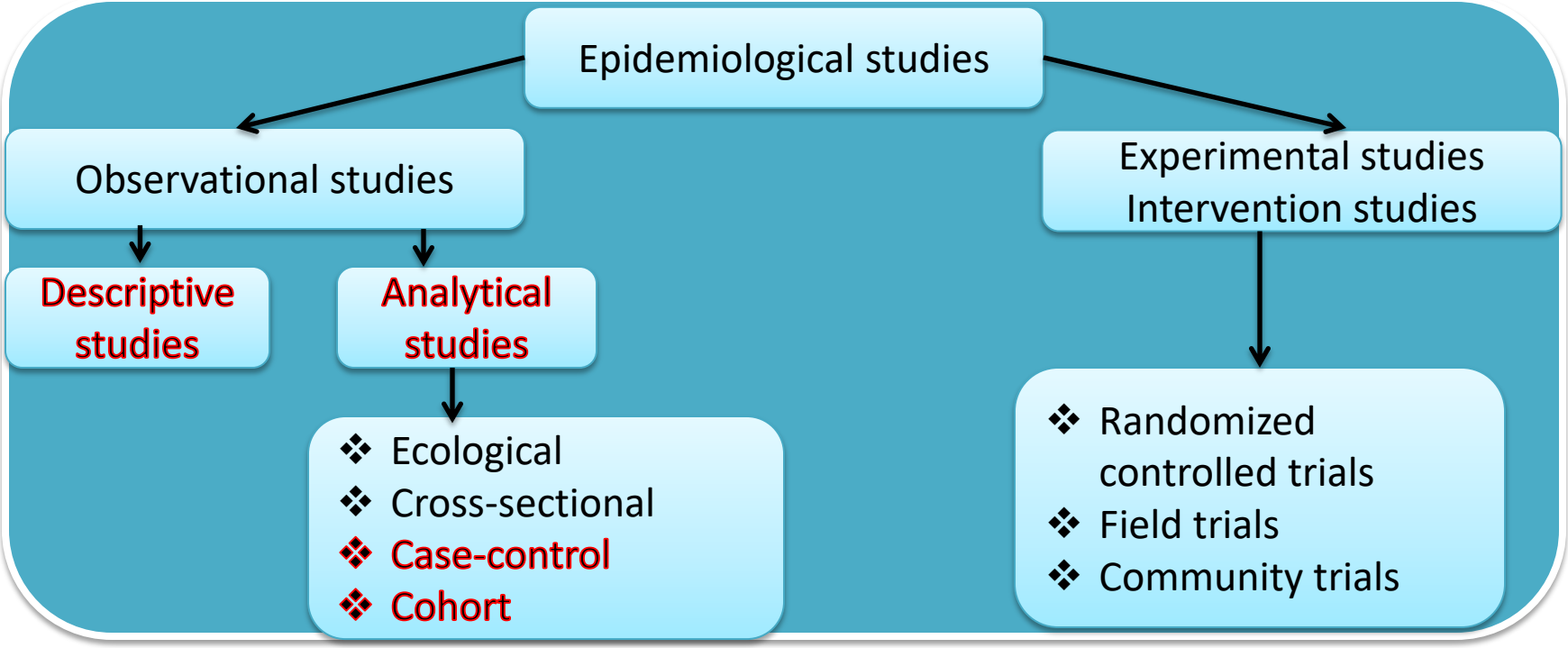
EXPERIMENTAL EPIDEMIOLOGY

PAPER4, UNIT 4

EPIDEMIOLOGIC METHODS



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Observational studies

Epidemiologist only observes the natural course of disease and its outcome

Epidemiologist may give suggestions based upon the outcome of the study at the end

Experimental studies

Some action, intervention, manipulation

Deliberate application or withdrawal of suspected cause in the experimental group, while making no change in the control group

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Aims of Experimental Epidemiology

To provide scientific proof of risk factors

To provide method of measuring effectiveness and efficiency of health services
prevention, control and treatment of disease
Improve the health of the community

Disadvantages

- Ethics
- Cost
- Feasibility

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Experimental study

Animal studies

Laboratory bred

Manipulated easily

Multiply rapidly

Not all human diseases can be reproduced in animals

All the conclusions derived from animal experiments may not be strictly applicable to humans

Human Experiments

Ethical issues

Before launching the experiment

Benefits of the experiment have to be weighted against risk involved

Volunteers should be made fully aware of all possible consequences of experiment

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Experimental study

- Randomized Controlled Trials
- Non Randomized Non experimental trial

Steps involved in Randomized Controlled Trials (RCT)

