

Study Designs in Health Research: An Overview

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Headlines

- **Health research**
- **Classification of study designs**
- **Qualitative methods**
- **Quantitative methods**
- **Choice of study design**

Health Research

- **Lab research:** develop procedures to prevent, control and treat mechanisms of health-related phenomena
- **Population-based (field) research:** study of distribution, determinants, control health-related phenomena in populations. Using suitable biostatistical techniques for generalization
- **Healthcare-facility (clinical) research:** application of epidemiological principles in research based in healthcare facilities, e.g. randomized clinical trials



hospital

Data Collection Methods

- **Primary:** where **the investigator is the first to collect the data.** Sources include: medical examinations, interviews, observations, etc. Merits: less measurement error, suits objectives of the study better. Disadvantage: costly, feasibility to be assessed.
- **Secondary:** where the data is collected by **OTHERS**, for other purposes than those of the current study. Sources include: individual records (medical / employment); group records (**census data, vital statistics done by MOH**)



Study design: Definition

A study design is a **specific plan** or protocol for conducting the study, which allows the investigator to **translate the conceptual hypothesis into an operational one.**



Study Designs: Types

- Qualitative
- Quantitative
 - Experimental
 - Observational

Qualitative Designs

Qualitative

- **Methods**
 - Focus Groups
 - Interviews
 - Surveys
 - Self-reports
 - Observations
 - Document analysis
 - **Sampling:** Purposive
- **Quality Assurance:**
 - **Trustworthiness:** Credibility, Confirming, Dependability, Transferability
 - **Authenticity:** Fairness, Ontological, Educative, Tactical, Catalytic

Quantitative

- **Methods**
 - Observational
 - Experimental
 - Mixed
 - **Sampling:** Random (simple, stratified, cluster, etc) or purposive
- **Quality Assurance:**
 - **Reliability:** Internal and External
 - **Validity:** Construct, Content, Face

Qualitative Research Techniques

- Participant observation (field notes)
- Interviews / Focus group discussions with key informants
- Video / Text and Image analysis (documents, media data)
- Surveys
- User testing



