Enrolment No.: .....

IIHMR UNIVERSITY

School of Pharmaceutical Management

MBA Pharmaceutical Management

Batch-16th (2024-2026)

First Year, Term 1, End Term Examinations, December 2024

CC – 617 Essentials of Pharmaco-epidemiology

Time - 3 Hour **Maximum Marks: 50 (Minimum Marks: 20)**

Instructions to students:

- **This question paper contains 2 printed pages.**
- **Don't write anything on the Question Paper except your Enrolment No.**

Part A

(Maximum Marks: 5)

Q1. Choose the correct option / Fill in the blank / Answer in one word, as applicable for the following (1 mark each):

(a). Pharmacoepidemiology is the study of _____ and _____ of drugs in populations.

(b). The term "confounding" in epidemiological studies refers to:
(i) Random error
(ii) Bias introduced by a third variable
(iii) A false positive result
(iv) The ethical implications of a study

(c). Calculate the % of ADR cases if a study observed 120 ADRs among 10,000 treated patients.

(d). The probability of correctly identifying a drug-related adverse event is measured by the _____ of the detection method used.

(e). In a cross-sectional study, data is collected:
(i) At a single point in time
(ii) Over a long period of time
(iii) At different points in time
(iv) After a specific intervention

Part B

(Maximum Marks: 15)

Answer the following questions (5 mark each).

Q2. Discuss the role of Pharmacovigilance in assessing adverse drug reactions (ADRs) and explain methods of reporting ADRs in healthcare practice.

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Q3. Compare the roles of observational and experimental studies in Pharmacoepidemiology with examples.

Q4. In a study of drug utilization patterns, 250 prescriptions were analyzed. Out of these, 100 included antibiotics, and 50 of these were determined as inappropriate. Calculate the following:

(a). Proportion of antibiotic prescriptions.

(b). Proportion of inappropriate antibiotic prescriptions.

(c). Suggest strategies to improve appropriate use of antibiotics in clinical practice.

Part C

(Maximum Marks: 30)

Answer the following questions in detail (10 mark each).

Q5. A cohort study included 1,000 patients, where 600 were exposed to a new drug, and 400 were not. Among the exposed group, 180 developed an ADR. In the non-exposed group, 40 developed an ADR.

(a). Calculate the rates/ratio, Risk Ratio (RR), Odd's Ratio (OR), Attributable Risk (AR), Absolute Risk Reduction (ARR), and Number Needed to Treat/Harm (NNT/NNH).

(b). Interpret the results and their implications for patient safety.

Q6. In a clinical trial conducted to evaluate the performance of a new medical device for diagnosing a specific disease. Results were observed as: out of 900 individuals tested, 450 individuals were identified as positive by the device while 50 healthy individuals were incorrectly identified as disease-positive by the device. 430 individuals who were healthy were correctly identified as disease-negative by the device while 20 disease-positive individuals were incorrectly identified as disease-negative by the device.
Using this data, calculate the following diagnostic performance parameters and share your analysis based on these:

(i) Sensitivity
(ii) Specificity
(iii) Positive Predictive Value (PPV)
(iv) Negative Predictive Value (NPV)
(v) Efficiency of the test
(vi) Odds Ratio (OR)
(vii) Risk Ratio (RR)
(viii) Absolute Risk (AR)
(ix) Absolute Risk Reduction (ARR)
(x) Number needed to be treated (NNT)

Also share which parameter/s were able to describe the result properly.

Q7. Discuss the impact of Pharmacoeconomics on the pricing and reimbursement policies for drugs. Use cost-minimization and cost-effectiveness examples to justify your points.

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