Epidemiological and Research Studies

L IX

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Epidemiology

The study of the **distribution and determinants of health- related states** in a **specified population**

AND

the **application of this study** to **control of this health problem**

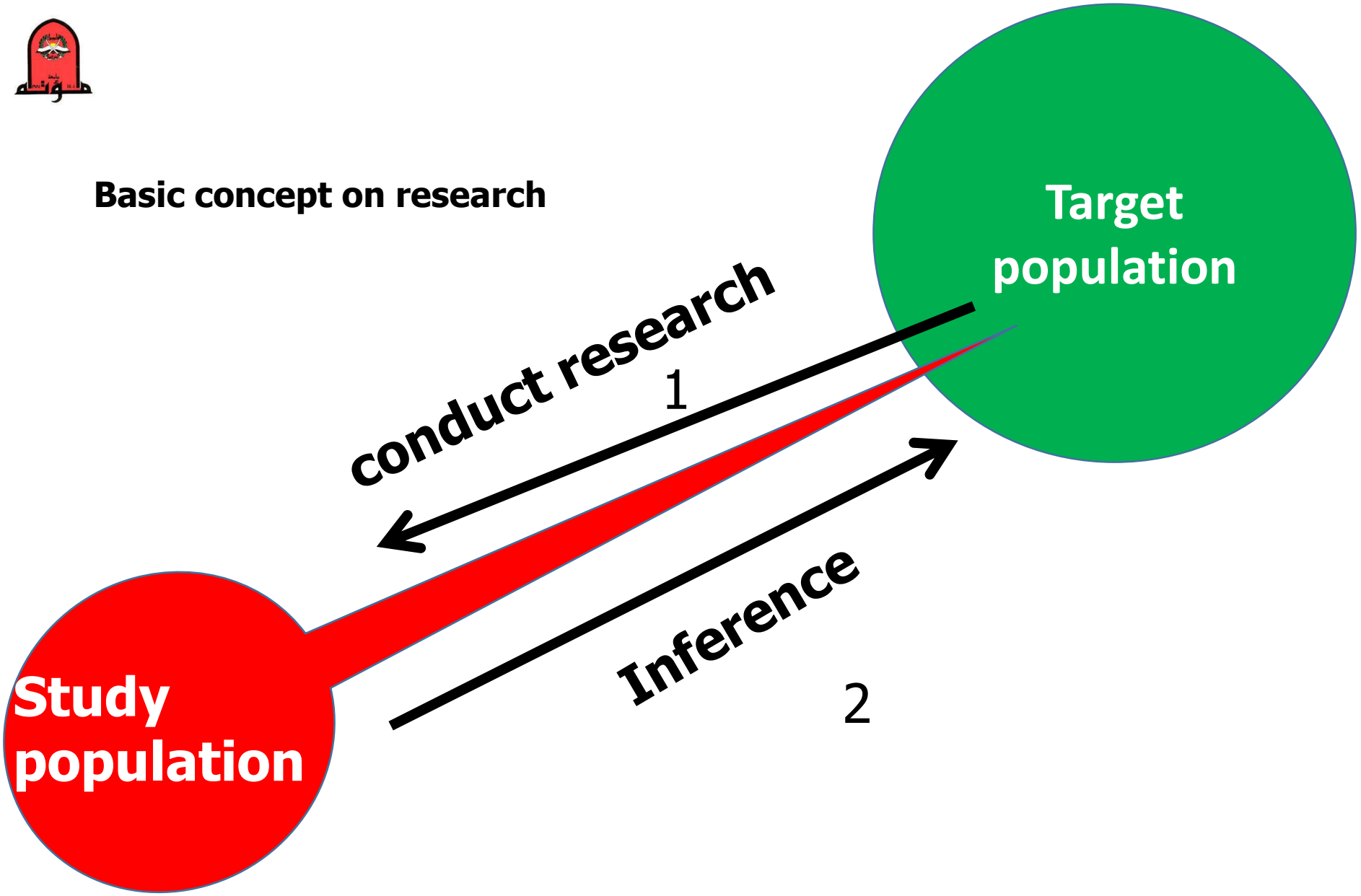
Epi =

Demo=

Logy=

The essence (core)of epidemiology is to measure disease occurrence and make comparisons between population groups.

