Non-experimental study designs

Outline

- Non-experimental designs
  - Surveys
  - Correlational studies (populations)
  - Analytic/relational studies
- Randomised controlled trials
- Role of bias, confounding, chance
- Choosing between designs
  - Advantages/disadvantages

Types of study

Experimental

- E.g., Milgram, clinical trials (of medicines, CBT)
- Descriptive (enumerative, cross-sectional surveys (synchronic), case studies)
- Analytic or relational (correlational, non-equivalent groups, case-control studies, family-based, longitudinal cohort studies (diachronic))

Non (or quasi)-experimental

Descriptive (enumerative) surveys

- Random sampling important
- May also include relational aspects (different nations, races, social class groups); generally synchronic
- Examples
  - General Household Survey
  - Cases of dementia
  - Gallup polls, television viewing statistics (cross-sectional)
  - May be used every 2 yrs, say, and can show trends
Analytic or relational studies

• These explore relationships among variables
• Ascertainment bias
• Representativeness?
• What is random ascertainment?
• Important to consider confounders (may need stratified sampling)- what else might be responsible for observed associations?

Correlational studies in populations

• Sampling units may be countries or areas within them
• Must be careful about inferences – studies good for suggestions for further follow-up
• French wine

Analytic studies in individuals

• Non-equivalent groups design
  – Treatment and control groups compared on measures collected at beginning and end of study, but treatment is not assigned at random.
  – Groups may differ on characteristics related to the outcome

Analytic studies – case-control

• Cases and controls selected on basis of factor (dyslexia, say; or clairvoyance) and compared on risk/promotional factors or other factors. Often are retrospective.
  – To control bias, must be selected from similar environments and in same way
  – Good for rare conditions/phenomena
  – Cause-effect: strength of relationship, other studies
  – May generate hypotheses for new studies
• Family control
Analytic studies – longitudinal cohort studies

- Good for rare exposures (e.g. radiation)
- Sample selected on basis of exposure (or classified after being recruited into study)
- Group then followed up to see who gets outcome of interest

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Analytic studies - interventions

- Randomised controlled trial (experiment)
  e.g., compare two drugs on effectiveness for treating Alzheimer's disease; randomisation
- Clinical trial (non randomised) – compare effect of smoking cessation v usual care on outcomes (cannot randomise the exposure) – e.g.: MRFIT trial

Assessing cause and effect in non-experimental designs

- Judging of statistical association
- Some study designs stronger for this
- Past evidence important (publication bias a problem)
- Must assess role of chance, bias and confounding as well as (biologic) plausibility of finding

Evaluating role of chance

- Large samples have lower variability
- Statistical tests (t-tests etc) used to test likelihood of finding as extreme as that only by chance (p<0.05)
- P-value reflects magnitude of difference and the sample size; confidence intervals help
The role of bias

- If case and comparison groups selected differently, and this relates to risk factors, then sample is biased
  - Selection bias: different criteria for selection of groups into the study, missing whole groups
  - Observation bias: different information collected from the groups (interviewer or recall, say)

Confounding

- Something besides exposure is responsible for observed relationship
- Must be associated with exposure, and independently of exposure, with the outcome
- Can control for this through study design, multivariate statistics, matching

Validity and generalizability

- Validity paramount – invalid results cannot be generalized even if sample is representative

Reviewing the judgement of cause and effect

- First, assess likelihood of chance, bias or confounding
- If above all OK, then look at effect size, time sequence
  - 20+ cigarettes/day: 20x increased risk of laryngeal cancer.
  - First degree relatives: 2x risk of schizophrenia
  - Must also weigh previous evidence
  - Look at dose-response; temporal relationships
On designing the perfect study

- You can’t, so do the best you can

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Experiments/Intervention studies (e.g., clinical trials)

- Advantages
  - Random assignment
  - Strong evidence for cause-effect
  - Can manipulate conditions

- Disadvantages
  - High cost (sometimes)
  - May not reflect ‘real life’
  - Confounding not such a problem so may be forgotten
  - Difficult to design well (and to avoid observer bias); ethical issues

Enumerative/cross-sectional surveys

- Advantages
  - Excellent for describing prevalence of ideas, behaviours, conditions
  - Good generalization (if valid)
  - Hypothesis forming

- Disadvantages
  - Single time point (synchronic)
  - Cannot test hypotheses (also applies to correlational studies in populations or individuals)
Non-equivalent groups design

- Advantages
  - Can study phenomena that are not able to be manipulated by researcher, or where it would be unethical to do so

- Disadvantages
  - Since groups are non-equivalent, result may reflect their inherent differences rather than treatment effects

Case-control studies

- Advantages
  - Quick and inexpensive
  - Good for rare outcomes
  - Can examine multiple causal factors

- Disadvantages
  - Not good for rare causal factors
  - Temporal relationship between putative cause and outcome difficult to show (may be reverse causation)
  - Prone to bias (esp. selection and recall)

Case-control studies

- Advantages
  - Good when causal factors rare
  - Can look at many outcomes in relation to one ‘risk factor’
  - Temporal relationship established, giving support to causal interpretations

- Disadvantages
  - Not good for rare outcomes
  - Expensive, time consuming
  - Losses to follow-up may affect validity of findings

Longitudinal studies (Cohort, time series and cross-lagged panel designs- diachronic)

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Suggested reading
