Introduction to Epidemiology and Study Designs

What is Epidemiology?

- **Epidemiology may be regarded simply as the study of disease and health in human populations.**

- **Here disease may be any adverse health outcome such as pre-term birth, it may not necessarily be a disease such as cancer.**

Goals of Epidemiological Research

1) Describe the health status of populations by enumerating the occurrence of diseases, obtaining relative frequencies within groups and discovering important trends.
2) Explain the etiology of diseases by determining factors that "cause" specific diseases or trends.

Goals of Epidemiological Research

3) Predict the number of disease occurrences and the distribution of health status within populations.
4) Control the distributions of disease in the population by prevention of new occurrences, eradication of existing cases, prolongation of life for those with disease, or otherwise improving the health status of afflicted persons.

Components of Epidemiology

- **Measure disease frequency**
  - **Quantify disease**
- **Assess distribution of disease**
  - **Who is getting disease?**
  - **Where is disease occurring?**
  - **When is disease occurring?**

  ➔Formulation of hypotheses concerning causal and preventive factors
- **Identify determinants of disease**
  - **Hypotheses are tested using epidemiologic studies**

Types of Primary Studies

- **Descriptive Studies**
  - **describe occurrence of an outcome**

- **Analytic Studies**
  - **describe the potential *association* between** Exposure And Outcome

Observational Studies

- **Non-experimental**
- **Observational because there is no individual intervention**
- **Treatment and/or exposures occur in a "non-controlled" environment**
- **Individuals can be observed prospectively, retrospectively, or currently** (i.e. cross-sectional)

Descriptive Studies

Case Report → **One case of unusual findings**

Case Series → **Multiple cases of findings**

Descriptive Epidemiology Study → **Population-based cases with denominator**

Case Reports

- Detailed presentation of a single case or handful of cases
- Generally report a new or unique finding
    - e.g. previous undescribed disease
    - e.g. unexpected link between diseases
    - e.g. unexpected new therapeutic effect
    - e.g. adverse events

Case Series

- Experience of a group of patients with a similar diagnosis
- Assesses prevalent disease
- Cases may be identified from a single or multiple sources
- Generally report on new/unique condition
- May be only realistic design for rare disorders

