Dr. Rabaa Mahmoud

Faculty of Dentistry

Mutah University

Credit to: Prof. Dr. Waqar Al-Kubaisy & Dr. Israa Al-Rawashdeh

Study Designs
(Observational Studies)

Learning Objectives

By the end of this lecture, students will be able to:

1. Identify the main types of epidemiological study designs.
2. Differentiate between Cross-sectional, Case-control, and Cohort studies.
3. Explain the measures of association, including Odds ratio (OR), Relative risk (RR), and Attributable risk (AR).
4. Identify the advantages, limitations, and appropriate uses of each observational study design.

Definition Of Epidemiological Studies

An epidemiological study is an investigation that examines the relationship between exposures and health outcomes in human populations to understand disease patterns and causes. (International Epidemiological Association, 2021)

Epidemiological Study Designs

Non-Experimental

A. Descriptive

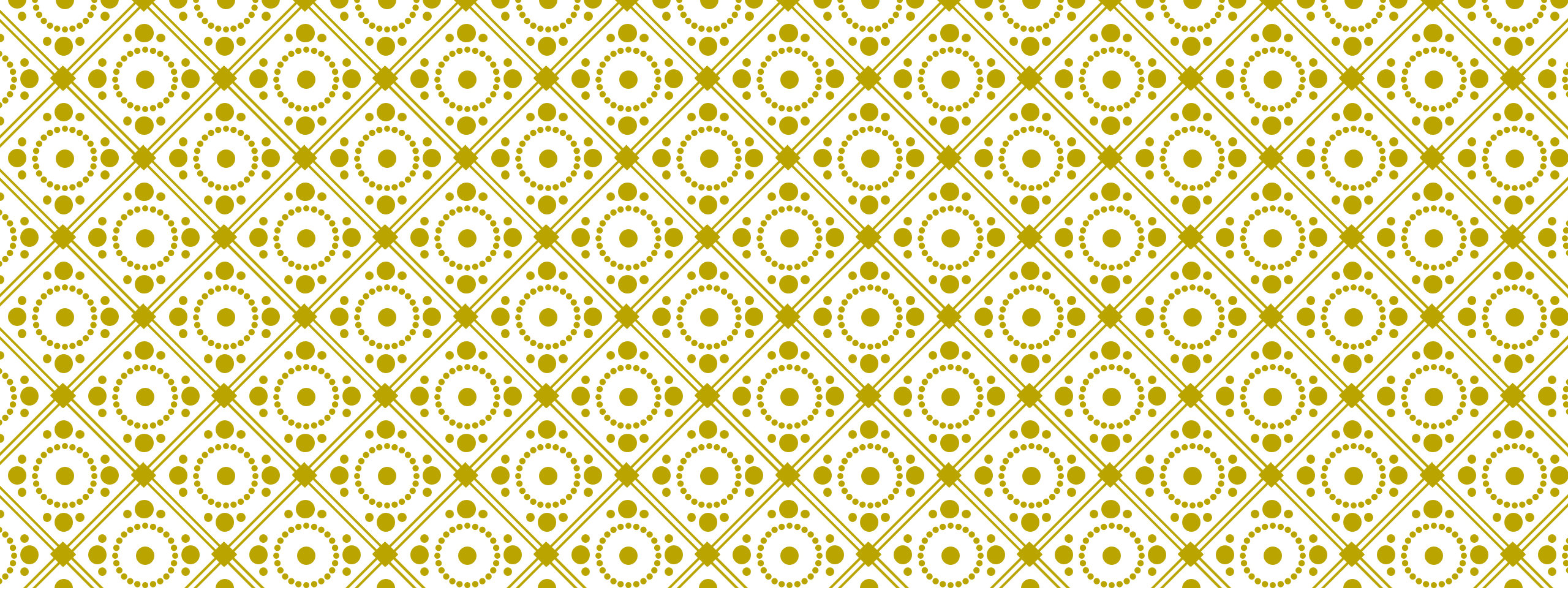
1. Case reports
2. Case series
3. Cross-sectional study

B. Analytic

1. Case-control
2. Cohort

Experimental

1. Clinical trial
2. Community interventional trial



Descriptive Studies

- Case Report
- Case Series
- Cross-sectional study

Comparison Between Case Report And Case Series

Feature	Case Report	Case Series
Definition	A detailed description of a single patient with an unusual condition, disease, or outcome.	A summary of multiple patients (usually 2 or more) with similar clinical features or exposures.

Cross-sectional Studies

• In a cross-sectional study, a sample is chosen and data on each individual (or case) is collected at one point in time.

