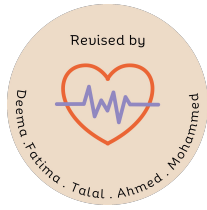


Research  
442



# Cohort study design

Lecture No. 10

## Objectives:

1. Describe the types of cohort studies
2. Describe the design of cohort studies
3. Identify steps for conducting cohort studies
4. Identify issues in the design of cohort studies
5. Describe the strengths and weaknesses of cohort studies

~ This lecture was presented by **Dr. Nura Alamro**

~ It is included in the **Midterm Exam**

~ We highly recommended reading the **Ayah** in the first page

## Slides

### Color code

Original text

Dr. Notes

Important

Golden note 

Extra

## Editing file

## Cohort study

- A cohort study is an analytical observational study in which a **group of people** with a common characteristic is **followed over time** to find how many reach a certain health outcome of interest (disease, condition, event, death, change in health status or behavior, or **Natural history of a Disease**).
- Term "**cohort**" is defined as a group of people, usually **100 or more** in size, who share a common characteristic or experience within a defined time period (e.g., age, occupation, exposure to a drug or vaccine, pregnancy, and insured persons).
- The **comparison group** may be the **general population** from which the cohort is drawn, or it may be another cohort (group of people) of persons thought to have had little or no exposure to the substance in question, but otherwise similar.



وَسِيقَ الَّذِينَ اتَّقَوْا رَبَّهُمْ إِلَى الْجَنَّةِ  
 زُمَرًا حَقَّ إِذَا جَاءُوهَا وَفُتِحَتْ أَبْوَابُهَا وَقَالَ لَهُمْ خَزَنَتُهَا  
 سَلِّمُوا عَلَيْكُمْ رَبِّكُمْ فَاَدْخُلُوهَا خَالِدِينَ ﴿٧٦﴾

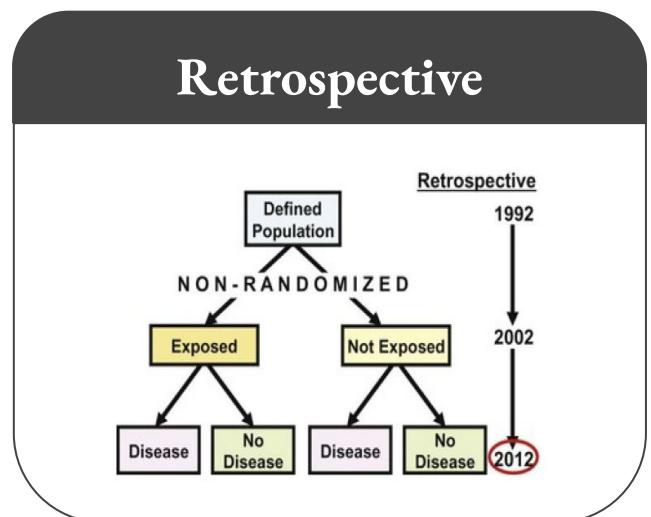
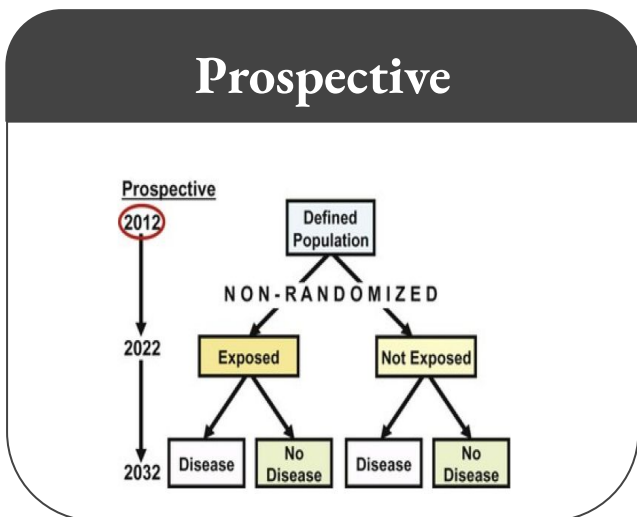
المختصر في التفسير

وساق الملائكة برفق المؤمنين الذين اتقوا ربهم بامثال  
 أوامره واجتنب نواهيهِ إلى الجنة جماعات مكرمة، حتى  
 إذا جاؤوا الجنة فتحت لهم أبوابها، وقال لهم الملائكة  
 الموكلون بها: سلام عليكم من كل ضرٍّ ومن كل ما  
 تكرهونه، طابت قلوبكم وأعمالكم، فادخلوا الجنة ماكثين  
 فيها أبدًا.

