the research questions.

Response rate

The percentage of the sample that returned the completed surveys.

Sample

A selected number of individual cases or research subjects, drawn from a larger population for a specific study.

Sampling frame

A complete list of all members of the target population.

Secondary sources

Summaries of existing research, literature reviews, analyses, textbooks etc written by those who did not carry out the original research.

Simple random sampling

A sample where each subject in the population has an equal chance of being selected for the study.

Snowball sample

Also known as referrals, the sample is made up of referrals from subjects who identified other suitable subjects, usually in areas that are difficult to conduct research in.

SPSS

'Statistical package for the Social Sciences': the computer software commonly used in the quantitative analysis of data.

Validity

A valid measurement is one which measures what it is supposed to measure.

Reliability

A reliable measure is one which when repeated gives a similar result on each occasion.

Section I: What is Research?

- **Research** is a systematic inquiry that uses disciplined methods to answer questions or solve problems. The ultimate goal of the research is to develop, refine, and expand a body of knowledge.

- **Applied Research** focuses on finding solutions to existing problems. For example; a study to determine the effectiveness of intervention to ease grieving would be applied research.

Section II: Formulating a Research Question

Research Question

- Before any data collection or research plan is formulated, it is important to properly specify a reasonable research question.
- Great protocols come from great questions
- Research question must be specific enough to be answerable. Broad questions such as what are the problems associated with cancer are far too broad to be answerable with just one study.
- Ensure that the research question has all elements needed is PICO. **PICO** stands for
    - **P** Patients or populations to be studied. More specifically, it describes patients‟ characteristics, such as age, gender, disease status, or any other patient-related characteristic.
    - **I/E** Intervention/exposure
    - **C** Comparison group(s)/Control group
    - **O** Outcome/ what are you measuring

Example

Is drug therapy associated with long-term morbidity and mortality in older persons with moderate hypertension?

P = Older persons with moderate hypertension

I = Drug therapy

C = Not stated (presumably any intervention other than the named drug therapy)

O = Long-term morbidity and mortality.

- A research question should fulfill the **FINER** criteria:

-Feasible: Will it be feasible to complete the research in terms of

- Scope,
- Time,
- Expense,
- Number of subjects,
- Technical expertise,
- Equipment?

-Interesting: to you, your group and others,

- Novel: a new idea, enforce/denies/extension to previous work: Your research should be something that no one has ever done before. It is OK to do a study similar to what has been done before, but there should be something unique and different about your research question.

- Ethical: Any research should not place the subject at undue risk or violate his or her privacy.

- Relevant to science and health/practice.

Section III: Overview of Study Designs

- Once you have formulated a research question, you must begin a study that will generate data that can be used to answer the question

1. Primary study design

- **Qualitative study design** aims to explain, discover or clarify situations, beliefs and attitude
- **Quantitative study design** aims to measure the magnitude,
- In clinical research, there are two broad categories of study designs, mainly observational and experimental:

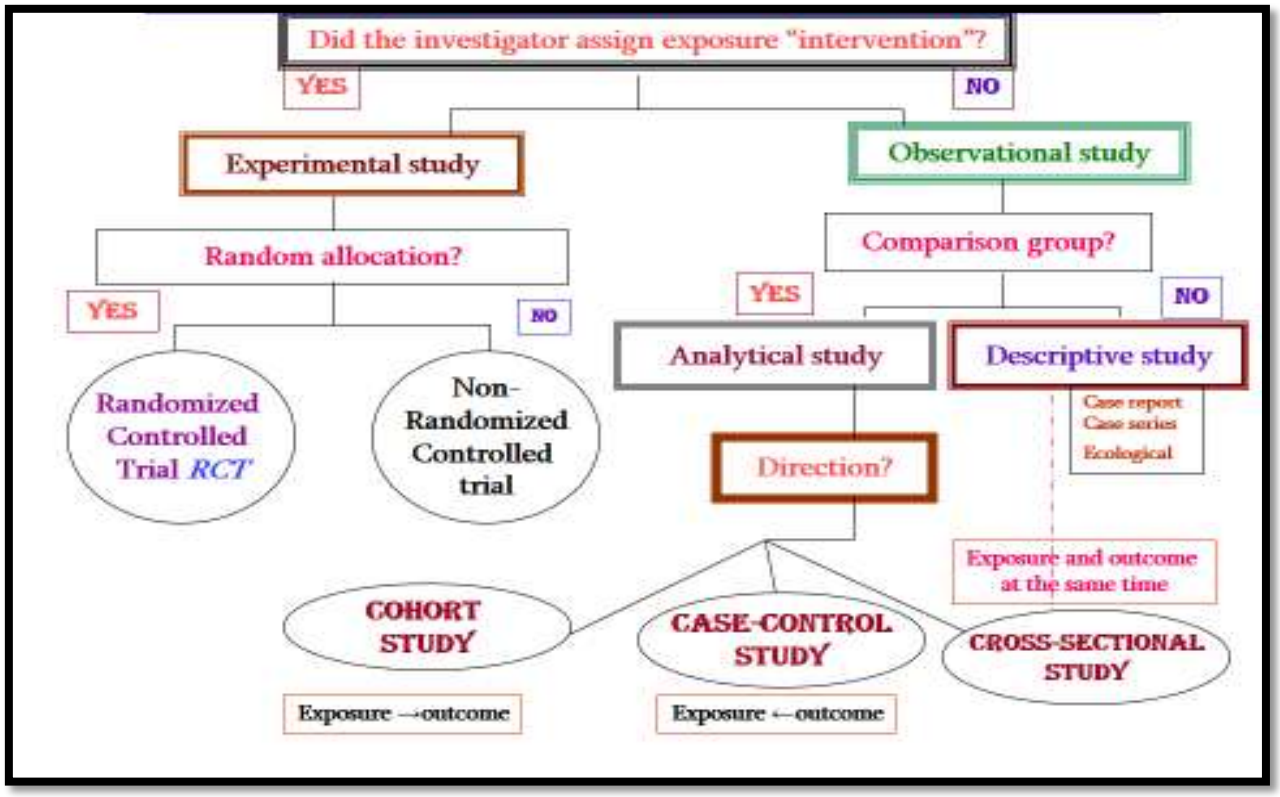

Fig.1. Epidemiological Study Designs

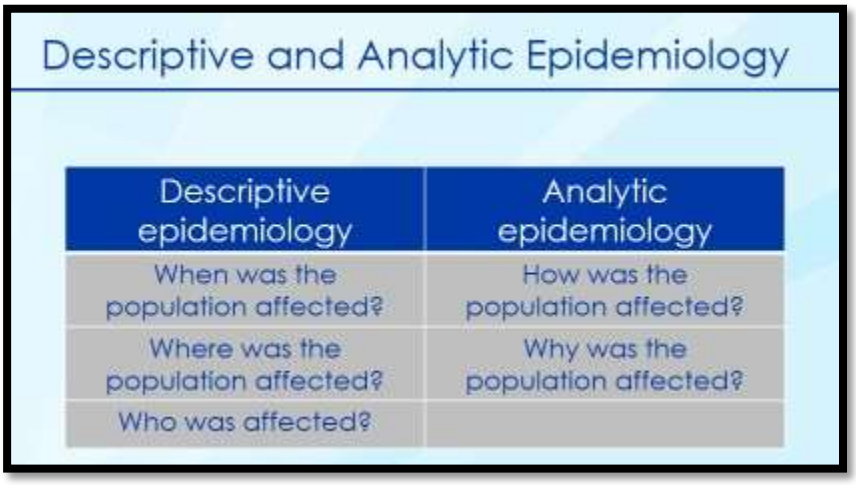

Fig.2.Difference between Descriptive and Analytical Epidemiological studies

I. Observational Descriptive Epidemiological Study Design

- **Purpose**

Characterize who, where, or when in relation to what (outcome)

- **Person**: characteristics (age, sex, occupation) of the individuals affected by the outcome
- **Place:** geography (residence, work, hospital) of the affected individuals
- **Time**: when events (diagnosis, reporting; testing) occurred

- Types
  - **Case report:** It is a report that documents unusual medical occurrences that can represent the first clue in the identification of new disease or adverse effect of exposures (based on one patient).
  - **Case series:** It is a collection of different case reports, thus based on more than one patient
  - **Cross-Sectional Study as a Descriptive Study**