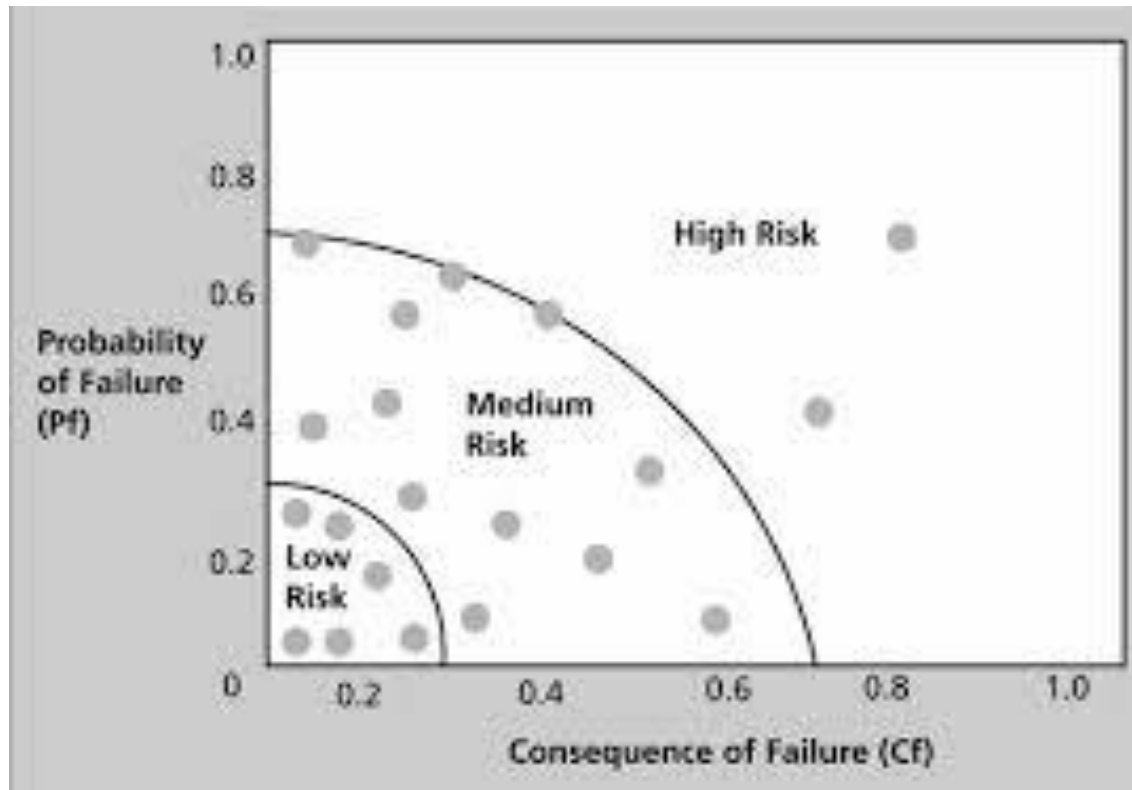
Involves Skills of

- **Observing**
- **Conversing**
- **Participating**
- **Interpreting**



Rigor in Qualitative Research

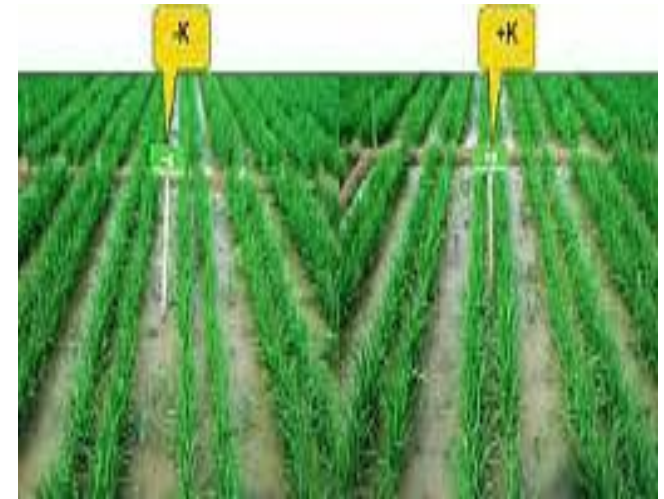
- **Dependability**
- **Credibility**
- **Transferability**
- **Confirmability**



Quantitative Designs

Quantitative designs

- **Observational:** studies do not involve any intervention or experiment.
- **Experimental:** studies that entail **manipulation** of the study factor (exposure) and **randomization** of subjects to treatment (exposure) groups





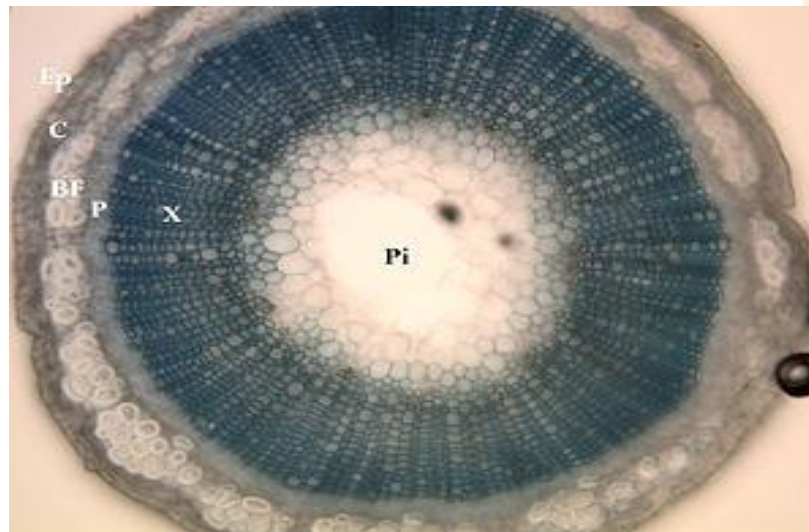
Observational Designs

Observation Methods

- **Selected Units:** individuals, groups
- **Study Populations:** cross-sectional, longitudinal
- **Data collection timing:** prospectively, retrospectively, combination
- **Data collection types:** primary, secondary

