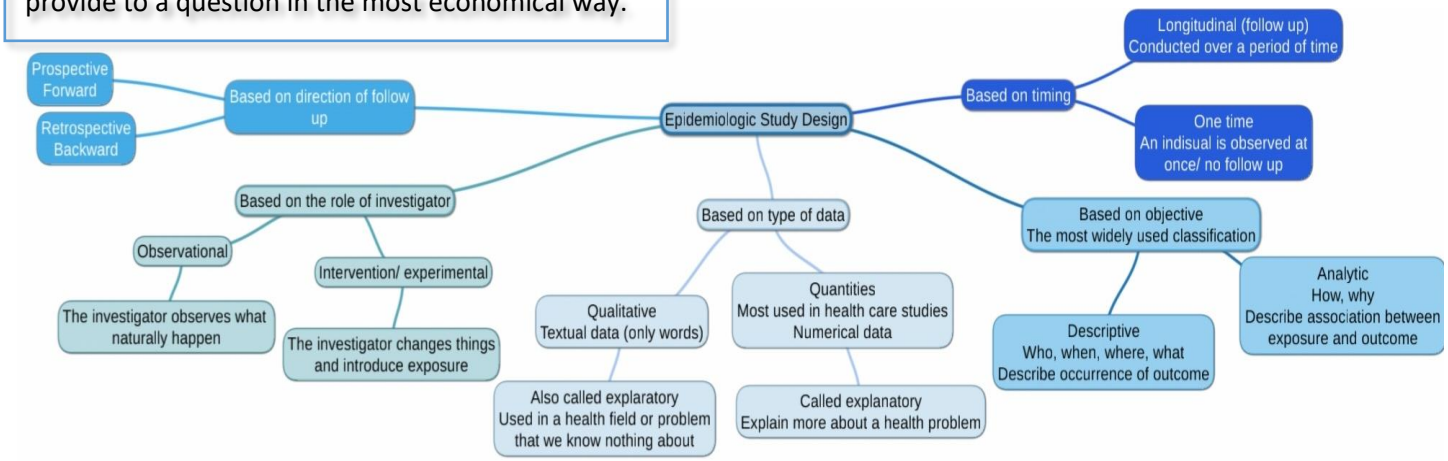
Epidemiologic Study Design:

The arrangement of conditions for the collection and analysis of data the most accurate answer to provide to a question in the most economical way.



Research Hypothesis: a supposition arrived at from observation or reflection

Null hypothesis (no difference) VS Research hypothesis (a difference)

It can be accepted or rejected using the techniques of analytical epidemiology.

A hypothesis should specify: 1. the **population**. 2. the **specific cause** (Risk factor) being considered. 3. Expected **outcome** – disease 4.**Time** response relationship (expectation) does the disease increase with time? Or decrease with time? 5. be **understandable, measurable, testable and realistic**

<table>
<tr><td colspan="2">Descriptive Studies:
• concerned with observing the distribution of disease or health
• Usually the first phase of an epidemiological investigation. → Usually the starting point.
• Useful for generating new hypothesis (provides clues to disease etiology)</td></tr>
<tr><td>1- Case Reports: presentation of a single case or handful of cases (1-5), This is the most quick and easy and very simple to do
Generally report a new or unique finding (previous undescribed disease, unexpected link between diseases, unexpected new therapeutic effect, adverse events)</td><td rowspan="2">Case report and Case Series advantages and disadvantages:
•Advantages
Useful for hypothesis generation
Informative for very rare diseases with few established risk factors
•Disadvantages
Cannot study cause and effect relationships
Cannot assess disease frequency in a population unless we do bigger studies</td></tr>
<tr><td>2- Case Series: Experience of a group of patients with a similar diagnosis (Larger than 5 cases)
Cases may be identified from a single or multiple sources
Generally report on new/unique condition, may be the only realistic design for rare disorders</td></tr>
<tr><td>3- Ecological Studies (correlation study): a hypothesis generating study.
It examines if two factors are correlated with each other.
It involves the collection of events over a defined population base and by the use of denominator data to determine rates.</td><td>It results in Ecological Fallacy: Failure in reasoning that arises when an inference is made about an individual based on aggregate data for a group,
e.g. The ecological fallacy is to conclude that people with high income are at high risk for coronary heart disease , this is the fallacy (error) in reasoning or judgment that we could do</td></tr>
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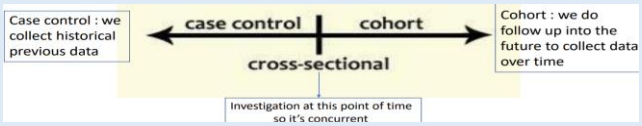
Analytical Studies (testing hypothesis):

