Research Methodology

Study Design

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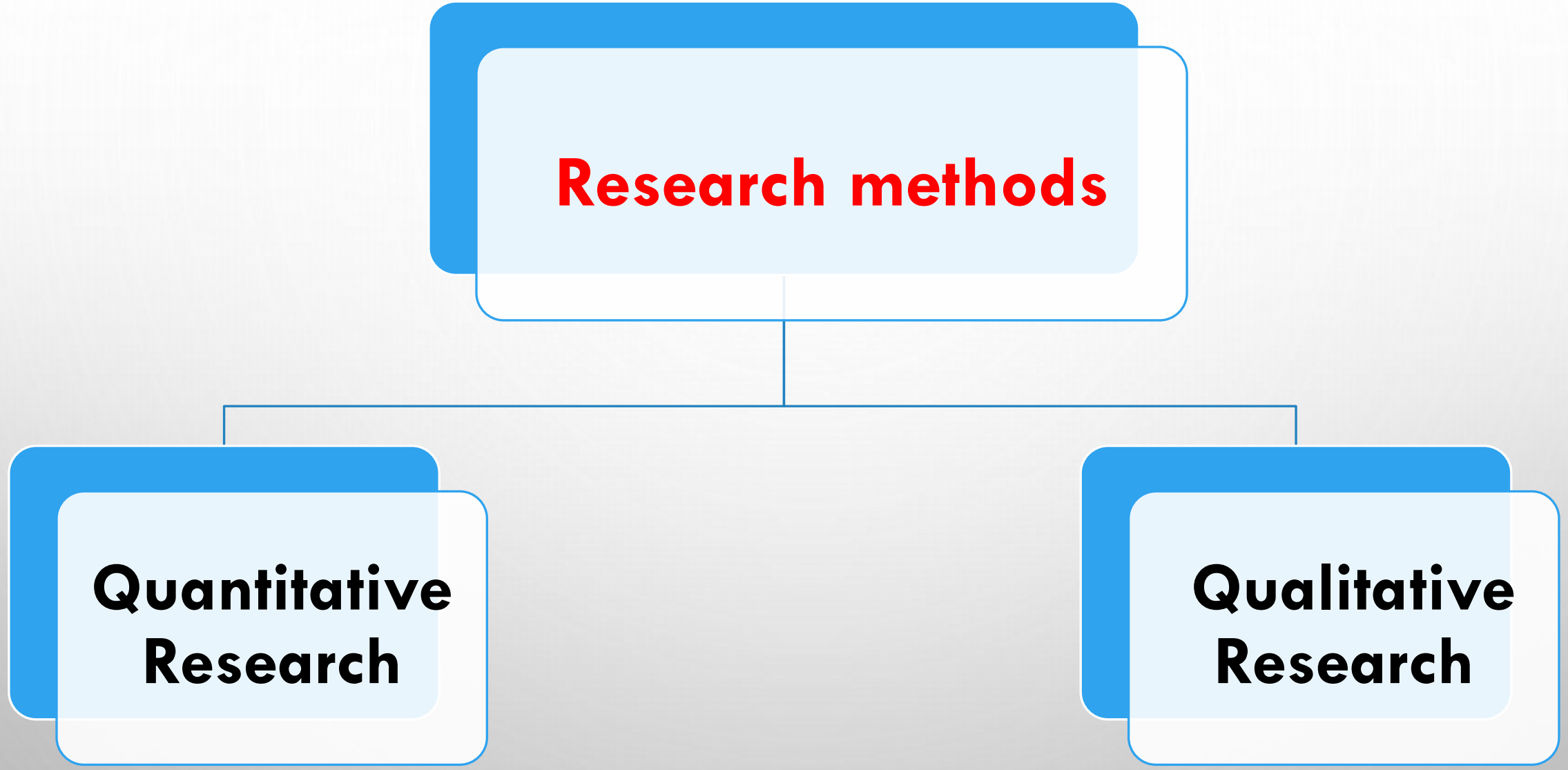