Study populations

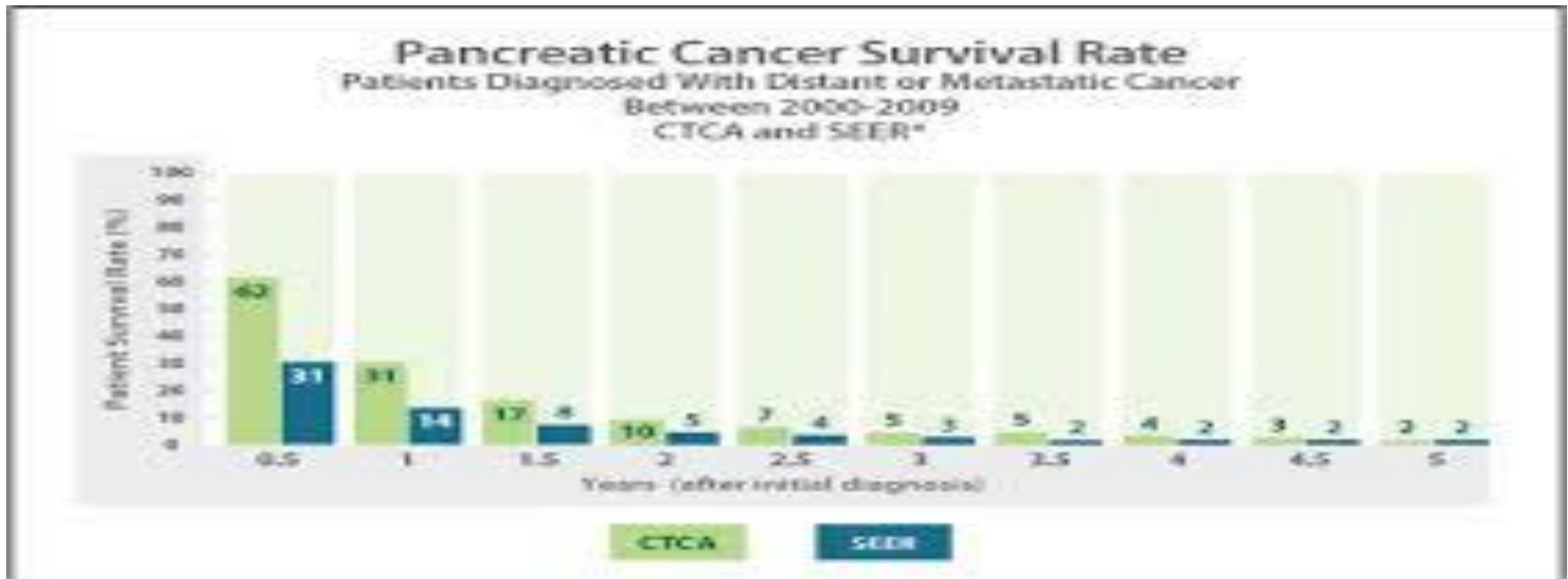
- **Cross-sectional:** where only **ONE** set of observations is collected for every unit in the study, at a certain point in time, disregarding the length of time of the study as a whole



- **Snap shot of a population**

Study population

- **Longitudinal:** where **TWO or MORE** sets of observations are collected for every unit in the study, i.e. follow-up is involved in order to allow monitoring of a certain population (cohort) over a specified period of time. Such populations are AT RISK (disease-free) at the start of the study.

