جامعة الملك سعود
King Saud University

CMED 305

Cohort Studies

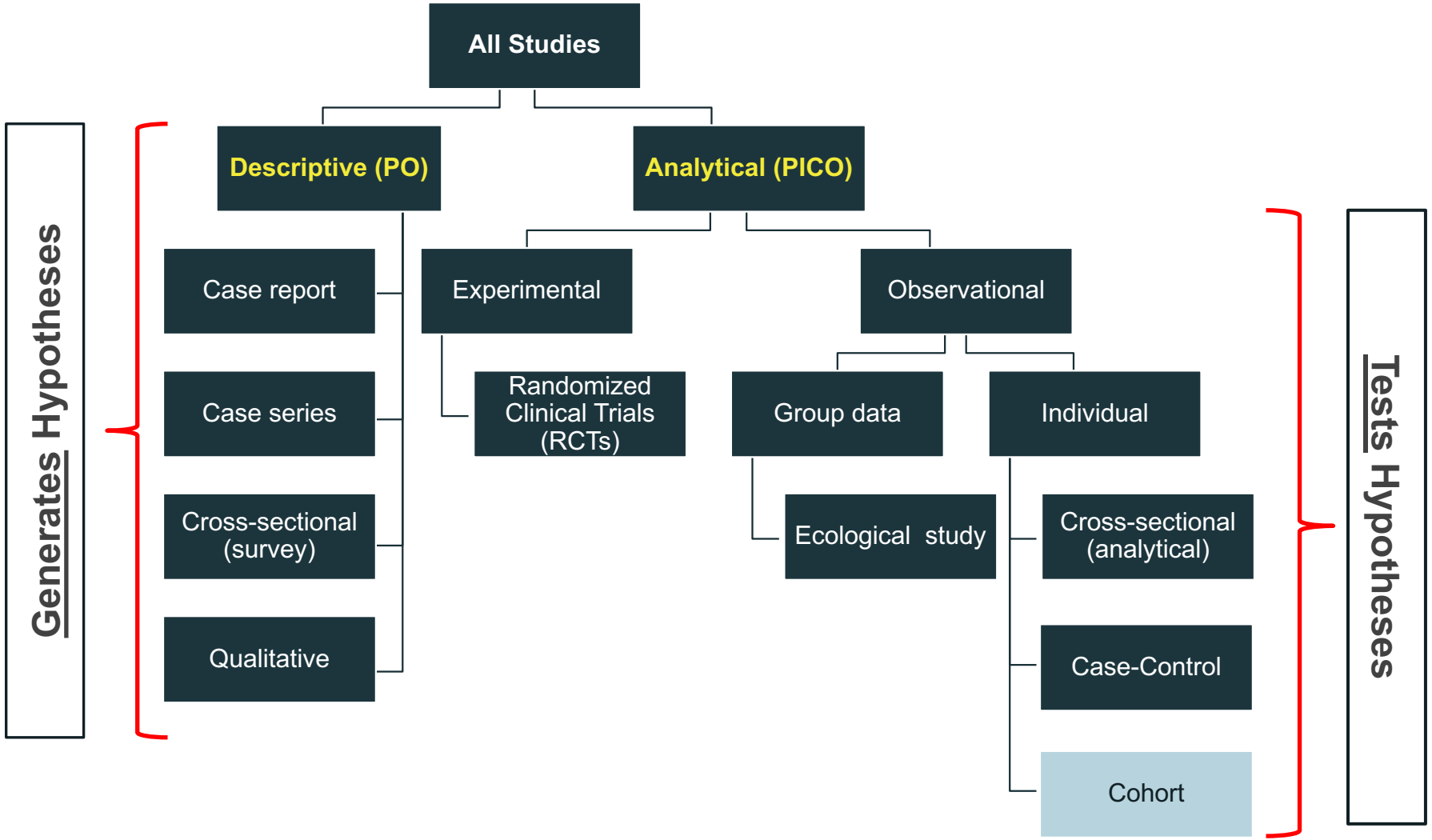
Kholood Altassan, MBBS, PhD

Assistant Professor - Community Medicine Unit,
Family & Community Medicine Department

Learning Objectives: By end of this session students will be able to:

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

1 Design of a Cohort Study


All Studies
Descriptive (PO)
Analytical (PICO)
Case report
Case series
Cross-sectional (survey)
Qualitative
Experimental
Randomized Clinical Trials (RCTs)
Observational
Group data
Individual
Ecological study
Cross-sectional (analytical)
Case-Control
Cohort
Generates Hypotheses
Tests Hypotheses

A cohort study is an analytical observational study in which a group of people with a common experience **(the cohort)** is **followed over time** to find how many reach a specified outcome of interest (disease, condition, event, death, or a change in health status or behavior).

