

به نام یگانه پروردگار



Research Methodology

Study Design (1)



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Evidence for action needs research

Conducting a research needs some tools

Study designs are these tools



Study Design Categories

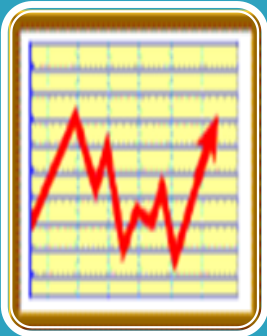


Qualitative	↔	Quantitative
Basic	↔	Applied
Observational	↔	Experimental
Descriptive	↔	Analytic

Study Design



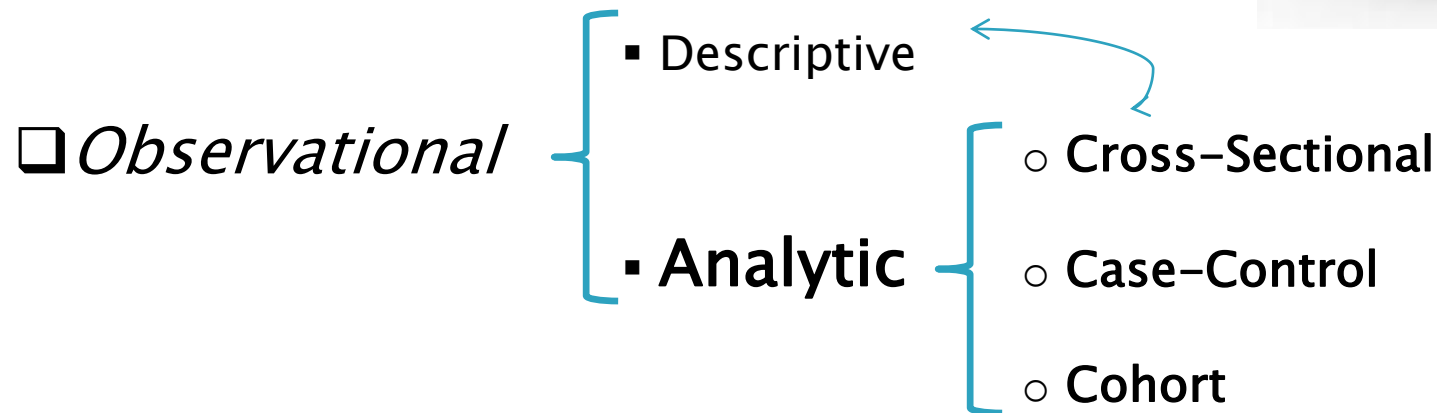
Qualitative



Quantitative

- Observational
- Experimental

Study Design



□ *Experimental* (Randomized Control Trial – RCT)

Descriptive Study



Who? When?
Where?

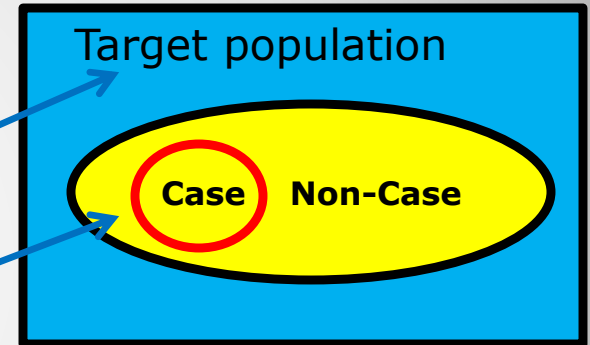
- ▶ Case Report
- ▶ Case series
- ▶ Cross sectional studies

Cross-Sectional Study or prevalence study

2 important questions to consider:

- ☐ Definition of the Population
- ☐ Definition of Case

AND/OR Definition of risk factors



Prevalence of Dis. = No. of disease+ / No. of subjects

Prevalence of R.F. = No. of risk factor+ / No. of subjects

Example 1: Medication Usage in Type 2 Diabetes: Adults in Primary Care Clinics, USA, 2018–2020

