Community / Epidemiology

Lecture 6+7

this sheet includes :

- ✓ All the points written in the slides on e-learning for lectures 6 + 7 (these are written in **black** and **red**)
- ✓ Additional notes mentioned by the doctor in the lecture to clarify some points in the slides (these are written in **green**)
- ✓ Some pictures and notes taken from osmosis (these are in **blue**) [you can skip them , they are only for further explanation]
  I recommend this video from osmosis : https://www.osmosis.org/learn/Study_designs?from=/md/foundational-sciences/biostatistics-and-epidemiology/epidemiology/study-design
  (from which I took the pics and notes) it helps make the topic clear if you face any problem

Lecture 6+7

Epidemiologic Study Design

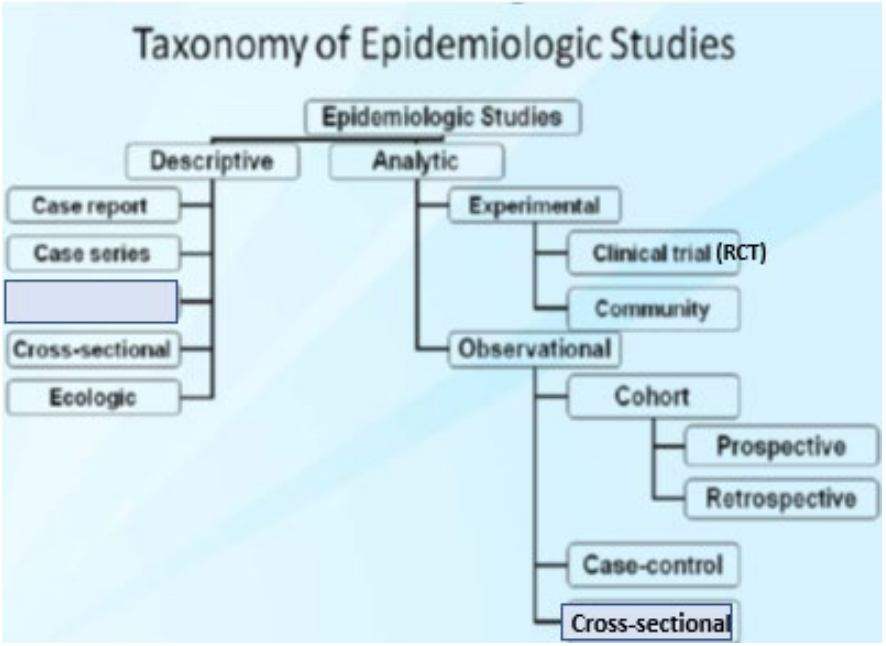
➔ Definition : Study design is the arrangement of conditions for the collection and analysis of data to provide the most accurate answer to a question in the most economical way.'

Types of Epidemiologic Study Designs

Based on	Types
I. Based on objective/focus/research question: **(The most widely used classification)**	**1. Descriptive studies** **Describe: what, who, when, where** **describe occurrence of outcome** **2. Analytic studies** **Analyze: How and why** **describe association between exposure and outcome**
II. Based on the role of the investigator	**1. Observational studies** • **The investigator observes what naturally happens** • **No intervention** **2. Intervention/Experimental studies** • **Investigator intervenes: changes things and introduce exposure.** • **Researcher has control over the situation**
III. Based on timing :	**1. One-time (one-spot) studies** • **Conducted at a point in time** • **An individual is observed at once** **2. Longitudinal (Follow-up) studies** • **Conducted over a period of time** • **Individuals are followed over a period of time**

IV. Based on direction of follow-up/data collection:	**1. Prospective** **Data collection occurs forward in time: into the future** **2. Retrospective** **Conducted backward in time: past events**
V. Based on type of data they generate:	**1.Qualitative studies:** • **Generate textual data** • **Also called exploratory studies** **2. Quantitative studies:** • **Generate numerical data** • **Also called explanatory studies**

Taxonomy of Epidemiologic Studies



Research Hypothesis

→definition : A hypothesis is a supposition, arrived at from observation or reflection

- **It can be accepted or rejected using the techniques of analytical epidemiology.**
- **A hypothesis should specify the following:**
  1. **The population.**
  2. **The specific cause being considered.**
  3. **Expected outcome – disease.**
  4. **Time response relationship (expectation).**
  5. **Be understandable, measurable and testable.**

Develop a research question & Hypothesis

- General concern – Hb of mother and Birth weight of baby.

