

BI476: Biostatistics - Case Studies

Assignment 2: Observational Studies

Spring, 2018

1 Case Report and Case Series

1.1 True or False

- (1) Case reports are not considered evidence-based study because they involve only one or several patients and are thus not systematic research.
- (2) Case reports can demonstrate causality or argue for the adoption of a new treatment approach.
- (3) The patient should be described in detail, allowing others to identify patients with similar characteristics.

2 Cross-sectional Studies

One hundred healthy troops go on a 1-year mission to a malariandemic area of North Africa. During their stay 5 new cases of malaria are identified, for a rate of 5%. This number is a:

- (A) prevalence rate
- (B) mortality rate
- (C) incidence-density rate
- (D) cumulative-incidence rate

Among untreated children under age 3, 20% of malaria cases are fatal. 20% is a:

- (A) case-fatality rate
- (B) mortality rate
- (C) attack rate
- (D) prevalence

During the past year, 7 new cases of multiple sclerosis were diagnosed in your community of 100,000 people. At any one time during the year, the prevalence of multiple sclerosis in your community was probably.

- (A) Substantially higher than 7/100,000
- (B) Substantially lower than 7/100,000
- (C) About 7/100,000
- (D) Equal to the cause-specific mortality rate

3 Case-Control Studies

3.1 Read the three articles

- Chambers C., et al. Selective serotonin-reuptake inhibitors and risk of persistent pulmonary hypertension of the newborn. NEJM 2006; 354(6): 579-587.

- Smedby K., et al. Autoimmune and chronic inflammatory disorders and risk of non-hodgkin lymphoma by subtype. JNCI 2006; 98(1): 51-60.
- Teo, K. et al. Tobacco use and risk of myocardial infarction in 52 countries in the INTERHEART study: A case-control study. Lancet 2006; 368(9536): 647-658.

and then answer the following questions.

- (1) Is this article paired or not?
- (2) Print out the contingency tables.
- (3) Can you compute each effect size (OR) of the association, also the corresponding 95% confidence interval, and the *p*-value.
- (4) Did the authors use appropriate inclusion and exclusion criteria to avoid effects of confoundings? Why?

3.2 Answer the question

How to correct for the effect of confounding factors on the association between the outcome and exposure of interest? Can you post some of the commonly-used methods.

3.3 Choices

1. Three years ago there was a multistate outbreak of illnesses caused by a specific and unusual strain of *Listeria monocytogenes*. As part of the investigation of this outbreak, CDC workers checked the food histories of 20 patients infected with the outbreak strain and compared them with the food histories of 20 patients infected with other *Listeria* strains. This study design is best described as which one of the following:

- (A) Analytical, experimental
- (B) Analytical, observational, case-control
- (C) Analytical, observational, cohort
- (D) Descriptive

2. The initial studies establishing maternal diethylstilbesterol (DES) intake as a cause of vaginal adenocarcinoma in female offspring were case-control studies. This was probably largely because:

- (A) A couple of decades ago cohort studies hadn't been invented.
- (B) A woman taking DES was always rare.
- (C) The disease outcome is rare.
- (D) The investigators had probably just happened to have a number of cases in their practices.

3. In a case-control study of alcohol intake and bladder cancer, cases and matched controls are each interviewed by interviewers who are not blinded as to whether the subject is a case or a control. Many of the interviewers are in fact convinced that drinking alcohol is a cause of bladder cancer. Is this likely to represent a bias?

- (A) No, because the interviewers can't affect whether the subjects are considered cases or controls; that's already decided
- (B) Yes, but it's hard to predict the direction of the bias.
- (C) Yes, and would predispose to a rejection of the null hypothesis.
- (D) Yes, and would predispose to an acceptance of the null hypothesis.

4 Cohort Studies

4.1 Choices

1. A published study follows a large group of women with untreated dysplasia of the uterine cervix, documenting the number who improve, stay unchanged, or progress into cervical cancer. This study design is best described as which one of the following:

- (A) Analytic, experimental
- (B) Analytic, observational, cohort
- (C) Analytic, observational, case/control
- (D) Descriptive, observational

2. A community assesses a random sample of its residents by telephone questionnaire. Obesity is strongly associated with diagnosed diabetes. This study design is best described as which one of the following:

- (A) Case-control
- (B) Cohort
- (C) Cross-sectional
- (D) Experimental

4.2 Cytomegalovirus and coronary restenosis

Each year cardiologists perform procedures to blocked coronary arteries only to have may of these repaired arteries re-clog (restenosis) afterwards. A study sponsored by the NIH Heart, Lung and Blood Institute was performed to determine whether prior

infection with cytomegalovirus was predictive of arterial restenosis. In 21 of the 49 patients with serologic evidence of cytomegalovirus infection, re-growth of arterial plaque was noted. In contrast, only 2 of the 26 patients seronegative patient had restenosis.

- (1) Calculate the risk ratio of restenosis associated with CMV infection. Include a 95% confidence interval.
- (2) Try to interpret results.
- (3) Conduct a chi-square test of $H_0 : RR = 1$.