Research methods
Quantitative Research
Qualitative Research

1. Quantitative Research

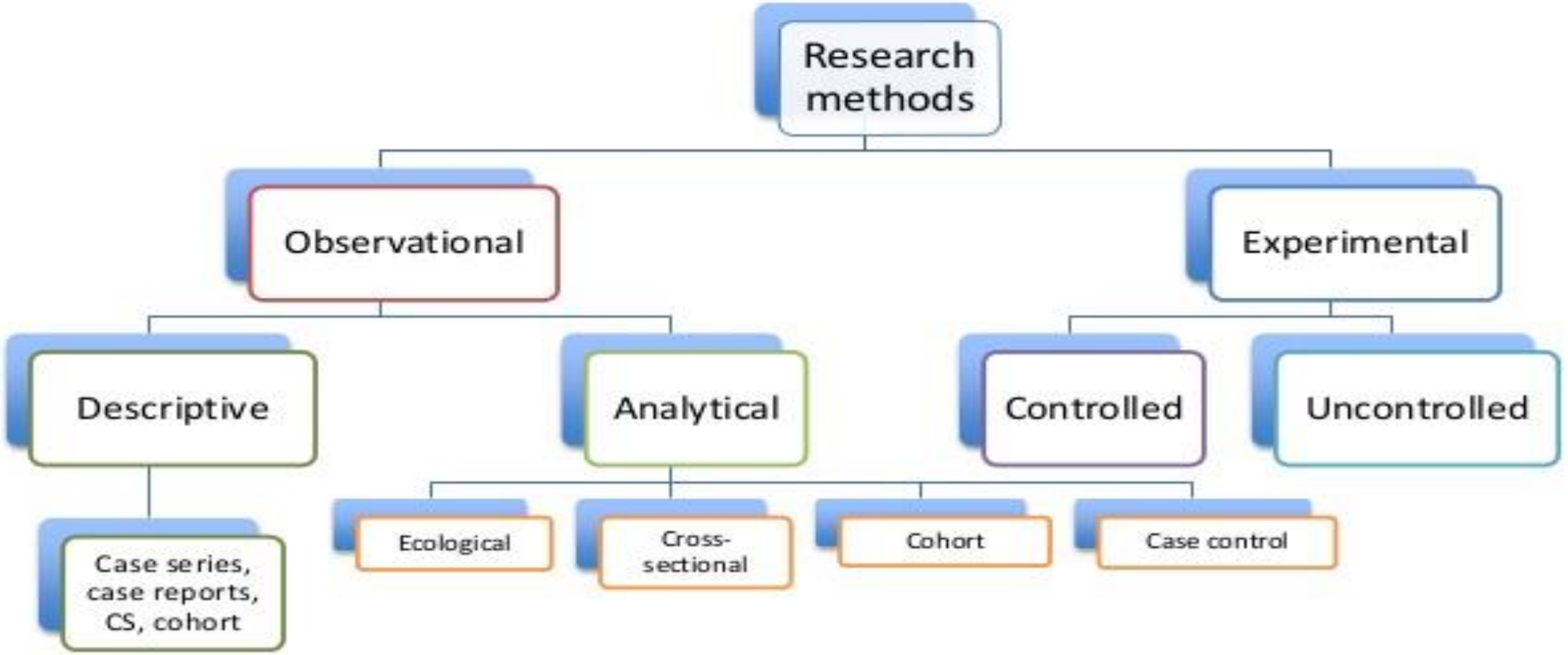
1. **Observation :**
   - Clinical Examination
   - Laboratory Testing
   - Visual Observation
2. **Interview and self administer questionnaire**
3. **Documents:**
   - Records
   - Registry
   - Certificates

- Check List

Qualitative Research

- Participatory rapid appraisal (pra)
- Focus groups
- In-depth interview
- Key informant interview
- Swot analysis

Classification of research methods



EPIDEMIOLOGICAL STUDIES

1. Descriptive Studies
2. Analytic Studies
   - 2A- Experimental
   - 2B- Observational
     - 1- Retrospective
     - 2- Prospective
     - 3- Cross Sectional
     - 4- Ecological