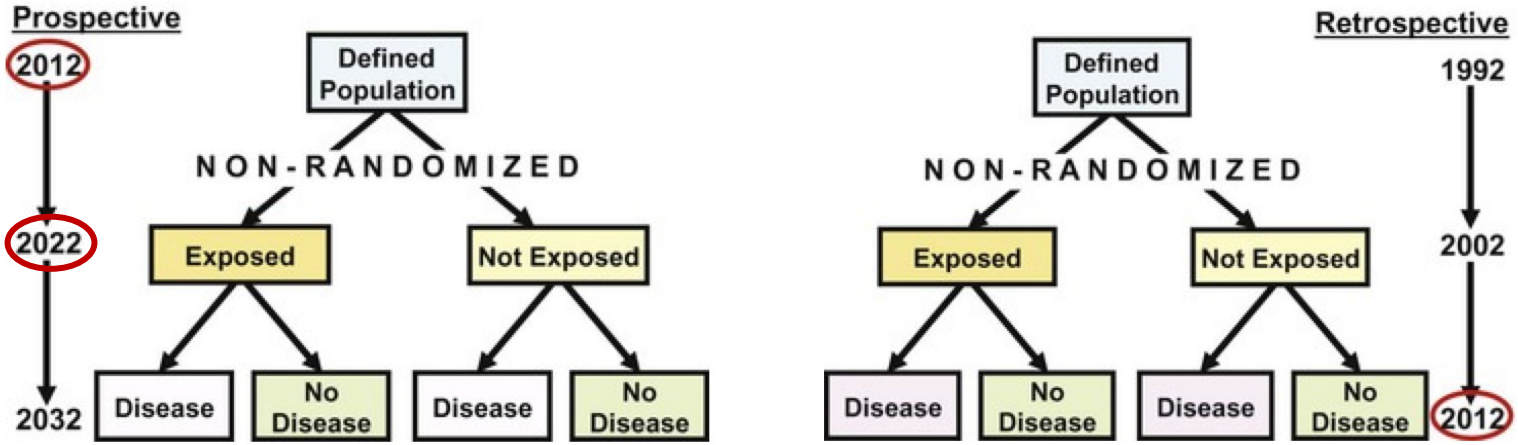
- Term "cohort" is defined as a group of people, usually 100 or more in size, who share a common characteristic or experience within a defined time period (e.g., age, occupation, exposure to a drug or vaccine, pregnancy, and insured persons).

- The comparison group may be the general population from which the cohort is drawn, or it may be another cohort of persons thought to have had little or no exposure to the substance in question, but otherwise similar.

When to Conduct a Cohort Study

- When there is good evidence of an association between exposure and disease based on previous studies
- 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
- 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 feasible because time and resources are available

2 Types of cohort studies



Two types of cohort studies have been distinguished based on the timing at which the investigation is initiated; before or after the outcome has occurred.

{3 How to conduct a cohort study?}

Steps in conducting a cohort study

1- Define a **source population**

2- Select **Study Populations (cohort & comparison): two methods:** based on **exposure status** OR based **on factor other than exposure** e.g. geographic location

3- Measure the **exposure**

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

5- **Analyze** data

Measuring Exposure	Measuring Outcome
Levels of exposure are measured for each individual at: 1. baseline at the beginning of the study and 2. assessed at intervals during the period of follow-up. ○ A particular problem occurring in cohort studies is whether individuals in the control group are truly unexposed. ○ 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 and biomarkers.	**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:

1. **Incidence rates** of outcome among exposed and non-exposed

2. **Estimation of risk**:

    - **Relative Risk (also knows Risk Ratio) (RR)**
    - **Attributable Risk (AR) or Rate Ratio**

What is the difference between prevalence and incidence?