- **Purpose:** To learn about the characteristics of a population at one point in time (like a photo "snap shot")
- **Design:** No comparison group
- **Population:** All members of a small, defined group or a sample from a large group
- **Results:** Produces estimates of the prevalence of the population characteristic of interest

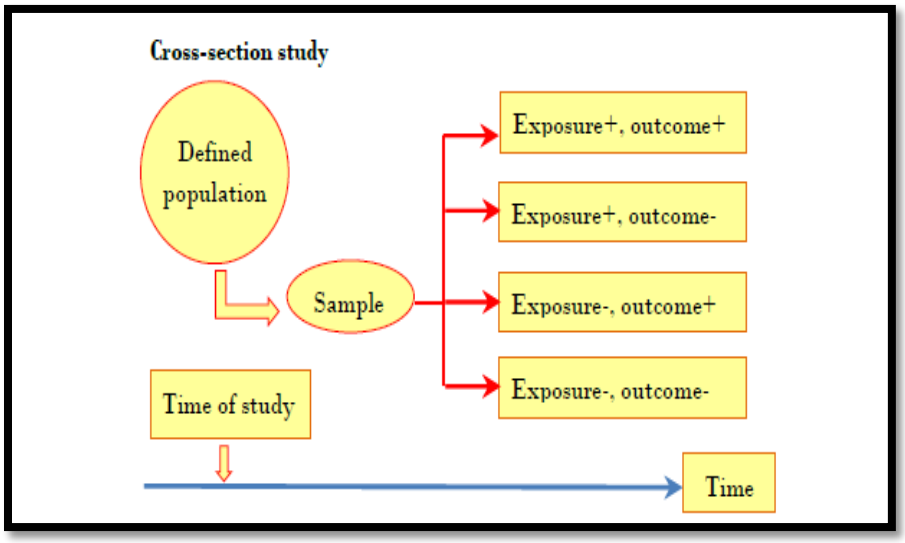

Fig.3. Cross Sectional Study Design

- **When to Conduct a Cross- Sectional Study**

- To estimate prevalence of a health condition or prevalence of a behavior, risk factor, or potential for disease
- To learn about characteristics such as knowledge, attitude and practices of individuals in a population
- To monitor trends over time with serial cross-sectional studies

- **Cross-Sectional Study Measures**

Prevalence of a condition: = number of existing cases / size of population (or population count)

- **Example:**

To estimate the magnitude and patterns of violence against pregnant women

- **Study**

Population-based, household, cross-sectional study in Cairo and Giza, Egypt, 2015-2016

- **Result**

Violence experienced by 7% in Cairo and 12% in Giza Governorate

II. Observational Analytical Epidemiological Study Designs

- Analytic studies test hypotheses about exposure-outcome relationships

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- easure the association between exposure and outcome

- Include a comparison group

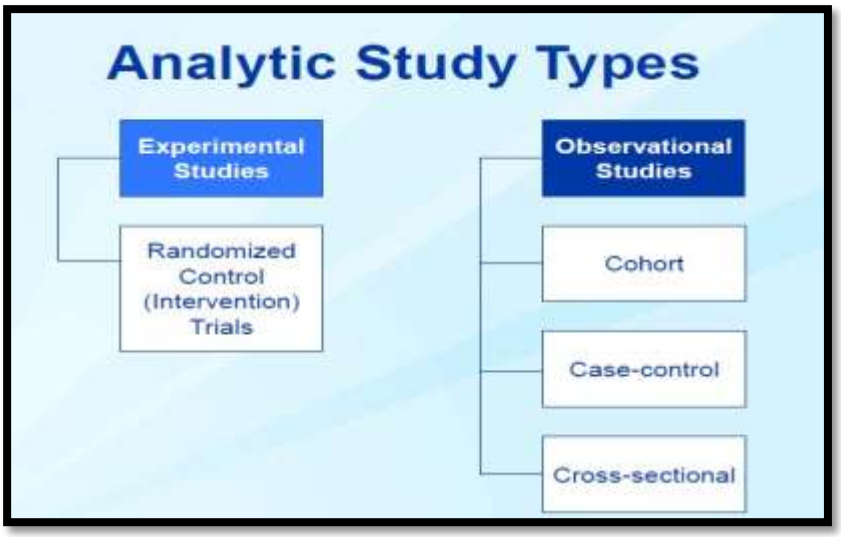


Fig. 4. Analytical Study Design

- **Cohort Studies**

- **What is a cohort? (longitudinal study, follow-up study)**

A well-defined group of individuals who share a common characteristic or

experience
•Example: Individuals born in the same year

- **Characteristics**

- Participants classified according to exposure status and followed-up over time to ascertain outcome.
- Can be used to find multiple outcomes from a single exposure
- Appropriate for rare exposures or defined cohorts
- Ensures temporality (exposure occurs before observed outcome)

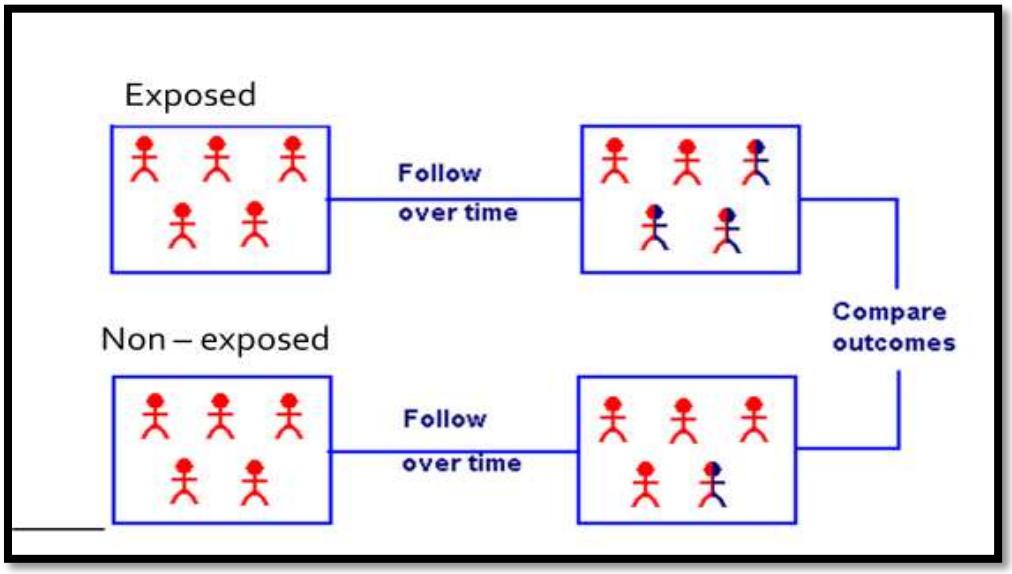


Fig.5. Cohort Study Design

- **Types of Cohort Studies**

- **Prospective cohort studies**

Group participants according to past or current exposure and follow-up into the future to determine if outcome occurs

- **Retrospective cohort studies**

At the time that the study is conducted, potential exposure and outcomes have already occurred in the past

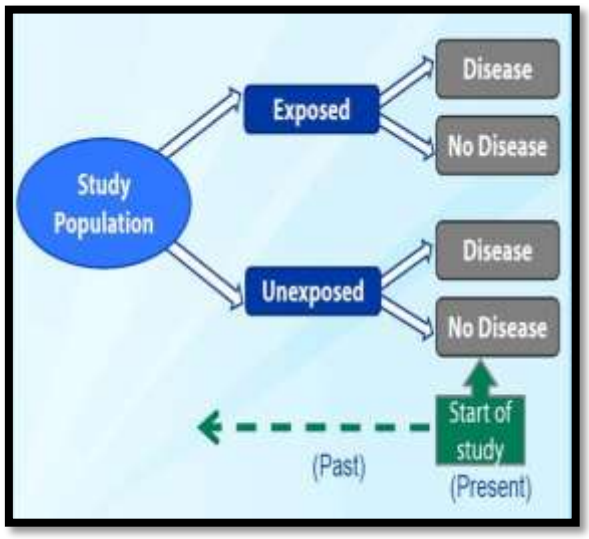


Fig.6.Retrospective cohort study

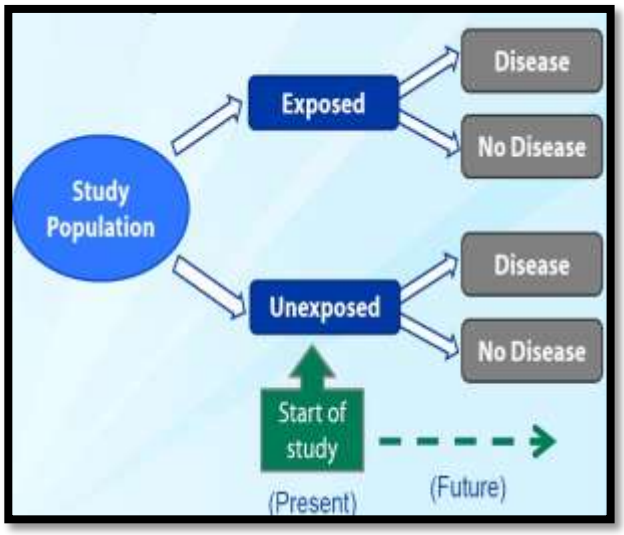


Fig.7. Prospective cohort study

- **Measurement of the Associations in Cohort Study Design**

Relative Risk (RR): Compare the risk of developing the disease when exposed to the risk factor to that in the absence of the risk factor.