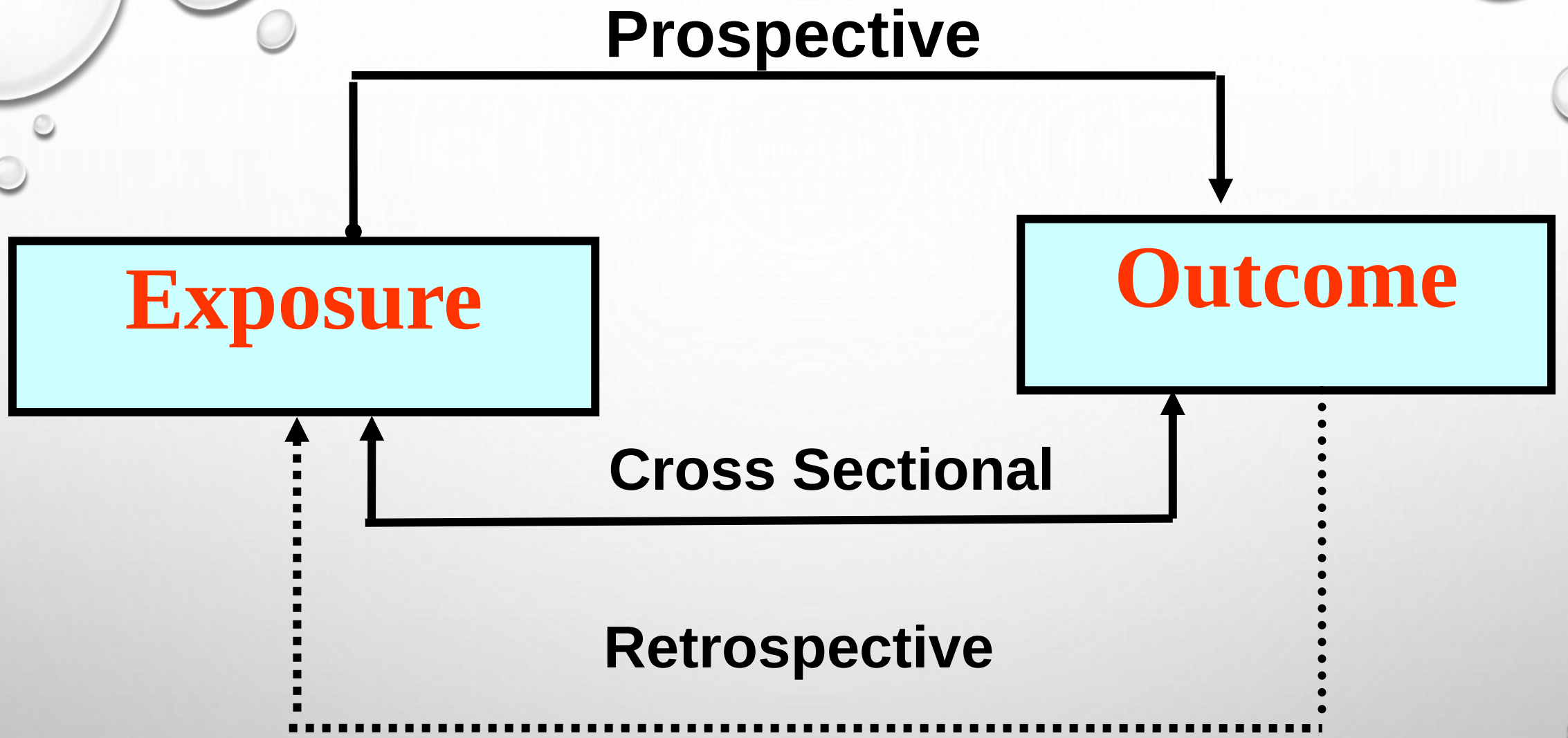
Descriptive Studies

1. Description of: persons – time - place
2. Incidence and prevalence studies
3. Case report
4. Case series report

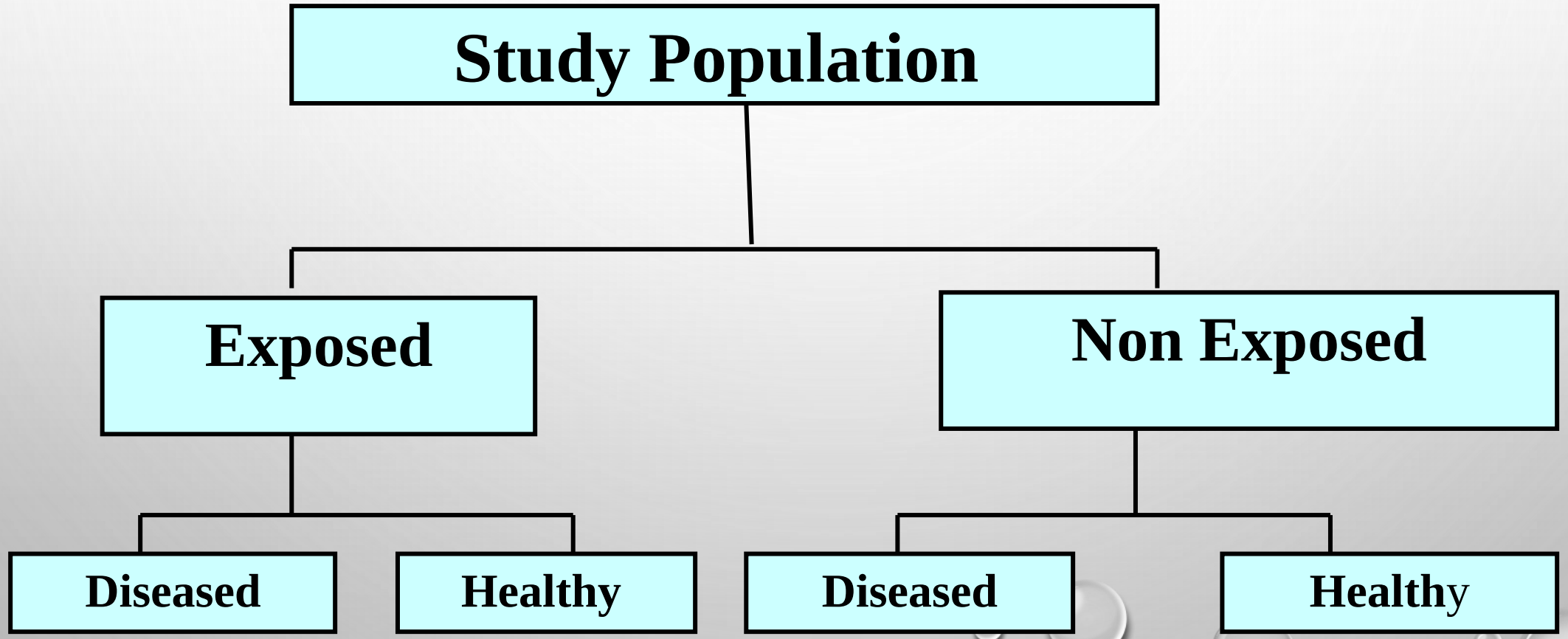
Cohort Study