Prevalence	Incidence
• Outcome has already developed and been ascertained • Prevalence rate uses unit of person (or ppl per 1000) • Cross-sectional studies	• Newly developed during the course of study based on the time till outcome develops • Incidence rate uses unit of per person-time (e.g. person-years or person-months) • Cohort studies

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

IR

Incidence Rate among exposed= a/a+b

Incidence Rate among unexposed= c/c+d

RR

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

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

"The ratio of the risk of developing the disease in exposed individuals to the risk of developing the disease in unexposed individuals."

AR

$$\frac{\text{Incidence rate among exposed - Incidence rate among unexposed}}{\text{Incidence among unexposed}} \times 100$$

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

"How much of the disease can be attributed to the exposure?"

Incidence Rate and Measures of Risk

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

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IR

IR among exposed
= 42/27,042
= 1.5/1000 person-year

IR among unexposed
= 7/63,007
= 0.1/1000 person-year

RR

= 1.5/0.1
= 15

AR

$$= \frac{1.5 - 0.1}{0.1} \times 100$$

= 93%

Translation

What does a relative risk of 15 mean?

The risk of developing pulmonary illness is 15 times higher among those who vaped compared to those who did not.

What does an attributable risk of 93% mean?

93% of pulmonary illness among subjects may be attributed to vaping

4 Issues in the design of cohort studies

Loss to Follow Up

- Cohort members may die, migrate, change jobs or withdraw from the study.

- In addition, losses to follow-up may be related to the exposure, outcome or both which can lead to biases.

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

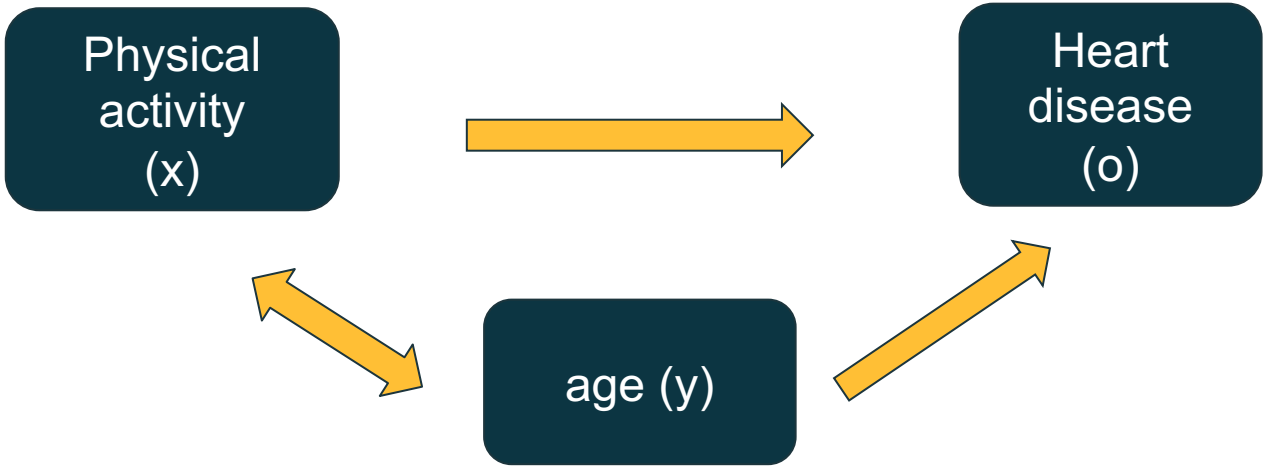
Selection Bias

- Selection bias is more common in case-control studies.

- However, it can happen in cohort studies if:
  1. Loss of follow-up is different among exposed and unexposed.
  2. Outcome ascertainment differs between exposed and unexposed.
  3. Healthy worker effect

Confounding

1. Associated with both exposure
2. Causing the outcome
3. Should not lie in the causal pathway



{5 Strengths & Weaknesses }

Strengths

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

Weaknesses

- Costly and time consuming.
- Prone to selection bias due to loss to follow-up and healthy worker effect.
- Prone to confounding.
- Participants may move between exposure categories.
- Observer bias
- 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 procedures.

Thank you!

Office Hours (by appointment via email):

k.k.altassan@gmail.com

nmalamro@ksu.edu.sa

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