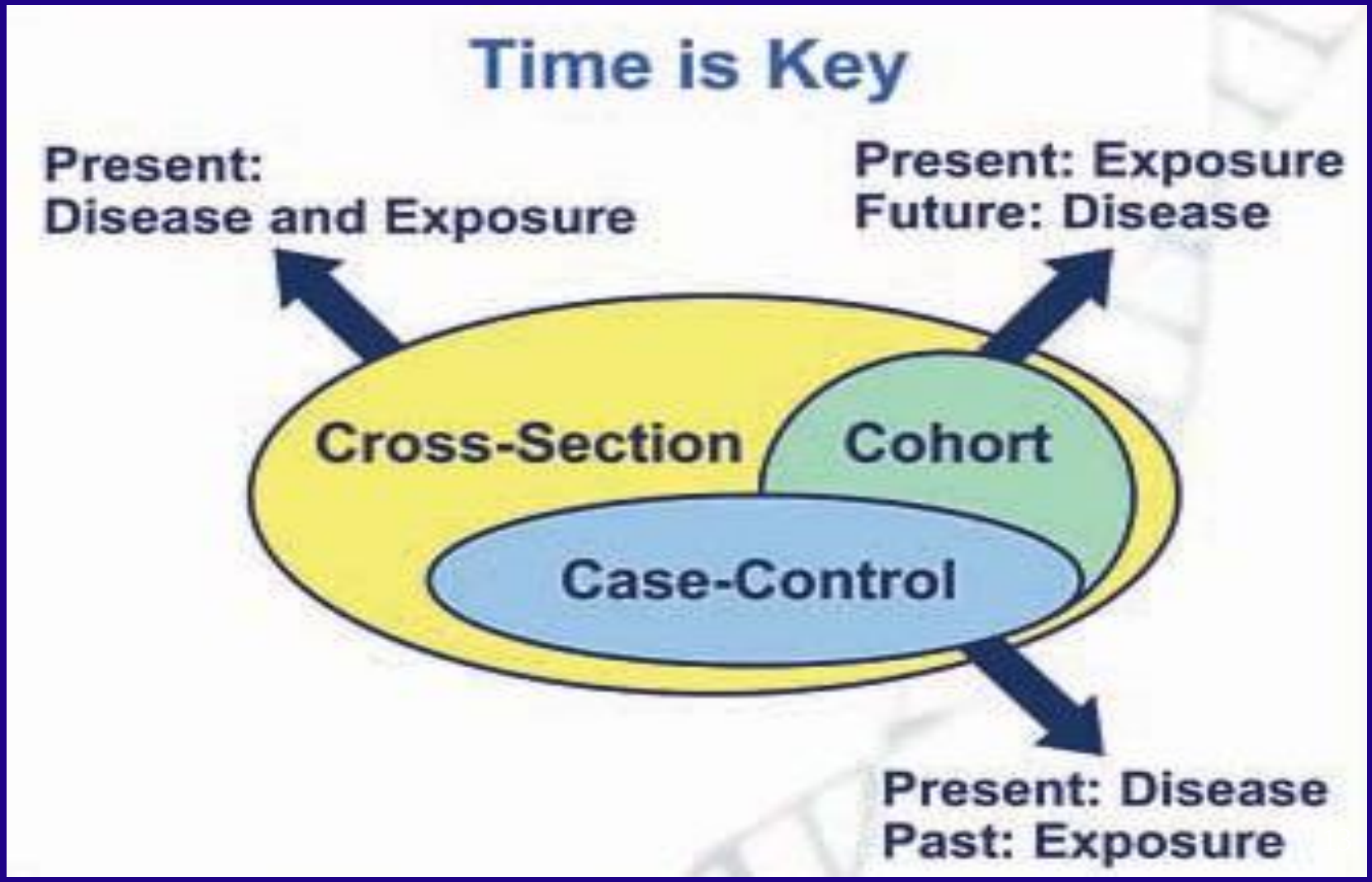
Case Series

- **Advantages**
  - **Useful for hypothesis generation**
  - **Informative for very rare disease with few established risk factors**
  - **Characterizes averages for disorder**
- **Disadvantages**
  - **Cannot study cause and effect relationships**
  - **Cannot assess disease frequency**