Basic concept on research



Learning objectives:

You will learn about

Commonly used epidemiological studies and measurements to **describe the occurrence of disease, that facilitate understanding of distribution of disease in a given population.**

Types of study Designs

Classification and sub-classifications may differ in different references

Qualitative studies

Quantitative studies

Quantitative studies

- **Observational**
  - Descriptive
  - Case report
  - Case series
  - Epidemiological reports
- **Analytical**
  - Cross-sectional
  - Case-control
  - Cohort
- **Experimental.**
  - randomized controlled trials
  - field trials
  - community trials

Qualitative studies:

TYPES OF STUDY DESIGNS

- ❑ Systematic review & meta analysis
- ❑ Intervention(experimental) studies
  - ➢ Clinical trials
  - ➢ Community trials

- ❑ Observational studies:
  - ➢ Case-control studies
  - ➢ Cohort studies
  - ➢ Cross sectional studies

- ❑ Descriptive studies:
  - ➢ case reports, case series

The **hierarchy** of **research** evidence - from well conducted meta-analysis down to ...

- Theoretical Design (Research Design)
- Design of Data Collection (Study Design)
- Design of data analysis (Statistical Methods)

Research Designs

- Etiologic Study
- Prognostic Study
- Diagnosis Study
- Interventional Study
- Prevalence Study

Study Designs

- **Observational:**
  - i. Cross sectional
  - ii. Cohort study
  - iii. Case control study
- **Experimental:**
  - i.Randomized Controlled Trial

Construct of a Research Design
Theoretical Design (**Research Design)**
Design of Data Collection (Study Design)
Design of data analysis (Statistical Methods

Design of Data Collection (**Study Design**)

Types of **study Designs**

Classification and sub-classifications may differ in different references

Qualitative studies:

Quantitative studies

Observational
Analytical
Experimental.

Type of studies

Quantitative studies:

- These are the studies we **use in medicine**, and **public health**
- Involving formal , objective information about the world, **with mathematical quantification**

Qualitative studies:

- It is used in public health studies
- It was introduced **from social sciences**
- Difficult to define
- But it does **not depend on mathematical quantification**,
- and relies on researcher(s) observation and opinion

Qualitative studies

Qualitative studies:

- ✓ In public health, most researchers consider **it exploratory research**.
- ✓ It is used to **gain an understanding** of **underlying reasons, opinions,** and **motivations.**
- ✓ It **provides insights** into the problem **or helps to develop ideas** or **hypotheses for potential quantitative research**.
- ✓ Qualitative research is also **used to uncover trends in thought** and **opinions,** and **dive deeper into the problem**.

Methods include

- **Focus groups discussion,**
- **In-depth interviews (detailed), and**
- **participatory observations.**

Quantitative studies

I. Observational studies

Descriptive

Case report

Case series

Epidemiological reports

Analytical studies

Cross-sectional

Case-control

Cohort

II Experimental.

Quantitative studies
Observational
Experimental

❑ Observational studies

Quantitative studies

Quantitative studies
Observational
Experimental

- **Allow nature to take its course:**
- **the investigator measures but does not intervene.**
- **They include studies** called :

❖ **Descriptive**

➢ A descriptive study is limited to a **description of the occurrence of a disease** (health problem) in a population and is often

➢ the **first step in an epidemiological investigation**.