RQ -

- Is Anemia in pregnancy associated with low birth weight in newborn?

Null Hypothesis

- There is no difference in the incidence of LBWs in the mothers who are anemic and those who are not anemic.

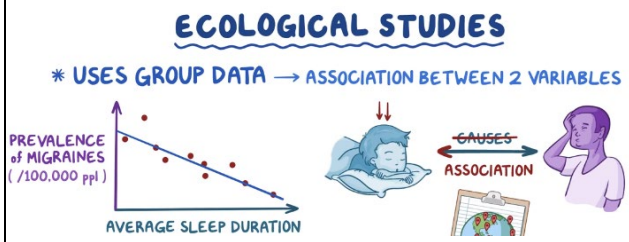
Research Hypothesis

- The incidence of LBWs in mothers who are anemic is higher than those who are not anemic

Descriptive Studies

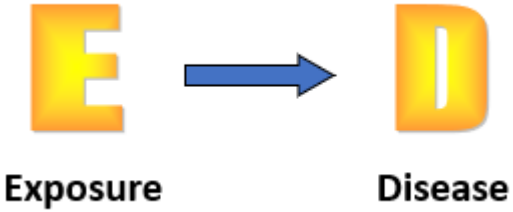
- Descriptive studies are usually the **first phase** of an epidemiological investigation.
- These studies are concerned with observing the **distribution** of disease or health – related characteristics in human populations.
- Such studies basically ask the questions of <u>what, who, where, and when</u>.
- Useful for generating <u>new hypothesis</u> (provides clues to disease etiology)

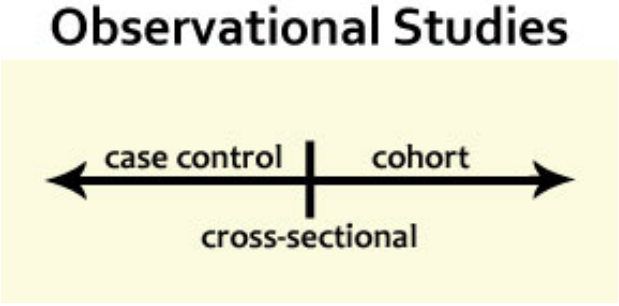
Type	Notes	Advantages	Disadvantages
1. Case Reports:	-presentation of a **single case** or handful of cases -Generally report a new or unique finding eg; (previous undescribed disease that has been identified recently in a very low number of patients 1-5 handful which means 1-5 cases / unexpected link between diseases/ unexpected new therapeutic effect /adverse events)	**For both 1 + 2** -Useful for hypothesis generation -Informative for very rare diseases with few established risk factors	**For both 1+2** -Cannot study cause and effect relationships -Cannot assess disease frequency in a population
2. Case Series	-Experience of a **group of patients** with a similar diagnosis larger than 5 -(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**		
3. Ecological Studies (correlation study)	-Usually using group-level data **(population-level)** -It involves the collection of events over a defined population base and by the use of denominator data to determine rates -it examines if **two factors** are **correlated** with each other. _____	**-**The ecologic study is a **hypothesis** generating study	**-**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

	Additional from osmosis [you can skip this]  For example, let's say you want to figure out if people who sleep less are more likely to get migraines. Generally, we can see that the less sleep a city gets, the higher the prevalence of migraines is for that city. The thing is, **we can't actually say that getting less sleep causes migraines**, since we don't have information about each individual in each city. **All we can say is that there's an association between sleep duration and prevalence of migraines**.		e.g. Higher rates of coronary heart disease in countries with higher income, the ecological fallacy [error] is to conclude that people with high income are at high risk for coronary heart disease Higher rates of leukemia in larger cities , higher rates of car accidents in countries or regions with higher smoking rates