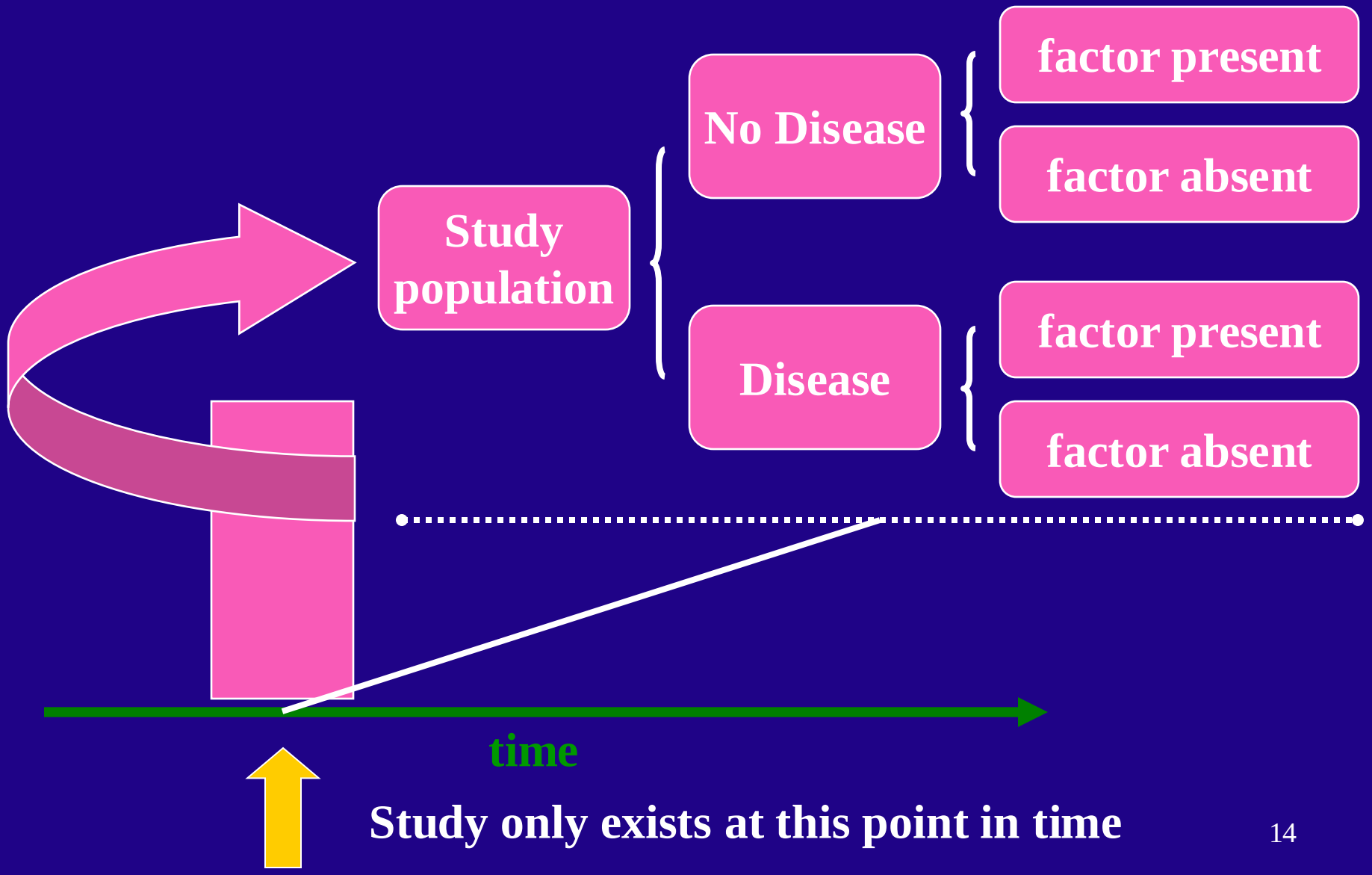
Cross-sectional studies

- An "observational" design that surveys exposures and disease status at a single point in time (a cross-section of the population)

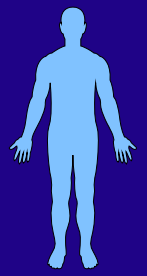
Observational Studies and Timeframe



Cross-sectional Design

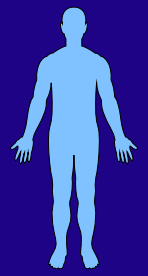


Cross-sectional Studies



- **Often used to study conditions that are relatively frequent with long duration of expression (nonfatal, chronic conditions)**
- ***It measures prevalence, not incidence of disease***
- **Example: community surveys**
- **Not suitable for studying rare or highly fatal diseases or a disease with short duration of expression**

Cross-sectional studies



- **Disadvantages**

1. Weakest observational design, (it measures prevalence, not incidence of disease). Prevalent cases are survivors
2. The temporal sequence of exposure and effect may be difficult or impossible to determine
3. Usually don't know when disease occurred
4. Rare events a problem. Quickly emerging diseases are also problem.

TYPES OF STUDY - HYPOTHESIS FORMING

- **case reports / case series**
- **cross sectional / prevalence studies measure personal factors & disease states - hypothesis forming - cannot indicate cause & effect**

