Analytical Study Designs

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Learning Objectives

By the end of the session, student should be able to:

- Explain the importance of Research study designs
- Classify study designs
- Describe the advantages and disadvantages of analytical study designs
What Is The ultimate goal of most epidemiologic research?

Elaboration of causes that can explain patterns of disease occurrence - DETERMINANTS

Quantification of occurrence of disease in any population - BURDEN, DYNAMICS & DISTRIBUTION (Person, Place, Time)

Case Report
Case Series
Cross Sectional
Longitudinal Studies

Generate Hypothesis

PREVALENCE
INCIDENCE

Test Hypothesis

RELATIVE RISK
ODDS RATIO

What needs to be measured?

Experimental
Cohort
Case Control
Examples:

**Hypothesis generation**
- Describe new phenomena
- Provide estimates

Examples:
- Describing unique findings (TB can present without fever and cough)
- Estimating prevalence (% of people with Hepatitis b infection in a population)

**Hypothesis testing**
- Studying the relationship between factor and outcome

Examples:
- Smoking and Cancer
- High cholesterol and IHD
- Vaccination and reduced infection
- New surgery and reduced complications
Why Study Designs?

- Help us choose the correct method to study the research question
Classification of Study Designs

DESCRIPTIVE
- CASE REPORT
- CASE SERIES
- CROSS SECTIONAL
- LONGITUDINAL

ANALYTICAL
- Observational
- Experimental
  - CASE CONTROL
  - COHORT
- Clinical Trial
  - Community Trial

Generate Hypothesis → Test Hypothesis
Types of Study designs

- **Non Intervention Studies**
  - Descriptive studies
  - Observational studies

- **Intervention Studies**
  The two categories of intervention studies are:
  - Experimental studies
  - Quasi-experimental studies.
Descriptive Study Designs
Descriptive studies

Answer 5 W s
Who has the problem? (age, sex, occupation, race)
What is the problem? (case definition)
Why did the problem arise? (clue about the cause)
When is the problem common? (season, weather)
Where does the problem arise? (geographical location)
Analytical Study Designs
When observational designs are preferred over experimental designs?

- When exposures/factors are obnoxious (HARMFUL)
  - Malnutrition and TB
  - Sheesha and COPD
Case Control Study Design

- **Exposure**
  - Yes
  - No

- **Outcome**
  - Case
  - Control

Backward direction: from outcome to exposure
Backward timing: study begins after outcome
Case Control Study: Steps

1. Selection of cases
   - Sources: Hospital patients/Clinic patients
   - Should be selected from multiple sites (multiple clinics and hospitals)
   - Incident cases preferred over prevalent cases

2. Selection of controls
   - Sources
     - Family members without disease, friends, neighbors (more likely to represent cases in terms of social and environmental factors)
     - Hospital controls (more economical but not likely to match cases and meet inclusion criteria)
   - Controls should be matched with cases on certain characteristics

3. Measurement of exposure

4. Analysis and Interpretation
# Matching in Case Control Study

<table>
<thead>
<tr>
<th>Description</th>
<th>Process of selecting the controls so that they are similar to cases in certain characteristics such as age, race, sex, SES and occupation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Types</strong></td>
<td><strong>Individual matching</strong></td>
</tr>
<tr>
<td></td>
<td>• For each case selected for the study, a control is selected</td>
</tr>
<tr>
<td></td>
<td><strong>Group matching</strong></td>
</tr>
<tr>
<td></td>
<td>• A proportion of controls with certain characteristics is identical to proportion of cases</td>
</tr>
<tr>
<td></td>
<td>• All the cases are selected first and a certain proportion with a characteristic in cases is matched with controls e.g: if 25% of cases are married, 25% of controls selected are also married</td>
</tr>
<tr>
<td><strong>Problems</strong></td>
<td><strong>Practical problems</strong></td>
</tr>
<tr>
<td></td>
<td>• Difficult to find if too many characteristics need to be matched</td>
</tr>
<tr>
<td></td>
<td><strong>Conceptual problem</strong></td>
</tr>
<tr>
<td></td>
<td>• Matched characteristics in cases and controls cannot be studied</td>
</tr>
</tbody>
</table>
Case-control

Advantages
- Easier to carry out
- Rapid and inexpensive
- Suitable to investigate rare disease

Disadvantages
- Recall bias
- Temporality can not be established (cause does not precede outcome)
In a study looking at the risk of colon cancer in smokers you found that out of hundred patients 50 were smokers. Now based on your design you will identify their controls who may be their friends or family members or matched controls (matched by age and sex). Out of their 100 controls selected you found that 20 were smokers.