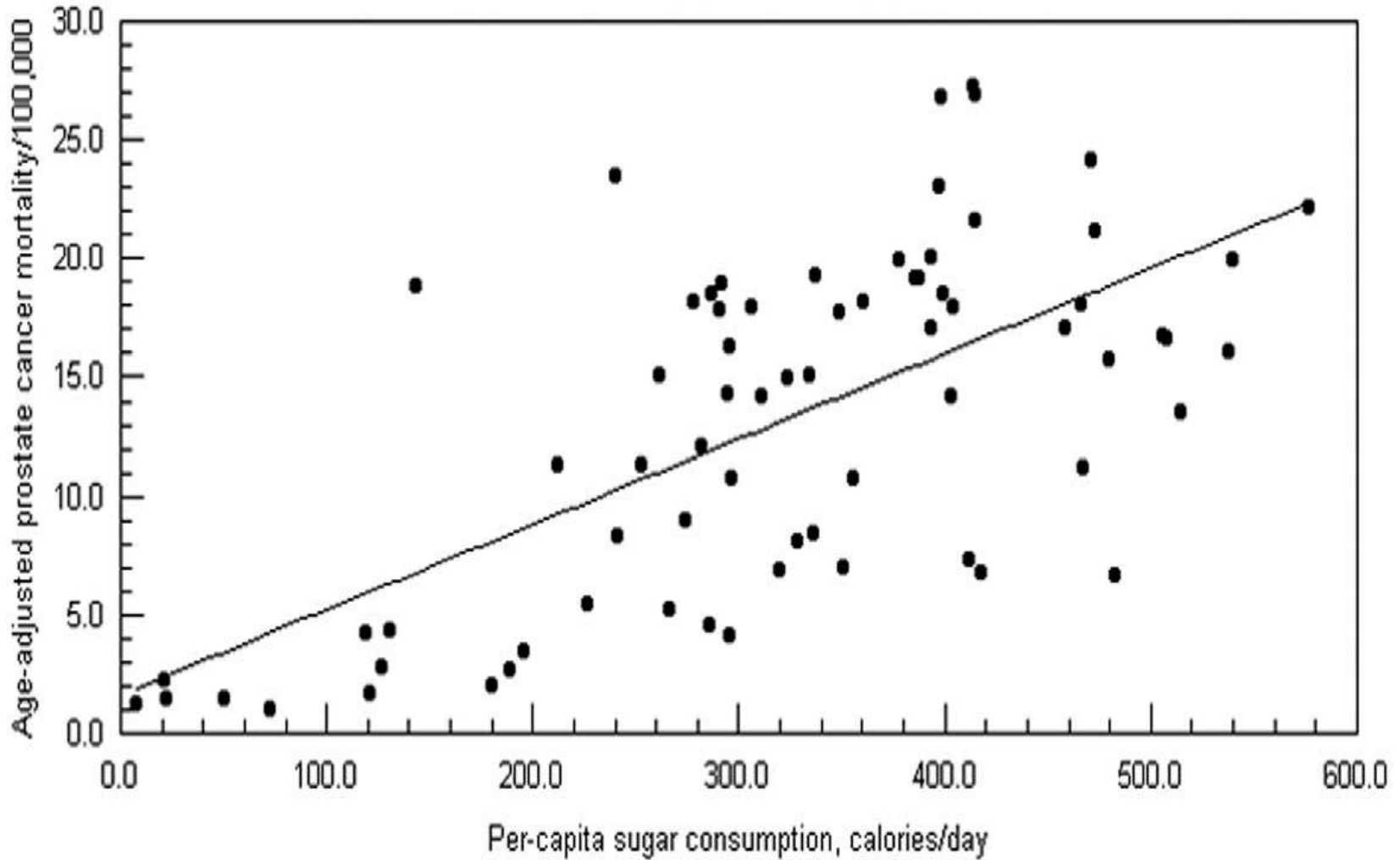


Observational Designs: Classification

- **Exploratory**: used when the state of knowledge about the phenomenon is poor: small scale; of limited duration.
- **Descriptive**: used to formulate a certain hypothesis: small / large scale. Examples: case-studies / series; cross-sectional studies
- **Analytical**: used to test hypotheses: small / large scale. Examples: case-control, cross-sectional, cohort.

Ecological studies (I)

- **E.g. hardness of water, are correlated with health data collected on individuals say CHD rates.**
- **Conceptually, the ecological component is an issue of data analysis; not study design.**
- **What is missing: relationship between exposure and outcome at the individual level (incomplete design)**
- **Could be hypothesis generating analyses/design**



Administrative data: group data at country level, not individual based

Ecological fallacy: example

- **INCOMErelated to-----CHD**
- **Within the cities studied, coronary heart disease is higher in the richer cities than in the poorer ones.**
- **We might predict from such a finding that being rich increases your risk of heart disease.**
- **In the industrialised world the opposite is the case - within cities such as London, Washington and Stockholm, poor people have higher CHD rates than rich ones.**
- **The ecological fallacy is usually interpreted as a major weakness of ecological analyses.**
- **Ecological analyses, however, informs us about forces which act on whole populations.**

Case-series:

Clinical case series

- **Clinical case-series:** usually a coherent and consecutive set of cases of a disease (or similar problem) which derive from either the practice of one or more health care professionals or a defined health care setting, e.g. a hospital or family practice.
- A case-series is, effectively, a **register** of cases.
- **Analyse cases together to learn about the disease.**
- **Clinical case-series are of value in epidemiology for:**
 - Studying symptoms and signs
 - Creating case definitions
 - Clinical education, audit and research

Case series:

Population based

- When a **clinical case-series** is complete for a defined geographical area for which the population is known, it is, effectively, a **population based case-series** consisting of a population register of cases.
- Epidemiologically the most important case-series are registers of serious diseases or deaths (usually NCDs), and of health service utilisation, e.g. hospital admissions.
- Usually compiled for administrative and legal reasons.

