* **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
* STUDY DESIGNS
* Observational Studies
* It allows nature to take its own course.
* We measure but not intervene.
* **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)**
* **The Basic Design Is 2x2 Contingency Table**
* 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**
* **(A) Selection of Cases**
* **Definition of cases**

 **(i) diagnostic criteria**

 **(ii) eligibility criteria**

**2. Sources of cases**

 **Hospitals - general population**

* **(B) Selection of Controls**
* **More difficult ( sub-clinical form)**
* **Free from the disease under study**
* **Similar to cases as possible**
* **Sources of controls**

**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**

* **How many controls**
* **One to one in large no. of cases**
* **2, 3 or 4 to one study subject in small no.of cases (< 50)**
* **2. Matching**

 **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**
* **Exposure rate
(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