
WRITTEN QUESTIONS
RESEARCH

(1) Enumerate steps for a research design. & Enumerate 8 steps model.

A) Steps in planning research study		B) Steps in conducting study	
Step 1	- Formulate a research problem	**Step 6**	- Collecting data.
Step 2	- Research design	**Step 7**	- Processing data.
Step 3	- Construct tools for data collection	**Step 8**	- Writing research report
Step 4	- Select a sample (size & method)		
Step 5	- Write research protocol (proposal)		

(2) Mention three elements of protocol.

Elements of protocol	Purpose
- **Research questions**	What questions will the study address?
Significance (Rationale)	Why are these questions important?
- **Design:** • Time frame • Epidemiologic approach	How is the study structured?
- **Subjects:** • Selection criteria • Sampling design	Who are the subjects and how will they be selected?
- **Variables:** • Predictor variables • Confounding • Outcome variables	What measurements will be made?
- **Statistical issues:** • Hypotheses. • Sample size.	How large is the study and how will it be analysed?

(3) Enumerate FINER criteria for a good research question.

Feasible	- Adequate technical expertise	- Affordable in time and money	- Manageable in scope
Interesting	- To the investigator		
Novel	- Confirms or refuses previous findings. - Extends previous findings.	- Provides new findings	
Ethical	- To scientific knowledge		
Relevant	- To clinical and health policy	- To future research directions	

(4) Mention three uses of descriptive studies.

1. It is the first phase in the epidemiological investigation.
2. Describing the pattern, characteristics and distribution of a disease or health problem in the population.
3. Give data about when the disease occurs (Time), where the disease occurs (Place) and who is getting the disease (Person).
4. Formulating (not testing) research hypotheses (It is the 1st step in the search for determinants or risk factors).

(5) Define cross sectional study and mention its advantages

Definition:	- It is observational study that carried out once (snapshot of a population) at a single point in time. - Both exposure (risk factors) and outcome (diseases) are present (we cannot determine if exposure preceded disease or not). - It measures prevalence, NOT incidence of disease.
Advantages:	1. Useful to study conditions that are relatively frequent with long duration (non-fatal, chronic conditions). 2. Good for generating hypotheses about the cause of disease. 3. Can estimate: • The Prevalence rates. • The Exposure proportions. 4. No follow up, relatively easy, quick and inexpensive. 5. It is the first step to develop causal association.

(6) Mention four disadvantages of cross-sectional study.

Disadvantages:	1. Not useful for studying: • Acute diseases. • Diseases with seasonal variations. • Highly fatal diseases. • Rare diseases. • Disease with short duration. 2. Can't estimate incidence rate. 3. It gives very little information about the natural history of diseases. 4. Can't determine if exposure preceded disease or not. 5. Not differentiate between causes of disease & factors associated with disease.

(7) Mention three uses of longitudinal study.

1. Incidence rate.
2. Natural history of dis. & its final outcome (case fatality, survival).
3. Risk factors of disease.

(8) Mention three advantages and disadvantages of case control studies.

Advantages	Disadvantages
1. Easy to carry out. 2. Quick & cheap. 3. Useful in early stages of the development of knowledge. 4. Can be used in rare diseases. 5. Allows the study of several risk factors. 6. Useful in the study of disease with a long latency. 7. Does not require large samples. 8. Can prove hypothesis (Exposure & Disease are related). 9. Can estimate risk (odds ratio).	1. Cannot calculate prevalence or incidence rates. 2. Not useful in rare exposure. 3. Liable to bias or mistakes.

(9) Mention the main differences between case control and cohort studies (criteria – advantages and disadvantages).

	Case-control studies	Cohort studies
Criteria	- Proceed from outcome to cause. (From disease to risk factor)	- Proceed from cause to outcome. (From risk factor to disease)
	Compares people with disease &those without disease	Compares exposed with non exposed
	Retrospective	Prospective
	Aims to prove or disprove that suspected cause occurs more frequently in diseased than non-diseased	Aims to prove or disprove that suspected disease occurs more frequently in exposed than non-exposed.
Advantages	1. Cheap &quickly done. 2. Does not require large sample. 3. Useful in studying rare diseases. 4. Can study several risk factors. 5. Can estimate risk (odds ratio)	1. Less bias in selection of control. 2. Methods can be standardized. 3. Study several outcomes. 4. Valuable in rare exposure. 5. Incidence rate and relative risk can be calculated
Drawbacks	1. Liable to bias. 2. Not useful in rare exposures. 3. Uncertain data due to incomplete records of past events& unstandardized observation. 4. Difficulty to be sure that the association is causal or not.	1. Expensive and time consuming. 2. Needs a very large sample even with common diseases. 3. Delayed results if latent period is long. 4. Prolonged follow up can cause drop out of cases and loss of standardization.

(10) Define experimental study and mention its characteristics and uses.

Definition:	- A prospective study comparing the effect and value of intervention (s) against a control in human being. - Confirm etiological hypothesis & assess effectiveness of preventive measures & new therapies.