It shows how many times the exposed are more likely to develop the disease compared to the non-exposed

	Diseased	Not Diseased	*Total*
Exposed	**A**	**B**	**A + B**
Unexposed	**C**	**D**	**C + D**

The incidence of disease among exposed =

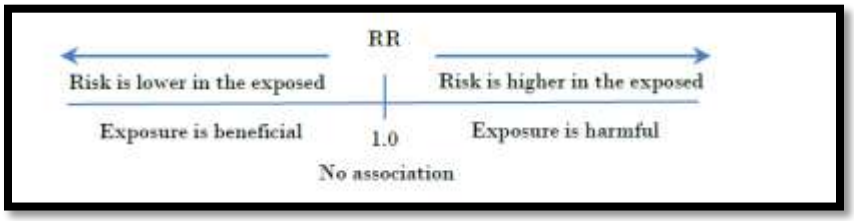
$$\frac{\#\ of\ disease\ cases\ among\ exposed\ individuals}{\#\ of\ followed\ up\ exposed\ individuals\ during\ a\ certain\ time\ period} = \frac{A}{A+B}$$

The Incidence of disease among non-exposed =

$$\frac{\#\ of\ disease\ cases\ among\ non-\ exposed\ Individuals}{\#\ of\ followed\ up\ non-exposed\ individuals\ during\ a\ certain time\ period} = \frac{C}{C+D}$$

Relative Risk = $\frac{Incidence\ of\ the\ diease\ among\ exposed}{Incidecne\ of\ the\ disease\ among\ non-exposed} = \frac{A}{A+B} / \frac{C}{C+D}$

Interpretation of Relative Risk (RR):



Example:

The risk of hypertension in the physically active group was 15%, whereas that for the non-physically active group was 20%. Thus, relative risk is the ratio of these two risks, which yields a relative risk of 0.75.

		Hypertension		
		Yes	No	Total
Physical Activity	Yes	30	170	200
	No	80	320	400
	Total	110	490	600

- **Case-Control Study**

It is an analytical epidemiologic study design that focuses on **past exposure.** The relation between disease and exposure is to be done by comparing between those having the disease (cases) and those who do not have the disease (controls) regarding exposure to the risk factor.

- **Purpose:**

- To study rare diseases
- To study multiple exposures that may be related to a single outcome

- **Participants selected based on outcome status:**

•Case-subjects have the outcome of interest

•Control-subjects do not have the outcome of interest

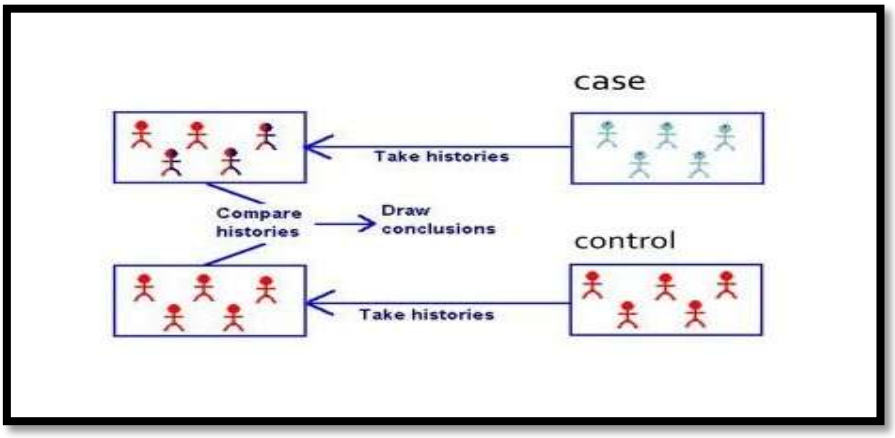


Fig.8. Case Control Study Design

- **When to conduct a case control study**

- The outcome of interest is rare
- Multiple exposures may be associated with a single outcome
- Funding or time is limited

- **Measurement of Association in Case-control Studies:**

The OR is calculated by dividing the odds of exposure among the cases over the odds of exposure among the controls. To illustrate the concept of the OR, the following is a hypothetical table:

Case-Control Study: Analysis Format

Exposure	Cases	Controls
Yes	a	b
No	c	d

Exposure odds ratio (OR) = RR when disease is rare

Odds of being exposed among the cases = a/c
Odds of being exposed among the controls = b/d

Exposure odds ratio = (a/c)/(b/d) = (a*d)/(b*c)
(Cross-product ratio)

Interpretation of Odds Ratio (OR):

- OR =1 means that the odds of exposure among cases are the same as the odds among controls. There is **no** evident association between exposure and disease
- OR > 1 means that larger odds of exposure among cases than among controls. The individuals who have the disease (cases) have a high probability of being exposed in the past to a certain risk factor than those without the disease (controls)
- OR < 1 means that the exposure has a protective effect.

Example:

Lead Poisoning

Work in mine?	Cases	Controls
Yes	17	13
No	83	87

Odds Ratio = 17/83 ÷ 13/87 = 17x87 / 13x83= 1.37

III. Experimental studies

Experimental studies are those studies where an investigator allocates different exposures to subjects based on different criteria, mainly in a random fashion, and consequently, the investigator is no longer observing the subjects, but is actually carrying out an experiment on them.

Those studies include the clinical trials which have the **objectives** of finding the best interventions to prevent, detect and treat diseases or health problems.

- **Steps of the Clinical Trial:**

1. Identify the study population (e.g. those having specific disease)
2. Select the cases according to inclusion criteria to be included in the trial
3. Randomly allocate the study group into "experimental" and "control"
4. The experimental group receives the new drug, and the control group receive the currently used drugs
5. Follow up the two groups for a certain period of time, and assess health status of both groups
6. Measure the efficacy of the new drug (effectiveness under control measures) compared with the currently used drug.

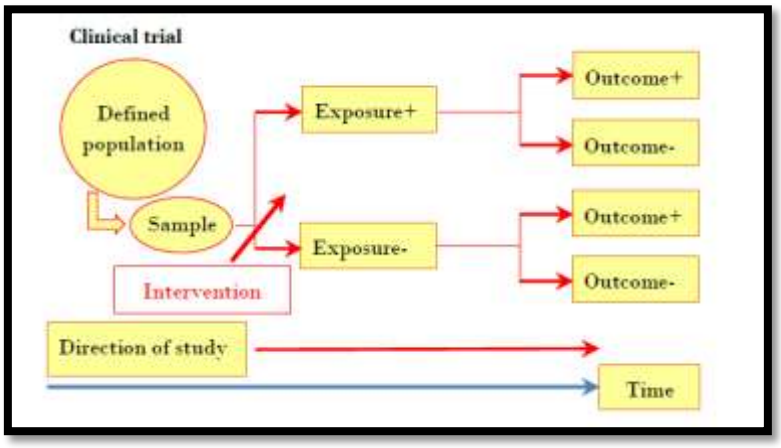


Fig.9. Clinical Trials

- **Advantages of the Intervention Studies:**

Properly conducted randomized clinical trials provide strong evidence of the effect of the intervention on health status

- **Disadvantages of the Intervention Studies:**

The design and implementation of randomized clinical trials (RCT) may be complex take long time and expensive

Quasi-experimental design:

- A Quasi- Experimental Design is exactly the same as the true experimental design EXCEPT that there is no random assignment of participants to groups. This is the only difference between the two types of designs,
- Quasi-experiments are subject to concerns regarding internal validity, because the treatment and control groups may not be comparable at baseline

II. Secondary study design

Definition: "analysis of data collected by someone else"

- **Systematic review (Qualitative evidence synthesis)**

- The systematic review is created after reviewing and combining all the information from both published and unpublished studies (focusing on clinical trials of similar treatments) and then summarizing the findings.