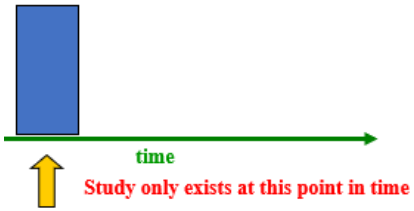
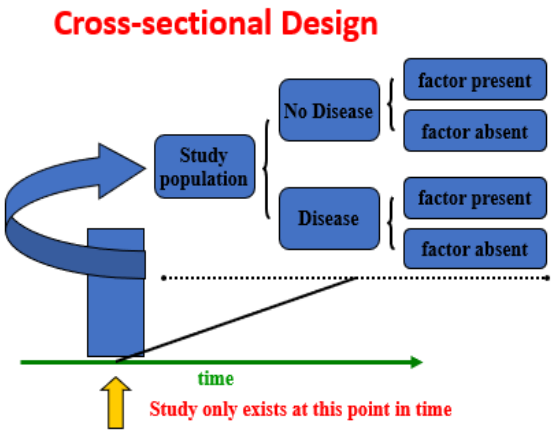
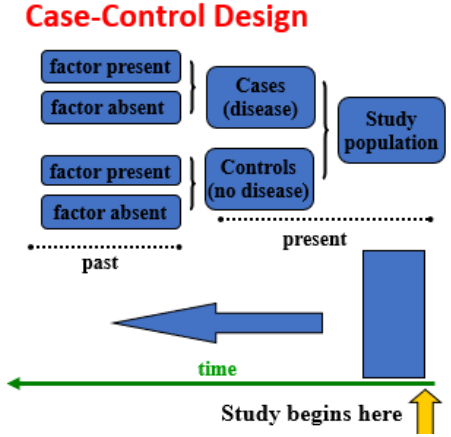
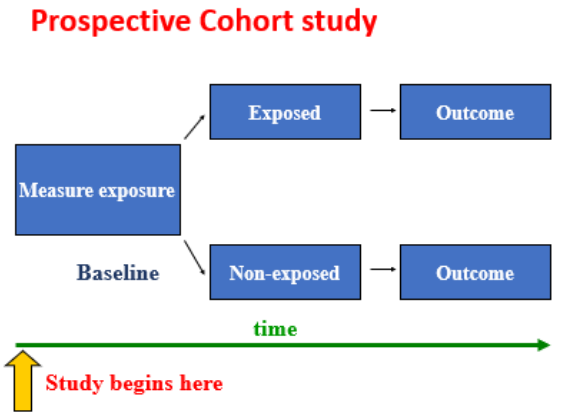
Analytical Epidemiology

- **Are exposure and disease linked?**
- **Analytical Studies (testing hypothesis)**



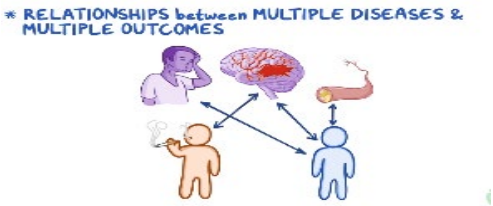
Analytical studies include :	**1) Observational Studies**	**2)Experimental Studies (Intervention studies)**
Notes	-Non-experimental study designs -Observational because there is no individual intervention -Treatment and exposures occur *naturally* -Individuals can be observed prospectively, retrospectively, or currently 	-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). Intervention: The researcher administers the exposure (treatment) to the subjects
Types	**1.Cross-sectional** **2.Case-control** **3.Cohort**	**1. Randomized Controlled Trial:** on patients in clinical settings (e.g. RCT). **2. Quasi-experimental:** Natural experiments, Field trial, **Community trial** (new Covid-19 vaccine), cross-over studies.