Exam will comes as scenarios

→ **Two types** of cohort studies have been distinguished on the **basis of the time of occurrence of disease** in relation to the time at which **the investigation is initiated** and continued:

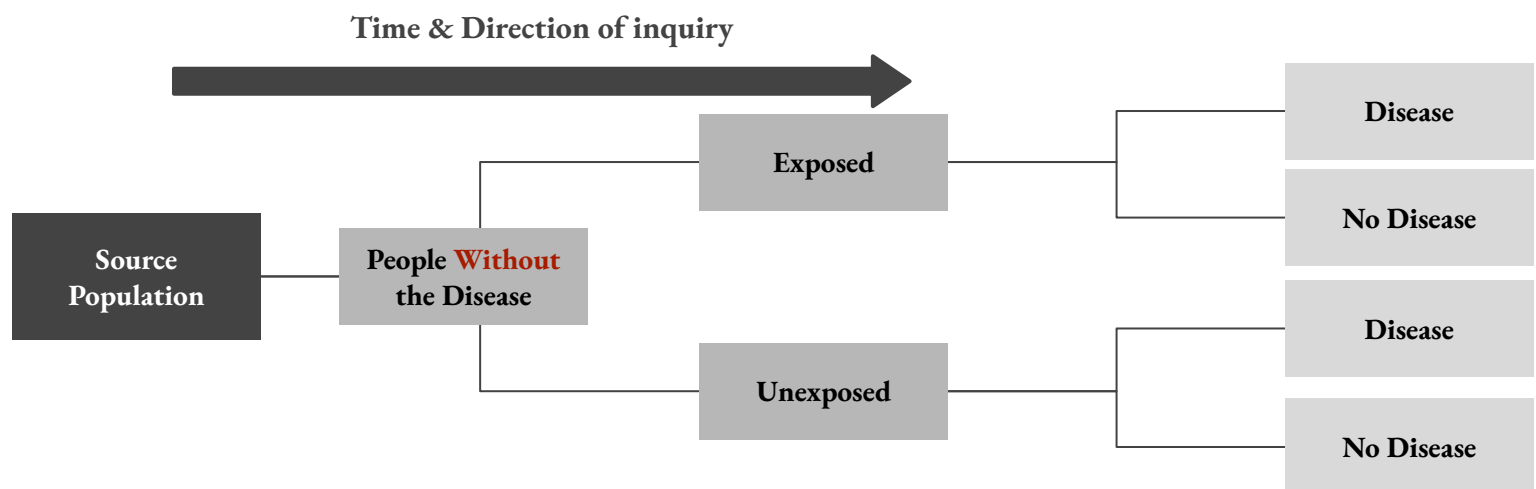
It more for Surgery Workers



# When to conduct a cohort study

- When there is **good evidence of an association** (we benefit from cross sectional and case control studies) between exposure and disease (**If we observe an association between an exposure and a disease or another outcome, the question is: Is the association causal?**).
- **When exposure is rare**, but the **incidence of disease high** among exposed, e.g., special exposure groups like those in industries, or exposure to X-rays. However, when the outcome is rare → case control
- When **attrition** (loss during follow up) of study population **can be minimized**, e.g. follow-up is easy, cohort is stable, cooperative and easily accessible
- When **funds & time are available**.

