- **Epidemiological Study Designs And Measures Of Risks**
  (1)
- Objectives of the Lecture

- To describe observational study designs

- To describe experimental study designs and clinical trials

- Calculate and interpret of measures of risk

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STUDY DESIGNS

- Observational Studies
- It allows nature to take its own course.
- We measure but not intervene.
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DESCRIPTIVE STUDY DESIGNS

– Uses:

- Describes magnitude of the disease load in terms of morbidity and mortality rates.
- Provides clues to disease etiology (formulation of etiological hypothesis).
- Provides data for planning, organizing and evaluating health services.
- Contribute to research by describing variation in disease occurrence by time, place and person.

- a/ Case studies

- Case studies

A case study describes in depth the characteristics of one or limited number of cases in its natural environment

- Case studies
- A case may be a patient, a health centre, a village etc…

- Can provide useful insight into the problem e.g. a new disease

- Common in clinical medicine, social sciences, management and administration etc..
- Case studies
- Features:

- Should be well planned and data will be collected thorough predetermined questions

- Should be flexible to deal with unexpected situations
- Case studies
- Advantage:
- It permits a holistic approach to the problem under investigation

- Disadvantage:
- Not representative
- b/ SURVEYS
- SURVEYS

- Use :
- To collect information on demographic characteristics. Age, sex, education etc…
- To study characteristics on health related variables. E.g. incidence rate, etc….
- To study attitudes, opinions and beliefs

- SURVEYS

■ Surveys answer the following questions:

■ WHEN IS THE DISEASE OCCURRING? (TIME DISTRIBUTION)

■ WHERE IS THE DISEASE OCCURRING?

- (PLACE DISTRIBUTION)

■ WHO IS AFFECTED?

- (PERSON DISTRIBUTION)

- **PROCEDURE**

- Define the problem under study.
- Define the population under the study.
- Describe the disease by TIME, PERSON and PLACE.

- Measurement of the disease.
- Comparing with known indices.
- Formulation of an etiological hypothesis.

- **Analytical Studies**

- Analysis of the relationship between health status and other variables.
- It is to test hypothesis.
- Interested in individual and inference is to population.
- **Analytical Epidemiology**

- **Ecological or correlation**
- **Cross-sectional or prevalence**
- **Case-control or case-reference**
- **Cohort or follow-up**
- **A) Ecological Studies**

- They look for associations between the occurrence of disease and exposure to known or suspected causes.

- The unit of observation is the population or community.
- Often the information about disease and exposure is abstracted from published statistics and therefore does not require expensive or time consuming data collection.
- **B) CROSS SECTIONAL STUDY**

- Prevalence rate study.

- The relationship between the disease & other variables of interest as they exist at one particular point of time.

- **Case Control Studies**

They are comparison studies

To determine

- **Whether or not a statistical association exist**
- **And its strength**
- **3 Distinct Features**

- **Both exposure & outcome have occurred before the start of the study**
- **The study proceeds backwards from effect to cause**
- **Uses controls to support or refute an inference**
- **Two populations** (cases & controls)

- **The unit is individual**
- **The focus is on the disease**
- **Because they are comparison studies, cases and controls must be comparable with**

respect to known confounding factors (age, sex, social status, occupation….etc)

- **<u>The Basic Design Is 2x2 Contingency Table</u>**
- If the frequency of risk factor (smoking) a/(a+c) is higher in cases (lung cancer) than in controls b/(b+d), an association is said to exist between smoking and lung cancer.

- **Basic Steps**
- **Selection of case & controls**
- **Matching**
- **Measurement of exposure**
- **Analysis & interpretation**
- **1. Selection of Cases & Controls**
- **Proper selection is crucial**

- **Avoid selection bias**
- **Conducting of more than one study in different geographical areas increases the validity of the inferences**
- **<u>(A) Selection of Cases</u>**
- **Definition of cases**
  (i) diagnostic criteria

(ii) eligibility criteria

2. Sources of cases

Hospitals - general population

- **<u>(B) Selection of Controls</u>**
- **More difficult (sub-clinical form)**
- **Free from the disease under study**

- **Similar to cases as possible**

- **<u>Sources of controls</u>**

Hospitals

same hospital

different illness

selection bias is common

Relatives

unsuitable in genetic conditions

Neighborhood

same locality
factory
school

General population
from defined geographic area
must reflect the population free from the disease

- **<u>How many controls</u>**
- **One to one in large no. of cases**

- **2, 3 or 4 to one study subject in small no.of cases (< 50)**
- **<u>2. Matching</u>**

  It is a process by which we select controls in such a way that they are similar to cases with regards to certain pertinent selected variables (e.g. age) which are known to influence the outcome

of disease & which,if not adequately matched for comparability, could distort or confound the results

- **Types of Matching Procedure**
- **They are many**
- **Grouping matching**

2. Pairs

- **3. Measurement of Exposure**
- **Definition & criteria are important**
- **By :**
  - **interviews**
  - **questionnaire**
  - **study past records**
- **4. Analysis**
- **Exposure rate**
- **Odd ratio**

- **<u>Exposure rate</u> (frequency of exposure)**
- **Exposure rates:**
- **Cases = a/(a+c) = 33/35 = 94.2%**

(b) Controls = b/(b+d) = 55/82 = 67%

Lung cancer is higher among smokers than non-smokers

- Odds ratio (cross-product ratio)
- So odd ratio is calculated from a case control study.
- It is the ratio of the odds of exposure among the cases to the odds in favour of exposure among the controls.
- It is a measure of the strength of the association between risk factor and outcome
- It is the cross product of the entries of the table above

  a/b c/d

= ad/bc

= 33X27/55X2 = 8.1

- So we can say smokers of less than 5 cigarettes per day showed a risk of having lung cancer 8.1 times that of non-smokers.

- Odds ratio
- OR=1 Exposure does not affect odds of outcome

- OR>1 Exposure associated with higher odds of outcome

- Exposure associated with lower odds of outcome

Thanks