Research in Medicine:

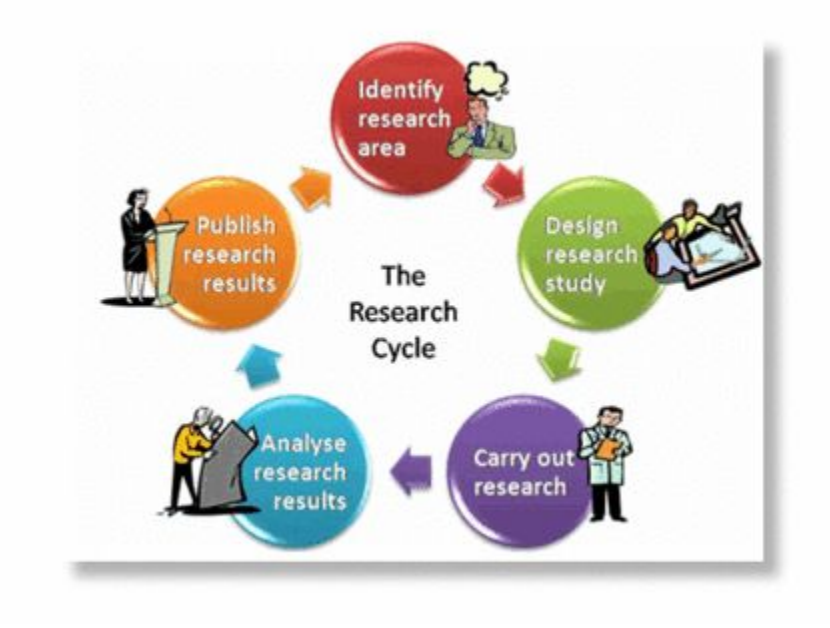
Basic Types and Methods

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 ⟶ 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

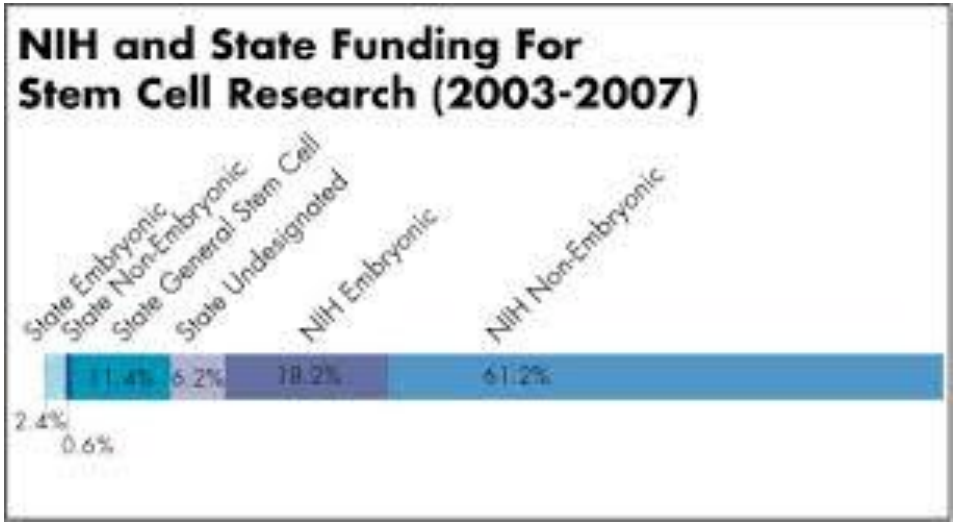
the units of analysis are to be described by the recorded variables (e.g. blood parameters or diagnosis)