Case series: Population

- Full epidemiological use of case-series data needs information on the population to permit calculation of rates
- Key to understanding the distribution of disease in populations and to the study of variations over time, between places and by population characteristics
- Case-series can provide the key to sound case control and cohort studies and trials
- Design of a case-series is conceptually simple
- Defines a disease or health problem to be studied and sets up a system for capturing data on the health status and related factors in consecutive cases

Case series:

Requirements for interpretation

To make sense of case-series data the key requirements are:

- The diagnosis (case definition) or, for mortality, the cause of death
- The date when the disease or death occurred (**time**)
- The place where the person lived, worked etc (**place**)
- The characteristics of the person (**person**)
- The opportunity to collect additional data from medical records (possibly by electronic data linkage) or the person directly
- The size and characteristics of the **population at risk**

Case series: Strengths

- Population case-series permit two arguably unique forms of epidemiological analysis and insight.**
- **Paint a truly national and even international population perspective on disease.**
 - **The disease patterns can be related to aspects of society or the environment that affect the population but have no sensible measure at the individual level**

Cross-sectional Studies

(Community health studies, surveys)

- **Characteristics:** detects point prevalence; relatively common conditions; allows for stratification; different from surveillance / registers
- **Merits:** feasible; quick; economic; allows study of several diseases / exposures; useful for estimation of the population burden, health planning and priority setting of health problems
- **Limitations:** temporal ambiguity (cannot determine whether the exposure preceded outcome); possible measurement error; not suitable for rare conditions; liable to survivor bias
- **Effect measure:** Odds Ratio \pm CI

