TT TEXTBOOK TESTBANKS

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CHAPTER 2

1. An investigator wants to assess whether smoking is a risk factor for pancreatic cancer. Electronic medical records at a local hospital will be used to identify 50 patients with pancreatic cancer. One hundred patients who are similar but free of pancreatic cancer will also be selected. Each participant's medical record will be analyzed for smoking history. Identify the type of study proposed and indicate its specific strengths and weaknesses.

Answer:

The study is a case-control study. Patients with pancreatic cancer are considered cases and patients free of cancer are controls. Strengths of the design include cost and time efficiency to identify a sufficient number of cases for analysis. Weaknesses include generalizability (study participants were all patients at one hospital) and ascertainment of exposure status (smoking). Exposure data will be collected from medical records, which may not have smoking recorded accurately.

2. What is the most likely source of bias in the study described in Problem 1?

Answer:

The most likely source of bias is misclassification bias, particularly with regard to classification of smoking status (exposure) because smoking information will be collected from the medical record.

3. An investigator wants to assess whether the use of a specific medication given to infants born prematurely is associated with developmental delay. Fifty infants who were given the medication and 50 comparison infants who were also born prematurely but not given the medication will be selected for the analysis. Each infant will undergo extensive testing at age 2 for various aspects of development. Identify the type of study proposed

and indicate its specific strengths and weaknesses.

Answer:

The study is a cohort study of children born prematurely. The cohort will be designed to include children who were given (exposed) and not given (unexposed) a specific medication after birth. The strengths of the study are its prospective nature, which will allow investigators to estimate incidence of developmental delay in the two comparison groups and also to assess the temporal relationship between exposure and outcome. The major weakness of the study is the possibility of confounding. There may be other exposures, other than the medication, that are not measured that relate to developmental delay.

4. Is bias or confounding more of an issue in the study described in Problem 3? Give an example of a potential source of bias and a potential confounding factor.

Answer:

Confounding is the major issue in this cohort study. Potential confounding factors include other medical treatments for prematurity and specific aspects of infant care (e.g., family, environmental factors). Bias is less of an issue, but misclassification bias could be an issue. If persons assessing the outcome (developmental delay) are aware of exposure status, they might differentially measure outcome status. Selection bias could also be an issue depending on the inclusion and exclusion criteria used to select participants who were exposed and not exposed to the medication.

5. A study is planned to assess the effect of a new surgical intervention for gallbladder disease. One hundred patients with gallbladder disease will be randomly assigned to receive either the new surgical intervention or the standard surgical intervention. The

efficacy of the new surgical intervention will be measured by the time a patient takes to return to normal activities, recorded in days. Identify the type of study proposed and indicate its specific strengths and weaknesses.

Answer:

The study is a randomized controlled trial or a clinical trial. The strengths of the study include randomization, which should minimize confounding. Thus, any observed differences in return to normal activities should be attributable to treatment. One weakness is generalizability. Details are not provided in terms of the number of centers involved: Multiple centers would promote generalizability. Clinical trials are often also criticized for being too narrow, specifically in terms of the patient eligibility criteria.

6. An investigator wants to assess the association between caffeine consumption and impaired glucose tolerance, a precursor to diabetes. A study is planned to include 70 participants. Each participant will be surveyed with regard to their daily caffeine consumption. In addition, each participant will submit a blood sample that will be used to measure glucose level. Identify the type of study proposed and indicate its specific strengths and weaknesses.

Answer:

The study is a cross-sectional survey. The strength of the study is that it will allow for estimation of the prevalence and extent of caffeine consumption and impaired glucose tolerance at a point in time. The weaknesses include inability to assess a temporal relationship and potential for nonresponse (some participants may refuse to provide a blood sample), limiting generalizability. Finally, the inferences that can be made from this study are associational and limited to the time of the study only.

7. Could the study described in Problem 6 be designed as a randomized clinical trial? If so, briefly outline the study design. If not, describe the barriers.

Answer:

To assess the association between caffeine consumption and impaired glucose tolerance in a clinical trial, participants would be randomly assigned to consume caffeine or not. It would likely be very difficult to recruit participants. For example, persons who do not consume caffeine would not participate. Persons who consume caffeine and were randomized to the no caffeine group might decide to have caffeine outside of the study, thereby contaminating the groups.

8. A study is planned to compare two weight-loss programs in patients who are obese. The first program is based on restricted caloric intake and the second is based on specific food combinations. The study will involve 20 participants and each participant will follow each program. The programs will be assigned in random order (i.e., some participants will first follow the restricted-calorie diet and then follow the food-combination diet, whereas others will first follow the food-combination diet and then follow the restricted-calorie diet). The number of pounds lost will be compared between diets. Identify the type of study proposed and indicate its specific strengths and weaknesses.

Answer:

The study is a crossover trial. The strengths include the ability to use each participant as their own control; therefore, there is no issue of comparability between groups in terms of other characteristics. One weakness is the possibility of carry-over effects—participants might get going with weight loss on the first diet and that momentum might carry over to the second. Another potential issue with crossover trials is loss to follow-up. If a

participant drops out of the study on the second diet, the information on the first diet in unusable. Thus, investigators must do everything possible to minimize drop out.

9. An orthopedic surgeon observes that many of his patients coming in for total knee replacement surgery played organized sports before the age of 10. He plans to collect more extensive data on participation in organized sports from four patients undergoing knee replacement surgery and to report the findings. Identify the type of study proposed and indicate its specific strengths and weaknesses.