1. Drawing up a protocol
2. Selecting references and experimental population
3. Randomization
4. Manipulation or Intervention
5. Follow up
6. Assessment of outcomes

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Drawing up a protocol

Aims and objectives of the study

Questions to be answered

Criteria for the selection of study and control groups

Size of sample

Treatments to be applied

Standardization of working procedure

Responsibiities of people involved in trials

Once the protocol evolved it should be strictly adhered to throughout the study

Preventing bias and to reduce sources of error

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Selecting Reference and Experimental population

Reference or target population

It is the population to which the findings of the trial if found successful, are expected to be applicable

Whole population, geographically limited, limited to persons in specific age, sex, occupational or social groups

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Experimental or study population

Derived from reference population

It is the actual population that participates in experimental study

Randomly chosen from reference population-→ Characteristics of reference population

Informed consent

Qualified or eligible for the trial

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Randomization

Statistical procedure

Participants are allocated into groups

Study groups

Control groups

Randomization is an attempt to eliminate “bias” and allow comparability

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Manipulation

Intervention

Study group is manipulated by deliberate aplication or withdrawal or reduction of suspected causal factor as laid down in the protocol

Manipulation creates independent variables (drug, vaccine or procedure) whose effect is determined by measurement of the final outcome, which constitutes dependent variable (eg incidence of disease, survival time, recovery period)

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Follow up

Examination of study and control groups

Short duration

At defined time interval
In a standard manner
With equal intensity
Under the same given circumstances

Long duration

Loss of follow up→ Attrition

Death

Migration

Loss of interest

Substantial Attrition-→ difficult to generalize the results

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Assessment of outcome

Positive results	Negative results
Benefits of the experiment	Increased incidence / Severity of disease
Reduced incidence / Severity of disease	Complications, side effects, death

Positive and Negative results are rigorously compared in both the groups and the differences if any are tested for statistical significance

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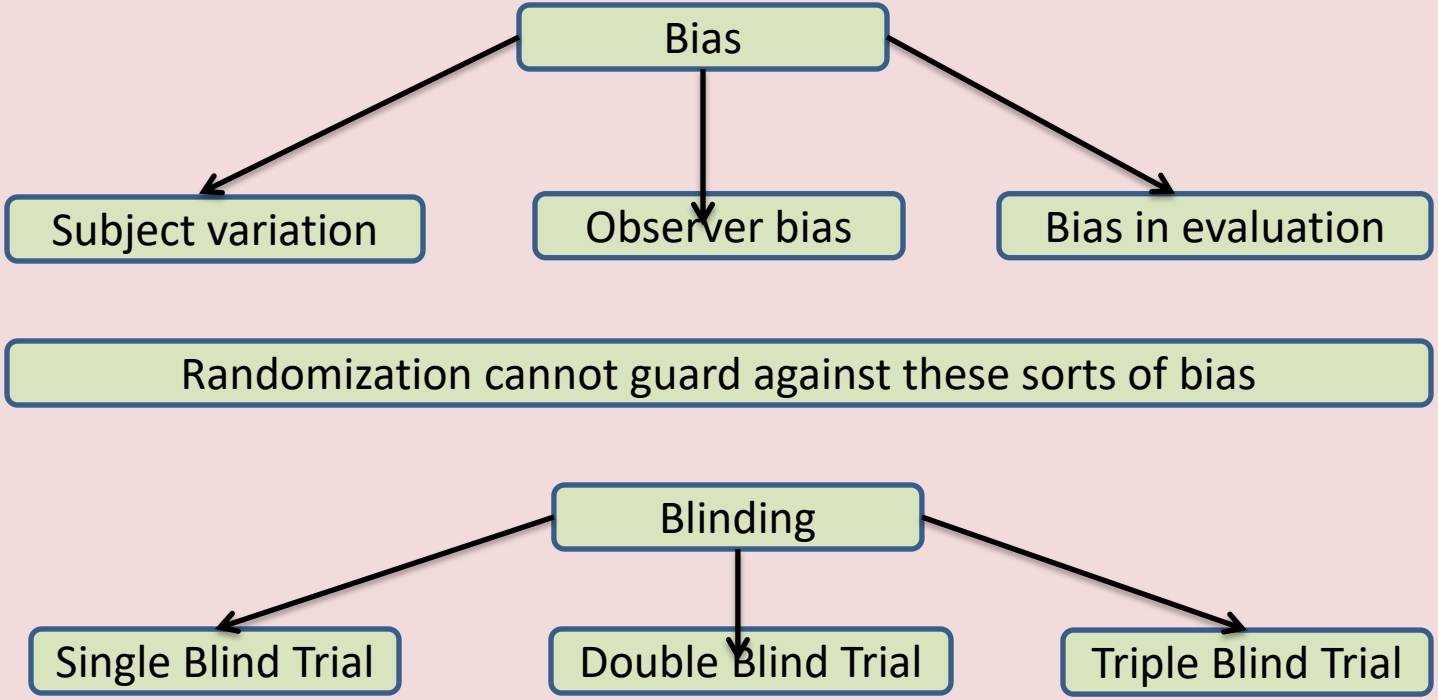