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

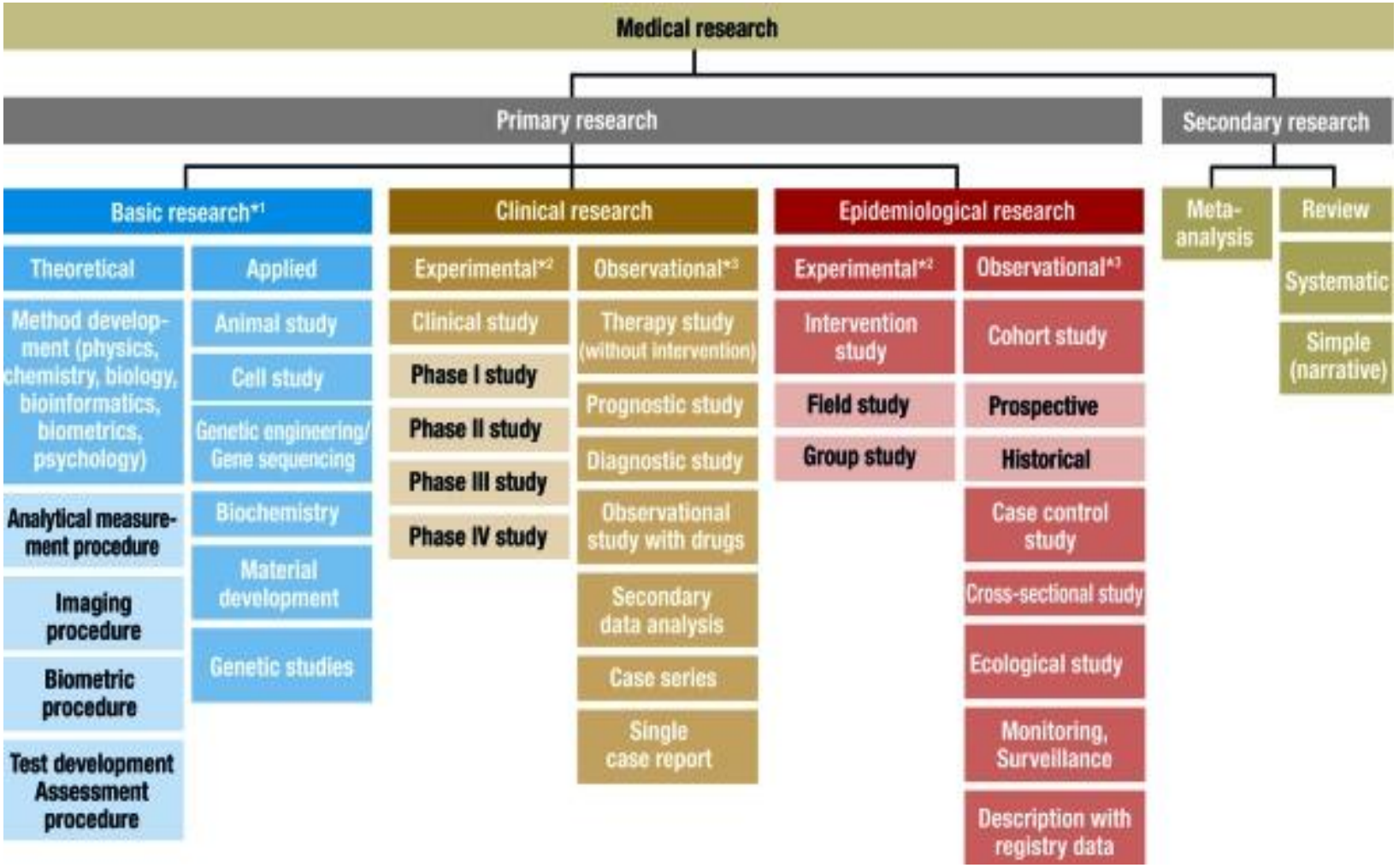
clinical study	systematic reviews
• patient • hereditary information, • a cell, • a cellular structure, • an organ, an organ system, • a single test individual (animal or man), • a specified subgroup or • the population of a region or of a country.	• a single study • The interesting information or data (observations, variables, characteristics) are recorded for the statistical units.

Measuring technique

measuring *instruments:*

- to record measuring data (such as blood pressure or laboratory parameters)

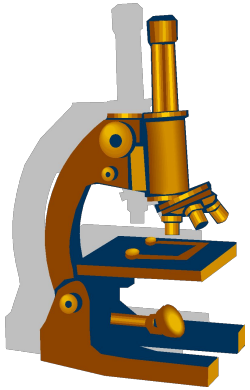
- to collect data with standardized or self-designed questionnaires (for example, quality of life, depression, or satisfaction).


Medical research
Primary research
Secondary research
Basic research*1
Theoretical
Method development (physics, chemistry, biology, bioinformatics, biometrics, psychology)
Analytical measurement procedure
Imaging procedure
Biometric procedure
Test development Assessment procedure
Applied
Animal study
Cell study
Genetic engineering/ Gene sequencing
Biochemistry
Material development
Genetic studies
Clinical research
Experimental*2
Clinical study
Phase I study
Phase II study
Phase III study
Phase IV study
Observational*3
Therapy study (without intervention)
Prognostic study
Diagnostic study
Observational study with drugs
Secondary data analysis
Case series
Single case report
Epidemiological research
Experimental*2
Intervention study
Field study
Group study
Observational*3
Cohort study
Prospective
Historical
Case control study
Cross-sectional study
Ecological study
Monitoring, Surveillance
Description with registry data
Meta-analysis
Review
Systematic
Simple (narrative)