❖ **Analytical**

An analytical study goes further by analysing relationships between health status and other variables

❑ **Almost all epidemiological studies are analytical in character.**

❑ **Pure descriptive studies are rare,**

But descriptive data in reports of health statistics are a useful source of ideas for epidemiological studies

Quantitative studies
Observational
Experimental

❑ Experimental studies

Experimental or intervention studies involve an active attempt to change a disease determinant – such as

- an exposure or
- a behaviour –
- or the progress of a disease through treatment,

❑ **Major experimental study designs include the following**:

- **Randomized controlled trials** using patients as subjects **(clinical trials),**
- **Field trials** in which **the participants are healthy people**, and
- **Community trials** in which the participants are the communities themselves

Observational studies
Descriptive
Case report
Case series
Epidemiological reports
Analytical studies
Cross-sectional
Case-control
Cohort
Experimental.

Observational studies

Descriptive

Case report

Case series

Epidemiological reports

Observational studies

Observational studiesdescriptive
- Case report
- Case series
- Epidemiological reports

Descriptive

Case report

- It is thorough description of a case whether a
- new discovered findings, description of signs and symptoms
- or response to new mode of treatment (descriptive or intervention).

Case report uses

- Detecting novelties
- generating hypotheses
- high applicability when other research designs are not possible to carry out,

The major limitations were:

- Lack of ability to generalize
- no possibility to establish cause-effect relationship,
- danger of over-interpretation, publication bias (not reporting negative findings

Case series

Descriptive

Observational --descriptive

- Case report
- Case series
- Epidemiological reports

It is expansion of case report.

The **description of more than one case and include some characteristics of the case(** age, sex, occupation)

Case series represents an **observational study that reports** on data from a subject group **without a comparison population.**

This is due to **lack of control subjects, making case series prone to bias.**

Case series have almost the same advantage and disadvantage of case reports

The information gained can be **used to generate hypotheses** that lead to focused studies of a stronger design.

- **The biggest advantage is that case series**
- **Feasible study designs,**
- **Easy to conduct and**
- **Require less time and financial resources** than other study designs

- **Observational --descriptive**
- Case report
- Case series
- Epidemiological reports

Descriptive

Epidemiological reports

- **A simple description of the health status of a community, based on:**
  - **routinely available data** or on
  - **data obtained in special surveys** ,
  - is often the **first step in an epidemiological investigation**.

In many countries this type of study is undertaken by a **national center for health statistics.**

- **Pure descriptive studies make no attempt to analyze the links between exposure and effect.**
- **They are** usually **based on mortality statistics** (life events) and may examine patterns of death by age, sex or ethnicity during specified time periods or in various countries.

Example: reporting data of child mortality rate in Jordan

Analytical studies

I. Cross-sectional
II. Case-control
III. Cohort

Observational studies
Descriptive
Case report
Case series
Epidemiological reports Analytical studies
Cross-sectional
Case-control
Cohort

Cross-sectional

.1. Issues in the design of cross-sectional studies
2. Potential bias in cross-sectional studies
3. Analysis of cross-sectional studies
4. Strengths and weaknesses of cross-sectional studies

Analytical studies
Cross-sectional

Issues in the design of cross-sectional studies
2. Potential bias in cross-sectional studies
3. Analysis of cross-sectional studies
4. Strengths and weaknesses of CSS studies

A cross-sectional study (CSS) examines the relationship between disease (or other health related state) **and other variables of interest** as they **exist in a defined population at a single point in time or over a short period of time** (e.g. calendar year). **???**

Cross-sectional studies can be thought of as providing a snapshot of the frequency of a disease or other health related characteristics (e.g. exposure variables) in a population **at a given point in time.**

CSS measure **the prevalence of disease** and thus are called **prevalence studies.**

A CSS measures the prevalence

- **A CSS measures the prevalence of health outcomes** or **determinants of health, or both, in a population** at **a point in time** or **over a short period.**
- **Such information can be used to explore aetiology.**

Data is collected from a **sample of population at a point in time.**

- CSS are used to **assess the burden** of disease or **health needs** of a population and are particularly **useful in**
- **forming the planning** and **allocation of health resources.**

- Data from **repeated CSS** using independent random samples with standardized definitions and survey methods provide **useful indications** of **trends.**

In sudden outbreaks

Cont….Cross-sectional studies

***In sudden outbreaks of disease**, a **CSS** to **measure several exposures** ***can** be the **most convenient first step in investigating the cause**

- In a **CSS** the **measurements of exposure and effect** are made **at the same time**.
- It is **not easy to assess** the **reasons for associations** shown in cross-sectional studies.
- **CSS** are useful for investigating **exposures that are fixed characteristics of individuals, such as ethnicity or blood group**.