We can conclude from analytical study whether the hypothesis (generated by descriptive studies) is true or false

Observational Studies: no individual intervention (Treatment and exposures occur naturally) Individuals can be observed prospectively, retrospectively, or currently



1- cross sectional: (a snapshot of the population) An "observational" design that surveys exposures and disease status at a **single point** in time (a cross-section of the population), by studying **a sample that represents the population**, and its **results can be generalized** to the whole population

→Longitudinal studies are Based on **multiple observations** in the same population over a multiple points of time.

→ It measures **prevalence**, not incidence of disease

→ Used to **learn more about the disease to explore factors** that have role in the etiology of the disease (Physical characteristics of people, Socio-economic characteristics [age, gender,..], Behavior or practices of people, knowledge, and attitude and beliefs (KAP), Events that occur in population)

→ Using survey, questionnaire or interview

- the simplest form of observational studies
- Often used to study **conditions that are relatively frequent with long duration of expression** (nonfatal, chronic diseases) not suitable for diseases with short duration, rare disease or fatal ones
- In practice cross-sectional studies include elements of both descriptive and analytical design ** the dr. considered it analytic
- **Advantages:**
  • Less time consuming • Less expensive • Provides more information (lots of variables) • Describes the population well • Generates hypothesis
- **Disadvantages**:
  • Weakest observational design (measured prevalence only) • The temporal sequence of exposure and effect may be difficult or impossible to determine. • Usually don't know when disease occurred • we can't study rare diseases or short duration diseases • Least useful in establishing causation.

2- Case-Control Study Design:

An "observational" design comparing exposures in disease cases vs. healthy controls from the same population.

→ The investigator compares one group among whom a health problem is present (a group of people with the disease) with another group, called a control or comparison group (free from the disease), to find out what factors have contributed to the problem. **Exposure data collected retrospectively.**

→ Selection of an appropriate control group is an important pre requisite because control group must be similar to the cases as possible, except for the absence of the disease under study (matching).

•This is the first approach to test causal hypothesis.

Strengths:

1**) Less expensive and less time consuming** [but more expensive compared to cross sectional study] 2) Efficient for **studying rare diseases** 3) Allows the study of **several different etiological factors for one disease**. 4) No attrition problems (**no follow-up**) 5) **Ethical problems are minimal** (no risk to participants).

Limitations:

1. **Selection of an appropriate control group** may be difficult. 2. Inefficient for **evaluation of rare exposure** 3. Difficult to **establish temporal sequence** 4. Determining exposure will often **rely on memory**, leading to bias (recall bias). 5. We **cannot measure incidence** & can only estimate the relative risk (RR).

3- Cohort Study: Is an "observational" design comparing individuals with a known risk factor or exposure with others without the risk factor or exposure.

→ Data usually collected prospectively with some retrospective at the beginning.

→ In a COHORT STUDY, a group of individuals that is exposed to a risk factor (study group) is compared with a group of individuals not exposed to the risk factor (control group)….and all followed up to monitor occurrence for new cases of the disease. (both groups start healthy)

→ measures **Incidence**

→ Prospective study, longitudinal study, incidence study & forward looking study.

Best (strongest) observational design.

When there is a good evidence of an association between exposure & disease.

