M. SC. (APPLIED STATISTICS) (MSCAST)

Term-End Examination

June, 2025

MST-019 : EPIDEMIOLOGY AND CLINICAL TRIALS

Time: 2 Hours Maximum Marks: 25

Note: Question No. 1 is compulsory. Attempt any two questions from question numbers 2 to 4. Use of Scientific (nonprogrammable) calculator is allowed. Symbols have their usual meanings.

- (a) Suppose, we have 1000 males and 500 females in an epidemiological study.
 What is the odds of being a female in the study?
 - (b) Calculate the crude death rate and infant mortality rate of a town whose

mid-year population is 5,00,000, live births in a year is 15,000, number of deaths in 7,000 and the number of infant deaths in 1875.

Select the appropriate option from the following questions (c) and (d):

- (c) In a double-blind trial:
 - (i) The patients do not know that they are receiving active treatment or placebo.
 - (ii) The assessors do not know which patient has received active treatment and which placebo.
 - (iii) Both of the above
 - (iv) The patients and the statistician do not know the allocation.
- (d) A clinical trial must involve: 1
 - (i) Randomisation
 - (ii) Control group
 - (iii) Blinding
 - (iv) None of the above

2. (a) Find the risk difference, risk ratio and odds ratio for lung cancer comparing smokers (exposed group) to nonsmokers (non-exposed group) from the data given as follows (Period of followup is 20 years):

	Lung Cancer (+)	Lung Cancer (–)	Total
Smokers	1200	1800	3000
Non-smokers	800	2400	3200
Total	2000	4200	6200

Also, interpret the result.

- (b) If the odds of males in a study are 0.40, then find the proportion of males in the study.
- Consider a trial on n = 16 patients of (c) kidney disease, randomly divided into two equal groups of size 8. The first group received dialysis-A and then dialysis-B, and the second group received dialysis-B and then dialysis-A. Abbreviate them as tr A and tr B. Washout period between the dialyses ensured that there was no carry-over effect. The response variable is serum creatinine level. This is one of the

parameters of kidney function, measured as mg/dL. The data obtained are as follows:

Group-I-AB Sequence

Subject No.		1	2	3	4	5	6	7	8
Period 1	tr A	1.2	1.0	0.8	0.7	1.3	1.2	1.1	1.5
Period 2	tr B	1.2	1.2	1.4	1.3	1.3	1.1	1.2	1.2

Group-II-BA Sequence

Subject No.		9	10	11	12	13	14	15	16
Period 1	tr B	1.7	1.4	1.0	1.3	0.9	1.3	1.2	1.2
Period 2	tr A	1.3	1.5	1.1	1.3	1.4	1.3	1.4	1.2

Test for group effect (use $t_{(14,0.025)} = 2.145$.)

- 3. For a case control study, explain the following in detail: 4+3+3
 - (i) Design of case control study
 - (ii) Analysis of data of case control study design
 - (iii) Advantages and disadvantages of case control study design
- 4. For a clinical trial, explain the following terms: 6+2+2
 - (i) Protocol
 - (ii) Objectives
 - (iii) Hypothesis

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