

Exercise - study design

Respiratory symptoms

Questionnaires were mailed to every 10th person listed in the city telephone directory. Each person was asked to list age, sex, smoking habits, and respiratory symptoms during the preceding seven days. About 20% of the questionnaires were completed and returned. About 10% of respondents reported having upper respiratory symptoms. This is an example of what type of study design? What measure of association can be estimated in this study?

Answer

This is an example of a cross-sectional or prevalence study. The prevalence and prevalence odds ratio can be estimated from this study.

Aircraft company

Approximately 1,500 employees of a major aircraft company were initially examined in 1951 and were classified by diagnostic criteria for coronary artery disease (CAD). New cases of CAD have been identified by examinations every three years and through death certificates. Attack rates in different subgroups have been computed. This is an example of what type of study design? What measure of association can be estimated in this study?

Answer

This is an example of a prospective cohort study. Incidence risk and incidence rate can be estimated.

Sedentary adults

A random sample of middle-aged sedentary adults were selected from four census tracts, and each person was examined for coronary artery disease (CAD). All persons without disease were randomly assigned to either a two-year program of aerobic exercise or a two-year arthritis-prevention non-aerobic exercise program. Both groups were observed semiannually for incidence of CAD. This is an example of what type of study design? What measure of association can be estimated in this study?

Answer

This is an example of a randomised controlled trial (or intervention trial). Incidence risk, incidence rate, measures of strength (e.g. relative risk) and measures of effect (e.g. attributable risk) can be estimated.

The sore throat

A 39-year old woman presents with a mild sore throat, fever, malaise and headache and is treated with penicillin, for presumed streptococcal infection. She returns in a week with hypertension, fever, rash and abdominal pain. She responds favorably to chloramphenicol, after a diagnosis of Rocky Mountain spotted fever is made.

Answer

This is a case report. It is not usually regarded as an epidemiological study, since there is neither a population or comparison group. Presentation of an interesting case can serve to alert other health care professionals of the possibility of misdiagnosing a potentially fatal disease.

Thyroid cancer

A total of 50 patients with thyroid cancer are identified and surveyed by patient interviews to identify previous radiation exposure.

Answer

This study is a case series. Since there is no comparison group of people without thyroid cancer, associations between thyroid cancer and various exposures cannot be examined except on the basis of information from outside of the study. Exposure prevalences among cases can be estimated and comparisons between different subtypes of the disease can be made. Case fatality can also be estimated by follow up.

Carcinoma of the stomach

Patients admitted for carcinoma of the stomach and patients without a diagnosis of cancer are interviewed about their chewing tobacco history to assess the possible association of chewing tobacco and gastric cancer.

Answer

This is an example of a case-control study. This study includes both diseased and non-diseased populations for comparisons of previous exposure to chewing tobacco. Incidence rates of cancer cannot be determined without additional information.

Household income

Data on median income for households in census tracts within a large metropolitan county were obtained from a recent census. Air pollution levels were measured in these same census tracts during a period of one-month. The data were analyzed using a geographic information system (GIS) to produce maps showing pollution and income levels by census tract.

Answer

This is an example of an ecological study (also known as a community, group level, correlational, or aggregate study). The census tract is the unit of analysis. The proportion of counties with high pollution levels can be estimated as a prevalence-type measure, but more often these data would be analysed with cross-tabulation, correlation, regression, and graphical methods.

Automobile drivers

You have developed the hypothesis that automobile drivers who regularly sleep less than six hours/night have a higher incidence of fatal automobile accidents. Think about the design of a case-control study to test this hypothesis. Consider:

1. How will you define a "case"? Are there any special considerations?
2. Name a suitable population from which to choose the controls.
3. What major characteristic must you strive to measure similarly in each study participant?
4. What difficulties will be encountered in measuring this characteristic?

Answer

1. Some states have a fatal accident reporting system, which provides a great deal of useful information. Medical examiner records are another possible source. If cases are identified through death certificates, police records will be needed to differentiate between drivers and passengers.
2. From the state's motor vehicle licensing records, choose a sample of drivers in the state who have not had fatal accidents. The controls should be drivers (or have been drivers during the period when the deaths occurred), since that is the population from which the cases arose (the study base). There is the question of what should be done about cases who were driving despite having their license revoked. Should different controls be chosen for them?
3. Information about sleep, of course, as well as safety features of the automobile, passenger restraint systems in use, road conditions, weather, driver age, sex, and medical history, and any other factor that influences crash rates and probability of fatality.
4. Information on sleep for deceased drivers will certainly be difficult to obtain with any degree of accuracy. Since such information will need to come from proxy respondents (e.g. spouse, other family member, co-

worker), should similar sources be used to obtain data for controls?

