POST GRADUATE DIPLOMA IN BIOETHICS (PGDBE)

Term-End Examination

December, 2015

MHS-014 : RESEARCH METHODOLOGY

Time : 2 hours   *Maximum Marks : 70*

PART - A

Attempt **all** questions. Each question carries **one (1)** mark. Select the most appropriate answer from the given alternatives for each of the following questions. Write answer in the Answer Sheet provided :   **1x50=50**

1. A phase 4 trial evaluates :
    (1)   Dosage
    (2)   Delivery mechanisms
    (3)   Short term safety
    (4)   Long term safety

2. The process to assign patients without bias to different patient groups in a clinical trial is called :
    (1)   Allocation
    (2)   Assignment
    (3)   Randomization
    (4)   Blinding

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3. The use of serially numbered opaque sealed envelopes is a method for :
   (1) Allocation concealment
   (2) Randomization
   (3) Blinding
   (4) Interventional compliance

4. Analysis by intention to treat is carried out without considering all of the following except :
   (1) Protocol deviation
   (2) Allocation assignment
   (3) Compliance
   (4) Withdrawal

5. A trial can be stopped before completion because of :
   (1) Unacceptable side effects
   (2) Fraud or misconduct
   (3) Treatment arm is convincingly different
   (4) All of the above

6. An example of an analytical study design is :
   (1) Case series
   (2) Case control
   (3) Cross-sectional
   (4) Ecological

7. A case control study :
   (1) May begin with exposure
   (2) Always begins with exposure
   (3) May begin with disease
   (4) Always begins with disease

8. Multiple outcomes are best studied in :
   (1) Randomized controlled trial
   (2) Case-control study
   (3) Cohort study
   (4) None of the above

9. When the period of follow up in a study varies, appropriate analytic techniques include :
   (1) Survival analysis, which predicts probability of an event at any point in the study
   (2) Proportional hazards model which provides a hazard ratio, similar to relative risk
   (3) Both of the above
   (4) Neither of the above

10. The advantages of a cohort study are all of the following except :
    (1) Ability to assess incidence
    (2) Ability to assess rare exposures
    (3) Ability to assess rare outcomes
    (4) Ability to study temporality between exposure and outcome

11. Which of the following is not included in the Bradford-Hill criteria for assessing causality ?
    (1) Consistency
    (2) Sensitivity
    (3) Specificity
    (4) Temporality

12. If 400 people are surveyed and 40 are found to have hypertension, the survey has measured :
    (1) Disease frequency
    (2) Disease probability
    (3) Disease incidence
    (4) Disease prevalence

13. Incidence rates can be best calculated in :
    (1) Case series
    (2) Case control studies
    (3) Cohort studies
    (4) Randomized controlled trials

14. A random error :
    (1) Is transient, inconsistent and cannot be corrected
    (2) Is not affected by sample size
    (3) Can be controlled by increasing accuracy
    (4) Can be corrected by adjusting for the error in measurement

15. Sources of variation in measurement may arise from :
    (1) Instrument
    (2) Observer
    (3) Biologic differences
    (4) All of the above

16. James Lind carried out the first controlled clinical trial. The disease he studied was :
    (1) Pellagra
    (2) Rickets
    (3) Scurvy
    (4) Angular chelitis

17. Critical evaluation of the quality of study requires all of the following except :
    (1) An understanding of study design
    (2) An understanding of analysis methods
    (3) An ability to reproduce the study
    (4) An ability to assess the strength of evidence

18. Translational research is :
    (1) Cycling of research and feedback from laboratory to clinic to laboratory
    (2) Development of potential new therapeutic modalities
    (3) Evaluation of safety and efficacy of treatment
    (4) Research conducted in an area with a predominantly different language

19. Preclinical research refers to :

(1) Testing of new products before marketing

(2) Testing of drug levels in patients to determine optimal dose

(3) Development of potential new therapeutic modalities

(4) Development of methods for evaluation of efficacy

20. An independent variable in a study :

(1) Is a parameter that can be determined or manipulated at the outset

(2) Is an outcome that is determined by an unbiased observer

(3) Cannot be determined by inclusion and exclusion criteria

(4) Can only be a single variable

21. T-tests are most useful for what type of data ?

(1) Continuous

(2) Ordinal

(3) Nominal

(4) Binary

22. Level of measurement for the variable temperature is :

(1) Nominal

(2) Ordinal

(3) Interval

(4) Ratio

23. If the grading of diabetes is classified as mild, moderate and severe the scale of measurement used is :

(1) Interval

(2) Nominal

(3) Ordinal

(4) Ratio

24. Appropriate graphical representation for the discrete data is :

(1) Bar graph

(2) Histogram

(3) Line chart

(4) None of the above

25. Variables which can be experimentally manipulated by an investigator are called :

(1) Dependent variables

(2) Independent variables

(3) Confounding variables

(4) Extraneous or secondary variables

26. Suppose that the probability of event A is 0.2 and the probability of event B is 0.4. Also, suppose that the two events are independent. Then $P(A/B)$ is :