## Design a cohort study

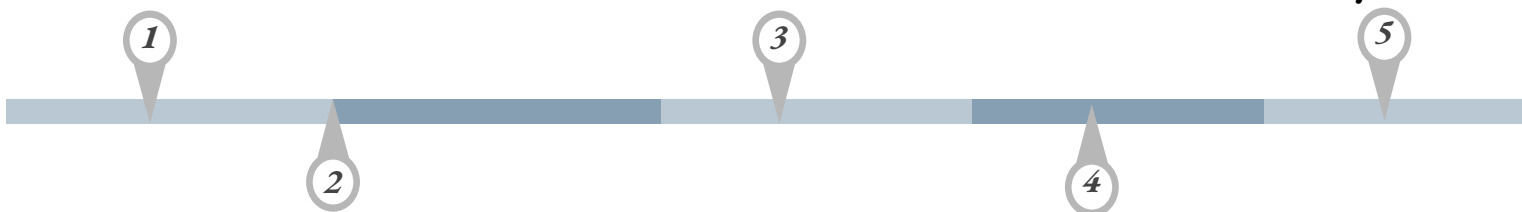


## Steps in conducting a cohort study

Define a **source population**

Measure the **exposure**

**Analyze** data



Select **Study Populations (subjects & controls)**

- **Two methods:**
  - A. Based on **exposure status**
  - B. Or based on **factor other than exposure**  
e.g., geographic location

**Follow up** at intervals to get accurate **outcome data**

To enroll the participant in the cohort study you have to know the Exposure status

# Steps in conducting a cohort study, cont.

## Measuring Exposure

- Levels of exposure (e.g. packs of cigarettes smoked per year) are measured for **each individual** at:
  - Baseline at the **beginning** of the study.
  - Assessed at intervals during the period of **follow-up (Prognosis)**.
- A particular problem occurring in cohort studies is whether **individuals in the control group are truly unexposed. For example**, study participants may start smoking or they may fail to correctly recall past exposure. Similarly, those in **the exposed group may change their behaviour in relation to the exposure** such as diet, smoking or alcohol consumption.
- Sources for Exposure data:** medical or employment records, standardized questionnaires, interviews and by physical examination.

## Measuring Outcome

- Sources for outcome data:**
  - routine surveillance of cancer registry data, death certificates, medical records or directly from the participant.
- Method used to ascertain outcome must be **identical for both exposed and unexposed groups**.

## Analysis in cohort studies

The data are analyzed in terms of:

- Incidence rates** of outcome among exposed and non-exposed (Incidence: New cases).
- Estimation of risk:**
  - Relative Risk** (also known as Risk Ratio, **RR**)
  - Attributable Risk (AR)**

		Then Follow to See Whether		Totals	Incidence Rates of Disease
		Disease Develops	Disease Does Not Develop		
First, Select	Exposed	a	b	a + b	$\frac{a}{a+b}$
	Not exposed	c	d	c + d	$\frac{c}{c+d}$
		$\frac{a}{a+b}$ = Incidence in exposed	$\frac{c}{c+d}$ = Incidence in nonexposed		

Dr. Afnan: The terms may vary between different books and sources. Just to make it simple for you, we'll follow (Gordis). So if it's only (attributable risk) then it's the difference between incidences. If the name is (attributable risk proportion) then it's the difference divided by the incidence of the exposed.

**Incidence rate:**

- Incidence Rate among **exposed** =  $\frac{a}{a+b} \times 1,000$
- Incidence Rate among **unexposed** =  $\frac{c}{c+d} \times 1,000$

**Attributable risk ratio:**

$$\frac{\text{Incidence rate among exposed} - \text{Incidence rate among unexposed}}{\text{Incidence among exposed}}$$

x 100

$$= \frac{[a/(a+b) - c/(c+d)]}{[a/(a+b)]} \times 100$$

$$\times 100$$

*“How much the disease can be prevented if we have an effective measure of eliminating the exposure?”*

**Relative risk:**

$$= \frac{\text{Incidence rate among exposed}}{\text{Incidence rate among unexposed}}$$

$$= \frac{a/a+b}{c/c+d}$$

*“What is the ratio of the risk of disease in exposed individuals to the risk of disease in unexposed individuals?”*

Measurement of association in Question

# Vaping and pulmonary “illness”

Cohort study of vaping and pulmonary illness followed for 1 year.

