RESEARCH DESIGNS

L11, L13, L14

JULY 26, 2019

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Descriptive Studies

Design	Definition	When, why do we use it?	Strengths	limitations
Ecological Studies	descriptive studies that examine populations, or groups, as the unit of observation. The types of measures in ecological studies are aggregates of individual-level data	when individual-level data would either be difficult or impossible to collect	1. they are cheap and quick to complete. 2. Exposure data often only available at area level. 3. Group level exposure estimates may be more accurate than individual level measures. 4. Useful to monitor population health so that public health strategies may be developed and directed.	1. Potential for systematic differences between areas in recording disease frequency. 2. Potential for systematic differences between areas in the measurement of exposures. 3. Lack of available data on confounding factors. 4. Measures of exposure are only a proxy based on the average in the population. (ecological fallacy).
Case Reports	An article that describes and interprets an individual case, often written in the form of a detailed story. Case reports are considered first line of evidence, because they are where new issues and ideas emerge.	• Unique cases that cannot be explained by known diseases or syndromes • Cases that show an important variation of a disease or condition • Cases that show unexpected events that may yield new or useful information • Cases in which one patient has two or more unexpected diseases or disorders	1. New observations and Generating hypotheses 2. Researching rare disorders 3. Solving ethical constraints 4. In-depth narrative case studies 5. Educational value 6. Expenses 7. Clinical practice can be changed 8. Exercise for beginner researchers 9. Communication between the clinical and academic fields 10. Studying the history of medicine	1. Weaknesses of case reports and case series are that they have no comparison (control) group, 2. they cannot be tested for statistical associations, 3. and they are especially prone to publication bias (especially where case reports/series describe the effectiveness of an intervention).
Case Series	In a case series, the researcher may describe a set of patients that they have seen who show similar symptoms or outcomes. Or, the researcher might have searched for similar cases in the literature to try and identify the issue.		Case series are useful in identifying epidemics. For example, the presence of AIDS identified by the report of a cluster of homosexual men with a similar clinical syndrome.	Same weaknesses as case reports
Cross-sectional Studies	Are based on a single examination of a cross-section of population at one point in time	- Collect information on the frequency and distribution of health-related exposures or outcomes in a defined population - Results can be projected on the whole population provided the sampling has been done randomly.	1. Can be used to study several associations at once 2. Can be conducted over a short period of time 3. Produce prevalence data	1. Unable to establish sequence of events 2. Not feasible to use these studies to investigate rare conditions 3. Potentially influenced by response bias.

Longitudinal	Observations are repeated in the same population (fixed sample) over a prolonged period of time by means of follow up examinations.	- They are able to demonstrate the change over a period of time - Useful to study 1. Natural history of disease and its future outcome. 2. For identifying risk factors of disease. 3. For finding out incidence rate.	-	-

Notes:

- **Ecological fallacy**
  - The **ecological fallacy** is an error in the interpretation of the results of an ecological study, where conclusions are inappropriately inferred about individuals from the results of aggregate data.
  - The fallacy assumes that individual members of a group all have the average characteristics of the group as whole, when in fact any association observed between variables at the group level does not necessarily mean that the same association exists for any given individual selected from the group.
- **Regarding Descriptive Cross-sectional Studies**
  - There is no follow-up period
  - Prevalence studies
  - A series of cross-sectional studies done at several points in time is known as serial survey design.
  - Cross sectional studies are relatively fast and inexpensive and form only design to give prevalence of disease
- **Prevalence**
  - **Point prevalence:** Is a proportion (dimensionless i.e. has no units) But useful to specify the point in time to which it refers

$$\text{Point prevalence} = \frac{\text{Number of cases of disease at a point in time}}{\text{Total number of people in the defined population at the same point in time}}$$

  - **Period prevalence:**

$$\text{Period prevalence} = \frac{\text{Number of cases of disease at any time during a specified (usually short) period}}{\text{Total number of people in that defined population}}$$

- **problem of recall bias**
  - May not remember if an event took place
  - May not remember when it took place