• **It is usually looked at as a snapshot.**

• **Examples**:

A. Prevalence of anxiety among medical students in Jordan

B. knowledge, attitude, and practice of breast self-examination among Jordanian women.

C. Studying the inter-relationships between variables of interest, for example, a study to determine the characteristics of heavy drinkers, a cross-sectional study allows comparisons by sex, age, and so on

NOTES:

We should not confuse the period of the study, which is the data collection period, with the fact that we collect data only once from everyone (a snapshot). A survey may be conducted over weeks or months, and everyone appears in the survey only once.

We do not know when the events occurred before the study. So, we can only say that there is an association between the factor of interest and disease, but we cannot say that the factor is likely to have caused the disease.

An example of a temporal relation

If we design a cross-sectional study to investigate the presence of an association between obesity and depression, we are not sure which problem started first, and we cannot conclude that one of them caused the other.

- **Cross-sectional studies can be used to estimate the prevalence of a disease in the population, but not the incidence.**

Prevalence

"Prevalence is an estimate of individuals in the population with a given disease, disability, or health state at a particular point in time."

Prevalence is a ***proportion*** and should usually be reported as a ***percentage***. Denominators in prevalence always include the entire population; the numerator encompasses both new and old cases.

Categories of prevalence:

1. Point prevalence
2. Period Prevalence

$$\frac{\textbf{Number of cases of disease at a point in time}}{\textbf{Total number of people in the defined population at the same point in time}}$$

Example on disease prevalence:

Among 10000 population. We found 50 with Type 1 Diabetes Mellitus (T1DM).

Calculate The Prevalence؟؟

The prevalence is 50/10000= 0.005x100=0.5%

Advantages of Cross-sectional Studies

1. Quick and inexpensive (No waiting for the occurrence of the outcome)
2. Easy and feasible
3. No loss to follow up (there is no follow-up)
4. Used for determining prevalence (but not incidence)
5. Associations can be studied
6. **Help in hypothesis generation (possible risk factors)**
7. Repeated cross-sectional studies on the same population at different points in time help in the evaluation of **trends** in the prevalence of the disease or risk factor.

Disadvantages of Cross-sectional Studies

1. Cannot determine causality (the temporal relationship can't be determined)
2. Not suitable for rare outcomes (diseases) or diseases of short duration.
3. High refusal or non-response can cause bias.

Analytical Studies

1. Case-control study
2. Cohort study

1. Case-control Studies (Retrospective study)

They are “observational” studies in which a group of patients (**cases**) is compared to a group of individuals who are free of this disease (**controls**) concerning exposure to a suspected agent or factor.

- **The first study to investigate the hypothesis generated from descriptive studies.**

Characteristics Of a Case-Control Study

We start with cases and controls, then we look for the past exposure: ***Retrospective study***

We work "backward" **(from outcome to exposure)**, and data related to risk factors are collected after the disease has been identified.

It determines the strength of the association between the risk factor (exposure) and the presence or absence of disease (outcome).

It cannot yield estimates of incidence or prevalence of disease in the population (if we select 50 cases and 50 controls, we cannot assume that the prevalence of the disease is 50%).

Requirements of a well-designed case-control study

A. **The presence of a preliminary hypothesis**

B. **Case definition:** Diagnostic criteria for the cases

C. **Source of cases:** Should be representative of all cases of the disease in the population.

D. **Selection of cases:** New cases are better as they are expected to remember the exposure status better.

E. **Source and selection of controls:** Controls should meet all the criteria for cases, except having the disease.

Advantages of a case-control study

1. Useful with rare diseases.
2. Inexpensive and efficient (may be the only feasible option)
3. Establishes association (Odds ratios)
4. Useful for generating hypotheses (multiple risk factors can be explored in one study)

Disadvantages of the Case-Control Study

1. Causality is still not easy to establish
2. Selection bias: If not choosing appropriate controls.
3. Recall bias: The study is retrospective, and participants may not report their exposure accurately, especially the controls.
4. Cannot give incidence or prevalence
5. The Accuracy and validity of information collected are questionable.

Measures Of Association in Case-Control Study

		Disease	
		Yes	No
Exposure	Yes	a	b
	No	c	d

Odds Ratio (OR)

The odds ratio is used to estimate the strength of the association between exposure and outcome.