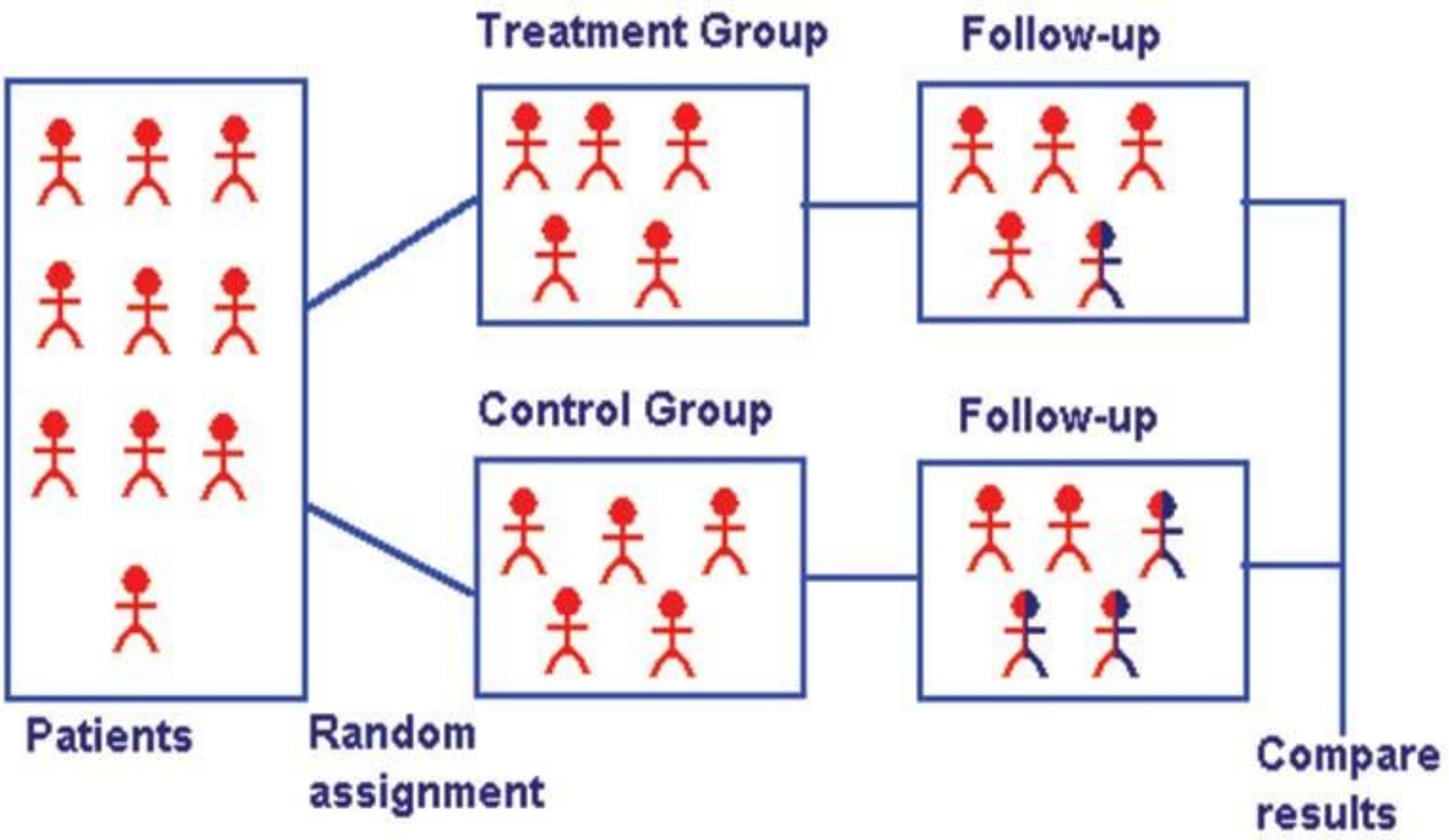
Treatment Group
Follow-up
Control Group
Follow-up
Patients
Random assignment
Compare results