Answer:

The study is a case series. The strength is that it may generate a hypothesis of an association that can be tested further with a more comprehensive study. The weaknesses include its small size and lack of a control or comparison group.

10. Suggest an alternative design to address the hypothesis in Problem 9. What are the major issues in addressing this hypothesis?

Answer:

An alternative design might involve a cohort study with children who did and did not participate in organized sports before the age of 10. A prospective study could enroll children and follow them through adulthood to see if they undergo knee replacement surgery. This could be a very inefficient study because it could take decades to observe the outcome. A retrospective study would be more efficient. A case-control study could enroll participants who are undergoing knee replacement and a comparable group who are not. Each participant could be assessed regarding participation in organized sports as a child.

11. In 1940, 2000 women working in a factory were recruited into a study. Half of the

women worked in manufacturing and half in administrative offices. The incidence of bone cancer through 1970 among the 1000 women working in manufacturing was compared with that of 1000 women working in administrative offices. Thirty of the women in manufacturing developed bone cancer as compared to nine of the women in administrative offices. This study is an example of a:

a. randomized controlled trial.

b. case-control study.

c. cohort study.

d. crossover trial.

Answer: C

12. An investigator reviewed the medical records of 200 children seen for care at Boston Medical Center in the past year who were between the ages 8 and 12 and identified 40 children with asthma. He also identified 40 children of the same ages who were free of asthma. Each child and their family were interviewed to assess whether there might be an association between certain environmental factors such as exposure to second-hand smoke. This study is an example of a:

a. randomized controlled trial.

b. case-control study.

c. cohort study.

d. crossover trial.

Answer: B

13. A study is designed to evaluate the impact of a daily multivitamin on students' academic performance. One hundred sixty students are randomly assigned to receive either the

multivitamin or a placebo and are instructed to take the assigned drug daily for 20 days. On day 20, each student takes a standardized exam and the mean exam scores are compared between groups. This study is an example of a:

a. randomized controlled trial.

b. case-control study.

c. cohort study.

d. crossover trial.

Answer: A

14. A study is performed to assess whether there is an association between exposure to second-hand cigarette smoke in infancy and delayed development. Fifty children with delayed development and 50 with normal development are selected for investigation. Parents are asked whether their children were exposed to second-hand cigarette smoke in infancy or not. This study is an example of a:

a. prospective cohort study.

b. retrospective cohort study.

c. case-control study.

d. clinical trial.

Answer: C

15. A study is planned to investigate risk factors for sudden cardiac death. A cohort of men and women between the ages of 35 and 70 are enrolled and followed for up to 20 years. As part of the study, participants provide data on demographic and behavioral characteristics, undergo testing for cardiac function, and provide blood samples to assess lipid profiles and other biomarkers. A new measure of inflammation is hypothesized to be

related to sudden cardiac death. What study design is most appropriate to assess the association between the new biomarker and sudden cardiac death? Describe its strengths and weaknesses.

Answer:

The main study is a cohort study and presumably, cardiac death is a relatively rare outcome. A nested case-control study is an appropriate means to investigate the association between the new biomarker and sudden cardiac death. The strengths of a nested case-control design include the opportunity to match cases (sudden cardiac deaths) with controls on characteristics that might be confounders. In addition, if the measurement of the new biomarker is costly, the nested case-control is an efficient design whereby only participants selected for the nested case-control study have the biomarker measured, which controls cost. A weakness of the nested case-control study is a possible bias in the selection of controls from the cohort. If some participants are lost to follow-up, drop out of the study, or die, the pool of possible controls might not be representative of the population.

16. An investigator is evaluating the effects of tocilizumab, as compared to placebo, on patient outcomes in participants with confirmed COVID-19 infection. Adults hospitalized for COVID-19 agree to participate in the study and are randomized to receive either tocilizumab or placebo and are monitored for adverse outcomes over the next 2 weeks. What study design is used here?

Answer: Randomized controlled trial

17. For each of the five study designs listed below, use the letters (a–e) to match each purpose with the appropriate design. Then, consider each of the five research questions below and use numbers (1–5) to match each research question with the study design that would be most suitable to address that question. Each purpose and research question may be used only once.

Study design	Purpose	Research question
Case-control study	**b**	**3**
Case-series	**e**	**5**
Cohort study	**a**	**1**
Cross-sectional study	**d**	**2**
Randomized controlled trial	**c**	**4**

Purpose:

a. To compare incidence of disease over a specified period of time between groups who are exposed or not, or have a particular risk factor or not.

b. To compare exposures or risk factors between individuals with and without disease.

c. To compare incidence of disease between groups who are randomly assigned to comparison groups.

d. To compare prevalence of disease between groups who are exposed or not, or have a particular risk factor or not at a specific point in time.

e. A systematic description of unusual features in a group of patients.

Research questions:

1. Are patients who are hospitalized for COVID-19 more likely to develop memory loss over 5 years following their COVID-19 diagnosis as compared to those who are not hospitalized for COVID-19?

2. What proportion of patients diagnosed with COVID-19 experience hair loss?

3. Is persistent low-grade fever (<100.4 ºF) among COVID-19 patients associated with organ failure, a rare complication?

4. Is a daily physical therapy regimen associated with fewer complications of COVID-19 among adults who are not hospitalized for COVID-19?

5. Are there any common demographic and clinical characteristics of patients who tested positive for COVID-19 in March 2020 in New York city?