Odds

$$\text{Odds} = \frac{number\ of\ indiviuals\ with\ the\ health\ outcome}{number\ of\ individuals\ without\ the\ health\ outcome}$$

The formula for the OR is:

$$\textbf{Odds Ratio} = \frac{\boldsymbol{odds\ among\ the\ exposed}}{\boldsymbol{odds\ among\ the\ unexposed}}$$

Interpretation Of Odds Ratio

The odds ratio is interpreted as follows:

1. OR of **1.0, indicating no association**
2. OR **greater than 1.0, indicating a positive association**
3. OR **less than 1.0, indicating a negative**, or protective association.

FOR EXAMPLE

A study aimed to investigate the relation between smoking and lung cancer.

The Exposure	Lung Cancer	No Lung Cancer	Total
Smokers	60	40	100
Non-Smokers	30	70	100

Calculate the odds ratio using the previous 2x2 table?

Odds of cancer in smokers = 60 / 40 = **1.5**

Odds of cancer in non-smokers = 30 / 70 = **0.43**

Odds Ratio (OR) = 1.5 / 0.43 = **3.5** **(OR = 3.5 → smokers are 3.5 times more likely to develop lung cancer).**

2. Cohort studies

- Cohort studies evaluate a possible association between exposure and outcome by **following two groups of individuals** (exposed and unexposed) over a period of time (often years) to see whether they develop the disease or outcome of interest.
- The rates of disease incidence among the exposed and unexposed groups are determined and compared.
- Subjects should not have the outcome variable (should be disease-free) on entry and should have the potential to develop the outcome.

Cohort studies may be **prospective or retrospective**, but both types define the cohorts **based on exposure**, not the outcome.

Elements Of A Cohort Study

A. Selection of a sample from the population.

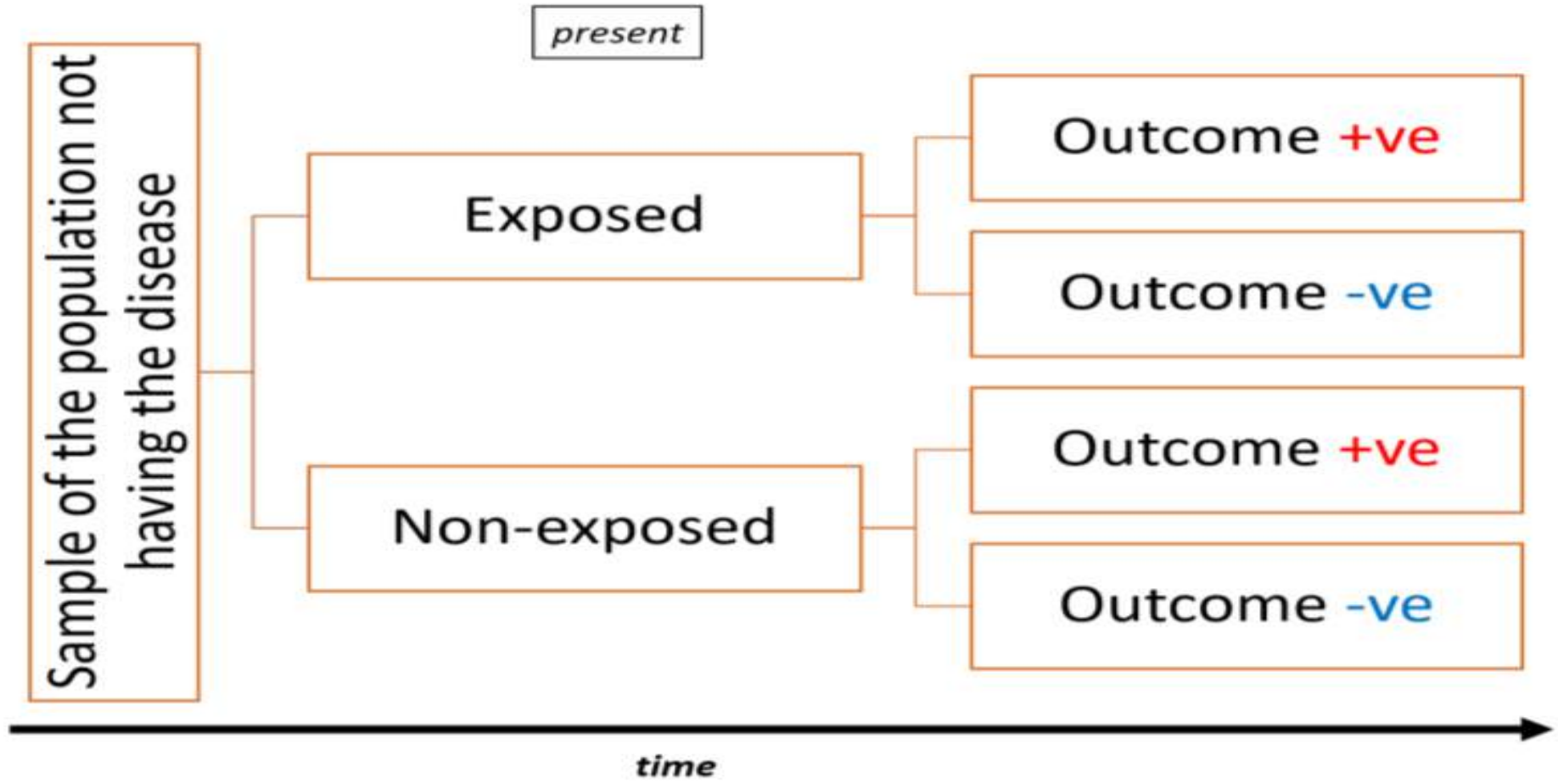
B. Measuring the exposure variable in the sample.