Case-Control Studies

- **Type of analytic study**

- **Unit of observation and analysis: Individual (not group)**

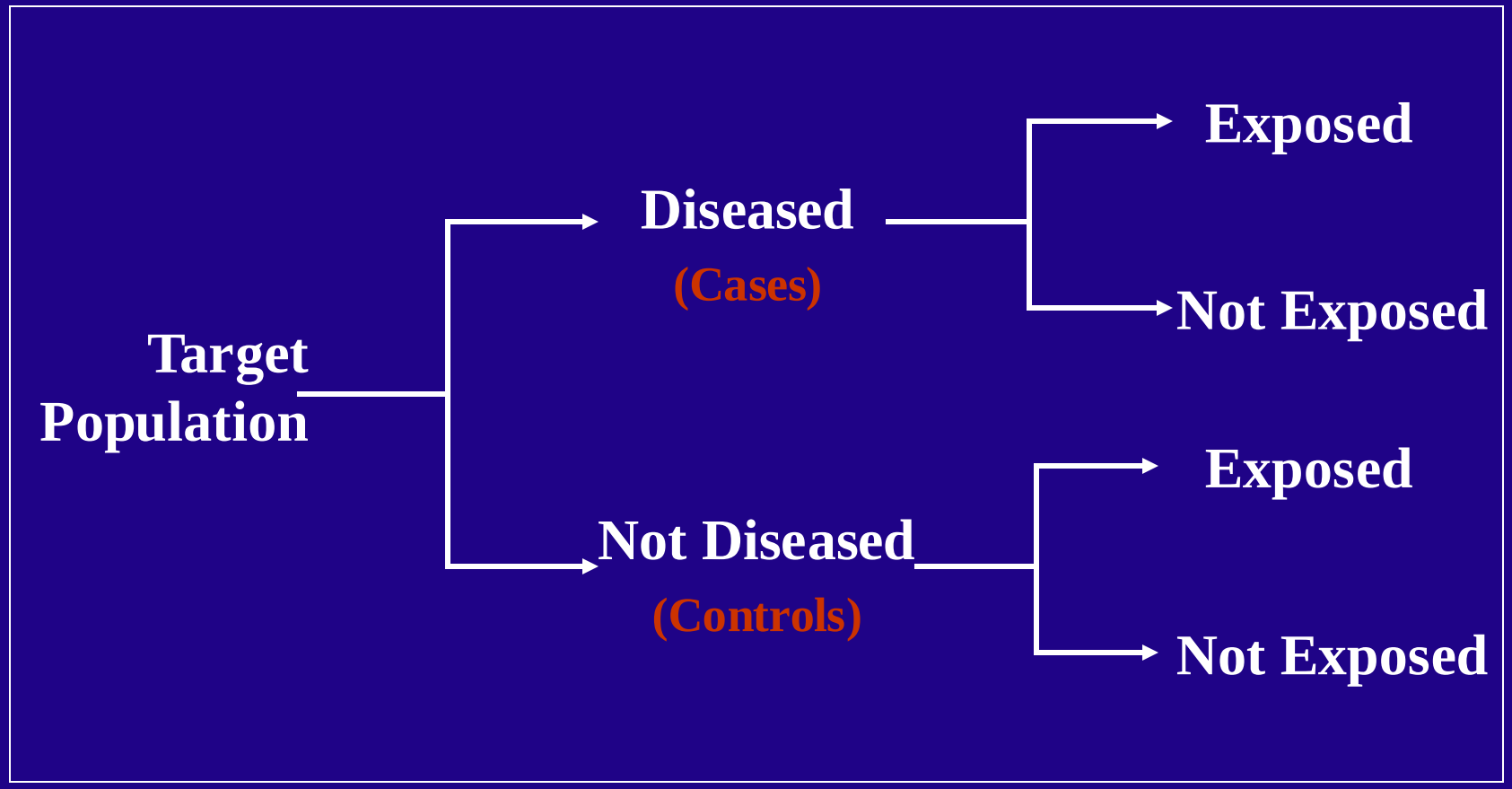
Case-Control Studies

- **Case-control studies are the most frequently undertaken analytical epidemiological studies**
- **They are the only practical approach for identifying risk factors for rare diseases**

Design

- **At baseline:**
  - **Selection of cases (disease) and controls (no disease) based on disease status**
  - **Exposure status is unknown**

Case Control Study Design



Selecting Cases

- **Select cases after the diagnostic criteria and definition of the disease is clearly established**
- **Study cases should be representative of all cases**

Selecting Controls

- **Controls should come from the same population at risk for the disease as the cases**
- **Controls should be representative of the target population**

Odds Ratio (OR)

- **A ratio that measures the odds of exposure for cases compared to controls**

- **Odds of exposure = number exposed ÷ number unexposed**

- **OR Numerator: Odds of exposure for cases**
- **OR Denominator: Odds of exposure for controls**

Calculating the Odds Ratio

Exposure Status	Disease Status: CHD cases (Cases)	Disease Status: No CHD (Controls)
Smoker	112	176
Non-smoker	88	224
Total	200	400

$$\text{Odds Ratio} = \frac{AD}{BC} = \frac{112 \times 224}{176 \times 88} = 1.62$$

Interpreting the Odds Ratio

The odds of exposure for cases are 1.62 times the odds of exposure for controls.

or

Interpreting the Odds Ratio

Those with CHD are 1.62 times more likely to be smokers than those without CHD

or

Those with CHD are 62% more likely to be smokers than those without CHD

	OR<1	OR=1	OR>1
Odds comparison between cases and controls	Odds of exposure for cases are less than the odds of exposure for controls	Odds of exposure are equal among cases and controls	Odds of exposure for cases are greater than the odds of exposure for controls
Exposure as a risk factor for the disease?	Exposure reduces disease risk (Protective factor)	Particular exposure is not a risk factor	Exposure increases disease risk (Risk factor)