Observational studies

Type	1. Cross-sectional studies	2. Case-Control Study Design	3. Cohort Study
Definition	-An "observational" design that surveys exposures and disease status **at a single point in time** (a cross-section of the population**)** - **It is named "prevalence study"** • **It measures <u>prevalence</u>, not incidence of disease** 	- 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 with another group, called **a control or comparison group**, where the health problem is absent to find out what factors have contributed to the problem**.**	- Is an "observational" design comparing individuals with a known risk factor or exposure with others without the risk factor or exposure - 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 of disease. - Cohort study is known by a variety of names: **prospective study, longitudinal study, incidence study & forward looking study**.
The study design			
Some notes	- Are the **simplest** form of observational studies.	- **exposure data** collected **retrospectively**.	- **Data usually** collected **prospectively (some retrospective).**

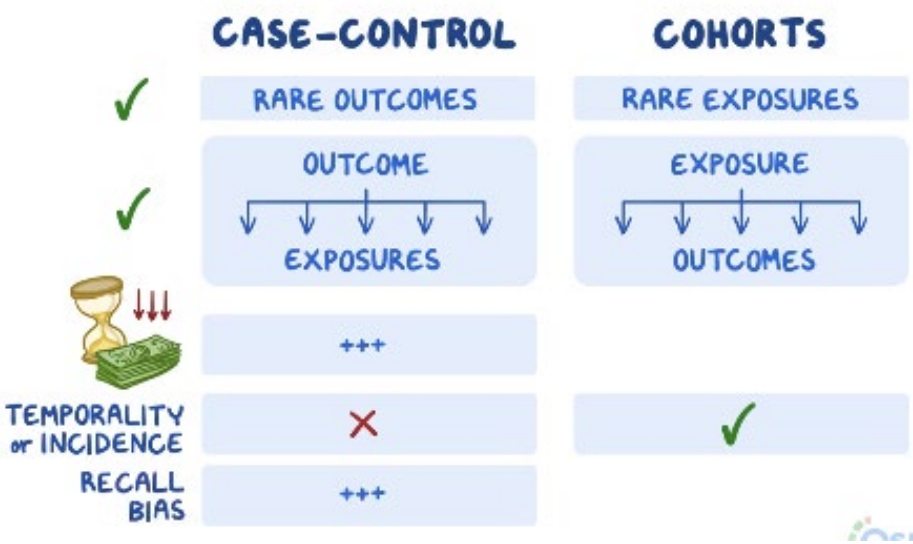
	-**Based on a single examination** of a cross section of population *at one point in time*, by studying a *sample* that represents the population. -Results of CS study can be generalized to the whole population (provided the sampling has been done correctly). - Often used to study conditions that are relatively **frequent** with **long duration** of expression (**nonfatal**, **chronic** conditions) // [Not suitable for studying rare or highly fatal diseases or a disease with short duration of expression.] - Used to learn more about the disease to explore factors that have role in the etiology of the disease: *Physical characteristics of people, material and environment *Socio-economic characteristics e.g., age, education , marital status, number of children and income *Behavior or practices of people, knowledge, and attitude and beliefs (KAP) *Events that occur in population	-most feasible design where disease is rare. -This is the **first approach** to test **causal hypothesis**. -Definition of a case is crucial to a case control study**.** → **SELECTION OF CONTROLS:** -The controls must be *free* from the disease under study. -They must be *similar* to the *cases* as possible, except for the absence of the disease under study (matching). -Each case needs *one* control or *more*. (Selection of an appropriate control group is an important pre requisite, because we will be making comparison with these controls..)	**-** Looking for a difference in the risk (**incidence**) of a disease over time. -**Best (strongest) observational design.** → **Indications:** **-** When there is a good evidence of an association between exposure & disease. -When **exposure is rare**, but incidence is high among the exposed. -When attrition of the study population can be minimized (due to long follow-up period). -When sample funds are available (it is expensive).