Cohort Study

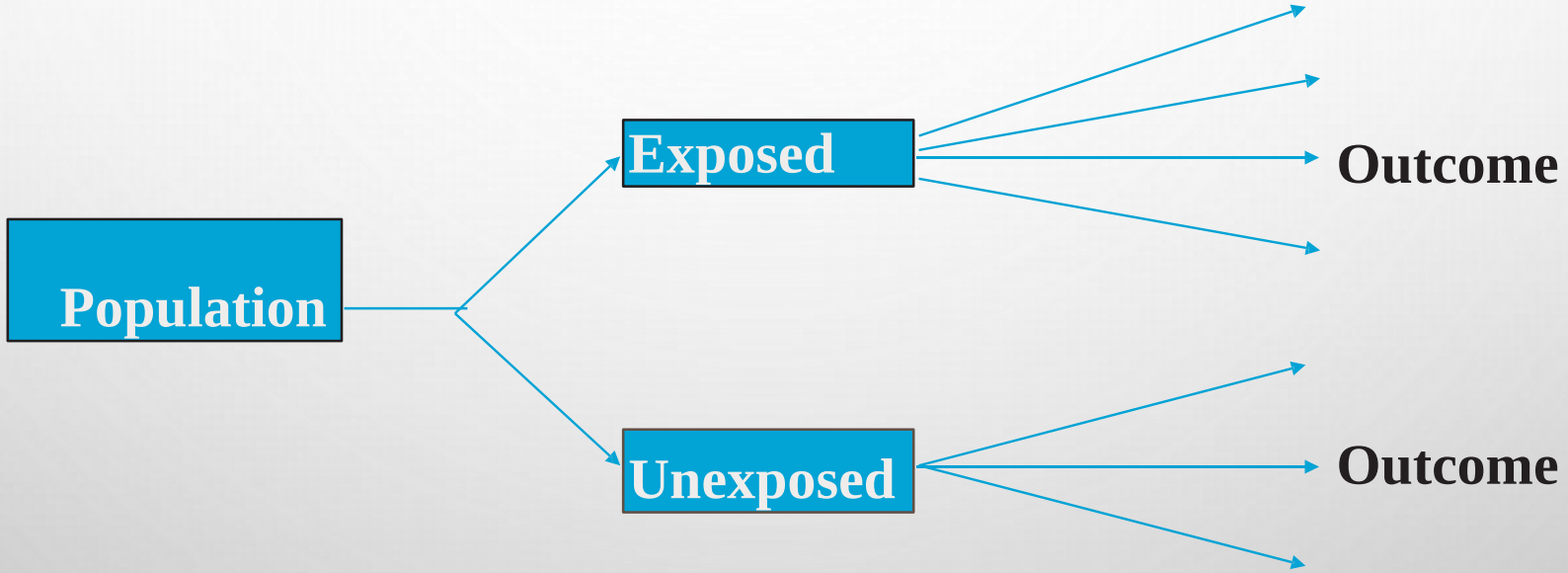
- Prospective (looking forward in time)
- Compare a group with a characteristic/exposure with a group without this characteristic/exposure
- Expensive and time consuming design