Who: Adults diagnosed with type 2 diabetes

Where: Multiple primary care clinics across the United States

When: Data collected between 2018 and 2020

Sampling Setting: Simple random sampling from electronic medical records of patients attending these clinics during the study period

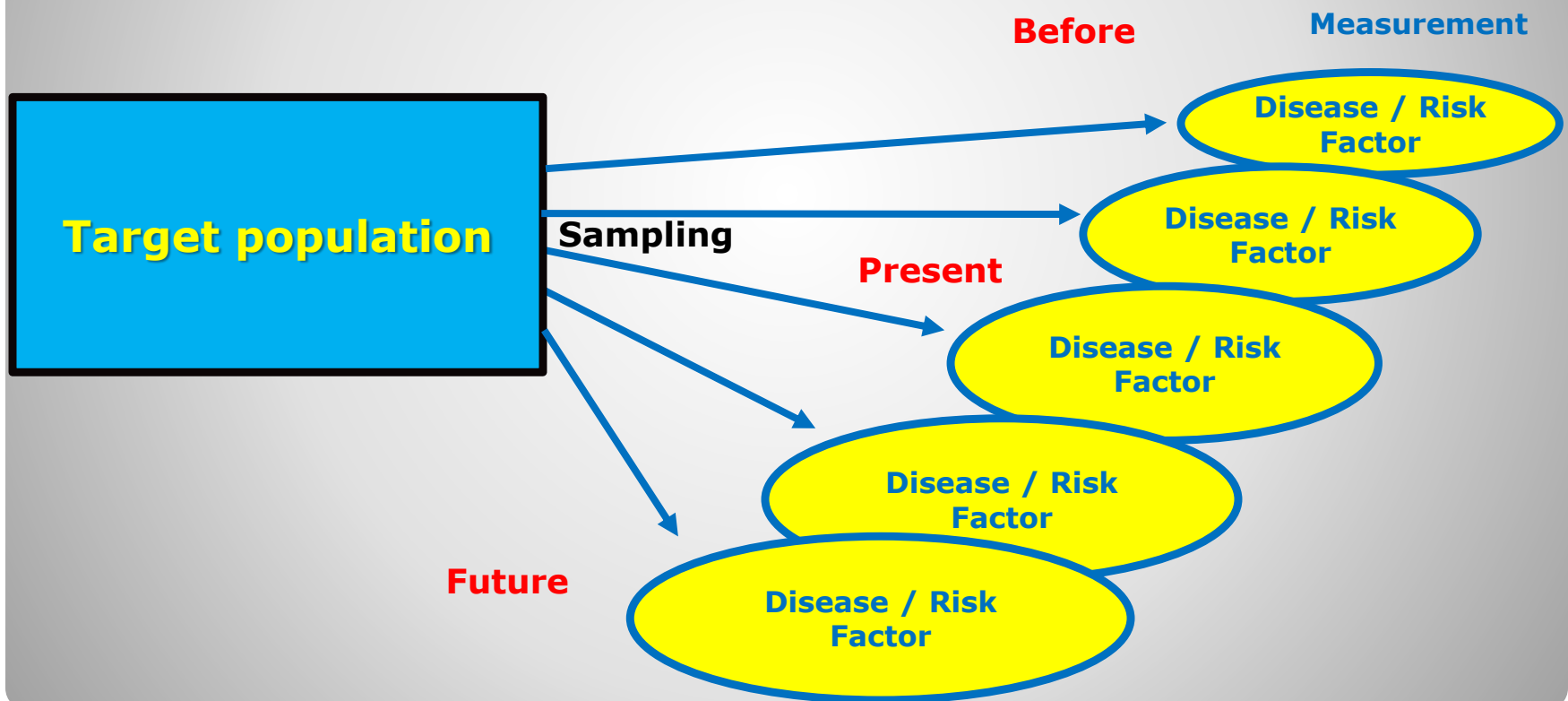
Objective: Assess eligibility and prescription rates for cardiorenal-protective medications (SGLT2i, GLP-1 RA)