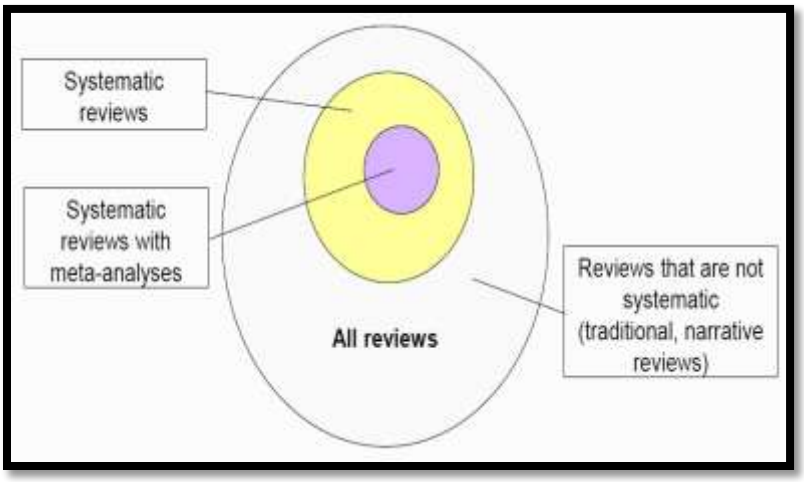


Fig.10. Different Types of Review

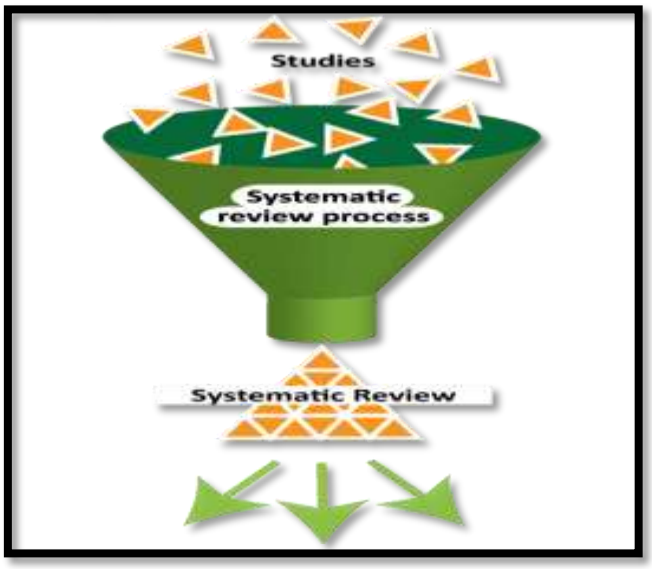


Fig.11. Systematic Review

- **Meta-analysis (Quantitative evidence synthesis)**

Meta-analysis, the statistical analysis of a large collection of results from individual studies to develop a single conclusion that has greater statistical power. This conclusion is statistically stronger than the analysis of any single study, due to

increased numbers of subjects, greater diversity among subjects, or accumulated effects and results.

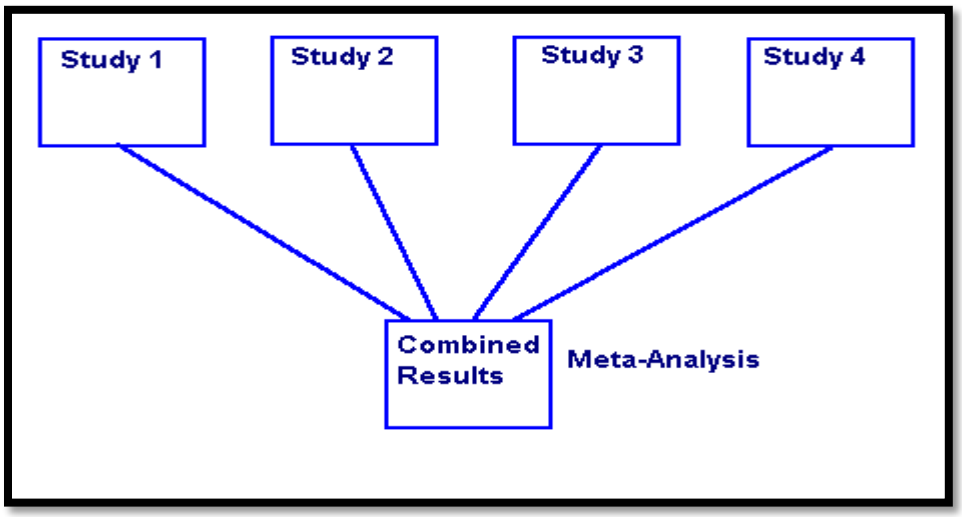


Fig. 12. Metanalysis Study Design

Qualitative Research

- **What is Qualitative Research?**

No <u>one</u> definition, however main features include:

- Qualitative research methods originated in the social and behavioral sciences: sociology, anthropology and psychology.
- Qualitative research is aimed at gaining a deep understanding of a specific organization or event, rather than surface description of a large sample of a population.
- It is more flexible in that it can adjust to the setting. Concepts, data collection tools, and data collection methods can be adjusted as the research progresses.
- Qualitative research does not test hypothesis.

- Qualitative data collection methods vary using unstructured or semi-structured techniques. Some common methods include focus groups (group discussions), individual interviews, participation/observations and content analysis.
- **DATA SATURATION**: sampling to the point at which no new information is obtained and redundancy is achieved

- **Problems with qualitative studies include:**

- more time consuming
- masses of data to transcribe
- more difficult to code data
- not applicable to widely dispersed social settings

Group Discussion

Practice Exercise #1

Non communicable diseases (NCDs) such as type 2 diabetes are poorly understood and under-prioritized in many low-to-middle income countries.

You want to determine the risk of type 2 diabetes associated with cardiovascular risk factors such as obesity and abdominal fat mass in your country.

Questions:

1. What type of study would you conduct and why?
2. What is the measure of association to calculate for this study?

Practice Exercise #2

The prevalence of prostate cancer has increased in your country over the last 5 years. You want to examine the association between calcium intake and prostate cancer risk. You have limited time and funding to conduct this study.

Questions:

1. What type of study would you conduct and why?
2. What is the measure of association to calculate for this study?

Practice Exercise #3

Cardiovascular disease (CVD) is of growing concern; however your country has no recent data on the burden of this disease.

You want to estimate the burden of cardiovascular disease in the two main cities in your country.

Questions:

1. What type of study would you conduct and why?
2. What is the measure of association to calculate for this study?

Section IV: Sampling Methods

- **Definition of Sampling**

Sampling is the process of selecting a portion of the population to represent the entire population.

A sample is a subset of individuals selected from a larger population.

- **Why do we use sampling?**

- Cannot get information on everyone in a population
- Efficiently gets information on a large population
- Obtains a representative sample of a population

- **The concept of sampling**

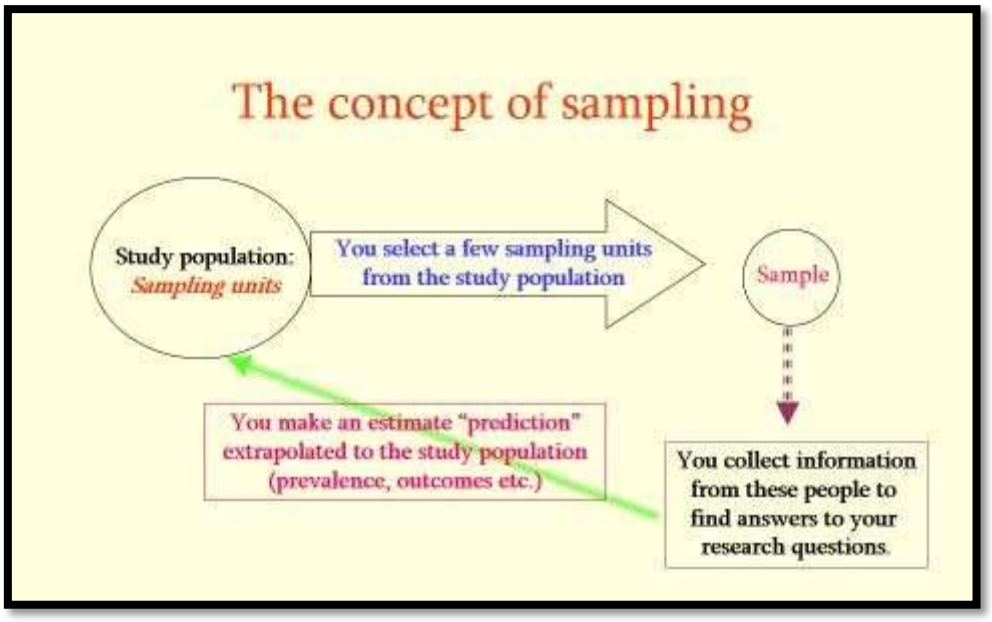


Fig.13. The Concept of Sampling

➢ Two main types of sampling methods:

- **Probability sample (Random sample):**
  - Units are selected according to probability laws i.e. everyone in the underlying population has an equal (a specified) and independent chance of appearing in that sample.
- **Non-probability sample (Non- Random Sample):**
  - Units are selected based on known factors.
  - In clinical research the study sample is usually made up of people who meet the inclusion criteria and are easily accessible to the investigator

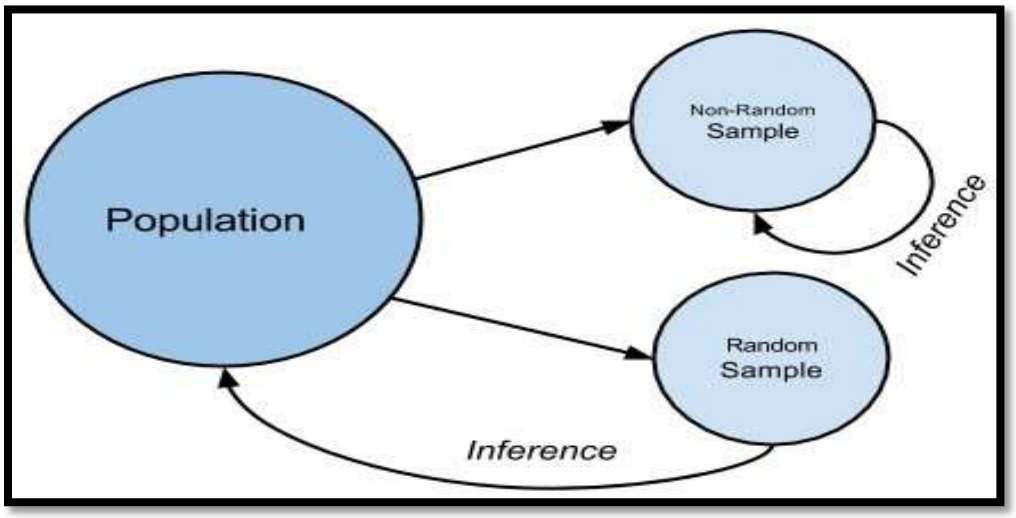


Fig.14. The Concept of Sampling

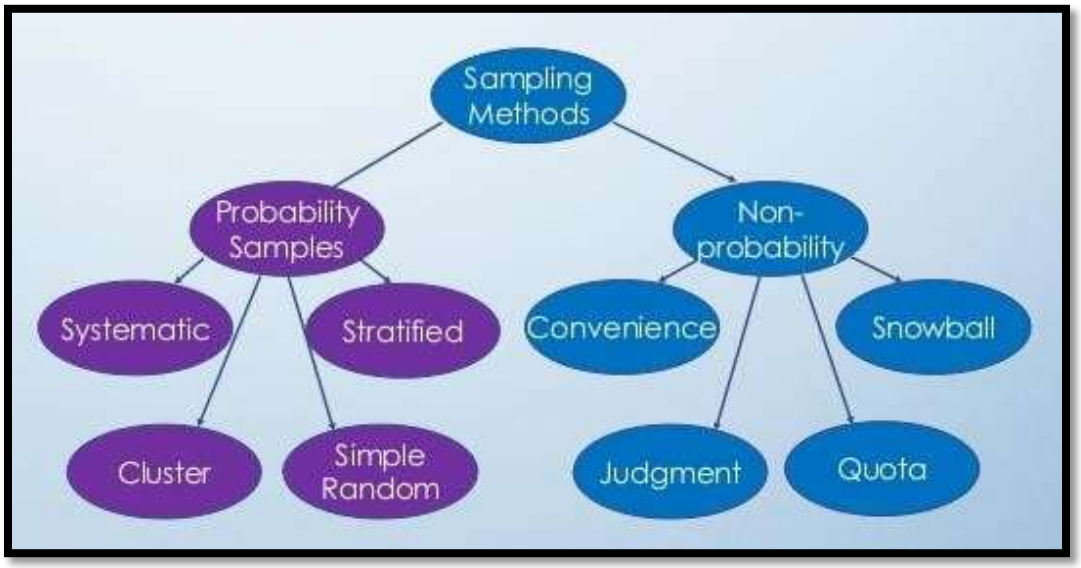


Fig.15 Classification of Sampling Methods

- **What are types of probability-based samples?**

- Simple random sampling
- Systematic random sampling
- Stratified random sampling
- Cluster sampling
- Multi stage cluster sampling

1. Simple Random Sample

Principle

- Equal chance/probability of drawing each unit

Procedure

- List all units (persons) in a population
- Assign a number to each unit
- Randomly select units

- **Advantages & Disadvantages:**

Advantages

- Simple

Disadvantages

- Need complete list of units

- **Example:**

Calculate the prevalence of tooth decay among 1200 children attending a school (sample size =100)

- List all children attending the school
- Each child assigned a number from 1 to 1200
- Randomly select 100 numbers between 1 and 1200

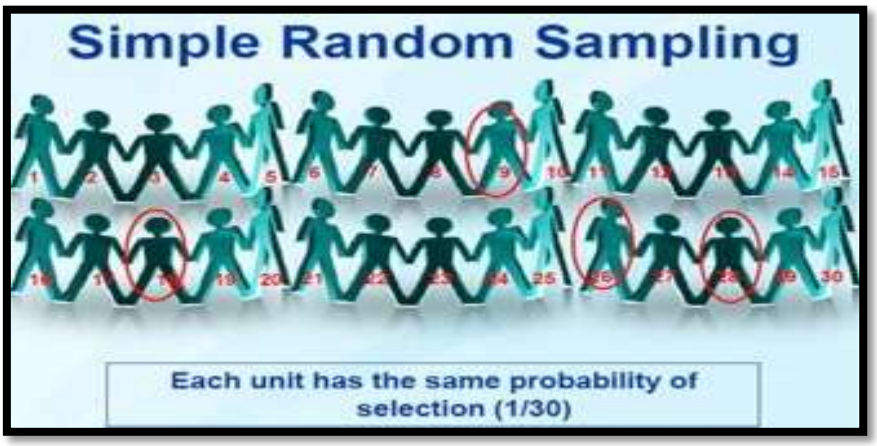


Fig.16. Simple Random Sampling

2. Systematic Random Sample

- **Principle**
  - Select sample at regular intervals based on sampling fraction
- **Procedure**
  - List all units (persons) in a population

- Assign a number to each unit
- Calculate sampling fraction (population size ÷ sample size)
- Select the first unit at random based on sampling fraction
- Subsequent units are chosen at equal intervals

- **Advantages & Disadvantages:**

Advantages

- Simple
- Can be implemented easily without software

Disadvantages

- Need complete list of units

- **Example:**

Calculate the prevalence of tooth decay among 1200 children attending a school (sample size =100)

- List all children attending the school
- Each child assigned a number from 1 to 1200
- Sampling fraction =1200/100 = 12
- Randomly select a number between 1 and 12 Example: 8
- Select every 12th child, starting with child #8 Example: 8, 20, 32, 44…