Prospective
Exposure
Outcome
Cross Sectional
Retrospective

Prospective Study
(Cohort Study – Longitudinal Study)



Prospective Study
(Cohort Study – Longitudinal Study)



Analysis Of Prospective Studies

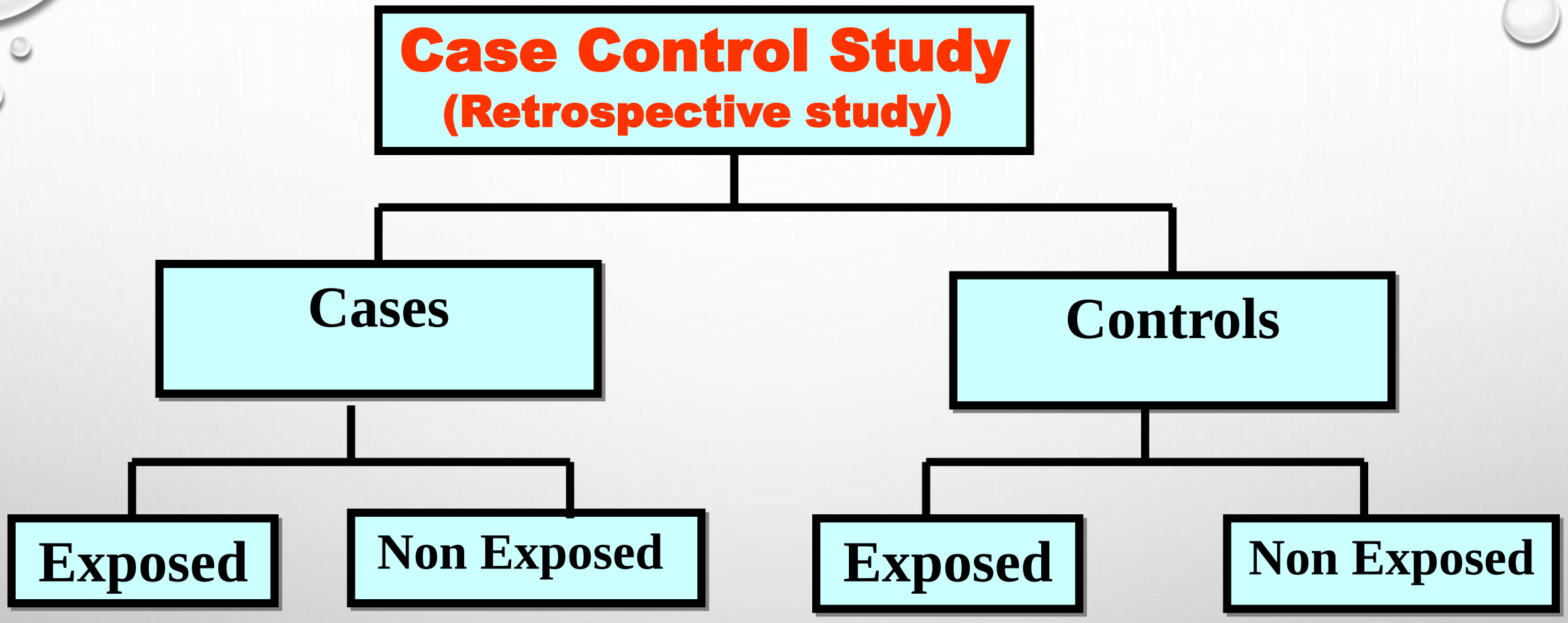
	Develop disease	Do Not	Total
Exposed	A	B	A+B
Not Exposed	C	D	C+D

- INCIDENCE AMONG EXPOSED = $\frac{A}{A+B}$
- INCIDENCE AMONG NON EXPOSED = $\frac{C}{C+D}$
- RELATIVE RISK = $\frac{\text{INCIDENCE AMONG EXPOSED}}{\text{INCIDENCE AMONG NON EXPOSED}}$