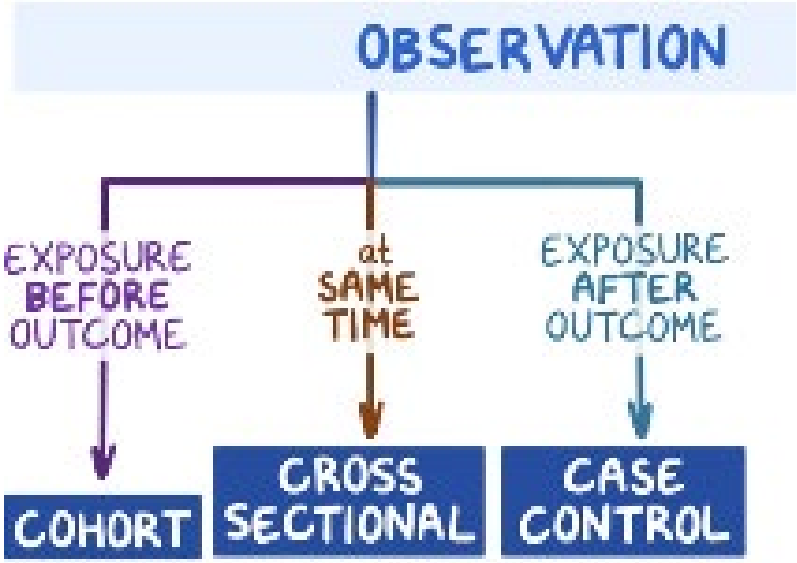
	Note : **Longitudinal studies** are **Based on multiple observations** in the same population **over a multiple points of time**. ➔ **Is Cross-sectional design Descriptive or Analytical?** -It may be difficult to decide whether the disease or the exposure came first, so causation should always be confirmed by stronger studies. -The collection of information about risk factors is retrospective, running the risk of recall bias. -In practice cross-sectional studies include elements of both descriptive and analytical design.		
Examples	-What is the *prevalence* of diabetes in Jordan? -What is the *prevalence* of malnutrition among children in Jordan? - community surveys: -A survey of asthma among animal handlers -A survey of dietary habits among university students	- e.g. A study to explore the relationship between obesity and breast cancer. -e.g. A study to assess the effect of mothers' educational level on malnutrition among children	- Does living in poor housing increases the risk of developing cancer? -Does following a healthy life style lower the risk of hypertension?.
Advantages	-Less time consuming -Less expensive	**Strengths:** **-**Less expensive and less time consuming	-Examines multiple outcomes of a single exposures

	-Provides more information (lots of variables) Additional from osmosis about the previous point :  Also, a lot of information can be collected from each participant, so cross-sectional studies are especially useful for looking at relationships between multiple diseases and multiple outcomes. For example, in addition to looking at migraines, you could also compare the prevalence of strokes and heart disease in people that smoke cigarettes or don't. -Describes the population well -Generates hypothesis -Cross-sectional study provides a snap-shot or a photograph of a population at a certain point in time.	- Efficient for **studying rare diseases** -Allows the study of several different etiological factors for one disease. -No attrition problems (no follow-up). -Ethical problems are minimal (no risk to participants)	-Valuable when **exposure is rare** -Temporal relationship is known -Allow direct measurement of risk -Minimize bias in ascertainment of exposure -Exposure status determined before disease detection (avoid **information bias**). -Subjects selected before disease detection (avoid **selection bias**).
Disadvantages	- Weakest observational design, (it measures prevalence, not incidence of disease). Prevalent cases are only the survivors.	**Limitations** -Selection of an appropriate control group may be difficult. -Inefficient for evaluation of rare exposure	- Expensive -Time-consuming -Inefficient for rare diseases or diseases with long latency -Loss to follow-up is a problem

	-The temporal sequence of exposure and effect may be difficult or impossible to determine. Temporal sequence : the exposure should become before the disease Additional from osmosis about the previous point : For example, you don't know if people started smoking before or after they started getting migraines, so you can't really say that smoking causes migraine -Usually don't know when disease occurred -Rare events a problem. -Quickly emerging diseases are also a problem. -Least useful in establishing causation (among analytical studies).	-Difficult to establish temporal sequence -Determining exposure will often rely on memory, leading to bias (**recall bias**). -We cannot measure incidence & can only estimate the relative risk (RR).	

