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Study Designs

- Study designs can be broadly classified into:
  - observational (non-experimental)
    - descriptive
    - analytical
  - experimental

- Study type tells us something about how the problem was investigated and the potential limitations of the study
Observational studies

- Descriptive epidemiology & surveillance
  - mortality statistics
  - disease incidence statistics
  - simple survey data
  - case-series reports

- Analytical studies
  - ecological
  - cross-sectional
  - case-control
  - cohort
Temporal relationship between measurement of exposure (E) and disease (D) in observational studies

(1) prospective  (2) cross-sectional  (3) retrospective
### 2 x 2 tables

<table>
<thead>
<tr>
<th></th>
<th>Diseased (D)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Exposed (E)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>yes</td>
<td>a</td>
<td>b</td>
</tr>
<tr>
<td>no</td>
<td>c</td>
<td>d</td>
</tr>
</tbody>
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Relative risk = \((a / (a+b)) / (c / (c+d))\).
Odds Ratio = \((a / c) / (b / d) = (ad) / (bc)\)
Surveillance

- A continuous & systematic process of collection, analysis, interpretation and dissemination of descriptive information for monitoring health problems (e.g. via a registry-based data collection)

- Surveillance systems used for acute and chronic, communicable and non-communicable disease, reproductive health, injuries, environmental & occupational hazards, and behaviours
Surveillance

- Fundamental tool in public health and disease control
- Also useful for generating hypotheses and for population sampling or data-linkage studies
- Feasibility of data collection, data quality and usefulness are key considerations in establishing surveillance systems
Ecological studies

- Units of observation and analysis are populations or groups of people rather than individuals e.g. workplaces, cities or countries.
- Generally disease quantified as incidence or mortality
- Exposure measured at group level e.g. national alcohol consumption from tax data
- Advantages – low cost, convenient, relatively simple
Ecological studies

- Examples:
  - dietary patterns and heart disease incidence
  - International comparisons of outcomes after AMI
- Ecological fallacy – associations at the group level do not necessarily represent associations at the individual level (exposure measurements averaged)
- Adequate control of confounding usually not possible
- Often useful for formulating hypotheses.
Cross-sectional studies

- A study that examines the relationship between diseases (or other health-related states) and other variables of interest as they exist in a defined population at one point in time.

- These studies measure disease prevalence.
Cross-sectional studies

**Advantages**
- can measure more than one exposure and outcome
- usually of short duration
- yield prevalence estimates
- often a good first step

**Disadvantages**
- cannot establish temporal sequence of events
- don’t yield incidence or true RR
- not good for rare exposures or outcomes
Case-control studies

- A study that starts with the identification of people with the disease of interest and a suitable control group of people without the disease.

- The relationship of an exposure to the disease is examined by comparing the diseased and non-diseased with regard to how frequently the exposure is present.
Case-control studies

- **Advantages**
  - good for studying rare conditions
  - relatively small number of subjects
  - relatively inexpensive and of short duration
  - yield odds ratios

- **Disadvantages**
  - limited to one outcome
  - prone to bias
  - temporal sequence of events not certain
Cohort studies

- Cohort studies are also known as follow-up or incidence studies.
- Begin with a group of people (cohort) who are free of disease and who are classified according to exposure to a potential cause of disease.
- The cohort is followed over time to see how the subsequent development of new cases of the disease differs between the groups with and without the exposure.
Cohort studies

**Advantages**
- exposure measured before disease occurs
  - temporal sequence established
  - exposure measurement less prone to bias
- can establish incidence of disease
- can assess more than one outcome
- can measure other relevant factors

**Disadvantages**
- large numbers needed for rare outcomes
- expense
- often long time frame
Types of cohort studies

Defined on the basis of the temporal relationship between the initiation of the study and the occurrence of the disease

- **Prospective** – exposures may or may not have occurred when study is initiated, but disease has NOT occurred

- **Retrospective** – both exposures and disease have occurred when study initiated (but exposure data collected before occurrence of disease).
Follow-up

- Cohort studies require follow-up of participants to ascertain outcomes.
- Failure to obtain information on a high proportion of subjects can be a major source of bias in cohort studies. (Try to minimise loss to follow-up and at least compare those retained and lost on key variables.)
- The longer the period of observation in a cohort study, the more likely there will be loss to follow-up.
- Follow-up can present major challenges in time, money, logistics and ingenuity!
Analysis of cohort studies

- Cumulative incidence
- Incidence rate or density
  - uses person-time of observation in the denominator
- Relative risk
- Standardised incidence and mortality ratios
- Population attributable risk
- Survival analysis