Formulate a 2X2 table and calculate odds ratio.
Measuring Association in Case Control Studies: ODDS RATIO (2X2 table)

- OR = \( \frac{ad}{bc} \)
- OR = \( \frac{50 \times 80}{50 \times 20} = 4 \)

<table>
<thead>
<tr>
<th>RISK FACTOR</th>
<th>Colon Cancer present</th>
<th>Colon Cancer Absent</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smokers</td>
<td>50</td>
<td>20</td>
<td>70</td>
</tr>
<tr>
<td>Non smokers</td>
<td>50</td>
<td>80</td>
<td>130</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100</td>
<td>100</td>
<td>200</td>
</tr>
</tbody>
</table>
This means that if a person has colon cancer then the chances that this person was a four times more smoker than the person who does not have colon cancer.
Cohort Study Design

**Perspective:**
Study begins

**Exposure**
- **YES**
- **NO**

**Outcome**
- **Case**
- **No Case**

**Forward direction:** from exposure to case
Cohort Study: Steps

1. Selection of exposed and non-exposed groups
2. Decide on follow up time
3. Measurement of outcome
4. Analysis and Interpretation
Cohort Studies

Advantages

• Establishes Temporality (cause precedes disease)
• Studies several possible outcomes
• Provides Incidence
• Good for rare/obnoxious exposures
• Minimum bias

Disadvantages

• Lengthy therefore Loss to follow up (ATTRITION)
• Resource consuming
• Not appropriate to study rare exposures
• Change in behavior of exposed group
Scenario

- 250 rural pregnant women involved in applying pesticides to cotton fields and 500 rural pregnant house wives were followed from 1st trimester to delivery of the baby. The birth weight of newborns were recorded in both groups. 125 newborns in each group had Low birth weight.

a) Identify the study design?
b) Construct 2*2 table?
c) Calculate measure of association and interpret?
<table>
<thead>
<tr>
<th></th>
<th>LBW</th>
<th>Normal weight</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pesticide exposed</td>
<td>125 (a)</td>
<td>125 (b)</td>
<td>250 (a+b)</td>
</tr>
<tr>
<td>Not exposed</td>
<td>125 (c)</td>
<td>375 (d)</td>
<td>500 (c+d)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>250 (a+c)</td>
<td>500(b+d)</td>
<td>750</td>
</tr>
</tbody>
</table>

**RR** = \( \frac{\text{Incidence of disease in exposed } a}{\text{a+b}} / \frac{\text{Incidence of disease in non-exposed } c}{c+d} \)

\[ \frac{125 \text{ } 250}{125 \text{ } 500} = \frac{0.5}{0.2} = 2.5 \]

**Interpretation:**
Women Exposed to pesticides are twice more likely to have Low birth weight babies as compared to those not exposed with pesticides.
<table>
<thead>
<tr>
<th>Interpretation</th>
<th>• Exposed persons are ......times more/less likely to develop disease as compared to non-exposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>RR=1</td>
<td>No Association</td>
</tr>
<tr>
<td>RR&gt;1</td>
<td>Positive Association (Causal Relationship)</td>
</tr>
<tr>
<td>RR&lt;1</td>
<td>Protective effect (exposure protects disease)</td>
</tr>
</tbody>
</table>
Case-control VS Cohort Study

Case Control
- Starts with outcome
- Easier to carry out
- Rapid and inexpensive
- Suitable to investigate rare disease
- No loss to follow up
- Recall bias
- Temporality can not be established (cause does not precede outcome)
- Measure of association is odds ratio

Cohort
- Starts with exposure
- More difficult to carry out
- Time taking and expensive
- Suitable for rare exposures
- Loss to follow up
- No Recall bias
- Temporality can be established (cause does precede outcome)
- Measure of association is relative risk
When experimental designs are preferred over observed designs?

- When exposures/factors are beneficial to health
- Ideal design for evaluating the effectiveness and side effects of new interventions

*Iron supplements and reduced anemia*

*New surgical procedure and reduction in complications*
Experimental Design

- An experiment is a study designed to compare benefits of an intervention with standard treatments, or no treatment, such as a new drug therapy or prevention program, or to show cause and effect.

- Performed prospectively.

- Subjects are selected from a study population, assigned to the various study groups, and monitored over time to determine the outcomes that occur and are produced by the new drug therapy, treatment, or intervention.
Design of an Experimental Study

Defined population

Randomized

- INTERVENTION
  - IMPROVED
  - NOT IMPROVED

- NO INTERVENTION
  - IMPROVED
  - NOT IMPROVED
THANK YOU