School lunches

You have developed the hypothesis that improving school lunches in elementary schools will decrease obesity among students. You have selected six primary schools at random to participate in this study. Think about the design of a group-level intervention trial to test this hypothesis. Consider:

1. What is the unit of analysis?
2. What is the unit of measurement? Think about what sort of measurements you need to take in order to evaluate the effectiveness of your intervention.
3. You decide to assign the primary schools to control or intervention group by randomization. What sorts of problems could arise? What is another method of assignment that might work better?

Answer

1. The unit of analysis is the primary school participating in the group-level intervention.
2. The unit of measurement is the individual student because you will need to measure height and weight of each student.
3. Because you only have six schools, you do not have many units to randomise. Consequently, there is a high probability that the control and intervention groups won't be well balanced on important characteristics (for example, baseline level of obesity, size of the school, etc). Another method of assignment would be to form three pairs by matching the schools on important characteristics. Then you could then randomly assign interventions to each group of two schools.

Caesarian section

In a cohort study evaluating the effect of caesarian section on reproductive performance in the subsequent lactation the control cohort was comprised of a random sample of all cows in the population.

1. Is this a valid choice, why or why not?
2. What would be the direction of the bias introduced in the relative risk if controls were selected inappropriately?
3. Would you select controls differently? If yes, how?

Answer

1. Caesarian section occurs more frequently in heifers and beef cows than in adult Friesian or Jersey cows. It is probably also related to herd management (e.g. bulls selected for mating). Hence cases are not a random selection of calving cows. One should therefore not compare them to randomly selected non-cases as this would introduce bias due to the factors age, breed, and herd.
2. Depends on the outcome: if the outcome is other diseases (mastitis, lameness) that are more frequent in adult cows than heifers, the relative risk would decrease (given that heifers that receive a caesarian suffer more disease during lactation). If the outcome was milk production, the difference between caesarian section (heifers) and adult cows would increase compared to a comparison between caesarian section heifers and normal heifers (given that caesarian section reduces milk production).
3. Match caesarian section cows to control cows for factors like age and breed, herd, i.e. all factors that are related to caesarian section but not in the interest of the study.

Crohn's disease

The relationship between exposure to cow manure as a child and occurrence of Crohn's disease is of interest.

1. What type of study design would you choose? Explain why.
2. Describe briefly the study that you would design. Include criteria for yes-exposure and no-exposure, and criteria

for yes-disease and no-disease. Describe how you would choose the reference population.

3. What measure of effect would you calculate in your study?

Answer

1. A case control study would be appropriate because Crohn's disease is relatively rare disease.
2. Cases: all Crohn's disease patients of all hospitals in the country according to defined diagnostic criteria. Controls: patients that were examined with the same methods as cases but were Crohn's negative. A fixed number (5) of such control patients per case. In this way, controls are matched by hospital, diagnostic methods and examiners. Exposure: all patients (or their relatives) to be asked for their childhood with regard to exposure and extent of exposure to cow dung.
3. Odds ratio adjusting for hospital, age at diagnosis (assuming recall bias is related to age) and sex.

Transfusions

Of 595 patients who had received blood transfusions and 712 patients who had not, 75 and 16 respectively, developed hepatitis during a 2.5 years follow-up in a study designed to evaluate the relative risk.

1. What is the type of study?
2. Calculate the relative risk of developing hepatitis following transfusion.

Answer

1. This is an example of a cohort study.
2. The relative risk of developing hepatitis following transfusion:

$$RR = (75 \div 595) \div (16 \div 712)$$
$$RR = 5.6.$$

Patients who receive a blood transfusion were 5.6 times more likely to develop hepatitis compared with patients who receive no transfusion.

Myocardial infarction

A case control study is planned to investigate the association between alcohol consumption and myocardial infarction. Cases are chosen from the cardiology department of a university hospital. Two possible control groups have been suggested. One group comprises patients with injuries caused by accidents who arrive at the emergency department of the same hospital. The second control group comprises a representative sample from the population of the hospital's catchment area.

1. Which control group would give the greater odds ratio?
2. What principal demand should be placed on the selection of a comparison group in this type of study?
3. Suggest a suitable control group bearing in mind your answer to question 2, as well as the risk of drop-outs and differential misclassification of exposure.

Answer

1. The population sample would give the greater odds ratio because there are likely less alcohol users in the general population than among accident patients.
2. The control group should be selected so that it reflects the presence of exposure in the population from which the cases are recruited, i.e. the controls should come from the population that gave rise to the cases.
3. A group of patients whose disease (as opposed to injuries caused by accidents) is not correlated to alcohol consumption.