

# Research in Medicine:

## Basic Types and Methods



# Medical Research and Study Design

- The scientific value and informativeness of a medical study are determined to a major extent by the study design.
- Errors in study design cannot be corrected afterwards.

# 5 phases of medical research

- Planning
- Performance
- Documentation
- Analysis
- Publication



# The importance of study design

Planning  study design:

a suitable type of study

an overall plan for all procedures

a bias to be minimized

# 6 aspects of study design

1. the question to be answered,
2. the study population,
3. the type of study,
4. the unit of analysis,
5. the measuring technique
6. the calculation of sample size

# The question to be answered

- research objectives = the key research question must be
- operationalized  $\longrightarrow$  converted into a measurable and evaluable form.
- main questions vs secondary questions.
- as a result open questions are answered and new hypotheses are possibly generated.

# Descriptive analysis

the units of analysis are to be described by the recorded variables (e.g. blood parameters or diagnosis)



# Exploratory analysis

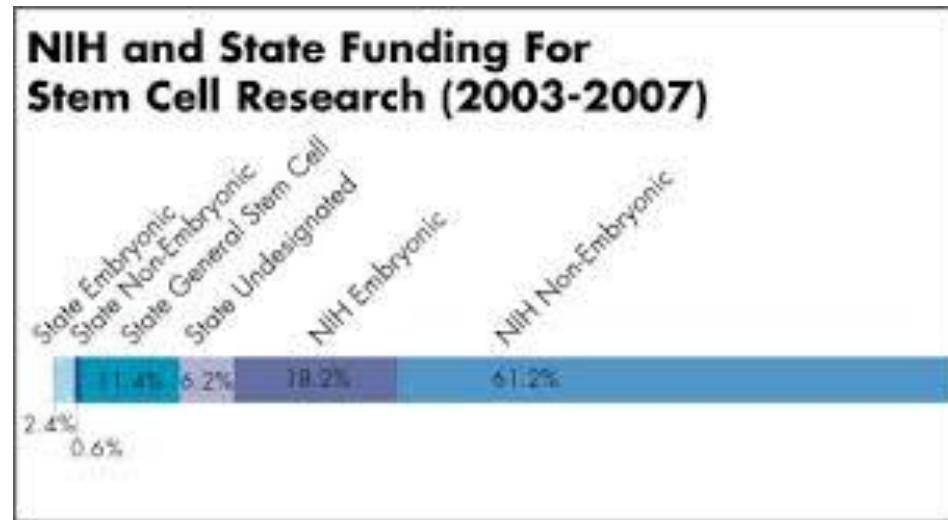
- to recognize connections between variables,
- to evaluate connections,
- to formulate new hypotheses.





# Confirmatory analysis

to provide statistical proofs by testing specified study hypotheses



# Unit of analysis

## clinical study

- patient
- hereditary information,
- a cell,
- a cellular structure,
- an organ, an organ system,
- a single test individual (animal or man),
- a specified subgroup or
- the population of a region or of a country.