Advantages of Case-Control Studies

1. Quick and easy to complete, cost effective
2. Most efficient design for rare diseases
3. Usually requires a smaller study population than a cohort study

Disadvantages of Case-Control Studies

1. Uncertainty of exposure-disease time relationship
2. Inability to provide a direct estimate of risk
3. Not efficient for studying rare exposures
4. Subject to biases (recall & selection bias)

COHORT STUDY

Cohort studies

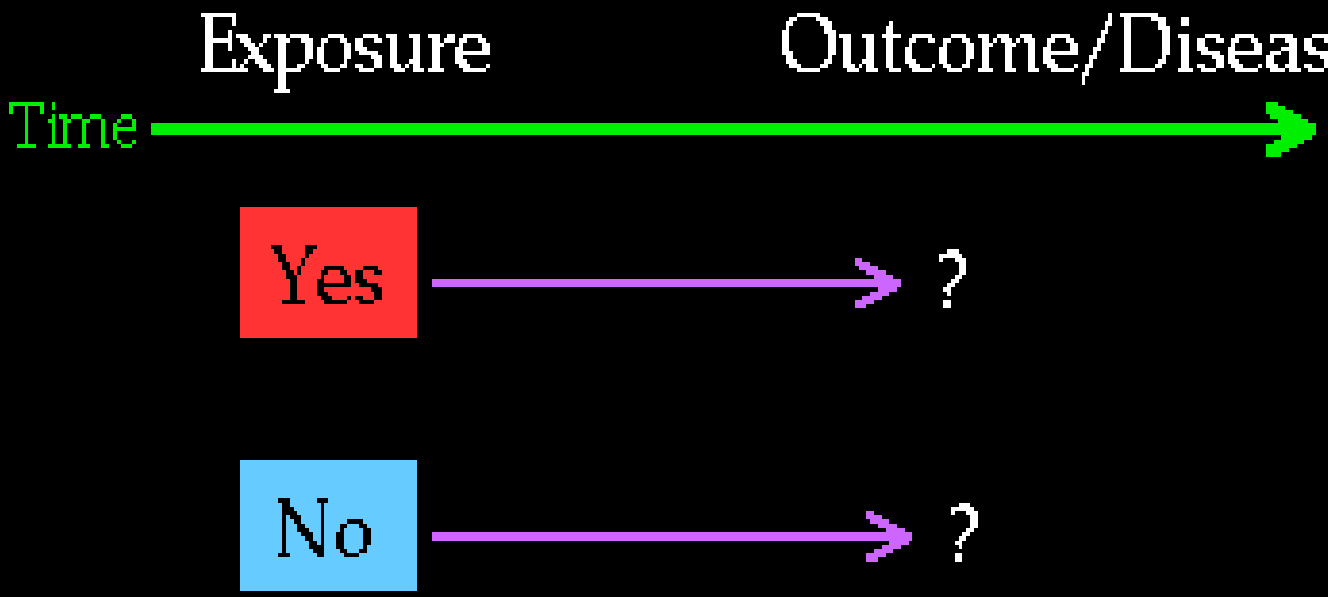
- longitudinal
- Prospective studies
- Forward looking study I
- Incidence study