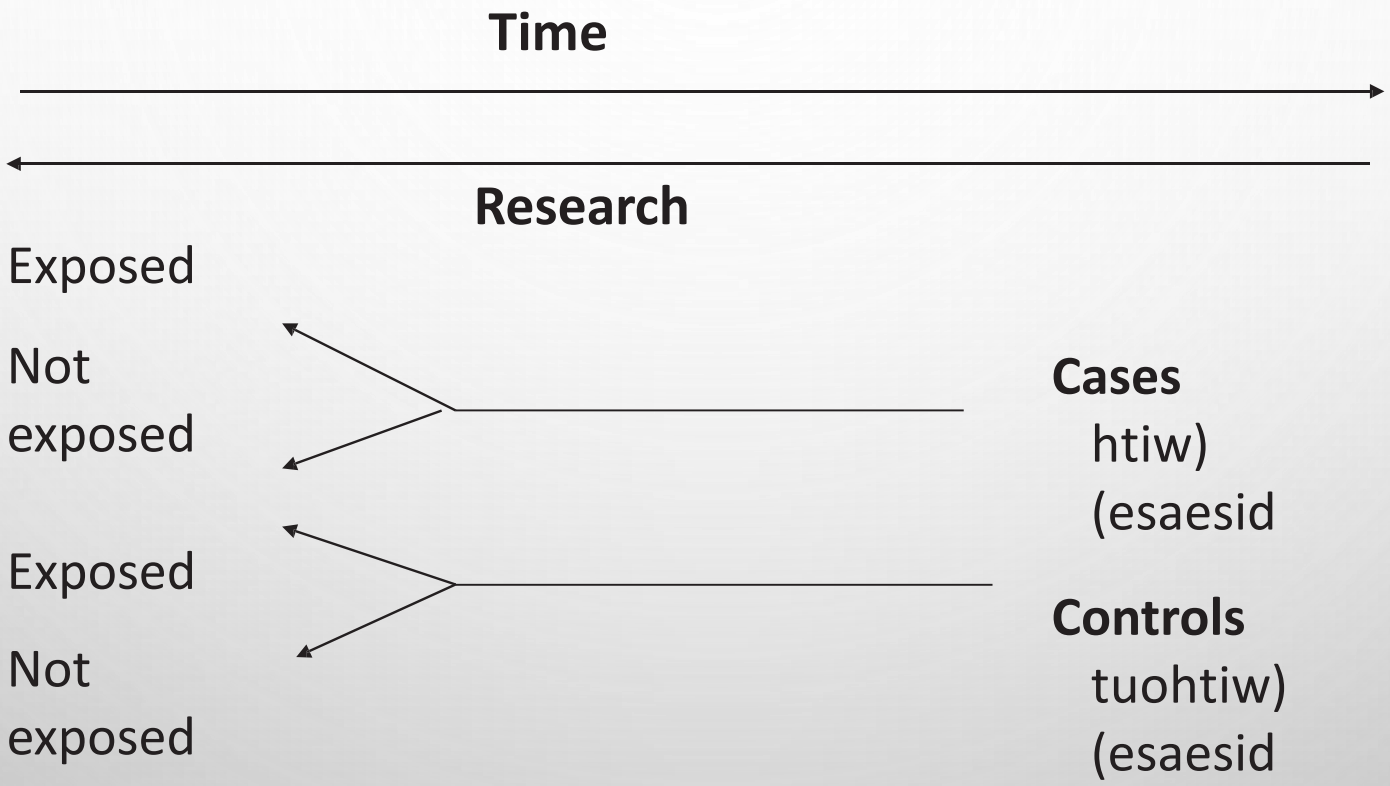
$$\text{prevALence} = \frac{\text{ALL cases}}{\text{Population @ risk}}$$

$$\text{iNcidence} = \frac{\text{New cases}}{\text{Population @ risk}}$$

Case Control Study
(Retrospective Study)


Case Control Study
(Retrospective study)
Cases
Controls
Exposed
Non Exposed
Exposed
Non Exposed