Characteristics:	1. **Manipulation**: the researcher does something to one group of subjects in the study. 2. **Control**: the researcher introduces one or more control group(s) to compare with the experimental group. 3. **Randomization**: the researcher takes care to randomly assign subjects to the control and experimental
Uses:	1. Confirm an etiological hypothesis to prove causation. 2. Assess the effectiveness of a preventive or curative measure. - New treatments - pharmaceutical agents, devices, surgical procedures - are being developed every day. - Before an intervention becomes a standard practice, assessment of its efficacy and safety in comparison to standard therapy should be undertaken.

(11) Mention uses of clinical trials.

- **Clinical trials are useful for evaluating New:**

1- Drugs, other treatments for disease.
2- Medical, health care technology.
3- Programs for screening & diagnosis.
4- Methods of prevention.
5- Methods of providing health care.
6- Health care policies.

(12) Enumerate aims of preclinical studies of testing a new drug.

Aim:	▪ to provide knowledge about safety and biliogic activity of drug to allow it to be administered to patients. **We look for 5 things:** 1. Pharmacokinetics. 2. Pharmaco-dynamics. 3. Drug metabolism. 4. Lethal dose (LD50). 5. Teratogenic effects

(13) Mention four phases of stage 2 of testing of a new drug.

Phase I	**(20-100 subjects): not randomized, volunteers.** ▪ Drugs with serious SE tested on seriously ill patients who have failed to respond to current established therapy. ▪ To assess pharmacokinetics, metabolic fate, safety and tolerance of treatment.

Phase II trials	**(100-200 subjects)** ▪ Therapy is still promising after phase I. ▪ Objectives are to set & test dose necessary for pharmacodynamic effects, to evaluate potential effectiveness and to determine optimal method of administration.
Phase Ill trials	**(500-1500 subjects)** ▪ Additional safety information & to establish or refute predicated benefit. ▪ Randomized double blind controlled trial with adequate sample size & power. ▪ Provide decision makers with scientific evidence about relative effectiveness and safety of competing treatments.
Phase IV trials:	▪ **Conducted after treatment is approved for general use (post-marketing surveillance.)** 1. Drug safety: long term effects, surveillance for rare 2. Drug interactions with other drugs or diets. 3. Pharmaco-epidemiology: distribution & determinant of drug use. 4. Pharmaco-economics: cost-effectiveness of drug. 5. Benefits & harms in presence of comorbidity.

(14) Mention basic steps in randomized clinical trials design.

1- Selection of study population.
2- Getting informed consent.
3- Random allocation of subjects to the experimental and control group.
4- Follow up.
5- Measure the outcomes.
6- Compare outcome measures between the groups using appropriate statistical tests.

(15) Define

Placebo	▪ Pharmacologically inert but identical in appearance to the active drug. ▪ It is unethical to use placebo when a known effective drug exists.

Efficacy	▪ The proportion of individuals in the control group who experience an unfavorable outcome who could have been expected to have a favorable outcome had they been in the active group instead of control. ▪ A high efficacy is an indicator that an intervention is successful.
Number needed to treat	▪ **Number needed to treat (NNT):** the expected number of people who would have to receive a treatment to prevent an unfavorable outcome in one person (or, alternately stated, to achieve a favorable outcome in one person) ▪ A small NNT indicates a more effective intervention.
Screening test	▪ Screening **is** the investigation of apparently healthy individuals to detect unrecognized cases or individuals with high risk of developing a disease. ▪ **Therefore, intervention can be done to:** a- Prevent occurrence of the disease or b- Improve its prognosis when it develops.

(16) Mention immediate and ultimate objectives of a screening tests.

Immediate	Ultimate
- Simple test applied on large number: • To exclude those free from disease. • To pick up those possibly suffering from disease. • To detailed investigation to prove or disprove the diagnosis (i.e. reference test).	- To reduce mortality

(17) Mention five differences between screening tests and diagnostic tests.

Screening test	Diagnostic test
Done on apparently healthy	Done on those with disease indication
Used on groups	Used on an individual basis
Less accurate.	More accurate.
Less expensive.	More expensive.
Not a basis for treatment.	Used as a basis for treatment.

(18) Define screening tests and mention its types.

Definition:	▪ Screening **is** the investigation of apparently healthy individuals to detect unrecognized cases or individuals with high risk of developing a disease. ▪ **Therefore, intervention can be done to:** a- Prevent occurrence of the disease or b- Improve its prognosis when it develops.	
Types:	**(1) Mass Screening**	▪ Offered to all individuals, irrespective of the presence of particular risk to the disease in question. e.g congenital hypothyroidism ▪ This is not a useful preventive measure unless it is backed-up by treatment & follow-up facilities for positive screening.
	(2) High Risk Screening	▪ Offered to those with special risk, e.g., screening of close relative of known DM (a greater number of cases can be identified at less cost).
	(3) Multiphase screening	▪ For a variety of diseases at one time. ▪ **This is a well-established procedure in:** • Antenatal care • School examinations. • Pre-employment • Biochemical profile for hosp.patients.