- **The key question** to be asked is **whether the exposure precedes or follows the effect.**

Observation

Population

Sa mple

Exposed

Not exposed

Disease

No disease

Cross-sectional studies

CSS the **measurements of exposure and effect** are made **at the same time**

Types of cross-sectional study

1-Descriptive

A CSS may be purely descriptive and used to assess the burden of a particular disease in a defined population.

For example a random sample of schools across Jordan may be used to assess the prevalence of asthma among 12-14 y olds

2-Analytical

Analytical CSS may also be used to investigate the association between a putative risk factor and a health outcome.

- However this type of study is limited in its ability to draw valid conclusions as to the association between a risk factor and health outcome.

In a CSS the risk factors and outcome are measured simultaneously, and therefore it may be difficult to determine whether the exposure preceded or followed the disease.

In practice, CSS will include an element of both types of design

1. Issues in the design of cross-sectional surveys

❑ Choosing a representative sample

❖ **A CSS should be representative of the population if generalizations from the findings are to have any validity.**

For example, a study of the prevalence of diabetes among women aged 40-60 years in Town A should comprise a random sample of all women aged 40-60 years in that town.

❖ Sample Size

The sample size **should be sufficiently large enough to estimate the prevalence** of the conditions of interest with adequate precision.

Sample size calculations can be carried out using sample size use as Epi Info. OpenEpi

2. Potential bias in cross-sectional studies

❖ **Non-response** is a particular problem affecting CSS and can **result in bias of the measures of outcome**. This is a particular problem when the characteristics of non- responders differ from responders.

3. Analysis of cross-sectional studies

- In a cross-sectional study **all factors (exposure, outcome, and confounders) are measured simultaneously.**
- The **main outcome measure** obtained from a cross-sectional study is **prevalence**, that is:

$$\text{Prevalence} = \frac{\text{Number of cases in a defined population at one point in time}}{\text{Number of persons in a defined population at the same point in time}}$$

Prevalence of disease Among exposed ,

$$\text{Prevalence} = \frac{\text{Number of cases in a defined population at one point in time}}{\text{Number of persons in a defined population at the same point in time}}$$

Prevalence of disease Among non exposed

$$\text{Prevalence} = \frac{\text{Number of cases in a defined population at one point in time}}{\text{Number of persons in a defined population at the same point in time}}$$

Prevalence of Exposure disease Among diseased

Prevalence of Exposure disease Among non-diseased

4. Strengths and weaknesses of CSS

Strengths of CSS

- **Relatively quick and easy** to conduct (no long periods of follow-up).
- Data on all variables is only **collected once.**
- **Able to measure prevalence for all factors under investigation.**
- **Multiple outcomes** & **exposures can be studied.**
- The **prevalence of** disease or other health related characteristics are important in public health for
- **assessing the burden of disease in a specified**
- population **and in planning and**
- **allocating health resources**.
- Good **for descriptive analyses** and for **generating hypotheses**

Weaknesses of CSS

- Difficult to determine whether the outcome followed exposure in time or exposure resulted from the outcome.
- Not suitable for studying rare diseases or diseases with a short duration..
- Unable to measure incidence.
- Associations identified may be difficult to interpret.
- Susceptible to bias due to low response and misclassification due to recall bias.

Thank you for attention

Analytical studies

1. **Cross-sectional**
2. **Case-control**
3. **Cohort**

Case control Study

basic concepts,
application and
strengths of CCS
Issues in the design CCS
Common sources of bias in a CCS
Analysis of CCS
Strengths and weaknesses of CCS