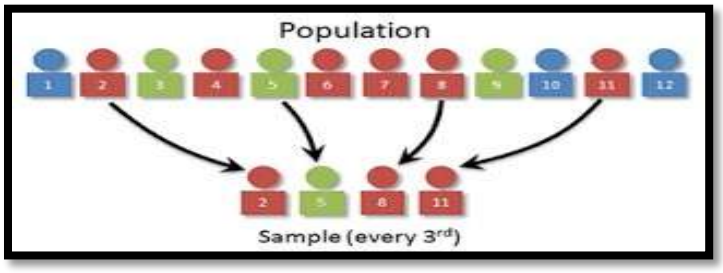


Fig.17. Systematic Random Sampling

3. Stratified Random Sample

- **Principle**
  - Select random samples from within homogeneous subgroups (strata)
  - Sampling frame divided into groups (age, sex, socioeconomic status)
  - Units in each group have the same probability of selection

- **Procedure**
  - List all units (persons) in a population
  - Divide the units into groups (called strata)
  - Assign a number to each unit within each stratum
  - Select a random sample from each stratum
  - Combine the strata samples to form the full sample

- **Advantages & Disadvantages:**

Advantages

- Precision increased if less variability within strata than between strata

Disadvantages

- Can be difficult to identify strata

- **Example:**

<u>Calculate the prevalence of tooth decay among 1200 children attending a school, with equal representation of males and females (sample size =100)</u>

- List all children attending the school
- Divide the children into two groups 540 males and 660 females
- Assign each child a number Males: 1 to 540
- Females 1 to 660
- Randomly select 50 males and 50 females

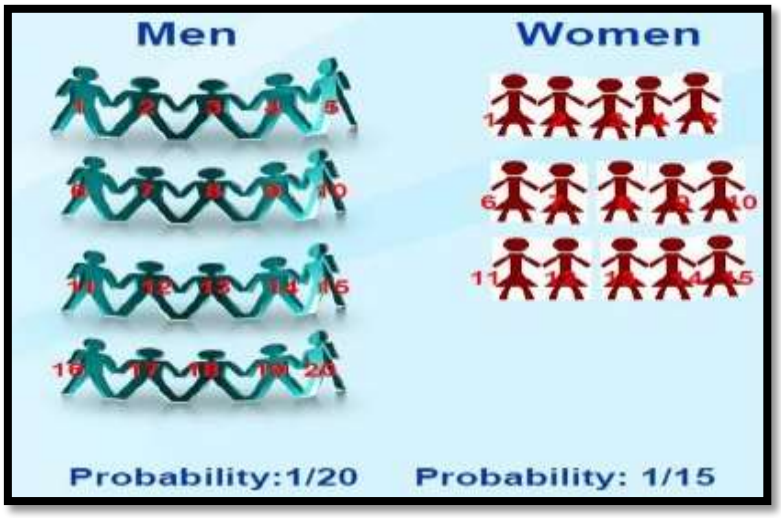


Fig.18. Stratified Random Sampling

4. Cluster Sample

- **Principle**
  - Select all units within randomly selected geographic clusters
- **Procedure**
  - Divide the population into geographic groups (clusters)
  - Assign a number to each cluster
  - Randomly select clusters
  - Sample all units within selected clusters OR select a random sample of units within selected clusters

- **Advantages & Disadvantages:**

Advantages

- More efficient for when units are dispersed over a large area

Disadvantages

- Cluster sampling is less efficient statistically than simple random sampling and so needs to be accounted for in the sample size calculations and subsequent analyses.

Example:

The objective of our study was to define the prevalence of obesity among primary school children in Giza . There are 150 primary schools in Giza. The estimated sample size is 20 clusters. Describe how would you proceed in drawing such sample?

- List all 150 schools
- Give each a number
- Use the random numbers tables in selecting the 20 schools whose numbers will fall between 001 and 150.

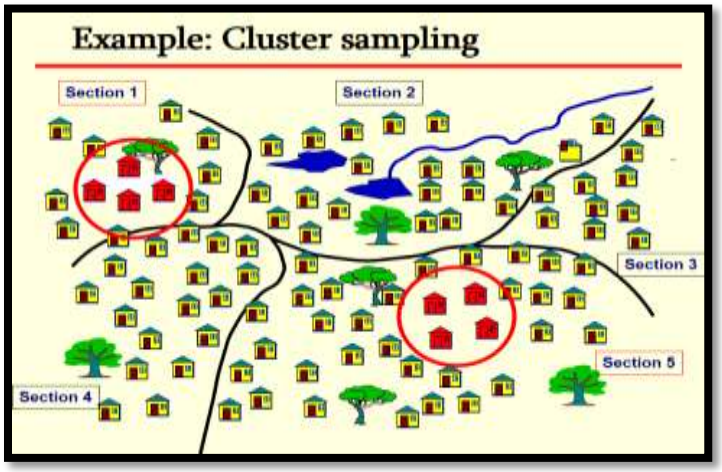


Fig.19. Cluster Random Sampling

5. Multi stage cluster sampling

▸ Principle

- We use this method if the target population is spread over wide geographic area and there is limited budget or resources (in community-based surveys).

▸ Procedure

- In this technique, the sample is drawn in many stages.
- The area is divided into smaller clusters, the clusters are divided into smaller clusters and so on. Random selection is carried out at each level successively.

▸ Example:

You were asked to head a research team to investigate the problem of hypertension in Egypt. How would you proceed in drawing your sample?

- List all governorates
- Select 4 governorates at random
- List the districts in each of the 4 governorates
- Select a district from each governorate at random
- List all villages and urban areas in each districts
- Select a village and an urban centre from each district randomly
- Study all or sub-sample of individuals in the selected villages and urban centres.

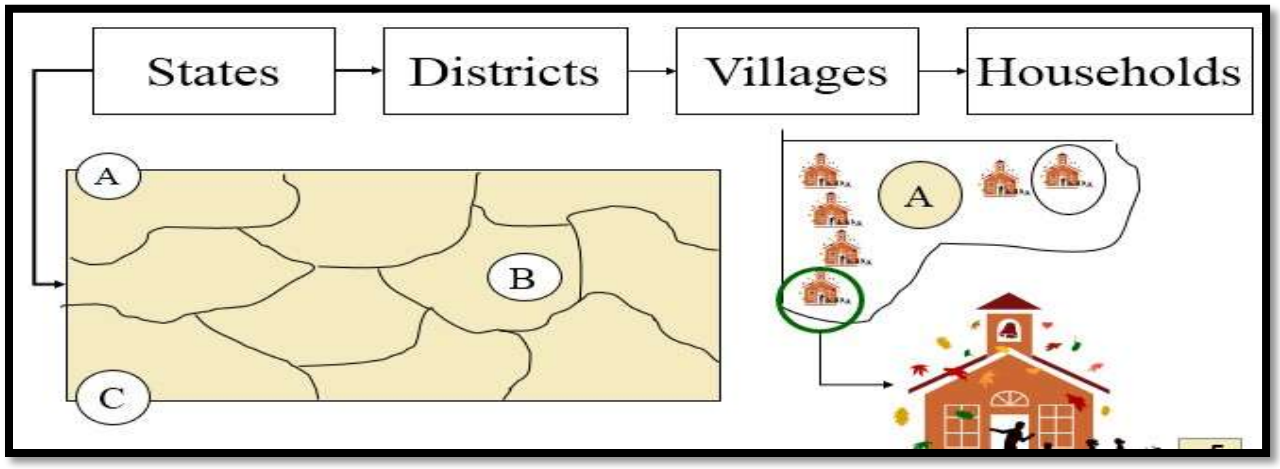


Fig.20. Multi Stage Cluster Sampling

Non random sampling

- Useful when descriptive comments about the sample itself are desired
- Thet are quick, inexpensive and convenient
- In applied social research, when it is unfeasible for impractical to conduct probability sampling

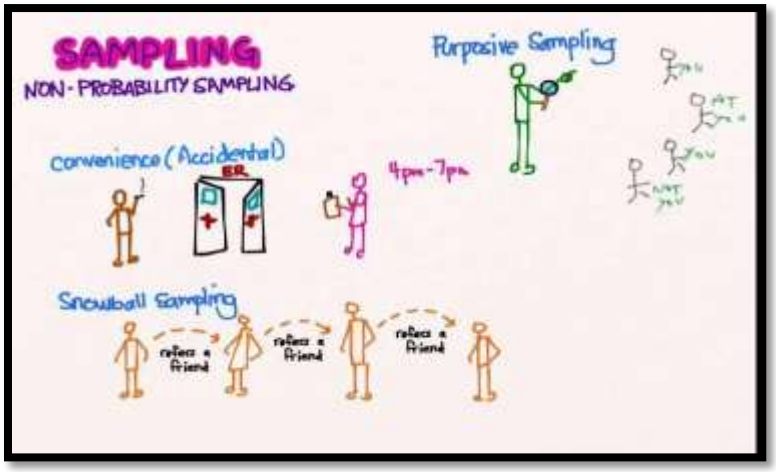


Fig.21. Different Non-Random Sampling Techniques

- **Convenience sample**

- Many studies use a sample of patients available at a particular time/place, for example patients who attend an asthma clinic may be recruited into a survey of the use of spirometers. The results of this study will apply to the population from which this sample is drawn and may not apply to other populations because patients' attendance at a clinic may be due to their response to treatment or their use of spirometers. Hence they may not be representative of all patients using spirometers.

