CMED 305

Cohort Studies

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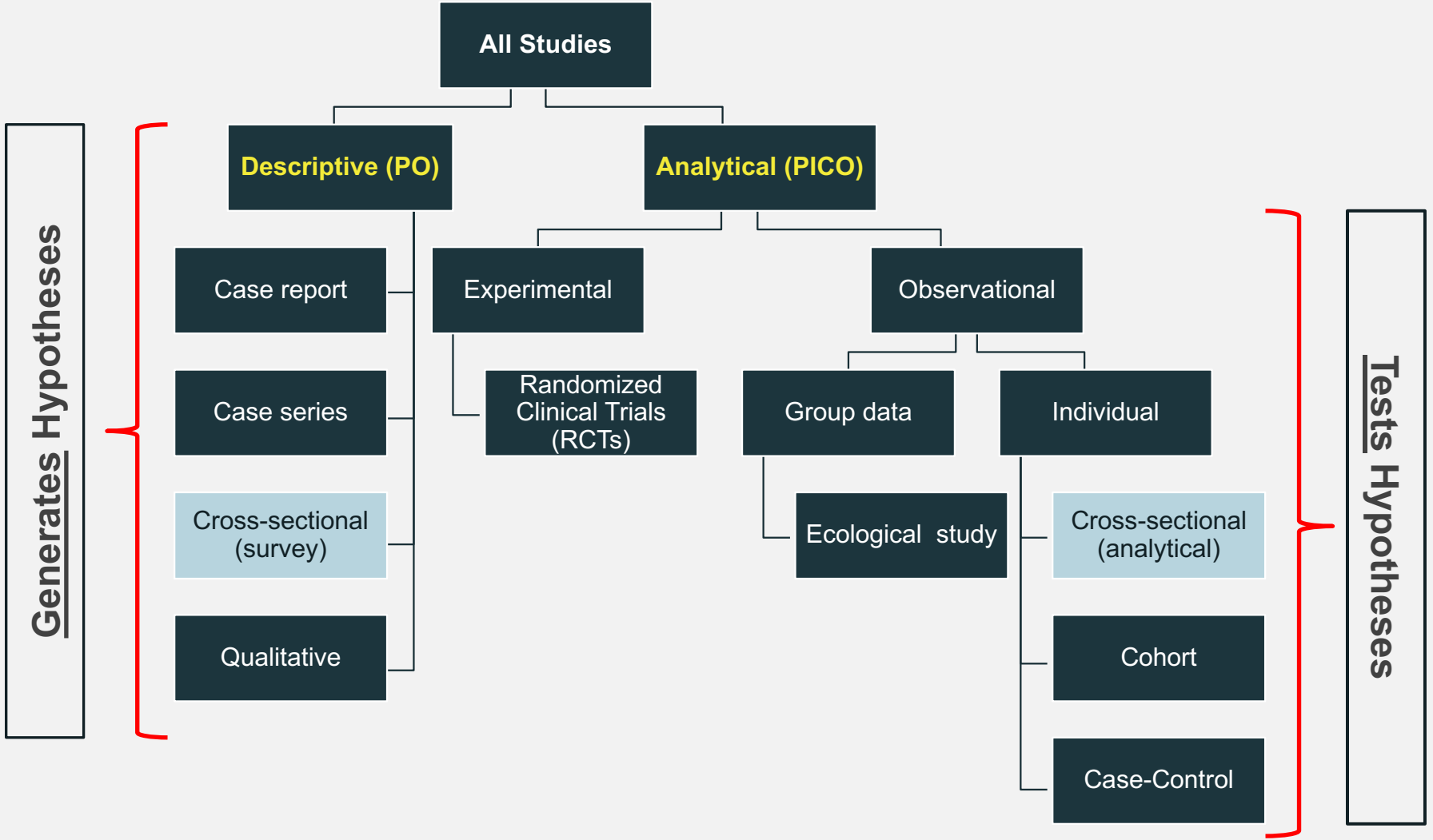
Learning Objectives: By end of this session students will be able to:

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

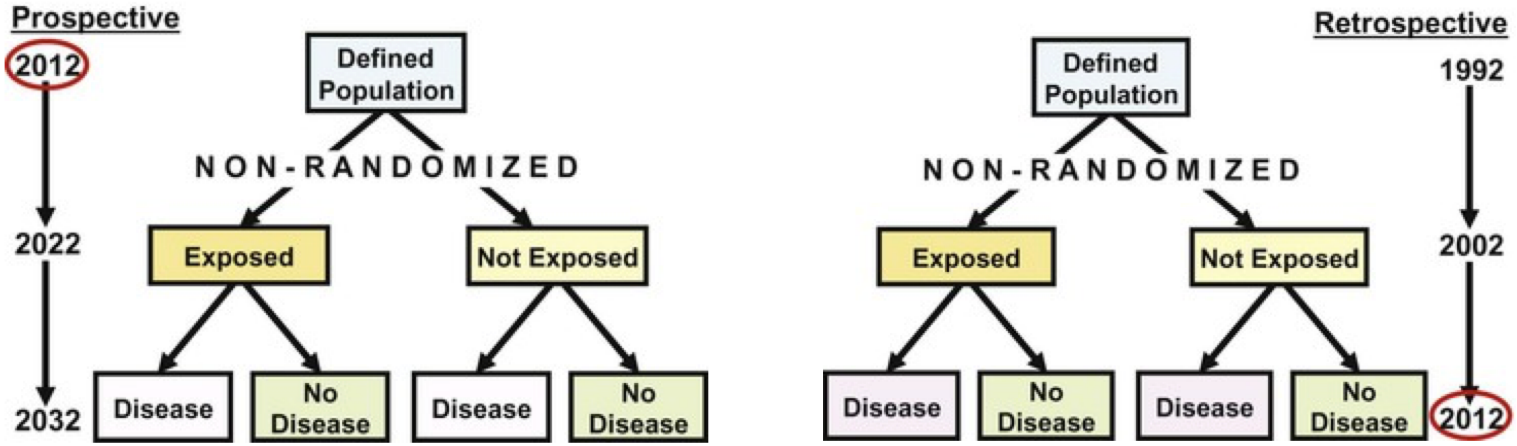
1 Types of cohort studies


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)
Cohort
Case-Control
Generates Hypotheses
Tests Hypotheses

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, 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.

