

**UNIVERSITY OF JAFFNA, SRI LANKA**  
**BACHELOR OF PHARMACY**  
**FOURTH YEAR FIRST SEMESTER EXAMINATION in BPharmHons - 2023**  
**PHAPE 4152 PHARMACOEPIDEMIOLOGY**

Date: 12.12.2024

Time: 02 hours

**ANSWER ALL FOUR QUESTIONS.**

**ANSWER PART A & B IN SEPARATE ANSWER BOOKS.**

**Part A**

- 1 1.1 An FDA approved medication "P" has been newly introduced to the market to reduce the risk of hypercholesterolaemia in patients with diabetes. A pharmacoepidemiologic study was designed to evaluate the efficacy of medication "P" in preventing hypercholesterolaemia among diabetic patients from a hospital. There were no deaths reported during the study period and all the patients remained.

Table 1 illustrates the results of this pharmacoepidemiologic study

**Table 1** Trends in hypercholesterolemia among diabetic patients taking medication "P"

Year	Total number of diabetic patients who have hypercholesterolemia	Total number of diabetic patients who take medication "P"
2022	25	500
2023	30	600

- 1.1.1 Define the terms prevalence and incidence. (10 Marks)
- 1.1.2 Calculate the prevalence of hypercholesterolemia in the year of 2022. (10 Marks)
- 1.1.3 Calculate the prevalence of hypercholesterolemia in the year of 2023. (10 Marks)
- 1.1.4 Calculate the incidence of hypercholesterolemia in the year of 2023 and interpret. (15 Marks)
- 1.2 In a study to evaluate the risk of allergic reactions due to amoxicillin in a ward, 25 patients among 1000 patients who have been prescribed with amoxicillin and 35 patients out of 2000 patients who have not been prescribed with amoxicillin have developed allergic reactions.
- 1.2.1 Prepare a  $2 \times 2$  table (20 Marks)
- 1.2.2 Calculate relative risk. (20 Marks)
- 1.2.3 Interpret the relative risk calculated in question 1.2.2. (15 Marks)

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- 2.1 2.1.1 List two (02) pharmacoepidemiologic analytical study methods. (10 Marks)
- 2.1.2 Briefly describe the advantages and disadvantages for each study methods mentioned in 2.1.1. (30 Marks)
- 2.1.3 Name one (01) main indication for each study method mentioned in 2.1.1. (10 Marks)
- 2.2 2.2.1 List two (02) pharmacoepidemiologic descriptive study methods. (10 Marks)
- 2.2.2 Briefly describe the two (02) pharmacoepidemiologic descriptive study methods mentioned in 2.2.1. (30 Marks)
- 2.3 You are requested to do a study to assess whether medications used to treat hypertension decrease or increase the risk of cardiovascular diseases. Name the pharmacoepidemiologic method that can be used for this study. (10 Marks)
- 3 3.1 Write short notes on
- 3.1.1 spontaneous reporting in Ad Hoc data sources. (15 Marks)
- 3.1.2 automated data systems. (15 Marks)
- 3.1.3 hospital pharmacoepidemiology. (20 Marks)

### Part B

3

- 3.2 3.2.1 What is prescription event monitoring (PEM)? (10 Marks)
- 3.2.2 Briefly describe the purpose of sending a personalized questionnaire to prescribers in PEM. (20 Marks)
- 3.2.3 Mention the outcome measure that is used to calculate the incidence density in PEM. (05 Marks)
- 3.2.4 List three (03) advantages of PEM. (15 Marks)
- 4 4.1 List the major components of a pharmacy-based medical record linkage system. (15 Marks)
- 4.2 Mention the record linkage method that is used when a record pair is classified as a 'match' based on the unique personal identification number in two records. (05 Marks)
- 4.3 Briefly describe the need for using self-controlled study designs to assess the vaccine safety. (20 Marks)



**4.4** A community-based case-control study was conducted to evaluate the occurrence of neural tube defects in newborns from January to December 2023 in relation to the maternal exposure to selected anticonvulsants (carbamazepine, phenobarbital and phenytoin).

Cases consisted of the mothers of 25 infants diagnosed with a neural tube defect. Control group consisted of the mothers of 55 healthy infants with no malformations. Mothers were interviewed within 6 months of delivery about the demographic factors and the usage of the selected anticonvulsants during the first or second months after the last menstrual period.

10 mothers of the infants diagnosed with a neural tube defect and 5 mothers from the control group have reported the usage of the selected anticonvulsants.

**4.4.1** Prepare a  $2 \times 2$  table. **(10 Marks)**

**4.4.2** Calculate the odds ratio. **(20 Marks)**

**4.4.3** Interpret the odds ratio calculated in 4.4.2 **(10 Marks)**

**4.4.4** Give four (04) potential biases that could be observed in this study. **(20 Marks)**