Key Findings: 66.3% eligible, but only 16.6%–19.4% prescribed these medications

Example 2: Prevalence of Complementary and Alternative Medicine Use Among Diabetic Patients in Iran, 2023

- **Who:** Adult diabetic patients under treatment
- **Where:** Diabetes clinics across multiple regions in Iran
- **When:** Data collected in 2023
- **Sampling Setting:** Convenience sampling of patients visiting diabetes care centers
- **Objective:** To assess the prevalence and factors associated with the use of complementary and alternative medicine (CAM) among diabetic patients
- **Key Findings:**
 - High prevalence of CAM use among diabetic patients
 - Significant associations found between CAM use and patients' socio-demographic characteristics and disease duration

Trend Design in Cross-Sectional studies

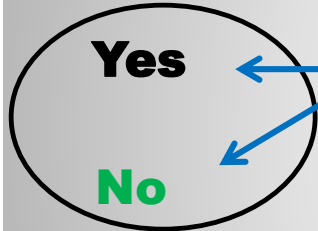


Diabetes Prevalence and Care Cascade in Iran Based on STEPS Surveys (2004–2021)

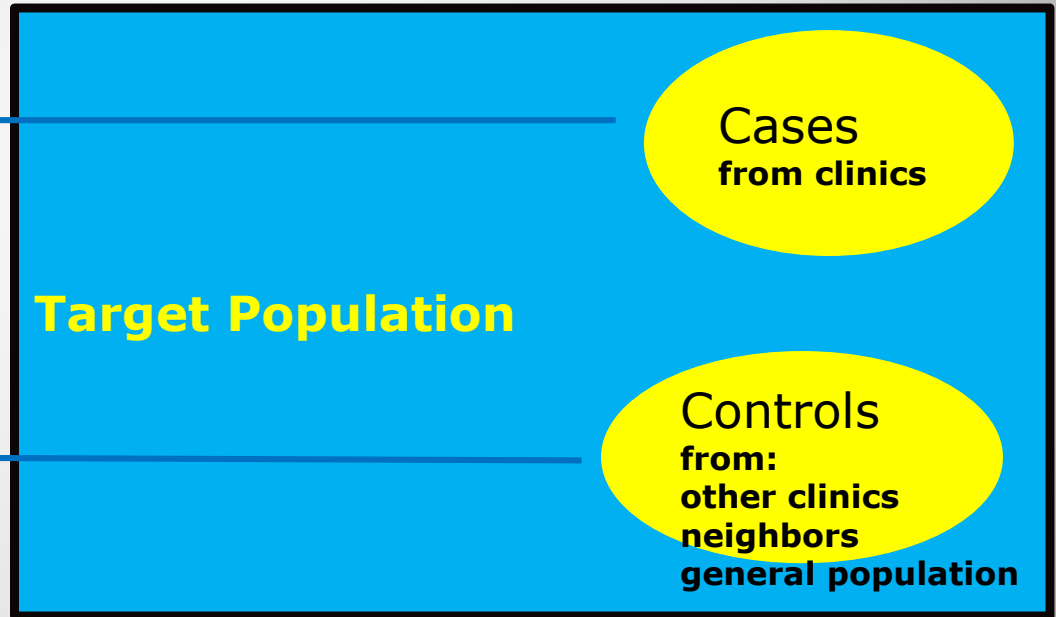
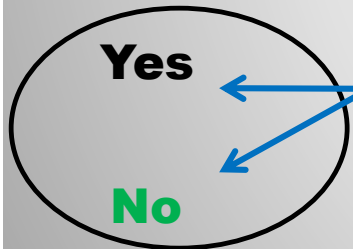
- **Who:** Iranian adults aged 25 years and older
- **Where:** Nationwide, urban and rural areas of Iran
- **When:** Four rounds of the WHO STEPwise approach to NCDs risk factor surveillance (STEPS) surveys in 2004, 2007, 2011, 2016 and a national STEPS survey in 2021
- **Sampling Setting:** Representative, multi-stage cluster sampling of the Iranian population at different time points
- **Objective:** To investigate trends in diabetes prevalence, awareness, treatment coverage, and glycemic control over 17 years in Iran
- **Key Findings:**
 - Diabetes prevalence increased from 8.4% in 2004 to 14.2% in 2021
 - Awareness of diabetes improved from 53.5% to 82.2% during this period
 - Treatment coverage rose from 35.9% to 65.0%, but glycemic control remained suboptimal (~18% with adequate control)
 - Despite progress in diagnosis and treatment, significant gaps remain in effective diabetes management