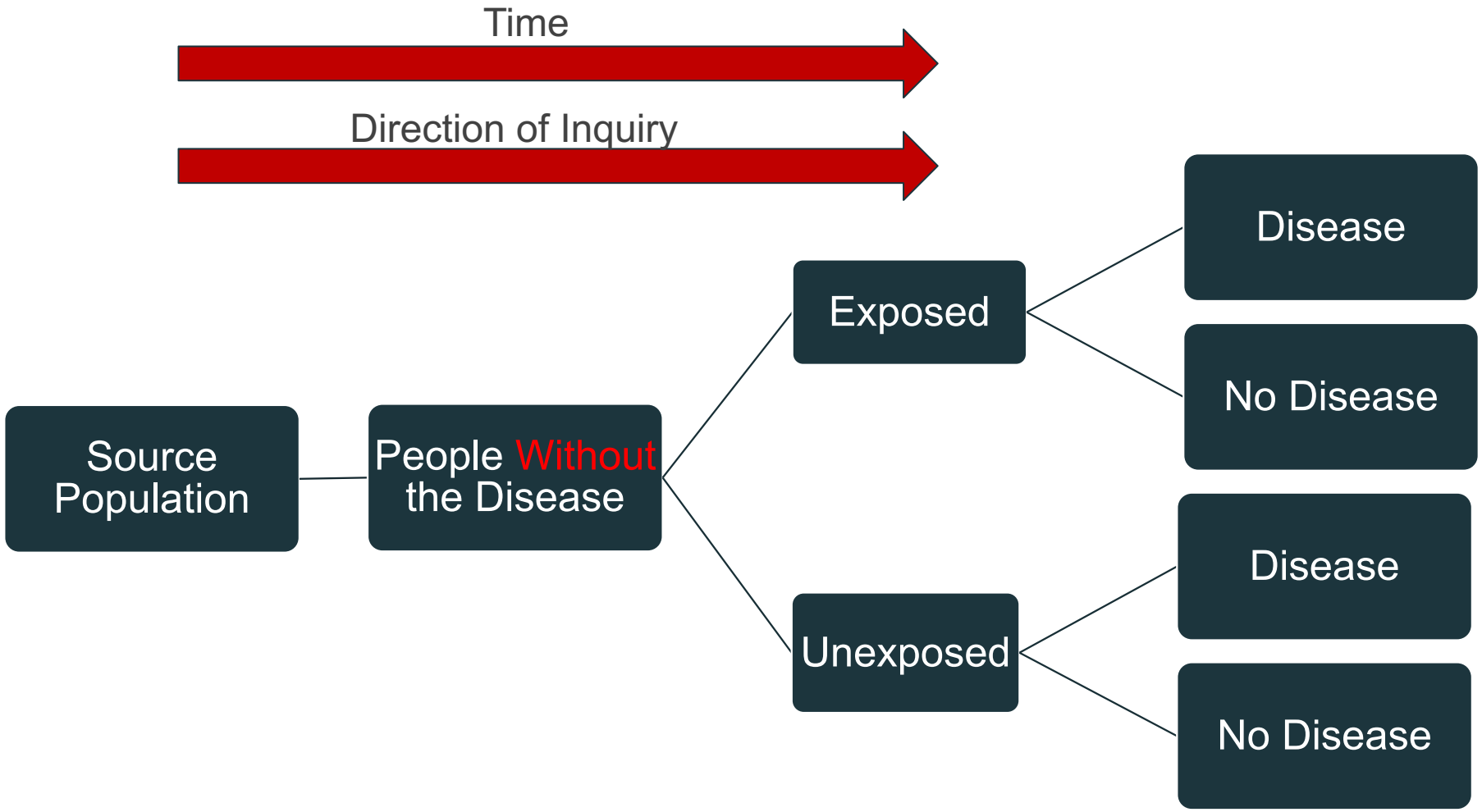


Two types of cohort studies have been distinguished on the **basis of the time** of **occurrence of disease** in relation to the time at which **the investigation is initiated** and continued

When to Conduct a Cohort Study

- When there is good evidence of an association 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
- 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 and time are available

{2 Design of a Cohort Study}


Time
Direction of Inquiry
Source Population
People Without the Disease
Exposed
Unexposed
Disease
No Disease
Disease
No Disease

{3 How to conduct a cohort study?}

Steps in conducting a cohort study

1- Define a **source population**

2- Select **Study Populations (subjects & controls): 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 (e.g. packs of cigarettes smoked per year) 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. 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.	• **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)**

		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	$c+d$	$\frac{c}{c+d}$

$\frac{a}{a+b}$ = Incidence in exposed

$\frac{c}{c+d}$ = Incidence in nonexposed

Incidence Rates:

Incidence Rate among exposed= a/a+b

Incidence Rate among unexposed= c/c+d

RR:

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

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

"What is the ratio of the risk of disease in exposed individuals to the risk of disease in unexposed individuals?"

AR:

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

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

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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Incidence Rates:

Incidence Rate among exposed= 1.5/1000/year

Incidence Rate among unexposed= 0.1/1000/year

RR

= 15

What does 15 mean?

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

AR

= 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

4 Issues in the design of case-control studies

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.

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

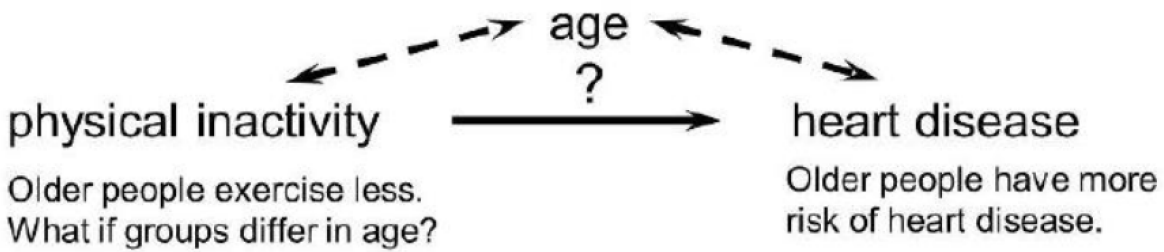
Selection Bias

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

- However, it can happen in cohort studies if:
  1. The completeness of follow-up is different among exposed and unexposed.
  2. Outcome ascertainment differs between exposed and unexposed.

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 above, 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).

{5 Strengths & Weaknesses }

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.

Weakness

- 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 procedures.

Thank you!

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