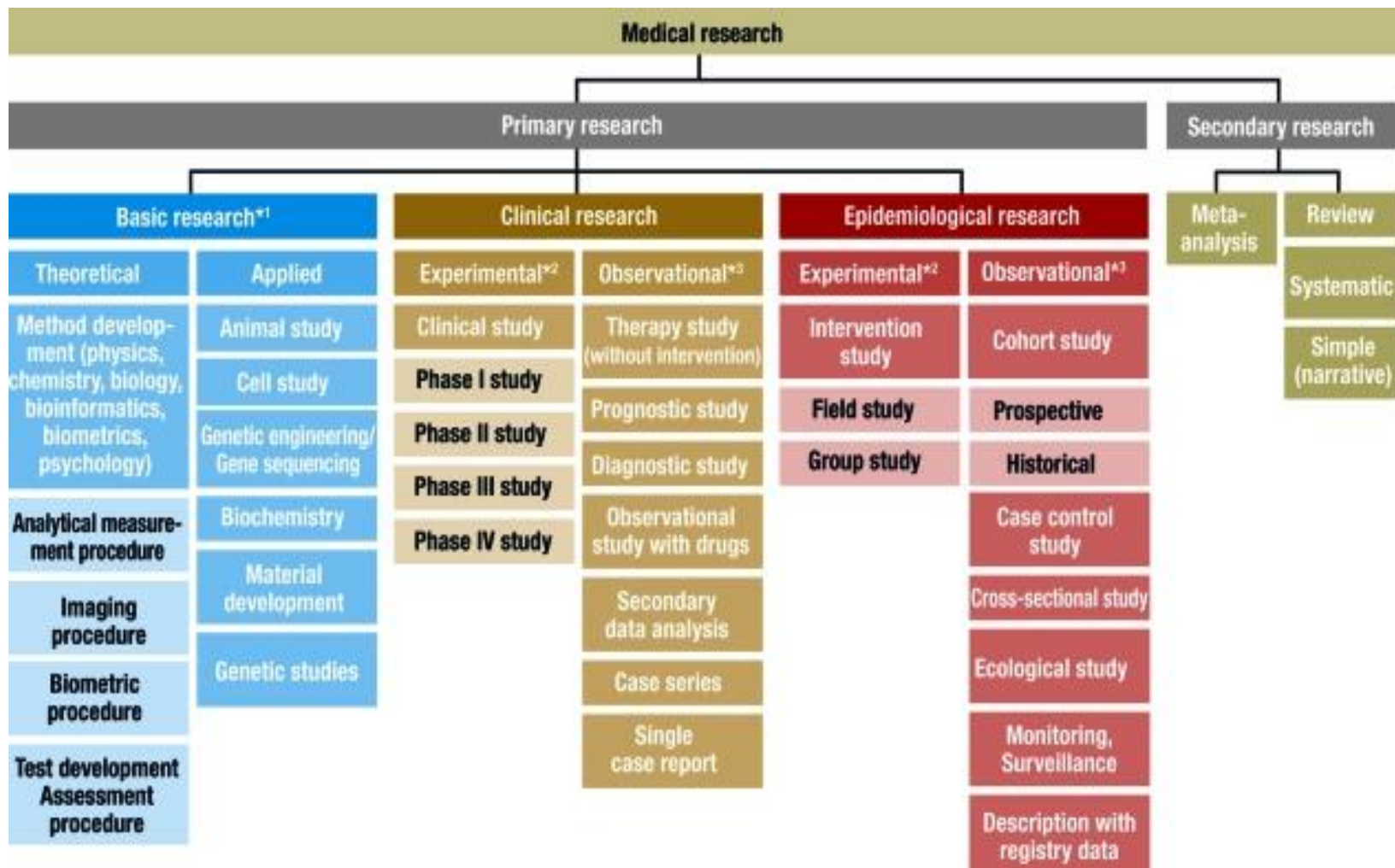
## systematic reviews

- a single study
- The interesting information or data (observations, variables, characteristics) are recorded for the statistical units.

# Measuring technique

measuring *instruments*:

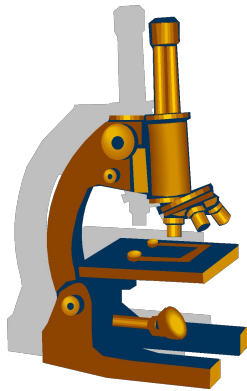
- to record measuring data (such as blood pressure or laboratory parameters)
- to collect data with standardized or self-designed questionnaires (for example, quality of life, depression, or satisfaction).



# Classification of study types

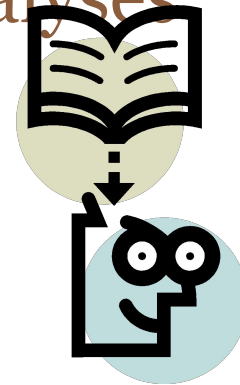
## Primary Research

actual studies



## Secondary Research

summarizes available studies in the form of reviews and meta-analyses



# Primary Research: Main Categories

- basic medical research ( or experimental research)
- clinical research
- epidemiological research

# BASIC MEDICAL RESEARCH



also known as **experimental** research

**Aim:** to **acquire new knowledge** without looking for long-term benefits other than the advancement of knowledge

**includes:** animal experiments, cell studies, biochemical, genetic and physiological investigations, and studies on the properties of drugs and materials



# CLINICAL RESEARCH

- **interventional (or experimental)**  
studies on drugs, medical devices and studies in which surgical, physical or psychotherapeutic procedures are examined.

- **noninterventional (or observational) -**  
a study in which knowledge from the treatment of persons is analyzed using epidemiological methods. The diagnosis, treatment and monitoring are performed exclusively according to medical practice.



# Clinical Studies (Clinical Trials)

Aim: to determine better ways to prevent, screen for, diagnose or treat diseases.

Controlled trial (a study group and a control group)

Randomization ( a randomized controlled trial)

Blinding ( single and double blind trial)

# EPIDEMIOLOGICAL RESEARCH



the description of *health and welfare* in populations through the collection of data related to health and the frequency, distribution and determinants of disease in populations, with the aim of improving health.

# Epidemiological: interventional or experimental

## field studies

- sample from an area, such as a large region or a country

e.g. investigation of the iodine supplementation of cooking salt to prevent cretinism in a region with iodine deficiency

## group studies

- sample from a specific group, such as a specific social or ethnic group.