Case-control Study

Compare { people who **got the disease**
people who **didn't get the disease**



Past/current "exposures"



First Step

- **Selection of cases**

- ❖ Precise definition of 'case'.
- ❖ Inclusion / Exclusion criteria.
- ❖ How are the cases identified? How recruited?

Second Step

- **Selection of Controls**

- ☐ Source (hospital patients without disease; neighborhood controls; random sample of population; sibs).
- ☐ Inclusion / exclusion criteria.

Controls must be related to the same population as the cases are.

Third Step

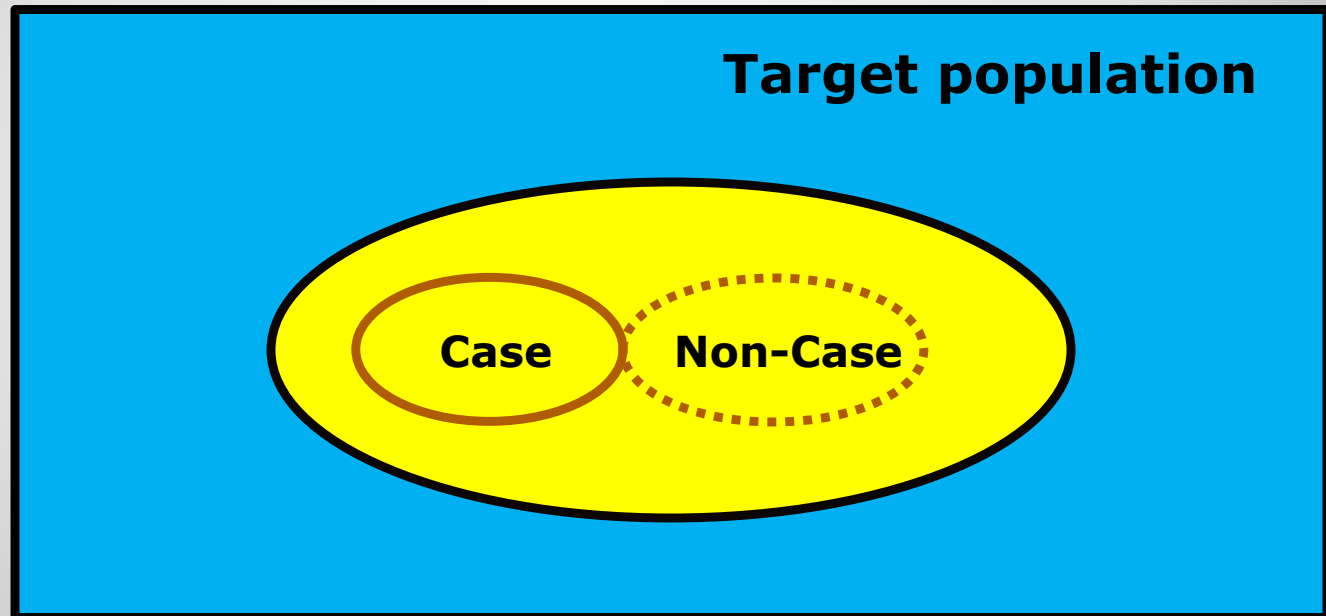
- **Collection of information**

- Identify risk factor of interest
- Method of collection of information (questionnaire; medical records; employment records)
- Same procedure to be used for cases and controls
- Interviewer should be unaware who is a case and who a control.

