Meeting 8: Observation studies 1

Reading
- Thrusfield 2nd Edn pp 221-224 or 3rd Edn pp 266-288 (Observational Studies).
- Thrusfield 2nd Edn pp 178-191 or 3rd Edn pp 228-246 (Surveys)
- Dohoo Chapter 7 ‘Introduction to observational studies’ pp 139-146

Presentations
1. Types of observational studies (including strengths and weaknesses)
2. Discuss the circumstances when a cross sectional study is most appropriate, the key design features and the statistics that can be calculated.
3. ‘Is Vitamin D intake associated with the risk of Multiple Sclerosis?’. One member of the group should briefly research MS – occurrence, hypothesised risk factors etc and bring their findings to the session (5 minutes worth). At the meeting members of the group allocate themselves to different study types (cross-sectional, case-control, cohort and intervention/clinical trial) and discuss how they would conduct a trial examining this question using their nominated design. The design should include exposure and outcome and concentrate on the strengths and weaknesses of their study type.

Exercises
1. Work two (or more) of the example examination questions below.
2. Select two (or more) of the following papers
   - Garner MG et al. (1997) A national serological survey to verify Australia’s freedom from porcine reproductive and respiratory syndrome. AVJ 75: 596-600.

Discuss the design and conduct of these studies
Example examination questions

1. Describe the circumstances where collection of data on disease occurrence from an abattoir would be appropriate. What are the limitations of this method? (2005 oral)

2. Write brief notes on selection of subjects for a cross sectional study (2005 written)

3. *Babesia gibsoni* has recently been found in Pit Bull terriers in Victoria. However little is known about its distribution or prevalence in Australia. You have been asked to design a study to identify the prevalence of *Babesia gibsoni* in the Australian dog population.
   What type of study would you use and what are the strengths and weaknesses of your chosen study design? Describe the study design, including study objectives, hypothesis, unit of interest, reference and study populations.
   What sampling methods would you use and how would you select your sample size?
   Discuss possible means of data collection and the advantages and disadvantages of alternative sources of data.
   Describe any potential biases and how you may control these.
   Discuss how you would analyse and interpret the results. (2003 written)

4. Canine coronavirus is becoming an agent of concern to small animal practitioners. In particular there is some controversy regarding the prevalence of seropositive dogs and the role that the virus may play in canine gastroenteritis. As a consultant epidemiologist you have been asked to design and carry out a cross-sectional study to investigate these problems. Describe how you would proceed with planning the study, including discussion of important factors affecting study design. (2002 written)

5. *Salmonella enteritidis* (SE) is a common cause of food poisoning in many countries, with the main source of infection being raw or partly cooked eggs and egg products. For example human illness from SE positive eggs in the United States is now approximately 637,000 cases per year. SE in chickens causes a silent systemic infection that can be detected by both bacteriological and serological techniques. Prevalence of infection in naturally infected commercial layers has been found to be very low.
   The Australian and New Zealand egg industries are thought to be free of SE infection and relatively few human cases occur in either country compared to overseas. No human cases of SE due to consumption of Australian or New Zealand eggs have been reported. You have been engaged by the egg industry in your country (Australia or New Zealand) to plan an epidemiological study to demonstrate freedom from SE. Describe how you would proceed with this project and discuss the key issues affecting study design.

6. A pharmaceutical company has commissioned you as an epidemiologist to identify the major health issues associated with pet dogs in NZ/Australia to help them review the direction of the R & D program. You have one year in which to complete the project and a generous, although not unlimited budget available to you.
   Describe how you would go about fulfilling this task, giving details of:
   a. The different sources of information on dog health that you might use (25%)
   b. The way in which you would collect data from these sources (50%)
c. The strengths and weaknesses of each with respect to data quality and ease with which the information can be collected (25%)

7. Infectious bovine rhinotracheitis (IBR) is a viral infection of cattle that is endemic in Australian herds. The virus occurs worldwide, but strains overseas appear to be more pathogenic and have been subject to eradication programs in some countries. Although we now that IBR occurs in Australia, and that Australian strains are less pathogenic than overseas strains, we know very little about the prevalence or distribution. You have been asked to design a survey to estimate the prevalence of IBR infected herds in the country.