Classification of study types

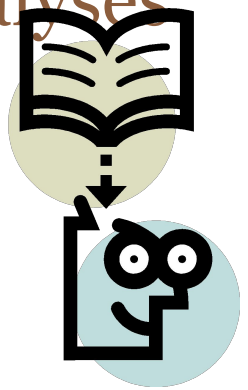
Primary Research

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

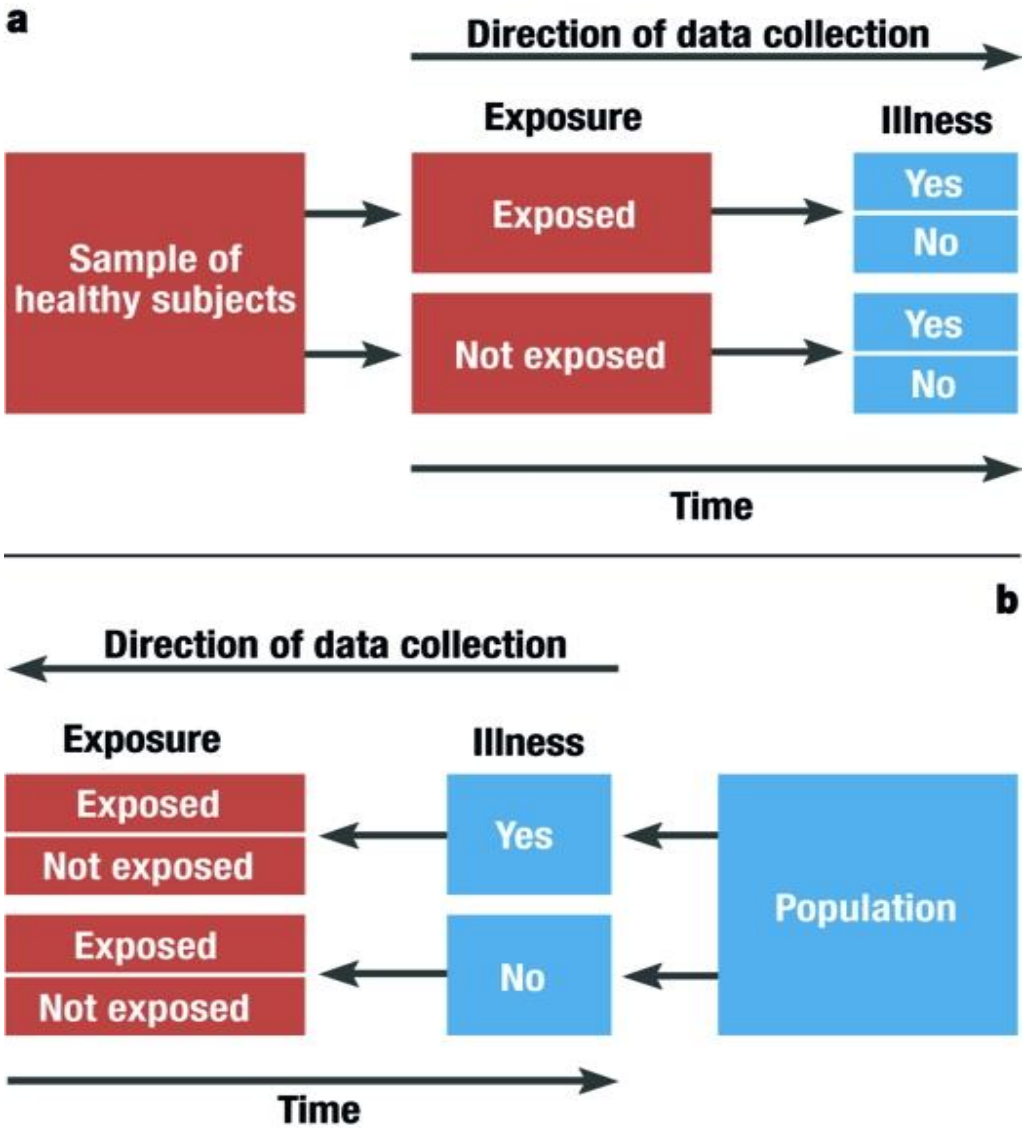
- Case control studies

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
Direction of data collection
Exposure
Illness
Sample of healthy subjects
Exposed
Not exposed
Yes
No
Yes
No
Time
b
Direction of data collection
Exposure
Illness
Exposed
Not exposed
Exposed
Not exposed
Yes
No
Population
Time

Common study types for epidemiological investigations

Study objective	Study type
Study of severe diseases such as cancers	Case control studies
Study of rare exposure, such as exposure to industrial chemicals	Cohort studies in a population group (e.g. industrial workers
Study of multiple exposures, such as the combined effect of oral contraceptives and smoking on myocardial infarction	Case control studies

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

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Thank you for attention