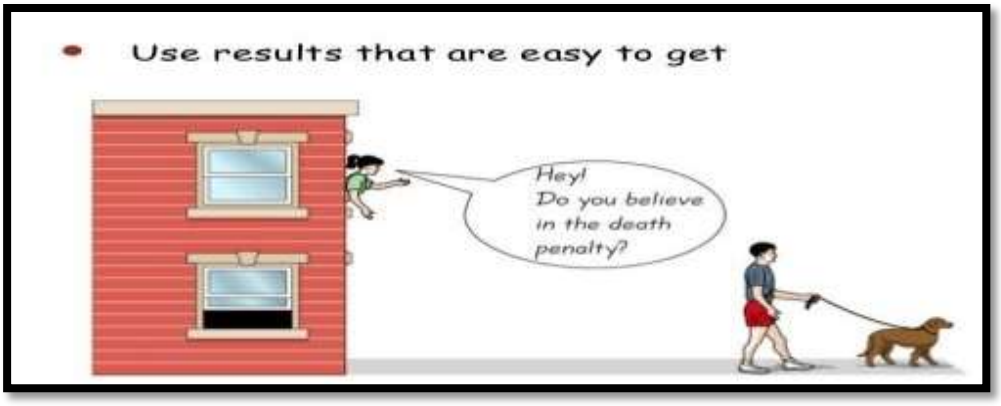


Fig. 22.Convenience sample

- **Purposive sample**

A sample made up of cases or individuals who meet the requirements of the study's design and possess the required characteristics.

Group Discussion

Section I:

1. Cardiovascular disease is an increasing problem in Tanzania. The last study to examine risk factors of cardiovascular disease in Tanzania was in 1987. You want to know about the current status of risk factors of cardiovascular disease and would like to examine how the risk factors have changed since the last study in 1987.

a. What type of study would you conduct and why?

2. In Thailand, breast cancer incidence is increasing, but little is known about the primary risk factors for breast cancer among Egyptian women. You want to learn about the risk factors for breast cancer in Egyptian females.

a. What type of study would you conduct and why?

b. How would you use simple random sampling to select 860 controls?

c. How would you use systematic random sampling to select 860 controls?

d. How would you use stratified random sampling to select 860 controls

Section V: Data collection tools

- **Definition:**

A research instrument is "a tool used to collect data. An instrument is a tool designed to measure knowledge attitude and skills."

- **<u>Differentiation between data collection techniques and tools</u>**

Techniques	Tools
Using available data	Data compilation sheet
observation	Check list , eye, watch , scales Microscope , pen and paper
Interviewing	Schedule , agenda, questionnaire, recorder
Self-administered questionnaire	Questionnaire

- **<u>Data Collection Tools</u>**

1. **Self-administered Questionnaire:**

A method of gathering self-report information from respondents through self-administration of questions in a paper and pencil format.

Keys to Success

- Pre-code the responses
- Try to avoid embarrassing or painful questions
- Avoid asking for more than one item of information in a single question

- Be sure to include all questions necessary to provide sufficient information
- Start with easier questions
- Ask all respondents each question in exactly the same way
- Always pretest questionnaires.
- Be specific about the purpose of the pretest.
- Use colleagues, potential participants, experts and potential users of the data.

2. Unstructured Interviews (In-depth Interviews)

- Since the drawback of the structured interview is the superficial responses, detailed open ended responses could be obtained by unstructured interview or in-depth interviews.
- The interview has an outline of topics to serve as a guide for information needed.

3. Focus Group Discussion (FGD)

- To reduce the amount of time and personnel required for conducting and analyzing in-depth interview, detailed qualitative information could be obtained by bringing respondents together in homogenous groups.
- The interviewer (facilitator has to use guidelines and probes).
- The participants are usually sampled purposively to reflect population variations that are of particular relevance to research topic (e.g. in case of study views of mothers towards primary health care services, FGDs have to be conducted with group of educated, group of uneducated mothers, group of young mothers (20-25 years old), group of older mother (35-40 years old).

4- Direct Observation of Operations

- This technique can generate either quantitative or qualitative data.
- Useful for exploratory studies
- Requires highly skilled observers and analysts and prolonged period of observation.
- Used in organizational studies as in case of using quality checklist to assess health facilities' performance (input, process, output). This method is used also to observe the service providers while providing specific service *e.g. IUD insertion*

- **Types**
- **Observation of human behavior**

- **Participant observation:**

The observer takes part in the situation he or she observes
Example: a nurse hospitalized with a broken hip, who now observes hospital procedures 'from within'

- **Non-participant observation: The observer watches the situation, open or concealed but does not participate**

Open
– (e.g., 'shadowing' a health worker with his/her permission during routine activities)
Concealed
– (e.g., 'mystery clients' trying to obtain antibiotics without a medical prescription)

- **Observations of objects**

– For example, the presence or absence of an operative room hand washing facilities and its state of cleanliness

5- Content Analysis

The content analysis could be done to the following types of materials:

- Documents related to training curriculum may be content analyzed to determine just what knowledge and skills the training is supposed to develop,
- Study of job descriptions, regulations and standards of practice manual,
- Information, education and communication (IE&C) materials, research, reports, press reports made by policy makers.

6-Service Statistics

- The quality of service statistics varies from country to country and even within countries
- The introduction of Management information system in health organizations had improved the quality of service statistics.
- The data derived from service statics, presents all data all over the year and for several years (not a sample)
- Service statistics often help the researcher define the parameters of the problem understudy (e.g. the problem is a reduction in Antenatal Care (ANC) coverage or reduction in the average number of ANC visits per mother)

Section VI: Ethical Principles in Clinical Research

- **Introduction:**

Clinical research has resulted in significant benefits for society, yet continues to pose profound ethical questions. This section describes ethical principles that guide clinical research.

- **What is Ethics, Bioethics?**

Ethics are ways of understanding and examining the moral life, or right and wrong human conduct. Bioethics is a way of understanding and examining the moral aspects of biomedical research and Practice.

- **Definition of Clinical Research**

Patient-oriented research:

Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual.

Patient-oriented research includes:

- Mechanisms of human disease,
- Therapeutic interventions,
- Clinical trials,
- Development of new technologies.

- **Ethics Principles**

- **Respect for Persons:** The principle of respect requires that subjects participating in the research should be fully aware of the nature of such research and assured that such participation is voluntary, with no pressure or duress.

- **Beneficence:** Beneficence requires researchers to maximize the potential benefits to the subjects and minimize the potential risks.

- **Justice:** The principle of justice requires fair selection of subjects and a fair and equitable distribution of risks and benefits of research.

- **Ethical requirements in clinical research aim to:**

- Ensure that the rights and welfare of subjects are respected while they contribute to the generation of knowledge.

- **What makes research ethical?**

Fulfilling all 7 requirements is necessary and sufficient to make clinical research ethical. These requirements are universal, although they must be adapted to the health, economic, cultural, and technological conditions in which clinical research is conducted.

1. Valuable scientific question
2. Valid scientific methodology
3. Fair subject selection
4. Favorable risk-benefit evaluation
5. Independent review
6. Informed consent
7. Respect for enrolled subjects

1. **Valuable scientific question**

Ethical clinical research should answer a valuable question, i.e., one that will generate new knowledge or understanding about human health or illness, i.e. a socially, clinically, or scientifically useful question.

2. **Valid scientific methodology**

Ethical clinical research should be designed in a methodologically rigorous manner (design, methods, statistical power and methods, etc.) that will yield valid, reliable, generalizable, and interpretable data, and that is feasible.

3. **Fair subject selection**

- No exclusion without justification
- Informed consent
- Respect for enrolled subjects

4. **Favorable Risk benefit ratio**

- Are risks to subjects necessary and minimized?
- Are risks justified by benefit to individual subjects and/or the importance of the knowledge to society?
- Compensation for participation in research is not considered to be a benefit but, rather, compensation for research-related inconveniences.