Describe how you would proceed with designing such a survey and discuss factors that influence your decisions at each major step of the design.

Additional reading/resources

Meeting 9: Observational studies 2

Reading
- Thrusfield, 2nd Edn, pp 220-223 or 3rd Edn, pp 266-269 (Observational studies)

Presentations
1. Advantages and disadvantages of case-control studies.
2. Advantages and disadvantages of retrospective and prospective cohort studies.
3. Hybrid study designs (for example, nested case-control studies).

Exercises
Critically appraise a selection of the following papers. What are the positive and negative features of the study design used in each study?

Example examination questions
1. Write brief notes to demonstrate your understanding of case-control studies (2001 written).

2. A veterinary practitioner asks you for epidemiological advice about an apparent problem amongst Huntaway dogs (a breed of sheep dog). On the basis of dogs presented to his clinic the practitioner suspects that Huntaways have a higher incidence of hip dysplasia (HD). This concern is of some importance as many sheep dogs in New Zealand are Huntaways. How would you advise this veterinarian to go about determining in Huntaways are, in fact, at greater risk than other breeds of dog of being affected by HD? (2000 written)

3. Crohn’s disease is a disease of humans with many similarities to Johne’s disease in ruminants. It is a chronic inflammatory condition of the intestines that is histologically similar to Johne’s disease. Mycobacterium paratuberculosis has also been isolated from some cases of Crohn’s disease, but this is not a consistent finding. There is increasing concern that exposure to M. paratuberculosis is a cause of Crohn’s disease, but existing evidence for causality is limited. There is particular concern about risks to people exposed to dairy cattle infected with M. paratuberculosis.

You are part of a research team of epidemiologists which has been asked to investigate this issue on an epidemiological, rather than bacteriological basis, focussing on risks to people exposed to infected dairy cattle. You have reasonable resources at your disposal. Describe how you would proceed (1999 written)

Additional reading/resources
Meeting 10: Intervention studies

Reading

- Dohoo Chapter 11 (controlled trials) Chapter 2 (sampling, sample size)
- Thrusfield 2nd Edn or 3rd Edn, Chapter 16 (clinical trials)

Presentations

1. Key considerations in designing an intervention study
2. Outcome measures: compare non-inferiority, superiority and equivalence trials; discuss power, p-values and confidence intervals when interpreting results.
3. Vaccine trials: vaccine efficacy, herd immunity, unit of interest, atomistic and ecological fallacies
4. Control of biases (randomisation, blinding)

Exercises

1. Read and assess the following papers (or any other recent papers you may find). You can use the CONSORT checklist to help with this:

1. Work through as a group one of the following exam questions.
Example examination questions

1. A new genetically engineered vaccine has recently been developed for infectious bronchitis virus in poultry. This vaccine can be applied to individuals as day-old chicks or as a mass vaccination. It has undergone extensive laboratory evaluation and the developers are now ready to commence field trials under commercial conditions. You have been asked to design a field study to evaluate the efficacy of the vaccine in preventing mortalities and production losses in commercial broiler enterprises. Describe how you would proceed (2001 written).

2. A live avirulent Toxoplasma vaccine is very effective in preventing Toxoplasma abortions in sheep. Toxoplasma gondii is closely related to Neospora caninum, so it is possible that the live Toxoplasma vaccine would be efficacious against Neospora abortions in cattle. This hypothesis requires investigation and a field trial is desired. Describe how you could investigate the efficacy of the sheep Toxoplasma vaccine in preventing bovine Neospora abortions using a field trial approach (2000 written).

3. You are a consultant to a veterinary pharmaceutical company that is about to try and register a new product for the treatment of osteoarthritis in dogs. The new product is a different formulation of the same active ingredient as an existing product already on the market. Accordingly, the company wants registration on the basis that the two products are equally effective. A clinical trial is required and a number of veterinary practises in Australia are available to assist. Describe in detail the study or studies that you would recommend in this situation (1999 written).


Additional reading/resources