Additional from osmosis : [you can skip these 2 pics]





Framingham study is the most famous cohort study in the world

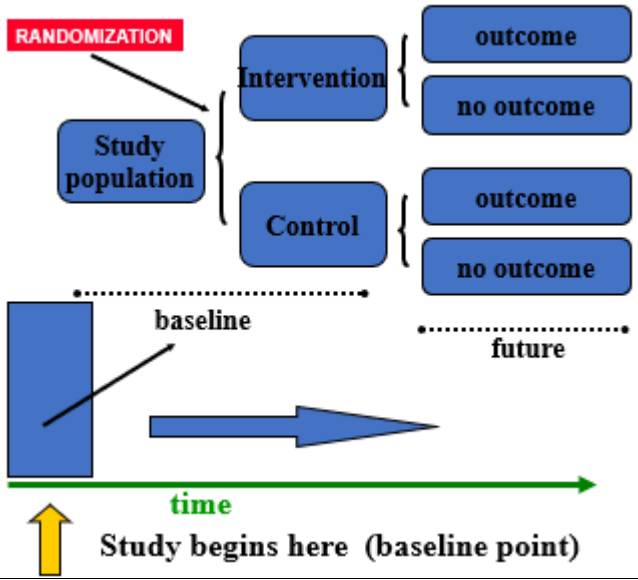
you can find the answers to this slide in

activity number 4

Framingham Study

What is the Framingham study?
When did it start? Where?
What was the disease studied?
What are the most important findings?
How many people participated?
When did it end?

Experimental studies (intervention studies)

Types	**1. RCT (Randomized Controlled Trial)**
Definition	- RCT is a clinical trial that is well-designed (controlled and randomized). (Controlled means: The researcher manipulates situations/objects.) - An experimental design with subjects randomly assigned by the investigator into a "**treatment**" **group** and a "**comparison" group**.
Experimental design	
notes	- Randomized Controlled Clinical trials are the most well known experimental design. - The **ultimate form of design in testing causal hypotheses** (provides most convincing evidence). - If properly done, experimental studies can produce high quality data. -**Thy are the gold standard study design (strongest, most robust).** → The quality of this "Gold standard" in experimental studies can be achieved through: **a)Randomization :** random allocation of study subjects in to treatment & control groups. Avoids bias & confounding, and increases confidence in the results**.**

	b) Blinding : Denying information on treatment / control status (single, double or triple blinding). This helps to avoid <u>reporting bias, observation bias and assessment bias</u>. **Single :** the patient does not know if he is in the control or treatment group (the patient doesn't know if he is taking the new medications or not) **Double :** both patients and the observing physician do not know if the patient …… **Triple (the strongest one) :** neither the patient nor the following physician nor the person who does the statistical analysis know if the person is in control group or treatment group **c)use of Placebo**.: Placebo is used as blinding procedure (placebo : an pharmacologically inert material indistinguishable from active treatment.) Used to avoid Placebo effect: tendency to report favourable response regardless of physiological efficacy. - It is not unexpected to find that observational studies find different results than for clinical trials. Eg; Clinical Trials of hormone replacement therapy in menopausal women found no protection for heart disease, contradicting findings of 100's of prior observational studies.
Examples	- The effectiveness of a new treatment for rheumatoid arthritis. - Comparing the length of stay in hospital between laparoscopy and surgery for appendicitis.
Disadvantages	- Very expensive -Not appropriate to answer certain types of questions for ethical reasons: It may be unethical, for example, to assign persons to certain treatment or comparison groups if exposure has well-known benefit.

-Example of experimental design:

It can be used to evaluate preventive strategies experimentally.

