

Post Graduate Diploma in Management (Hospital & Health Management)

PGDM – 2024-2026 Batch

2nd Year – 4th Semester End Examination

Subject & Code : Clinical Epidemiology (CE)-HOM 717

Reg. No.:

Semester & Batch : IV, 2024-2026

Date : 27-02-2026

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: Q.1 to Q.10 all questions are compulsory (10 X 2 Marks = 20 Marks)

One liner, MCQs, True/False

Q.1. What is the primary purpose of randomization in a clinical trial?

- A) To ensure equal number of participants in each group
- B) To distribute confounders equally across groups at baseline
- C) To increase the external validity of the study
- D) To ensure participants adhere to the protocol

Q.2. Which document provides a checklist and flow diagram for reporting parallel-group randomized controlled trials?

- A) STROBE statement B) PRISMA statement C) CONSORT guidelines D) CARE guidelines

Q.3. Likelihood ratio involves

- a) Incidence and prevalence
- b) Sensitivity and specificity
- c) PPV and NPV
- d) Risk and odds

Q.4. Which value represents the probability of disease in a person who has tested positive?

- A) Sensitivity B) Specificity C) Positive Predictive Value D) Negative Predictive Value

Q.5. What is Lead time bias in screening?

- A) The bias occurring when a test detects disease earlier, making survival appear longer without actually extending life.
- B) The error introduced when a screening test has low sensitivity.
- C) The cost associated with early diagnosis.
- D) The psychological burden of knowing a diagnosis earlier than usual.

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Q.6. What is a censored observation in survival analysis?

- A) A participant who died from the disease being studied.
- B) A participant who experienced the outcome of interest early.
- C) A participant who is lost to follow-up, withdrew, or did not experience the event by the end of the study.
- D) A data point removed due to calculation errors.

Q.7. ROC curve is a graph of

- a) Sensitivity vs Specificity
- b) Sensitivity vs 1-Specificity
- c) PPV vs NPV
- d) Prevalence vs incidence

Q.8. Case fatality rate is best described as:

- A) The number of people who die from the disease out of the number of people who have the disease.
- B) The number of people who have the disease out of the total population.
- C) The number of people who recover from the disease.
- D) The rate of new cases appearing in a population over time.

Q.9. A Case-Control study- a type of observational study can estimate the following measure of association

- A) Hazard rate ratio B) Prevalence proportion C) Incidence rate ratio D) Odds ratio

Q.10. Phase III clinical trials mainly evaluate:

- a) Safety in animals
- b) Dose and toxicity
- c) Efficacy in large populations
- d) Post-marketing surveillance

Part B: Q.11 to Q.15 attempt any four questions (4 X 5 Marks = 20 Marks) - Short Notes

Q.11. What is prognosis? Enumerate different ways of estimating prognosis and define any one.

Q.12. Define "Time Zero" in prognosis studies and its significance in survival analysis.

Q.13. Evidence pyramid

Q.14. Describe the difference between process and outcome measures in hospital surveillance with examples from infection control.

Q.15. Comparison between Intention to treat (ITT) vs Per Protocol analysis in RCT

Part C: Q.16 to Q.19 attempt any three questions (3 X 10 Marks = 30 Marks) - Long Notes

Q.16. In a study, researchers have analyzed the association between age and hospital acquired infection (HAI) among patients admitted in a hospital in last 3 months. The study revealed more HAIs among patients aged >60 years compared to those who are aged 60 years or less. The result showed an Odds ratio 3.2 (95% Confidence Interval 0.21 - 6.5) [Reference group age 60 years or less]. "

- Please interpret this finding. Comment on the statistical significance of this finding and provide justification for your comment. Define Risk factor and Relative risk.

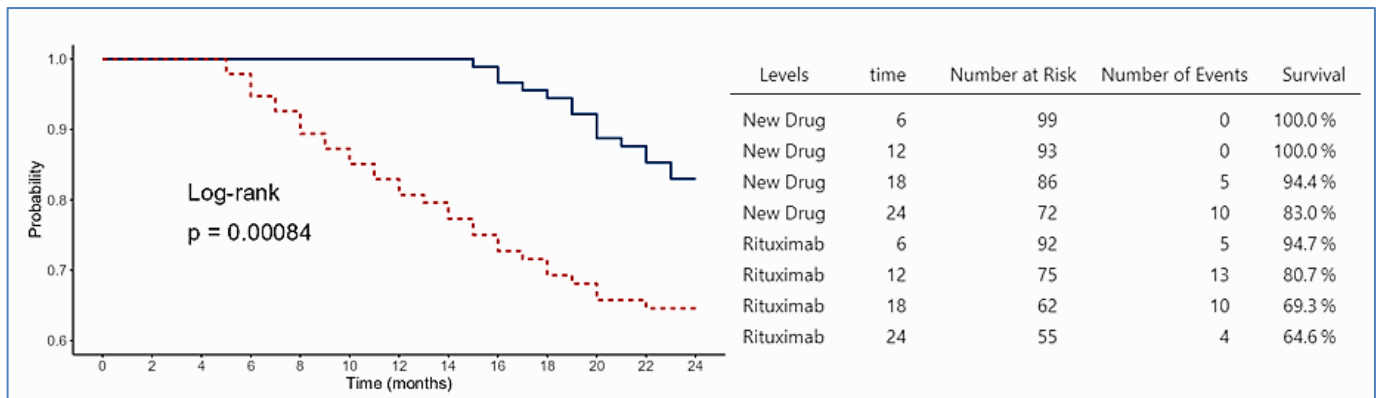
Q.17. You are conducting a study in a clinic to validate a new rapid NAAT (Nucleic Acid Amplification Test) test against the Sputum Culture (Gold Standard) for diagnosis of Pulmonary Tuberculosis.

You enroll a total of 100 patients with cough symptoms. Based on the Culture (Gold Standard), 20 patients are confirmed to have TB. Among the 20 diseased patients, the NAAT correctly identified 16 as positive. Among the 80 non-diseased patients, the NAAT incorrectly identified 4 as positive.

Questions:

- Construct the 2x2 Table.
- Calculate Sensitivity.
- Calculate Specificity.
- Define Negative Predictive Value (NPV).

Q.18. Analyze the Kaplan-Meier chart and survival table below based on analysis of recurrence (Event) following Rituximab or New Drug among Lymphoma patients



Answer the questions-

- Compare the survival with Rituximab and New drug at time 0, 12 months, and 24 months.
- Calculate the Absolute Survival Benefit of the New Drug compared to Rituximab at the 24-month.
- Interpret the image explaining the p Value.
- In the **New Drug** group, look at the time interval between **6 months** and **12 months**. The Number at Risk drops from **99** to **93**, yet the Number of Events is listed as **0**. Explain why the number at risk decreased if no one relapsed.

Q.19. Define the terms “diagnosis” and “prognosis” in clinical epidemiology. Describe the significance of sensitivity, specificity, likelihood ratio, ROC curve, survival analysis, and censoring in hospital management.