



TECHNICAL UNIVERSITY OF MOMBASA

FACULTY OF APPLIED AND HEALTH SCIENCES

DEPARTMENT OF ENVIRONMENT & HEALTH SCIENCES

UNIVERSITY EXAMINATION FOR:

MASTER OF PUBLIC HEALTH

APH 5114: EPIDEMIOLOGY IN PRACTICE

END OF SEMESTER EXAMINATION

SERIES: AUGUST 2019

TIME: 3 HOURS

DATE: Pick Date Jul 2019

Instructions to Candidates

You should have the following for this examination

-Answer Booklet, examination pass and student ID

This paper consists of Choose Nochoose Sect/Quest. Attempt Choose instruction.

Answer question ONE (COMPULSORY) and any other three questions

Do not write on the question paper.

QUESTION ONE

(30 MARKS)

- a) Describe three methods for controlling confounding in the study design, and give one advantage and one disadvantage for each method (6 marks)

- b) An investigator proposes to work with the community organization of a population where many of the residents are exposed to high levels of mercury through occupational exposure. A previous study indicated that the harms resulting from exposure to a similar heavy metal contaminant could be mitigated through the use of a behavioral intervention. The investigators propose testing the intervention to see if mercury exposure can be reduced in this population. The research design involves randomizing human subjects either to the experimental behavioral intervention in addition to conventional therapy, or to conventional therapy alone. Should the behavioral intervention be determined to be successful, participants who received only conventional therapy will be offered the behavioral intervention after the completion of the study. Research participants will know which intervention they receive because conventional therapy does not include a behavioral component. Does this study require a data and safety monitoring plan? (4 marks)

- c) A case-control was conducted to determine if using antihistamines around the time of conception increased the risk of birth defects in the offspring. No personal interviews were conducted regarding the antihistamine use. Instead, women were considered exposed if computerized pharmacy records from their health maintenance organizations indicated that they had filled at least one prescription for antihistamines within 500 days before the birth of the child (4 marks)
- Which type of information bias is this data collection method most susceptible to?
 - Which type of information bias is this data collection method least susceptible to?
- d) Some types of research involve a significant commitment from research participants in terms of time or effort, and investigators may wish to provide compensation. During the informed consent process, investigators should explain to potential research participants that compensation **is not** a benefit of the research and explain situations in which compensation may be provided. Describe the information that investigators should provide to potential research participants during the consenting process (6 marks)
- e) After the conclusion of a clinical trial in a small rural community, an investigator is anxious to publish findings. Understanding the research grant donor policies which encourage the reporting of demographic differences in intervention effect, and concerned about protecting the confidentiality of research participants, the investigator publishes only general demographic data such as sex, age, state, and county. Is this an appropriate and acceptable way to protect the confidentiality of research participants? (4 marks)
- f) Each of the following problems represents a major threat to the validity of an experimental study. Briefly describe one method for avoiding these problems (6 marks).
- Low compliance (2 marks)
 - Lack of baseline comparability (2 marks)
 - Biased information on the outcome (2 marks)

QUESTION TWO (30 MARKS)

- a) A child has a rare genetic disorder. No treatment is currently available. You have designed a longitudinal study that will examine the progression of the disorder. The study will involve standard physical and psychological examinations, including drawing 10ml of blood 4 times per year.

After enrolment, at which time the parents provided permission for the child to participate in the study and the child provided assent, he panics and screams that he doesn't want to participate and wants to go home when he sees the nurse holding a needle for the blood draw. The parents are present and want the child to participate. What ethical issues should the investigator consider when making the decision on how to proceed? (10 marks)

- b) In research ethics, risk is the "probability that certain harm will occur." All research involves some level of risk. Discuss the five types of risks that individuals may be exposed to when participating in research (20 marks)

QUESTION THREE (30 MARKS)

The 58th annual convention of the American Legion was held Philadelphia from July 21 until July 24, 1976. People at the convention included American Legion delegates, their families, and other Legionnaires who were not official delegates. Between July 20 and August 30, some of those who had been present became ill with type of pneumonia that was subsequently named Legionnaires' disease. No one attending the convention developed the disease after August 30. The numbers of delegates and non-delegates who developed Legionnaires' disease during the period July 20 to August 30 (a 41-day period) are as follows:

Convection status	Developed Legionnaire's disease		
	Yes	No	Total
Delegate	125	1724	1849
Non-delegate	3	759	762

- Compute the cumulative incidence of Legionnaires' disease among delegates and non-delegates (4 marks)
- Calculate the cumulative incidence ratio of Legionnaires' disease among delegates compared with non-delegates (4 marks)
- State in words the meaning of this measure (5 marks)
- Calculate the cumulative incidence difference of Legionnaires' disease among delegates compared with non-delegates (4 marks)
- State in words the meaning of this measure (4 marks)
- Calculate the attributable proportion of Legionnaires' disease among the delegates (5 marks)
- State in words the meaning of this measure (4 marks)

QUESTION FOUR (30 MARKS)

These data are from a case-control study on biomass cooking fuel exposure and tuberculosis [Perez-Padilla et al. Int J Tuberc Lung Dis 2001;5:1-7.]. Cases were 288 patients with an active smear or culture positive tuberculosis, and controls were 545 patients with ear, nose and throat ailments from the same hospital, seen at the same time. Past or present exposure to biomass smoke was obtained by interview. The table gives the data for the association between current exposure to biomass smoke and TB:

Biomass exposure status	Cases	Controls	Total
Exposed	50	21	71

Unexposed	238	524	762
Total	288	545	833

The authors found a significant association between indoor smoke and TB (OR = 5.2). After adjusting for several confounders, a significant association remained (adjusted OR = 2.2).