- 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

Forward Directionality



Cohort studies

Clinical trials

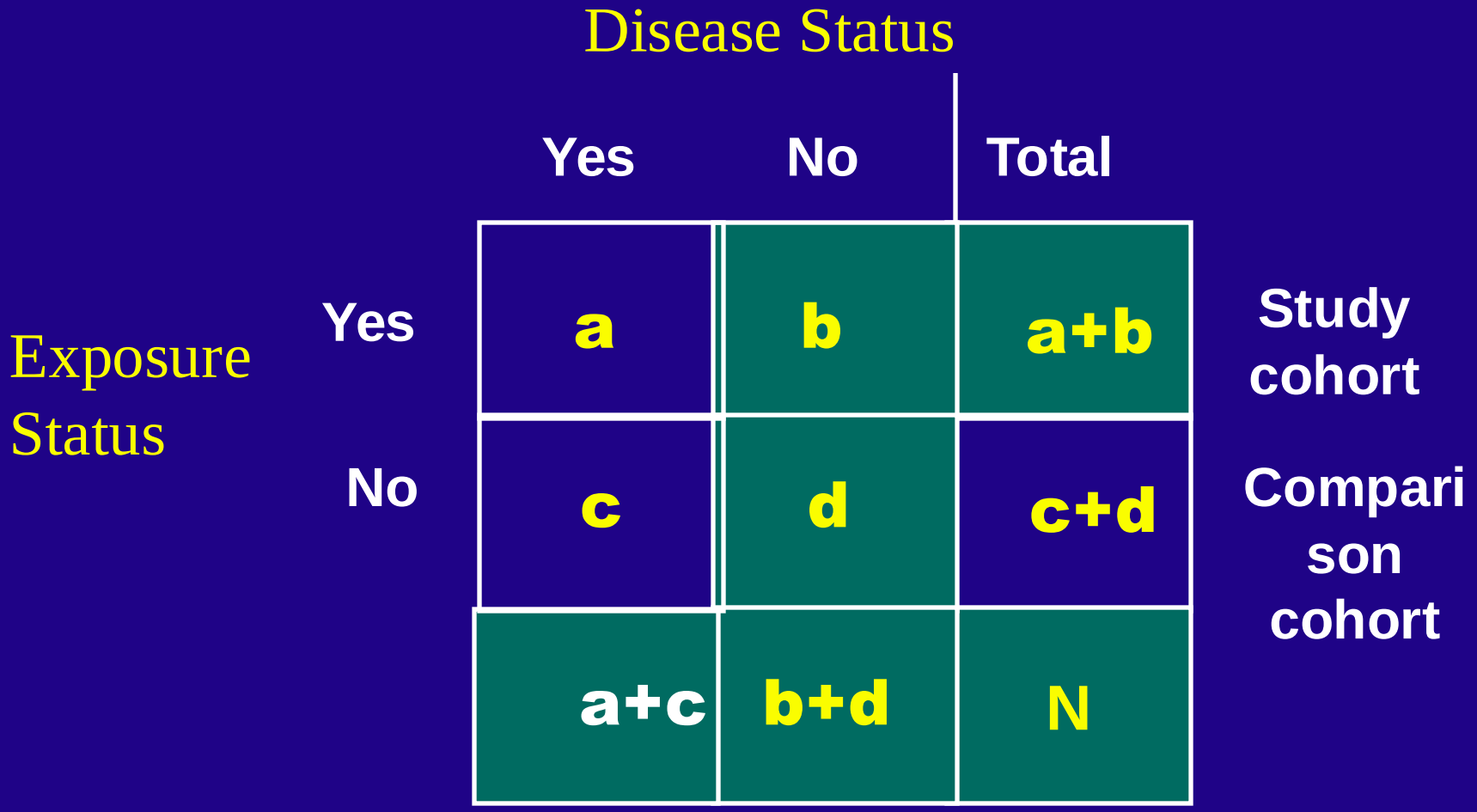
Follow-up

- To obtain data about outcome to be determined (morbidity or death)
  - Mailed questionnaire, telephone calls, personal interviews
  - Periodic medical examination
  - Reviewing records
  - Surveillance of death records
  - Follow up is the most critical part of the study
- Some loss to follow up is inevitable due to death change of address, migration, change of occupation.
- Loss to follow-up is one of the draw-back of the cohort study.

ANALYSIS

- Calculation of incidence rates among exposed and non exposed groups
- Estimation of risk

Incidence rates of outcome



Incidence rate

- Incidence among exposed =

$$\frac{a}{a+b}$$

- Incidence among non-exposed =

$$\frac{c}{c+d}$$

Estimation of risk

- Relative Risk

$$RR = \frac{\text{incidence of disease among exposed}}{\text{Incidence of disease among non-exposed}}$$

$$= \frac{a/a+b}{c/c+d}$$

Smoking	Lung cancer		Total
	YES	NO	
YES	70	6930	7000
NO	3	2997	3000
	73	9927	10000

Find out RR

- Incidence of lung cancer among smokers

  70/7000 = 10 per 1000

- Incidence of lung cancer among non-smokers

  3/3000 = 1 per thousand

RR = 10 / 1 = 10

(lung cancer is 10 times more common among smokers than non smokers)

Cohort studies

Strengths (advantages)

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

Weaknesses (disadvantages)

1. losses to follow-up
2. often requires large sample
3. ineffective for rare diseases
4. long time to complete
5. expensive
6. Ethical issues