Risk Factors for Diabetic Complications in Iranian Patients

- Cases:** Patients with diabetes and documented diabetic complications (e.g., neuropathy, retinopathy, nephropathy)
- Controls:** Patients with diabetes but without documented diabetic complications matched by age and sex
- Objective:** To investigate factors associated with the occurrence of diabetic complications
- Key Findings:**
 - Significant associations between poor glycemic control, longer duration of diabetes, hypertension, and the presence of complications
 - Other risk factors included dyslipidemia and smoking status

Cross-Sectional Case-Control Study



Cohort Study

- A major limitation of cross-sectional surveys and case-control studies is difficulty to determine if exposure or risk factor preceded the disease or outcome.

- Cohort Study:

is the Key Point:



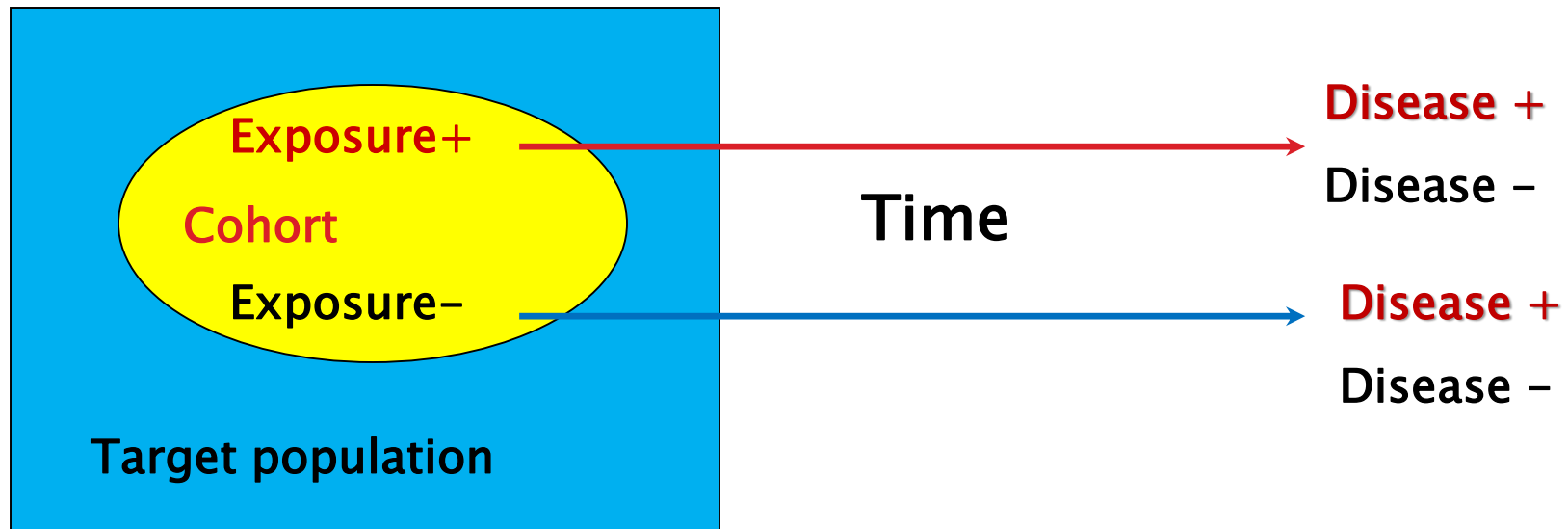
Presence or absence of risk factor determine
before outcome occurs.

WHAT IS COHORT

- Ancient Roman military unit, A band of warriors.
- Persons banded together.
- Group of persons with a common statistical characteristic. [Latin]
- E.g. age, birth date,



Cohort Study



Cohort studies

- Forward looking study (Prospectively or Retrospectively)
- Incidence study
- starts with people free of disease
- assesses exposure at “baseline”
- assesses disease status at “follow-up”

