IIHMR DELHI | INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH

Post Graduate Diploma in Management (Hospital & Health Management)

PGDM – 2022-24 Batch

2nd Year - 6th Term Examination

Course & Code	:	**Clinical Epidemiology-HOM 717**	**Reg. No.**	:	
Term & Batch	:	**VI, 2022-24**	**Date**	:	**29.01.2024**
Duration	:	**3 Hrs.**	**Max. Marks**	:	**70**

Instructions:

- Budget your time as per the marks given for each question and write your answer accordingly.
- Don't write anything on the Question Paper except writing your Registration No.
- Mobile Phones are not allowed even for computations.

Part A: Please attempt ALL questions: Q1 to Q20 (20 questions*2 marks = 40 marks)

Q1. Which phase of a clinical trial is referred to as post-marketing surveillance?

a. Phase 1
b. Phase 2
c. Phase 3
d. Phase 4

Q2. What is meant by 'randomization' in randomized controlled trials?

a. Allocation of study participants randomly into the treatment and control groups
b. Selection of study participants randomly to participate in the study
c. Both a and b
d. None of the above

Q3. Which of the following is true about an ideal 'placebo'?

a. It should look different from the treatment drug
b. It can be another drug/current treatment
c. It should be inert
d. All of the above

Q4. Blinding of participants in a clinical trial is done to remove which type of bias?

a. Selection bias
b. Information bias
c. Confounding bias
d. None of the above

Contd…2..

Q5. Which of the following statements is **true**?

a. It is always preferred to select historical controls for RCTs
b. Presence of association always implies causation
c. Intention to treat analysis excludes participants who are lost to follow up
d. Crossover RCTs are considered to be more ethical if the new treatment shows benefit

Q6. Reporting of clinical trials is done using which of the following reporting guidelines?

a. STROBE
b. SRQR
c. PRISMA
d. CONSORT

Q7. The purpose of a double-blinding in a clinical trial is to

a. Achieve comparability of all arms of a clinical trial
b. Avoid observer and participant bias
c. Avoid confounding
d. Achieve desired sample size

Q8. Which of the following types of random allocation ensures equal number of study participants in intervention and control arms?

a. Simple randomization
b. Block randomization
c. Both
d. None

Q9. If a research study is externally valid, it means that the results can be generalized to the population from where the sample was obtained.

a. True
b. False

Q10. Which of the following is NOT censored in survival analysis?

a. Patients who die during the follow up period
b. Patients who survive beyond the duration of follow up
c. Patients who are lost to follow up
d. Patients who withdraw from the study

Q11. Sensitivity of a screening test means its ability to correctly identify

a. True positives
b. False positives
c. True negatives
d. False negatives

Q12. Kappa statistics is computed to assess which of the following parameters of a screening test?

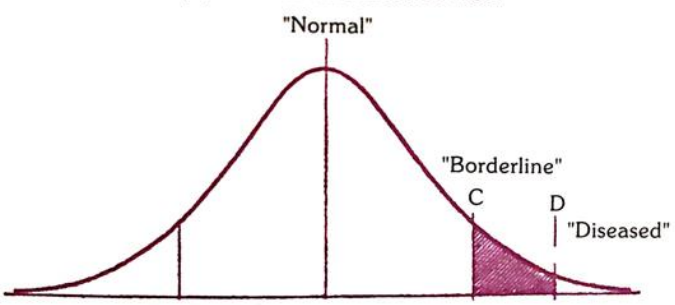
a. Reproducibility
b. Validity
c. Cost effectiveness
d. Acceptability

Contd…3..

Q13. A clinical trial may be stopped in which of the following cases?

a. Trial investigator moves to a different location
b. Trial drug poses unacceptable risk to the health of the participants
c. Few participants drop out of the trial
d. None of the above

Q14. The diagram below depicts blood glucose levels of individuals in city X. a new screening test for diabetes is being introduced, which labels a person as 'diabetic' based on a cut-off point for blood glucose level. If the cut off for blood glucose level in the test is increased from point C to point D, it makes the test:



a. More sensitive
b. More specific
c. Neither more sensitive nor more specific

Q15. A screening test for a disease which is highly fatal should be

a. More sensitive than specific
b. More specific than sensitive

Q16. Case fatality rate is ideally used to assess the prognosis of

a. Acute short-term diseases
b. Chronic long-term diseases

Q17. A clinical trial may be stopped in which of the following cases?

e. Trial investigator moves to a different location
f. Trial drug poses unacceptable risk to the health of the participants
g. Few participants drop out of the trial
h. None of the above

Q18. A new device to test hemoglobin levels has been released into the market. As a hospital manager you want to understand whether you should procure the new device for hemoglobin testing in your hospital in place of the old standard device. What is the best way to make this decision?

a. Conduct a survey among patients regarding their preference
b. Consult other hospitals who have adopted the new device
c. Compare the market cost of the two devices
d. Conduct a study to assess the validity of the new device

Contd…4..

Q19. An RCT is being conducted to assess the effect of a new treatment on disability reduction in osteoarthritis. Which indicator will be most appropriate to compare treatment effect between patients in treatment and control groups?

a. Crude death rate
b. Case fatality rate
c. Quality of life
d. All of the above

Q20. Data on outcome surveillance of hospital acquired infections (infection count) is sufficient to control these infections in the hospital.

a. True
b. False

Part B: Please attempt ANY THREE questions: Q1 to Q5 (3 questions*10 Marks = 30 Marks)

Q1. Explain the following:

i. Participant screening vs recruitment in context of RCT (4)
ii. Disadvantage of uncontrolled trials (3)
iii. Importance of interim analysis in RCT (3)

Q2. Answer the following questions:

i. Bradford Hill's criteria for causality (5)
ii. Applications of clinical epidemiology (5)

Q3. Explain the following briefly:

iv. Serial vs parallel testing for disease screening (4)
v. Four characteristics of a disease to make it suitable for screening (3)
vi. Importance of blinding in studies to assess validity of screening tests (2)

Q4. What is the hierarchy of evidence? Explain with a suitable diagram. Where do RCTs feature in the hierarchy? Explain how risk of bias changes across the hierarchy. (2+4+2+2)

Q5. You are asked to evaluate the family planning clinic of a hospital. Frame and explain the structure, process and outcome indicators (at least three each) that you will use for evaluation. (10)