Case-control Study – Retrospective Study

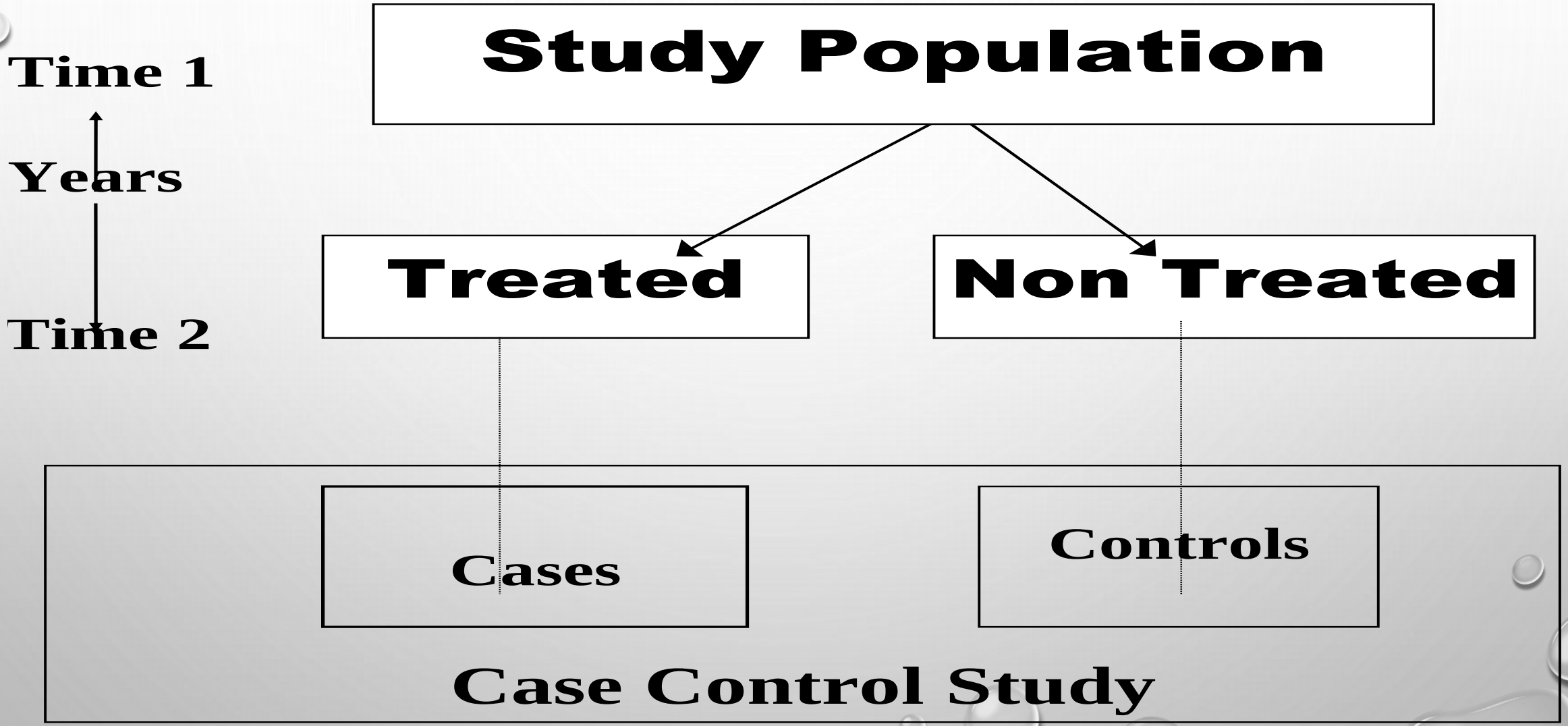


Analysis In Case Control Studies

	Cases	Controls
Exposed	A	B
Non Exposed	C	D

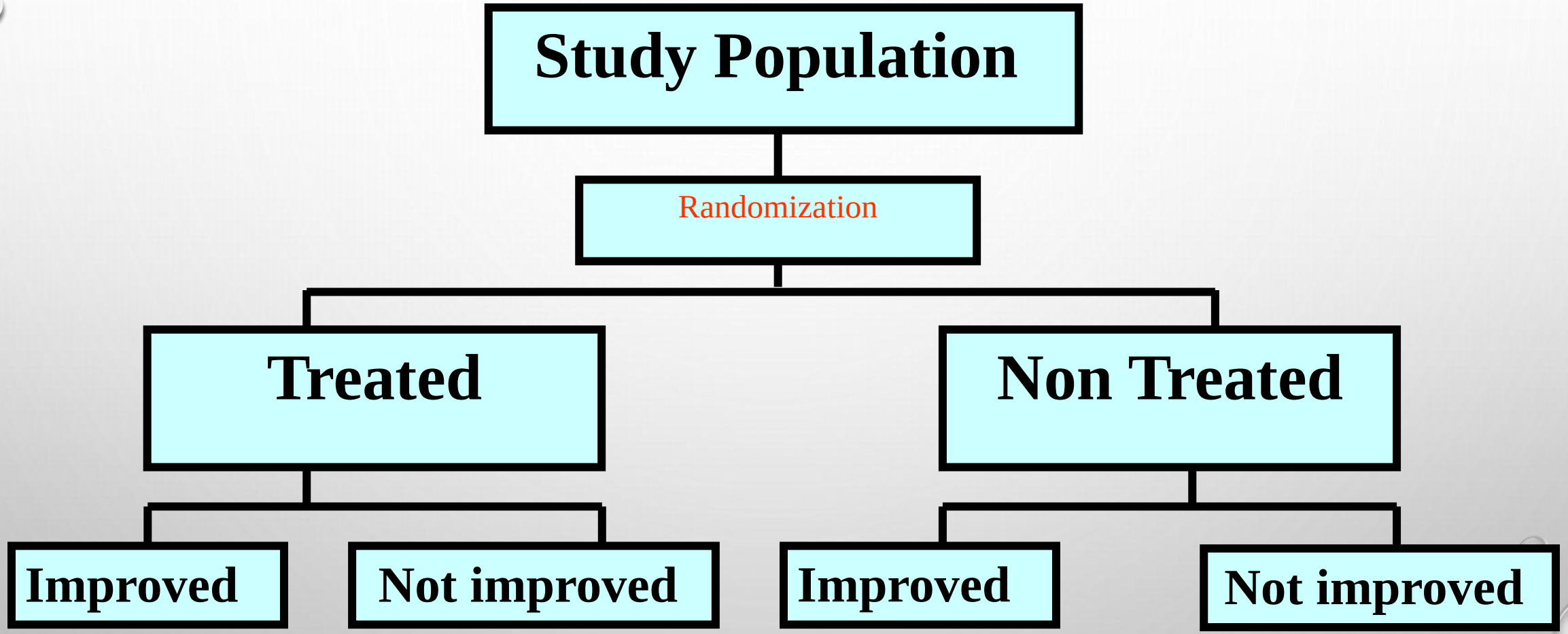
ODD'S RATIO = $\frac{A \times D}{B \times C}$