(19) Enumerate requirements for a screening program (dse , test).

Requirements Of Screening Program regarding (The disease):	**1) Importance of the disease:** - The disease should be an important health problem, ie., high frequency and/or bad sequelae, e.g., congenital hypothyroidism, although rare, should be detected early because of its serious sequelae if untreated and because it is treatable. **2) Adequate understanding of the natural history of the disease:** - to identify the points at which the disease can be detected by screening with effective intervention before irreversible damage, - to evaluate the effectiveness of any intervention.

	3) A recognized latent period or asymptomatic stage. **4) Can be detected before onset of symptoms and signs.** **5) At risk individuals can be identified and screened** **6) Available facilities for diagnosis and treatment.** **7) Agreed policy on whom to treat as patients.** **8) An effective treatment, available, effective and acceptable** **9) Benefits of early**	
Requirements of a screening test:	**A. General requirements**	1. Simple, not too many steps involved to avoid errors. 2. Inexpensive for mass application. 3. Least time consuming. 4. Not painful. 5. Objective rather than subjective. 6. Acceptable by the population
	B. Special requirements	1. Precise & reliable; gives the same results when repeated under standard conditions. 2. Valid (sensitive & specific; test is accurate giving true, not false reading (+ve or -ve)

(20) Define validity.

Definition:	▪ Validity is the extent to which a test measures what it aims to measure, i.e., it is the capacity of a test to give true results. ▪ Therefore, a valid test is the test which correctly detects the presence or absence of a condition, e.g., glucosuria as a test to detect DM has poor validity compared to glucose tolerance test.

(21) Enumerate disadvantages of screening tests (false negative, false positive results) ?

A false positive test	A false negative test
▪ **Can lead to:** 1. Needless anxiety, 2. Exposes individuals to the costs and risks of further investigation and perhaps unnecessary treatment, 3. Imposes economic burdens on the health-care system that would better be avoided.	▪ **Can lead to:** 1. Result could have disastrous consequences if persons suffering from early cancer are incorrectly reassured that there is nothing wrong with them.

(22) Define reliability and its importance.

Definition:	▪ It is the level of agreement between repeated measurements; therefore, a technique will give the same values on repeated application on the same individual
Importance:	▪ **It measures the instability in both:** 1. Subject (biological) variation either random or systemic (HR BP Blood sugar) 2. Observer (measurement) variation either random with the same observer or systemic between different observers (ECG X Ray)

(23) Define sample and mention characters of a good sample and its advantages.

Def	▪ Sample is a subset of population that is used to gain information about the entire population.
characters:	▪ **A good sample is:** 1. Representative 2. Adequate 3. Unbiased
Advantage	1.Lower cost 2. Saves time 3.Provides more intensive and accurate investigations and information

(24) Define mean, median, mode and mention advantages and disadvantages.

	Mean (Average)	Median	Mode
Def	▪ Is obtained as sum of all values divided by the no. of values. ▪ **Mean** = Σ x/n	▪ Middlemost value in a distribution arranged in an ascending or descending order of values. ▪ The median is the value that lies in the middle of the ordered observations	▪ The mode is the most frequent observation ▪ This is done by finding the observation which has the highest frequency
Advantages	▪ Used in quantitative continuous data	1. It can be used with quantitative & qualitative ordinal variables (e.g. median number of patients in cancer stages). 2. It is useful for summarizing data with extreme values as it is not affected by extreme values.	1. It can be used in all types of variables 2. It is not affected by extremes or out-lying observation
Disadvantages	1. Affected by extreme values. 2. It should not be used for non-parametric or skewed data	1. It cannot be used with qualitative nominal variables. 2. It is not easy to be used in statistical analysis	1. Sometimes the mode cannot be determined, this happens when all observations have the same frequency (i.e. uniform distribution). 2. Sometimes we may obtain two modes (bimodal) or more (multimodal) from the same group of data. e.g. 22, 24, 26, 28, 24, 26 Mode= 24 & 26

(25) Enumerate steps of hypothesis testing.

1. Define the null and alternative hypotheses.
2. Choose the level of significance (< 0.05)
3. Pick & compute the test statistic (t or chi)
4. Compute the p-value
5. Check whether to reject the null hypothesis by comparing the p-value to the level of significance.
6. Draw conclusion from the test.

(26) Define maternal mortality rate and mention the causes of it.

Def	Maternal mortality means death among mothers due to causes related to and/or aggravated by pregnancy, labor & puerperium.
Causes	1) Hemorrhage: • May occur during pregnancy, labor, or puerperium. • It forms the most important causes in Egypt. 2) Hypertensive disease of pregnancy (eclampsia & preeclampsia). 3) Puerperal sepsis: most preventable cause. 4) Pre-existing diseases aggravated by pregnancy, labor & puerperium e.g. Rheumatic heart disease. 5) Chronic glomerulonephritis complicated by renal failure. 6) Uncontrolled D.M