# Epidemiological: observational

- Case control studies

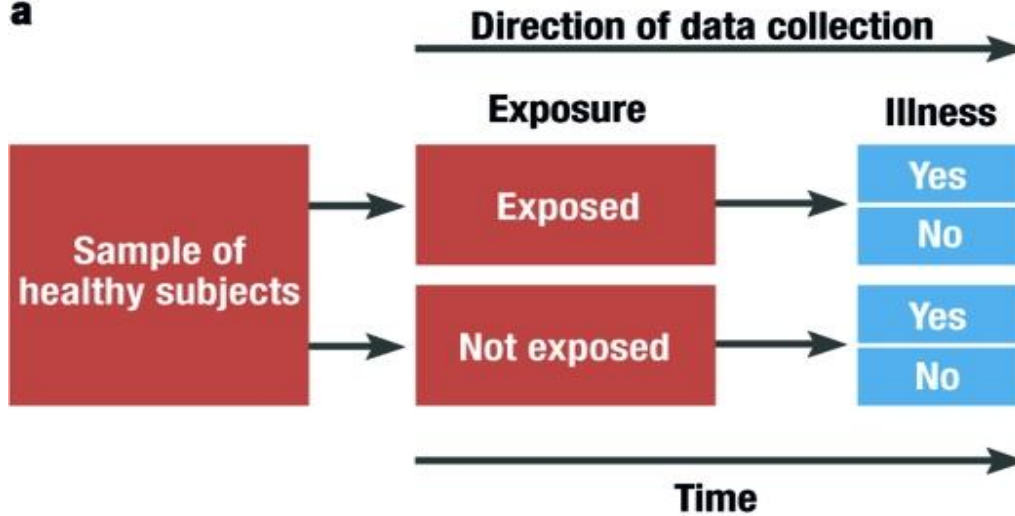
**Cases** are compared with **controls**. **Cases** are persons who fall ill from the disease in question. **Controls** are persons who are not ill, but are otherwise comparable to the cases. A retrospective analysis is performed to establish to what extent persons in the case and control groups were exposed. Possible exposure factors include smoking, nutrition and pollutant load.

# Epidemiological: observational

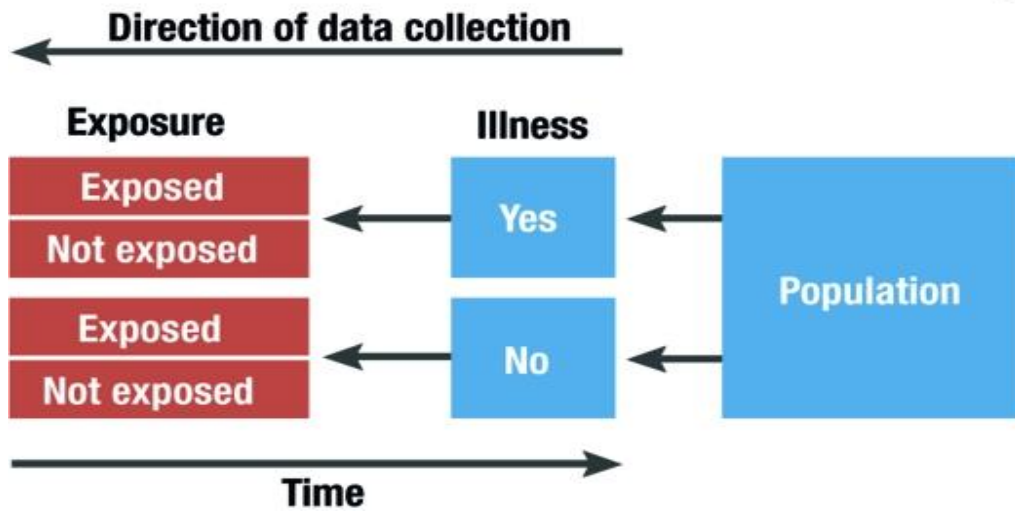
- Cohort studies ( prospective and retrospective)

cohort studies involve the observation of **two healthy groups of subjects** over time. One group is exposed to a specific substance (for example, workers in a chemical factory) and the other is not exposed. It is recorded prospectively (into the future) how often a specific disease (such as lung cancer) occurs in the two groups.

**a**



**b**



# Common study types for epidemiological investigations

## **Study objective**

Study of severe diseases such as cancers

Study of rare exposure, such as exposure to industrial chemicals

Study of multiple exposures, such as the combined effect of oral contraceptives and smoking on myocardial infarction

## **Study type**

Case control studies

Cohort studies in a population group (e.g. industrial workers)

Case control studies

(Dtsch Arztebl Int. 2009 April; 106(15): 262–268. )

# References

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Thank you for attention