Nested Case Control Study



Randomized Clinical Trials

Randomized Clinical Trials



Types and Examples of Clinical Trials

Type	*Example*
Therapeutic	1. Laser treatment for diabetic retinopathy 2. Simple mastectomy for Breast Cancer.
Intervention	1. Antihypertensive drugs to reduce the risk of developing a stroke. 2. Physical exercise for decreasing the risk of myocardial infarction.
Preventive	1. BCG vaccination for tuberculosis 2. Isoniazid for prevention of tuberculosis.

General Outline of a Protocol for a Clinical Trial

1. Rationale and background for study.
2. Specific objectives of study.
3. Concise Statement of the study design (masking, randomization, types and duration of treatment, number of patients).
4. Criteria for including and excluding subjects.
5. Outline of treatment procedures.
6. Definition of all clinical, laboratory, etc, methods.
7. Methods of assuring the integrity of the data.
8. Major and minor endpoints (e.g. death, myocardial infraction)
9. Provisions for observing and recording side effects.
10. Procedures for handling problem cases.
11. Procedures for obtaining informed consent of subjects.
12. Procedures for analyzing results.
13. Appendices: Forms

Ethical Considerations in a clinical Trial

1. Is the proposed treatment safe for (unlikely to bring harm to) the Patient?
2. For the sake of a controlled trial, can a treatment ethically be withheld from any patient in the doctor' care ?
3. What patients may be brought into a controlled trial and allocated and only to any of the different treatments?
4. Is it ethical to use a placebo or dummy treatment?
5. Is it proper for the trial to be in any way blind?

Source: Adapted from Bearman

Quasi-experiments

- Research design that does not utilize random assignment to construct an initial equivalence between groups
- Quasi-experimental designs use a control group which is separate from the experimental group and not randomized
- Used because RCTS are
  - Costly,
  - Time consuming,
  - Can be subject to methodological flaws, and
  - May not be considered ethical to conduct.

Rank of Epidemiological Studies

A. Case Series Report B. Case-control study (Retrospective)
C. Clinical trial D. Cohort study (Prospective)
E. Case report.

1. A total of 300 newly diagnosed patients with laryngeal cancer are allocated to treatment with either surgical excision alone or surgical excision plus radiation treatment.

2. A 39 - year- old man who presents with mild sore throat, fever, malaise, and headache is treated with penicillin for presumed streptococcal infection. He returns after a week with hypotension, fever, rash, and abdominal pain. He responds favorably to chloramphenicol, after a diagnosis of Rocky Mountain spotted fever is made.

3. A total of 3500 patients with thyroid cancer are identified and surveyed by patient interviews regarding past exposure to radiation.

4. A total of 10,000 Vietnam veterans, half of whom are, known by combat records to have been in areas where agent orange was used and half of whom are known to have been in areas where no Agent Orange was use, are asked to give a history of cancer since discharge.

5. Patients admitted for carcinoma of the stomach are age and sex matched with fellow patients without a diagnosis of cancer and surveyed as to smoking history to assess the possible association of smoking and gastric cancer.

THANK YOU