- **Factories participating in a coronary heart disease prevention project were assigned to two groups, one receiving a programme of screening for coronary risk factors and health education, and the other being left alone.**
- **Subsequent disease incidence was then compared between the two groups.**
- **The main application of experimental studies, however, is in evaluating therapeutic interventions by randomized controlled trials.**
- **In a trial to prevent onset of diabetes among high-risk individuals, investigators randomly assigned enrollees to one of three groups — placebo, an anti-diabetes drug, or lifestyle intervention.**
- **At the end of the follow-up period, investigators found the lowest incidence of diabetes in the lifestyle intervention group, the next lowest in the anti-diabetic drug group, and the highest in the placebo group.**

2.the last slide from lecture 7

Quasi-Experimental Studies

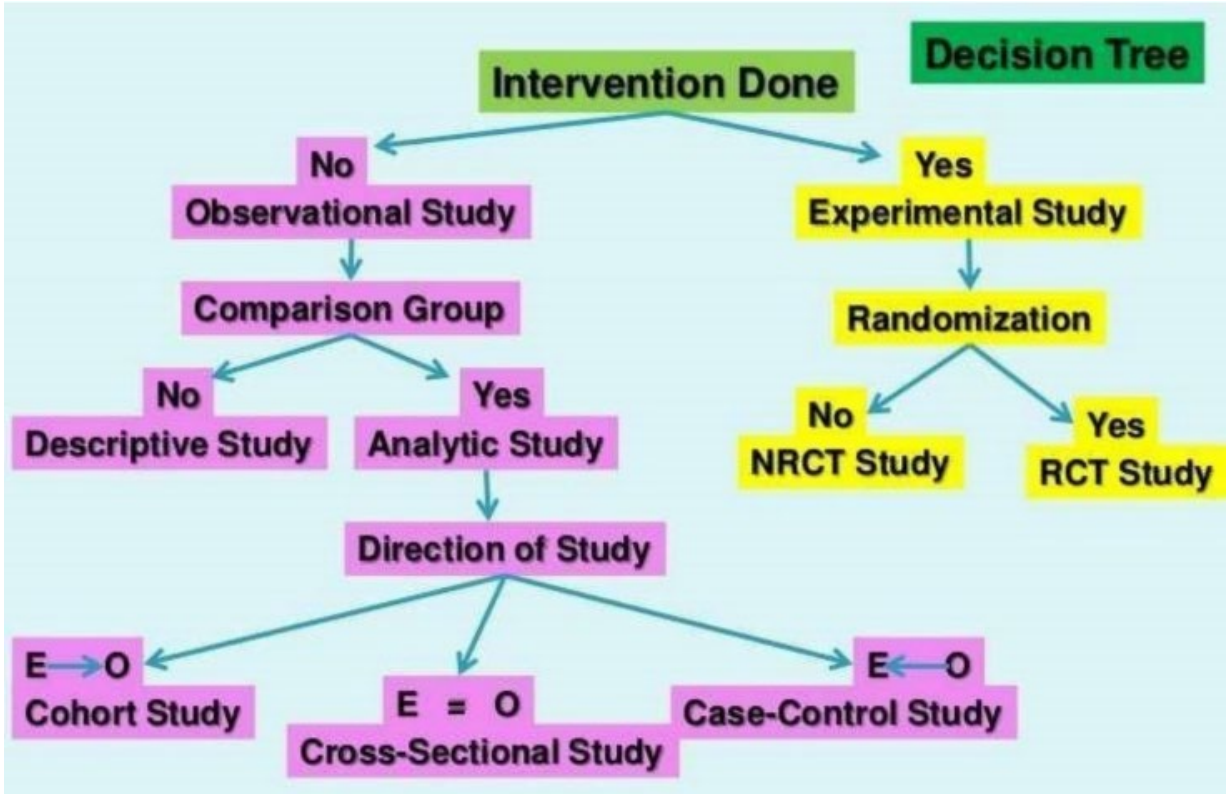
The researcher does not decide or plan the intervention (e.g. changes in using health care after removing ophthalmic services from health insurance), no Randomization or no control group.

Natural experiments

Factor occurred naturally : e.g. Increase in mental disorders following an earthquake.

Crossover Studies participant work as a control for himself (e.g. New pain relief medication)

This is additional (not present in the slides) (taken from the modified slides uploaded on ju medicine)



Note that (the table below is explained in lecture 8)

Study design	Measure of association used
Cohort study	RR (relative risk , risk ratio)
Case – control study	OR (odd ratio)