C. Ensuring that the outcome is not present (and participants can develop it).

D. Follow up the population (the different exposure groups) for a period of time.

E. Measure the occurrence of the outcome variable.

Cohort Study Framework



Advantages Of Cohort Study

1. Knowing that a predictor variable (exposure) was present before the outcome variable occurred (some evidence of causality).
2. Valuable in studying rare exposures.
3. Directly measures the incidence of a disease or an outcome.
4. Can study multiple outcomes of a single exposure.
5. Relative risk (RR) and Attributable risk (AR) are the measures of association.
6. The temporal relation is confirmed.

Disadvantages Of Cohort Study

1. Expensive and inefficient for studying rare outcomes.
2. A large number of subjects is usually needed.
3. Often needs a long follow-up period or a very large population.
4. Loss to follow-up can affect the validity of findings.
5. Retrospective cohort studies need complete and accurate records.

Measures Of Risk In Cohort Studies

A. Attributable Risk
B. Relative Ris

A. Risk Difference (Attributable Risk)

It provides the difference in risk between two groups, indicating how much excess risk is due to the exposure of interest.

Risk difference is the Risk among the exposed – Risk among the unexposed

Risk (cumulative incidence)=

$$\frac{\text{Number of new cases during a defined period}}{\text{total number of individuals at risk at the beginning of the period}} \text{ x } 100$$

$$\textbf{Risk difference} = \frac{number\ of\ cases\ in\ exposed\ group}{total\ number\ at\ risk\ in\ exposed\ group} - \frac{number\ of\ cases\ in\ unexposed\ group}{total\ number\ at\ risk\ in\ unexposed\ group}$$

B. Risk Ratio And Rate Ratio (Relative Risk=RR)

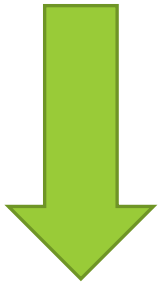
Risk Ratios and Rate Ratios are measures of the strength of the association between the exposure and the outcome.

They are defined as: *the ratio of the **Risk** in the exposed group to the risk in the unexposed group*, or the ratio of the ***Rate*** in the exposed group to the rate in the unexposed group.

$$\textbf{Risk ratio} = \frac{Risk\ among\ exposed}{Risk\ among\ the\ unexposed}$$

$$\textbf{Rate ratio} = \frac{Rate\ among\ exposed}{Rate\ among\ the\ unexposed}$$

Differences between case control and cohort study ?????



Case Control Study

1. Proceeds from "disease to cause"
2. Starts with the disease
3. Usually, the first approach to test a hypothesis.
4. Involves fewer number of subjects
5. Gives quick results
6. Suitable for the study of rare diseases
7. Gives Odds Ratio
8. Inexpensive

Cohort Study

1. Proceeds from "cause to disease"
2. Start with people exposed to risk factors
3. Reserved for testing of precisely formulated hypotheses.
4. Involves a larger number of subjects
5. Needs a longer follow–up period
6. Suitable for the study of rare exposure
7. Gives RR and AR.
8. Expensive

REFERENCES

1. A Textbook of Public Health Dentistry, CM Marya, **Jaypee Brothers Medical Publishers, 1st ED;** 2011 (**Section** 1: **Chapter 2, Page 9-23**)

2. Medical statistics at a glance, Aviva Petrie and Carolen Sabin, **Wiley Blackwell Publisher. 3rd edition; 2009. (Chapters 12-16, page 36-49)**

THANKS