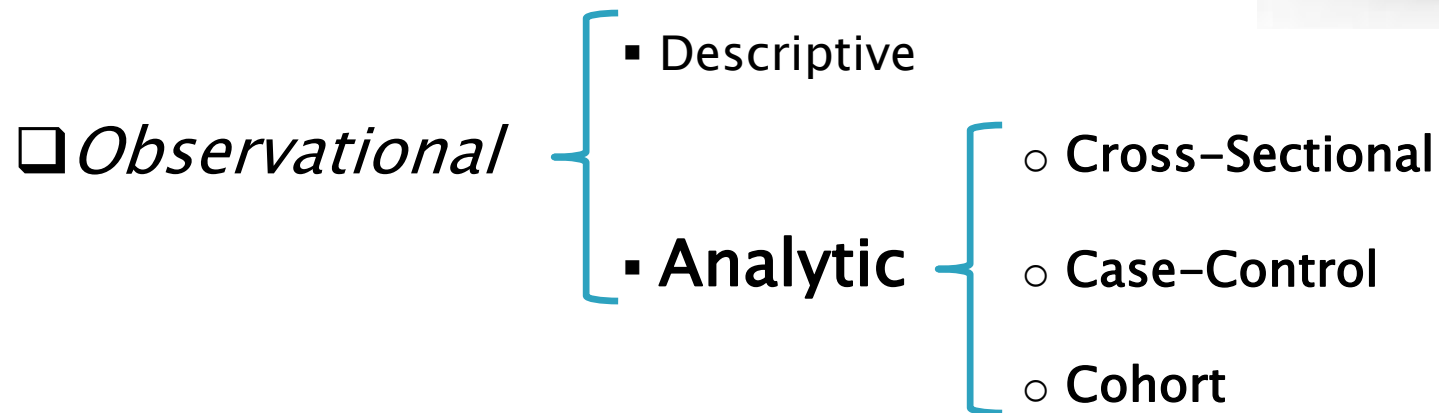
Indication of a cohort study

- ▶ When there is good evidence of exposure and disease.
- ▶ When exposure is rare but incidence of disease is higher among exposed
- ▶ When follow-up is easy, cohort is stable
- ▶ When ample funds are available

Elements of cohort study

- ▶ Selection of study subjects
(A defined population)
- ▶ Obtaining data on exposure
- ▶ Follow up to detect outcome

Study Design



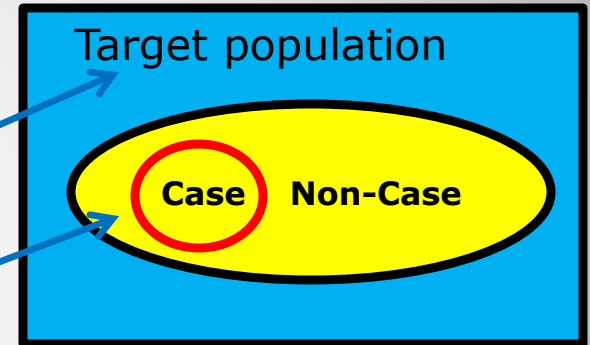
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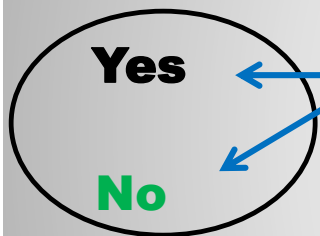