5. **Independent Review**

- Independent review allows evaluation of the research for adherence to established ethical guidelines by individuals with varied expertise and no personal or business interest in the research. For most clinical research, this

independent review is carried out by an Institutional Review Boards (IRB) or research ethics committee (REC).

- Institutional Review Boards evaluate the benefits of doing the study, the risks involved, the fairness of subject selection, and the plans for obtaining informed consent; they then decide whether to approve a study, with or without modifications, to table a proposal for major revisions or more information, or to disapprove a study as unacceptable.

6. Informed consent

For all biomedical research involving human subjects, the investigator must obtain the informed consent of the prospective subject or authorized representative. Informed consent ensures that individuals have the opportunity to decide whether they want to participate in research or continue participation and whether it is compatible with their goals, values and interests.

- **In seeking informed consent, the following information shall be provided to each subject:**

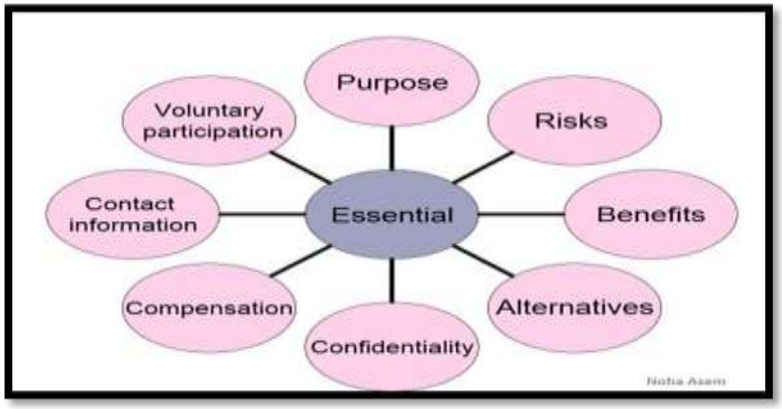


Fig. 24. Essential Elements of Informed Consent Form

- **Who can consent?**

– A competent adult, or
– The patient's legally authorized representative.

- **Vulnerable (or Potentially Vulnerable) Research Subjects**

Vulnerable subjects frequently are individuals who are unable to consent (e.g. unable to understand the research in question).

- Comatose people
- Critically ill people
- Mentally retarded people
- People with dementias/some psychiatric diseases
- Children
- Educationally/economically deprived people
- Prisoners
- Seriously/terminally ill people.

- **Consent and Children in Research**

- Children may be required to "assent," but they cannot legally "consent" to participate in research.
- Generally, permission of both parents, and his or her legal guardian, is required for a child to participate in research.

7. Respect for enrolled subjects

Ethical research requires continued respect for the rights of participants throughout research, including:

- Protecting confidentiality
- Recognizing right to withdraw
- Informing participants of findings

Are these studies ethical? (Group Discussion)

1. **High-Altitude Experiments.** Experiments were conducted to investigate the limits of human existence at extremely high altitudes. The experimental subjects were placed in a low-pressure chamber and after that the simulated altitude there was raised.

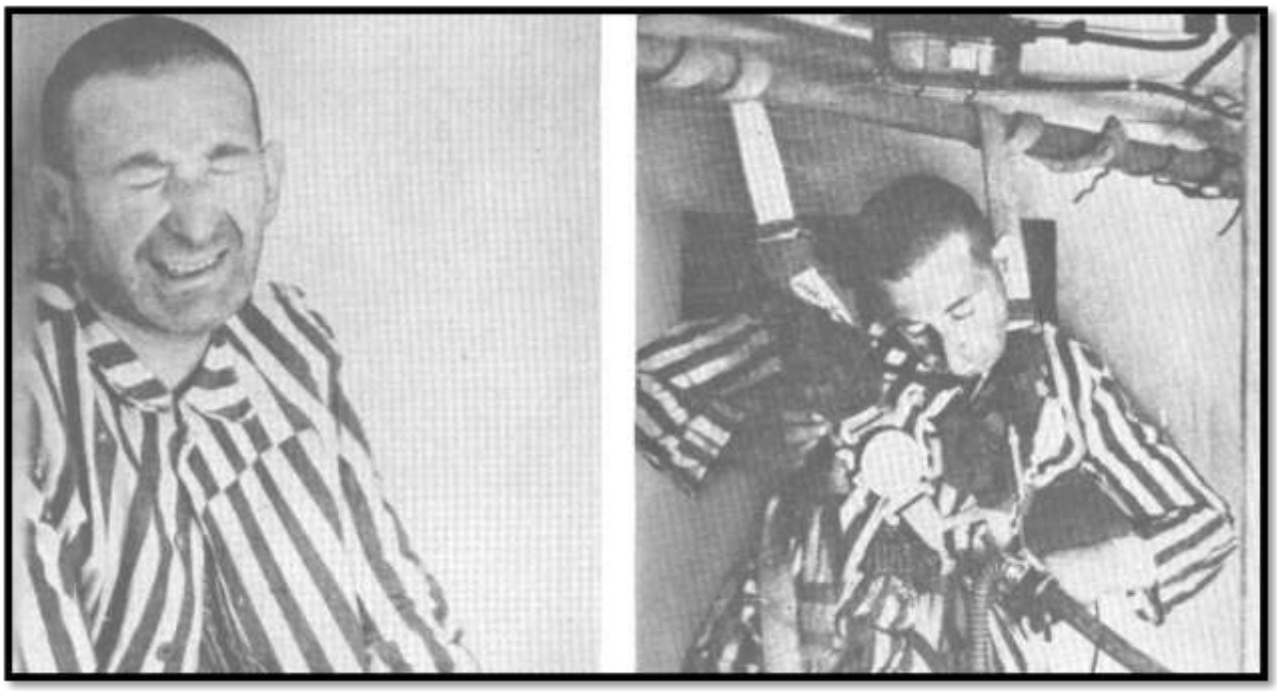


Fig.25 High-Altitude Experiments.

2. **Freezing Experiments**: Experiments were conducted to investigate the most effective means of treating persons who had been severely chilled or frozen. In one series of experiments the subjects were forced to remain in a tank of ice water for periods up to 3 hours. In another series of experiments, the subjects were kept naked outdoors for many hours at temperatures below freezing.

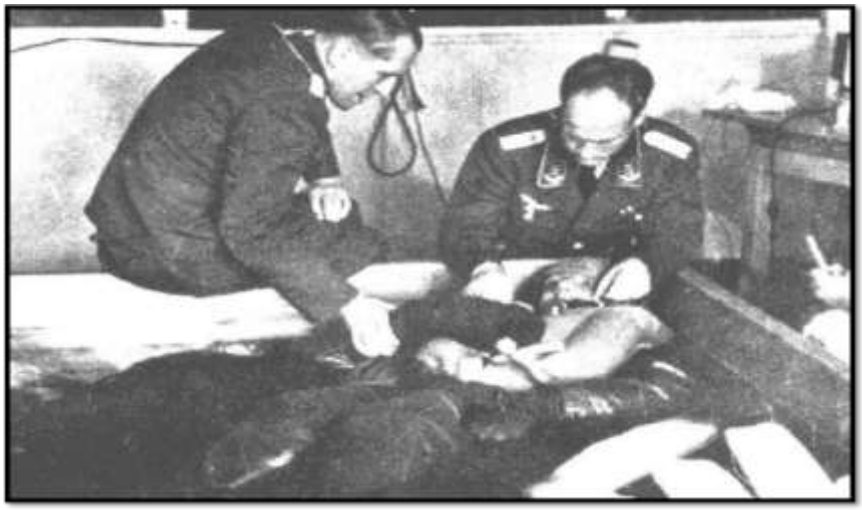


Fig.26 Freezing Experiments

3. **Experiments with Poison:** Experiments were conducted to investigate the effect of various poisons upon human beings. The poisons were secretly administered to experimental subjects in their food. The victims died as a result of the poison or were killed immediately in order to permit autopsies.

4. **A medical device for corneal transplantation surgery:** In 1994, eye surgeon James Rowsey invented a medical device that he thought would revolutionize corneal transplantation surgery and make millions of dollars. It did neither. Instead, it cost

him a high paying university job and led to federal findings that he performed unapproved research on more than 60 people, including children.