Analytic Studies

Design	Definition	When, why do we use it?	Strengths	limitations
Case-Control (Always retrospective)	- First, identify the cases (a group known to have the outcome) and the controls (a group known to be free of the outcome). - Second, look back in time to learn which subjects in each group had the exposure(s), comparing the frequency of the exposure in the case group to the control group. - A case-control study is designed to help determine if an exposure is associated with an outcome - By definition, a case-control study is always retrospective	• Appropriate for investigating outbreaks • The outcome of interest is rare • Multiple exposures that may be associated with a single outcome. • Funding or time is limited • Outcomes with long latent periods (AIDS) • Ideal for preliminary investigation of a suspected risk factor for a common condition; conclusions may be used to justify a more costly and time-consuming longitudinal study later	1. DIRECTIONALITY: Outcome to → exposure 2. TIMING: Retrospective for exposure, but case-ascertainment can be either retrospective or concurrent. 3. SAMPLING: Almost always on outcome, with matching of controls to cases	• Particularly prone to bias; especially selection, recall and observer bias • Problems with assessing direction (potential for reverse causality) • Not suitable for rare exposures • Not suitable for studying multiple outcomes for a single exposure • Cannot estimate incidence or prevalence • Further limitations if using prevalent cases
Cohort (descriptive, analytical)	– Cohort: a group of individuals who share a common characteristic – Cohort defined by its exposure to a potential risk factor – Cohort members should be free of the outcome under investigation at the start of the study	The outcome of interest could be: – Development of a disease (so the cohort are disease free at the start) – Death (or survival) in a cohort of people with a disease Other outcomes e.g. admission to hospital A major limitation of cross-sectional surveys and case-control studies is the difficulty in determining if exposure or risk factor preceded the disease or outcome. → Cohort Study: Presence or absence of risk factor is determined before outcome occurs.	1. Useful for rare exposures 2. Can study the effect of exposure on disease risk for a wide range of diseases 3. Accurate and detailed exposure assessment can be carried out prospectively – assess dose response – see if there is a threshold 4. Data on potential confounders can be collected prospectively 5. Meet the temporality criterion for causality i.e. cause comes before effect	1. Large sample size may be required 2. Impractical for rare diseases 3. Costs: – Relatively expensive (less of an issue with retrospective cohort studies) – active follow-up more costly than passive follow-up 4. Time required for follow-up – overcome by retrospective cohort studies 5. Retrospective cohort studies – may not have the advantages of accurate and consistent exposure assessment – may lack data on confounders 6. Ethical issues
Also known as	– incidence studies – longitudinal studies – follow-up studies – (prospective studies)			
Cohort prospective	Start now and follow-up into the future			
Cohort retrospective	Use existing data on exposures and outcomes			

Analytic Cross-sectional Studies	**Cross-sectional studies:** An "observational" design that surveys exposures and disease status at a single point in time (a cross-section of the population) **Analytic Cross-sectional Studies:** Investigate the association between exposure to risk factors and the outcome of interest Information collected simultaneously on each individual	- Collect information on the frequency and distribution of health-related exposures or outcomes in a defined population - Results can be projected on the whole population provided the sampling has been done randomly.	1. Relatively quick to carry out 2. Provides prevalence of risk factors and disease in a defined population 3. Useful when planning health services 4. Repeated studies can monitor changes over time	1. Exposure and disease information collected simultaneously 2. Studying prevalent cases (so less likely to include cases that recover quickly or have short survival) 3. Other problems (recall bias, non-response bias)

Intervention Studies

Design	Definition	When, why do we use it?	Ethical issues	Strengths	limitations
Intervention Studies	A study in which participants are actively allocated an intervention by the investigators i.e. an experiment	It is similar to cohort but the key different is that cohort studies test exposures whereas intervention test medications **Characteristics of an intervention study** - The intervention (the preventative or therapeutic measure) being tested is allocated by the investigator to a group of two or more study subjects (individuals, households, communities). - Subjects are followed prospectively to compare the intervention vs. the control (standard treatment, no treatment or placebo).	1. A major consideration – guidelines exist 2. Control group actively denied the intervention – give intervention to all when trial is over and intervention is beneficial 3. Placebo – unethical is if established intervention exists – compare with "usual" treatment 4. Informed consent – participants who do not wish to participate should not be disadvantaged	1. Minimize risk of bias and confounding – properly randomized – blinding 2. Multiple outcomes can be studied 3. Measure "incidence" of the outcome 4. Provide strong evidence of causal relationships between intervention and outcome	1. Expensive – e.g. large study team – multi-center studies 2. May need long follow- up – drop-out rates 3. Ethical concerns 4. Conflicting evidence from trials – meta-analysis
Therapeutic studies	A type of intervention studies that are conducted among *individuals with a particular disease* to *assess the effectiveness of an agent or procedure* to diminish symptoms, prevent recurrence, or reduce mortality from the disease.				
Preventative studies	are conducted to evaluate whether an agent or procedure reduces the risk of developing a particular disease among individuals free from that disease at the beginning of the trial				