Prevalence of Dis. = No. of disease+ / No. of subjects

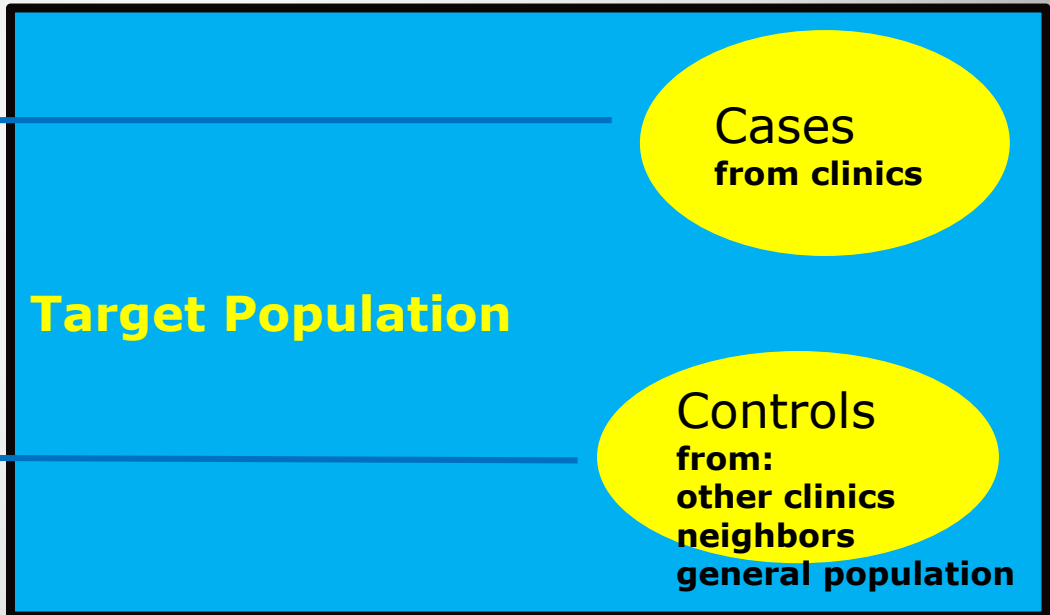
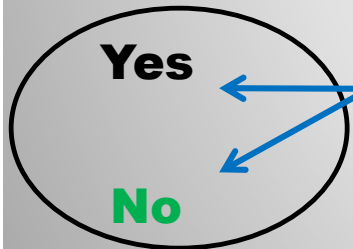
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Case-control Study