- **Exposure:** vaping
- **Outcome:** pulmonary illness

	Pulmonary illness	No Pulmonary illness	Total
Vaping	42	27,000	27,042
No vaping	7	63,000	63,007
Total	49	90,000	90,049

## Incidence Rates:

(Must multiply by 1,000 after you subdivide the numbers(a/a+b))

- Incidence Rate among **exposed:**  
= **1.5/1000/year**
- Incidence Rate among **unexposed:**  
= **0.1/1000/year**

## Relative risk:

= **15 Ratio**

### What does 15 mean?

The risk of pulmonary illness is 15 times higher among vapers than non-vapers

## Attributable risk:

= **93%**

### What does 93% mean?

93% of the morbidity from pulmonary illness among vapers may be attributable to vaping and could be prevented by elimination of vaping

## Issues in the design of cohort studies

### 1. Loss to follow up:

- Cohort members may **die, migrate**, change jobs or **refuse to continue** to participate in the study.
- In addition, losses to follow-up may be **related** to the **exposure, outcome** or both.
- For example, individuals who develop the outcome may be less likely to continue to participate in the study.

### 2. Differential Misclassification of Subjects:

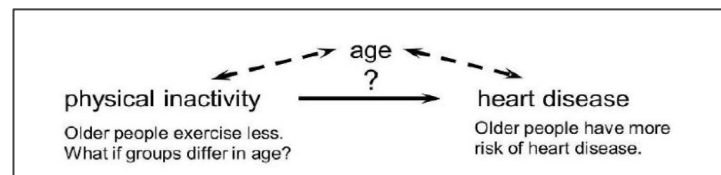
- A major source of potential bias in cohort studies arises from the degree of **accuracy** with which subjects have been **classified** with respect to their **exposure** or **disease** status.
- Differential misclassification can lead to an over or underestimate of the effect between exposure and outcome.

### 3. Selection Bias:

- Selection bias is more common in case-control studies.
- However, it can happen in **cohort studies** if:
  - a. **The completeness of follow-up is different among exposed and unexposed.**
  - b. **Outcome ascertainment differs between exposed and unexposed.**

### 4. Confounding:

- Confounding is a distortion (**inaccuracy**) in the estimated measure of **association** that occurs when the primary exposure of interest is mixed up with some other factor that is associated with the outcome.
- In the figure below, the primary goal is to ascertain the strength of association between physical inactivity and heart disease. Age is a confounding factor because it is associated with the exposure (meaning that older people are more likely to be inactive), and it is also associated with the outcome (because older people are at greater risk of developing heart disease).



## Strengths & weakness

### Strengths

- Multiple outcomes can be measured for any **one exposure**.
- Can look at multiple outcomes.
- Exposure is measured before the onset of disease (in prospective cohort studies).
- Good for measuring **rare exposures**.
- Demonstrate causality.
- Can measure **incidence**.

### Weaknesses

- **Costly and time consuming**.
- Prone to bias due to loss to follow-up.
- Prone to confounding.
- Participants may move between one exposure category.
- Knowledge of exposure status may bias classification of the outcome.
- Being in the study may alter participant's behavior.
- **Poor choice for the study of a rare disease (rare outcome)**.
- Classification of individuals (exposure or outcome status) can be affected by changes in diagnostic procedure.

القارة:  
عبدالله الشهري وهي المتحفي

نواف التركي  
ريان الفنامي

### الأعضاء:

رغد النظيف  
ريما الجريبة  
شهد البخاري  
نوف الضلعان  
أثير الاحمري  
وعد ابونخاع  
نراء الهويش  
في الدوسري  
منار الزهراني

عبدالله التركي  
محمد الزير  
عثمان الدريهم  
عبدالعزیز القوطاني  
ناصر الفيت  
سعد السهائي  
رائد الماضي  
سعود الشعلان  
عبدالله المياح  
عبدالله النجريس  
تركي العتيبي  
عبدالله القرني  
عامر الفامري  
سعد الاحمري  
معاذ آل سلام  
محمد الحصيني

### MCQ:

Q1: In cohort study?

- A. Association is indirect
- B. No association
- C. Association is causal
- D. None

Q2: In cohort study we select the population based on?

- A. Exposure status
- B. Geographic location
- C. A&B
- D. A or B

### MCQ:

Q3: Sources for exposure data?

- A. Medical records
- B. Death certificates
- C. Routine surveillance
- D. Registry data

Q4: The data in cohort study is analyzed in term of?

- A. Prevalence
- B. Incidence rate
- C. Incidence proportion
- D. None