- a. In this study, exposure assessment was made by interviews. If tuberculosis patients provide more accurate histories about past exposure to biomass smoke compared to controls, what bias can occur? Would it be differential or non-differential? (3 marks)
- b. If tuberculosis patients changed their cooking fuel to cleaner fuels like gas after developing the disease, how could it affect the odds ratio for current use of a biomass stove? (3 marks)
- c. In this study, patients with ear, nose and throat (ENT) conditions were chosen as controls. If some ENT conditions are associated with biomass smoke (like allergic rhinitis), could this affect the odds ratio? What would this type of bias represent? (4 marks)
- d. If cases and controls had similar problems in remembering the cooking fuels they used in the past, what type of misclassification could have occurred? How will that affect the odds ratio? (4 marks)
- e. If the interviewers who did the exposure assessment had known the disease status of the cases and controls, how could this have affected the odds ratio? What type of bias would this be? (4 marks)
- f. Biomass smoke is known to contain many toxic chemicals. If exposure to biomass smoke is one cause of tuberculosis, and if it leads to rapid progression of disease and death among these patients, how would it affect the odds ratio in a case-control study examining biomass smoke as a risk factor for TB? (4 marks)
- g. The authors could have improved the measurement of exposures in this study by actually quantifying indoor air pollution levels due to biomass smoke using instruments. If they had done that, how would it have affected the precision of their OR estimates? (4 marks)
- h. Suppose instead of interviews, biomass smoke exposure was assessed using air monitors worn by individuals in the study. You classify exposure to biomass smoke as high, medium and low using the monitor results. After you finish your study, the monitor company calls to tell you their monitors have been acting strangely. A random set of monitors in your study malfunctioned such that some over-estimated smoke exposure while others under-estimated smoke exposure (malfunctions affected cases and controls equally). What, if anything, can you say about the odds ratios you calculated in your study? (4 marks)

QUESTION FIVE**(30 MARKS)**

The following questions relate to the paper:

Mausezahl D et al. Solar drinking water disinfection (SODIS) to reduce childhood diarrhoea in rural Bolivia: cluster-randomized, controlled trial. PLoS Med 6(8) 2009. (Article provided)

- a. Describe the randomization process used in this study. Specifically, discuss the unit of randomization and method of randomization (6 marks)
- b. What is the main benefit of randomization? What is the main worry regarding randomization when conducting cluster-randomized trials (6 marks)
- c. The authors explain how they assessed compliance (page 3 column 2). Explain why it is important to evaluate compliance (adherence) in trials. How should non-compliance be handled in the analysis if you use a per protocol analysis? What about intent to treat analysis? (6 marks)
- d. Discuss how compliance affected efficacy vs. effectiveness in the laboratory setting, previous RCTs and in the Mausezahl study (6 marks)
- e. Would it have been possible to blind participants and/or assessors in this trial? Please explain your response (6 marks)

QUESTION SIX**(30 MARKS)**

- i. Public health practitioners wanted to evaluate the impact of a community-wide bicycle safety intervention on the incidence of head concussions. Community A was exposed to an intensive bicycle helmet use campaign, and community B, which did not receive the intervention, was chosen as a comparison population. Rates of injury associated with bicycle accidents and the use of helmets were measured in both communities.

Table 1 below presents data on the “true” injury status of study participants. Although generally the extent of misclassification is unknown to the investigators, in this example we know both the “true” injury classification status and the proportions of injured and not injured individuals that are misclassified with respect to head injury status.

Table 1: True injury status (injured vs. not injured)

	Injured	Not injured	Total
Community A	40	60	100
Community B	20	80	100

- a. Calculate the relative risk of injured participants in Community A vs. Community B (3 mark)

- b. Suppose that 20% of participants with head injuries are incorrectly classified as not injured, and that 5% of participants without head injuries were incorrectly classified as injured. This misclassification of injury occurs irrespective of community of residence (the “exposure”). Fill in the cells for the “observed” data in Table 2, below and calculate the relative risk based on the data in Table 2 (as if misclassification of injury had occurred) (5 marks)

Table 2: “Observed” injury status (injured vs. not injured)

	Injured	Not injured	Total
Community A			100
Community B			100

- c. What type of misclassification is apparent? (4 marks)
- d. Compare this “observed” relative risk to the true relative risk that we found with no misclassification present (calculated in part A above) (3 marks)
- e. Describe what particular concerns in regards to selection bias are associated with case-control studies and cohort studies (5 marks)
- ii. It has recently been reported that, in the 1950s, researchers conducted prostate biopsies on over 1,000 individuals who were homeless and addicted to alcohol on "skid row" in New York's Bowery area. The purpose of the research was to learn whether this procedure could diagnose prostate cancer early and, if detected, study the effectiveness of various treatments. While the biopsy procedure had been used in patients with prostate problems, it had not been used in the general population to screen for prostate cancer. These homeless alcohol addicts were used as subjects because no one else would volunteer for such an invasive study. The subjects were offered free meals, shelter, and treatment in return for being subjects in the research. While they were told about the procedure, they were not told about the risks of the biopsy or of the treatments. In what way does this research violate the Belmont’s principles of justice, respect for persons and beneficence?