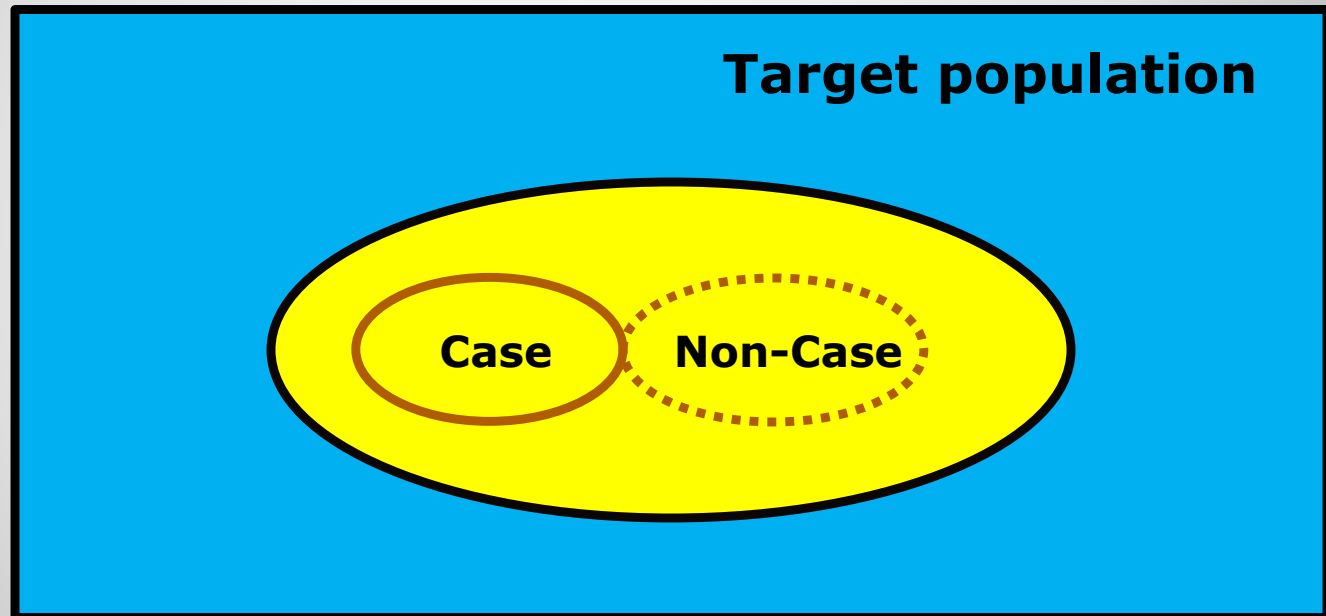
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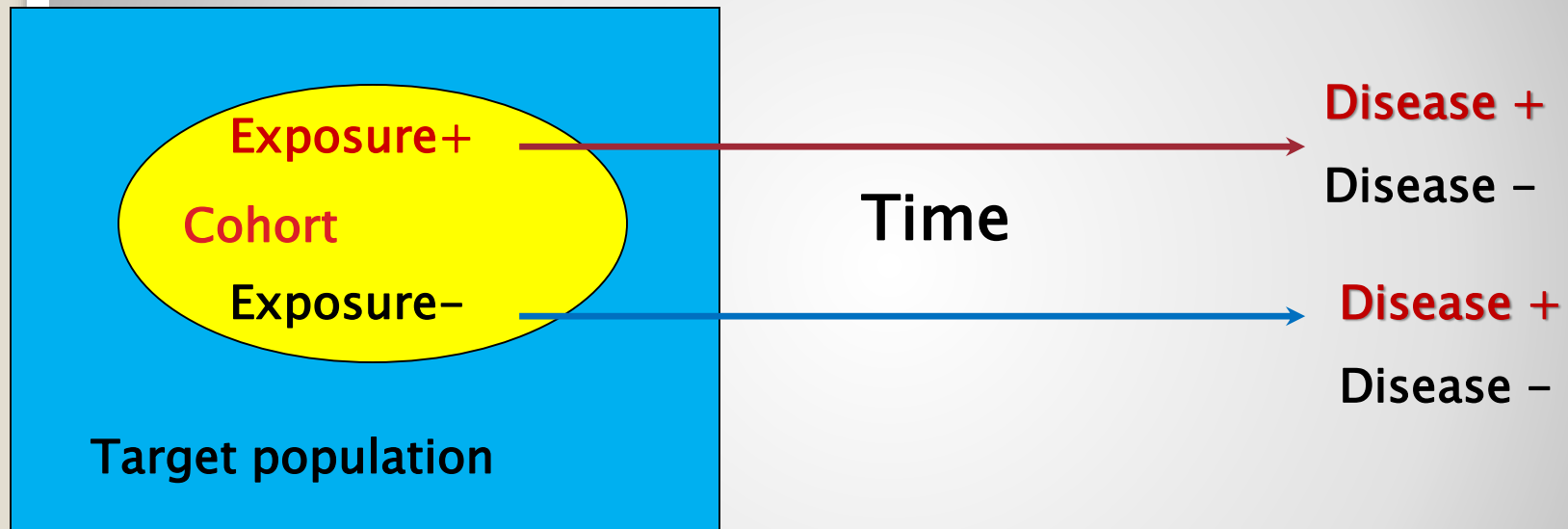
Past/current "exposures"



Cross-Sectional Case-Control Study



Cohort Study



Advantages

- Useful for descriptive studies
- Rapid, inexpensive, can provide analytic clues.
- Less prone to error about exposure recall bias

Disadvantages

- Prone to sample distortion bias.
- Unable to sort out what came first exposure or outcome
- Prone to seasonal and time to time variations

cross-sectional studies

ADVANTAGES

- Relatively cheap compared to cohort studies
- Relatively quick
- Useful for study of rare diseases.
- No ethical problems
- Useful for diseases with long latent period.

Disadvantages

- Estimate of disease incidence cannot be done
- At times difficult to measure exposure accurately
- Open to selection bias.
- Difficult to interpret.

Case-control Studies

Cohort studies

Strengths

- We can find out incidence rate and risk
- More than one disease related to single exposure
- can establish cause - effect
- good when exposure is rare
- minimizes selection and information bias

Weaknesses

- losses to follow-up
- often requires large sample
- ineffective for rare diseases
- long time to complete
- expensive
- Ethical issues

Any Question?

Time of team working.



TEAM

T	Together
E	Everyone
A	Achieves
M	More