

Post Graduate Diploma in Management (Hospital & Health Management)

PGDM – 2023-25 Batch

2nd Year – 4th Semester End Examination

Subject & Code : Clinical Epidemiology-HOM 717

Reg. No.:

Semester & Batch : IV, 2023-25

Date : 11-02-2025

Time & Duration : 10:30 A.M.-01:30 P.M. (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.
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Part A: All questions are compulsory (10 X 2 Marks = 20 Marks)

Please write option and answer BOTH. E.g.- c. Randomized controlled trial (0.5 marks will be deducted from each answer where only option or only answer are mentioned)

1. What is the primary purpose of including a Data Safety Monitoring Board (DSMB) in a clinical trial?
 - a. To interpret trial results.
 - b. To monitor the trial's progress and participant safety.
 - c. To recruit participants for the trial.
 - d. To analyze adverse events after the trial concludes.
2. In a clinical trial comparing two therapies for hypertension, researchers notice a discrepancy in treatment effects between ITT and per protocol analyses. What could explain this difference?
 - a. Variability in participant demographics across treatment groups
 - b. Differences in statistical methods used for analysis
 - c. Adherence issues or dropout rates among participants
 - d. Ethical concerns related to participant recruitment
3. A study needs to be undertaken to understand the prognostic factors which are significantly associated with ICU admission in patients of human metapneumovirus. Which study design will be suitable?
 - a. Descriptive cross sectional
 - b. Analytical cross sectional
 - c. Descriptive longitudinal
 - d. Analytical longitudinal

Contd...2..

4. In a CONSORT flow diagram of a clinical trial, which section typically represents the number of participants assessed for eligibility?
 - a. Enrollment
 - b. Allocation
 - c. Follow up
 - d. Analysis
5. In a study assessing a diagnostic test, the area under the ROC curve (AUC) quantitatively represents:
 - a. The diagnostic accuracy of a test.
 - b. The prevalence of the disease in the tested population.
 - c. The variability of test results.
 - d. The cost-effectiveness of the diagnostic test.
6. Which method is commonly used for active surveillance of Hospital Associated Infections in healthcare facilities?
 - a. Review of patient medical records
 - b. Surveying hospital staff satisfaction
 - c. Conducting patient satisfaction surveys
 - d. Regular microbiological sampling
7. The primary difference between efficacy and effectiveness lies in:
 - a. The cost of treatment.
 - b. The magnitude of treatment effect.
 - c. The setting in which the treatment is studied.
 - d. The duration of follow-up.
8. In Kaplan-Meier analysis, what does the "censored" data indicate?
 - a. Missing data points due to study limitations.
 - b. Participants who did not consent to participate in the study.
 - c. Events of interest that occurred during follow-up.
 - d. Participants who were still alive or lost to follow-up at the end of the study.
9. The placebo effect is considered a challenge in clinical trials because it:
 - a. Can obscure the true effectiveness of active treatments
 - b. Increases the cost of conducting research studies
 - c. Leads to unreliable and inconsistent treatment outcomes
 - d. Requires additional ethical approvals from regulatory authorities
10. In health services research, inclusion of micro-level stakeholders gives a clear understanding of policies and organizational structures which support the implementation of the health service.
 - a. True
 - b. False

Part B: Attempt any four questions (4 X 5 Marks = 20 Marks)

11. What is meant by 'SMART' indicators for health services research? A tertiary care hospital has introduced a cervical cancer screening program. Frame Structure, Process, Outcome and Impact indicators (two each) for assessing the program success. (1+4)
12. List and define FOUR measures used for expressing prognosis of a disease. Write one advantage of Kaplan Meier curve over life table analysis. (4+1)
13. What are the advantages of using a combination of screening tests? A clinician wants to improve diagnostic accuracy for a highly fatal disease so that no cases of the disease are missed. Suggest how the use of multiple available screening tests can achieve this. (3+2)
14. A clinical trial is underway to evaluate a potential new treatment for a life-threatening condition. The trial involves randomized assignment of participants to either the experimental treatment or standard care. Participants are informed about the risks and potential benefits of participation, and their consent is obtained before enrollment. Discuss two ethical challenges that researchers might encounter in conducting this clinical trial. Propose how these can be addressed. (2.5+2.5)
15. In the context of experimental studies, what is meant by 'true treatment effect'? Explain three factors which might distort the true treatment effect. (2+3)

Part C: Attempt any three questions (3 X 10 Marks = 30 Marks)

16. A research team is designing an RCT to investigate treatments for hypertension. They are considering to simultaneously evaluate the effects of two different interventions: Drug A (a new antihypertensive medication) and Lifestyle Modification B (diet and exercise regimen), and assess the independent as well as combined effects of Interventions A and B.
 - a. What study design is appropriate for this RCT? (2)
 - b. Justify your answer. (3)
 - c. Construct a suitable diagram representing the design of the trial. (5)
17. What is the difference between risk factor and prognostic factor of a disease? List and explain **three** risk factors and **three** prognostic factors of tuberculosis. (4+6)
18. Explain the chain of infection using catheter associated urinary tract infection (CAUTI) as an example. Describe one intervention to break the chain of infection with respect to each link in the chain. (5+5)
19. A clinical trial evaluates the efficacy of a new drug for treating chronic migraine. Participants are randomized to receive either the new drug or a placebo. The trial includes subjective endpoints such as self-reported pain intensity and frequency of migraine attacks. Explain the importance of blinding in this trial. Who, according to you, should be blinded and why? (5+5)