(1) $P(A) = 0.2$

(2) $P(A)/P(B) = 0.2/0.4 = 1/2$

(3) $P(A) \times P(B) = (0.2)(0.4) = 0.08$

(4) None of the above

27. A sampling distribution is the probability distribution for which one of the following :

(1) A sample

(2) A sample statistic

(3) A population

(4) A population parameter

28. Which of the following statements best describes the relationship between a parameter and a statistic ?
    (1) A parameter has a sampling distribution with the statistic as its mean
    (2) A parameter has a sampling distribution that can be used to determine what values the statistic is likely to have in repeated samples
    (3) A parameter is used to estimate a statistic
    (4) A statistic is used to estimate a parameter

29. Which of the following is the most common example of a situation for which the main parameter of interest is a population proportion ?
    (1) A binomial experiment
    (2) A normal experiment
    (3) A randomized experiment
    (4) An observational study

30. The expected value of a random variable is the :
    (1) Value that has the highest probability of occurring
    (2) Mean value over an infinite number of observations of the variable
    (3) Largest value that will ever occur
    (4) Most common value over an infinite number of observations of the variable

31. Which one of these variables is a binomial random variable ?
    (1) Time it takes a randomly selected student to complete a multiple choice exam
    (2) Number of textbooks a randomly selected student bought this term
    (3) Number of women taller than 68 inches in a random sample of 5 women
    (4) Number of CDs a randomly selected person owns

32. Hallmark of the qualitative study is :
    (1) It is contextual and the context is studied
    (2) It is subjective and acknowledges this truth
    (3) It is often naturalistic and interpretive
    (4) All of the above

33. A sample mean is a _____ estimate and we do not know how close it is to the population mean.
    (1) Point
    (2) Sample
    (3) Distribution
    (4) Confidence

34. Which of the following is a measure based on every item of the observation ?
    (1) Mode
    (2) Standard Deviation
    (3) Range
    (4) Quartile Deviation

35. Which one of the following is stronger correlation ?
    (1) – 1
    (2) 0.98
    (3) 0.0
    (4) 0.5

36. In a single-factor ANOVA, the computed value of F will be zero when :
    (1) There is no difference in the treatment means
    (2) There is no difference in the block means
    (3) The data are skewed left
    (4) F will never be zero

37. To test whether or not two population variances are equal, the appropriate distribution is :
  (1) Z distribution
  (2) Chi-square distribution
  (3) F distribution
  (4) T distribution with $n1 + n2 - 2$ degrees of freedom

38. Error deviations measure distances :
  (1) Within groups
  (2) Between groups
  (3) Both (1) and (2)
  (4) None of the above

39. A larger sample size is required when :
  (1) The population of interest for a study is less diverse
  (2) A low level of precision is required
  (3) The population of interest is easily recruited to the study
  (4) High level of precision is required

40. Representative sample is used so that the results of a study are :
  (1) Reliable
  (2) Generalisable
  (3) Convenient
  (4) Limited

41. Statistical test allows us to make inference based on which of the following ?
  (1) Standard Deviation
  (2) Population
  (3) Sample
  (4) All of the above

42. A random sample is expected to approximate a normal distribution because :

(1) A small sample size is not an issue

(2) There are equal numbers of below and above average cases

(3) The sample will contain mainly average cases

(4) The goal is to maximise the sampling error

43. The population from which the study sample is selected is called the :

(1) Accessible population

(2) Target population

(3) Total population

(4) Universal population

44. A clinical trial is more valuable when :

(1) Sensitivity and Specificity have higher values

(2) Sensitivity is higher than specificity

(3) Specificity is higher than sensitivity

(4) The sensitivity and specificity values are close, even equal, regardless of their values

45. In which of the following conditions, there is no need for informed consent from patients ?

(1) Vaccination

(2) Abortion

(3) Research on children

(4) Incompetence adults

46. A research team is evaluating the prevalence of diabetes patients presenting to a community hospital. All patients presented to the hospital are prospectively analyzed, and the percentage of diabetes is determined during a period of one month. Which of the following term describe this study ?

(1) Case-control study

(2) Case report

(3) Cohort study

(4) Cross-sectional study

47. A multi-center clinical trial in lung cancer is comparing traditional treatment, and a new treatment protocol. The remission rates are found to be similar for both traditional treatment and the new one. P value is 0.45. Which of the following conclusion can be reached ?

(1) Both traditional and new drugs are effective in lung cancer

(2) Not enough information to have conclusion

(3) Neither is effective

(4) Statistical power of the study is 55%

48. A prospective or longitudinal study is the same as which of the following terms ?

(1) Cohort study

(2) Cross-sectional study

(3) Case-control study

(4) Randomized controlled trial

49. Which of the following is not an essential element of report writing ?

(1) Research Methodology

(2) Reference

(3) Conclusion

(4) None of these

50. Testing a hypothesis is a _____.
    (1) Inferential statistics
    (2) Descriptive statistics
    (3) Data preparation
    (4) Data analysis

PART - B

Write short notes (in about **200-300** words) on **any four** of the following. Each carries **five (5)** marks.   **5x4=20**

51. Measures of Central Tendency

52. Graphical Presentation of data

53. Assessing strength of evidence in clinical research

54. Odds Ratio of Relative Risk

55. Chi-Square Test

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