Advantages:

1. Valuable when exposure is rare 2. Examines multiple outcomes of a single exposures 3. Temporal relationship is known 4. Allow direct measurement of risk 5. Minimize bias in ascertainment of exposure

Limitation:

1. Expensive 2. Time-consuming 3. Inefficient for rare diseases or diseases with long latency 4. Loss to follow-up is a problem

Assignment: 4- Framingham Study

- What is the Framingham study? a long-term, ongoing cardiovascular cohort study, the study has provided substantial insight into the epidemiology of cardiovascular disease and its risk factors
- When did it start? Where? The study began in 1948 from Framingham
- What was the disease studied? cardiovascular disease
- What are the most important findings?
  Cigarette smoking increases risk of heart disease. Increased cholesterol and elevated blood pressure increase risk of heart disease. Exercise decreases risk of heart disease, and obesity increases it. Elevated blood pressure increases risk of stroke. In women who are postmenopausal, risk of heart disease is increased, compared with women who are premenopausal. Psychosocial factors affect risk of heart disease.
- How many people participated? 5,209 adult subjects
- How many generations? Now in the fourth generation
- When did it end?

Experimental Studies (Intervention studies):

In an experiment, we are interested in the effect or consequences of **a new therapeutic treatment or procedure on an outcome.** The subjects are allocated into a treatment group and a control group (old treatment or placebo).

1- RCT (Randomized Controlled Trial): clinical trial that is **well-designed (controlled and randomized)**. Controlled means: The researcher manipulates situations/objects; the most well-known experimental design.

→ An experimental design with subjects **randomly** assigned by the investigator into a "treatment" group and a "comparison" group.

→ The **ultimate** form of design in testing causal hypotheses; provides **most convincing evidence** that should overrule any evidence from any other type of design that is weaker than the RCT; They are **the gold standard** study design (strongest, most robust).

→ The quality of this "Gold standard" in experimental studies can be achieved through:

- **Randomization:** random allocation of study subjects into treatment & control groups. Avoids bias & confounding, and increases confidence in the results.
- **Blinding:** Denying information on treatment / control status (single [the patient does not know if he is in control group or treatment group], double [both patient and the observing physician] or triple blinding [strongest one; the patient, the following physician, clinician, the person who does the statistical analysis]. This helps to avoid observation bias.
- **Placebo** is used as blinding procedure (where we use the placebo and the patient thinks that they are using the new medication)

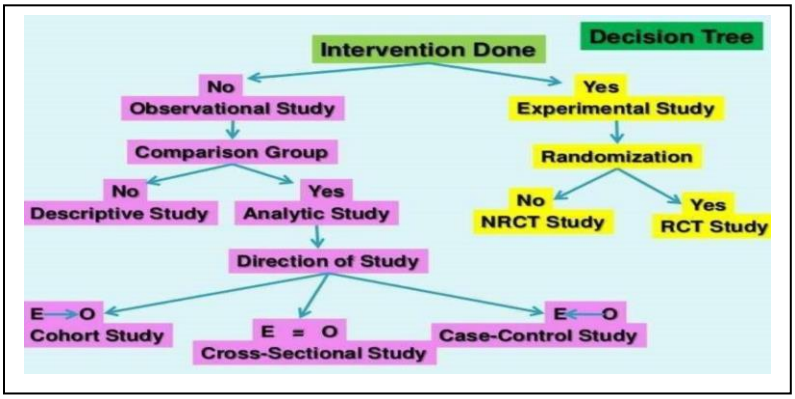
→ If a randomized controlled trial comes up with new evidence, this should overrule any older results that have been produced by weaker types of studies, given that the trial has been carried out properly.

Disadvantages: •Very expensive •Not appropriate to answer certain types of questions •It may be unethical, for example, to assign persons to certain treatment or comparison groups if exposure has well-known benefit.

2- Quasi-Experimental Studies The researcher does not decide or plan the intervention (e.g. changes in using health care after removing ophthalmic services from health insurance), no Randomization or no control group "things that happened by themselves".

3- Natural experiments Factor occurred naturally: e.g. Increase in mental disorders following an earthquake.

4- Crossover Studies participant work as a control for himself (e.g. new pain relief medication); The person take by self the old medication and then the same person take the new one and compare the change



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