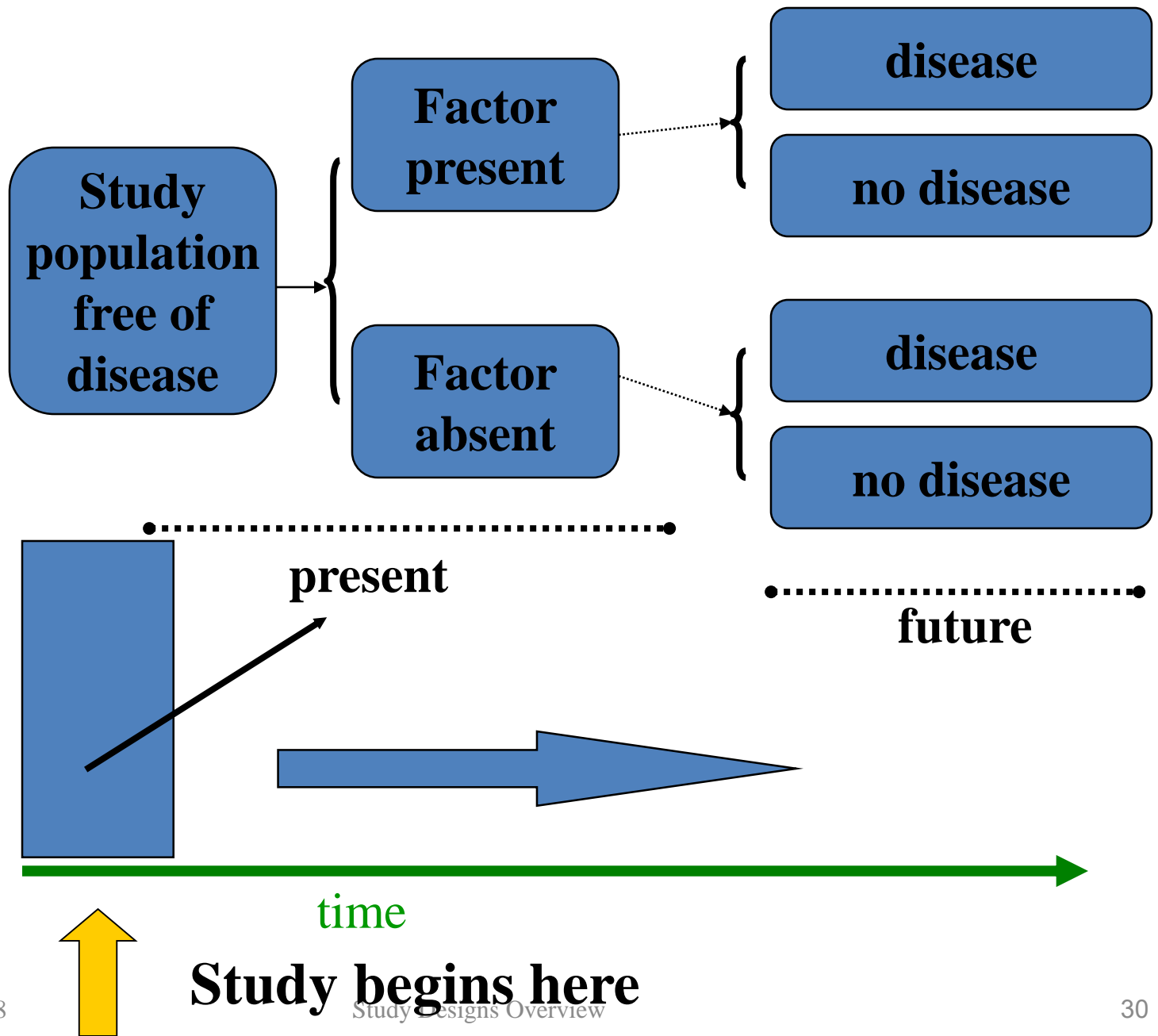
Case - Control Studies

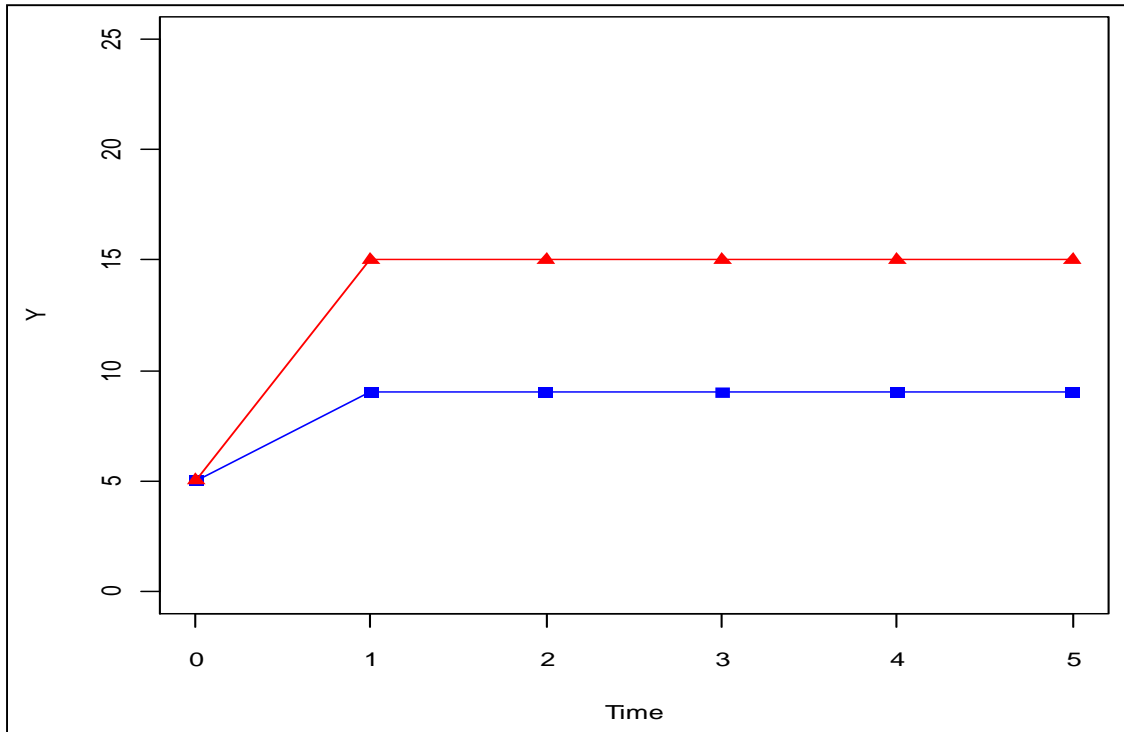
- **Characteristics:** two source populations; assumption that non-cases are representative of the source population of cases.
- **Merits:** least expensive; least time-consuming; suitable for study of rare diseases (especially NCDs)
- **Limitations:** not suitable for rare exposures; liable to selection bias and recall bias; not suitable for calculation of frequency measures.
- **Effect measure:** Odds Ratio \pm CI

Cohort Studies

- **Characteristics:** follow-up period (prospective; retrospective)
- **Merits:** no temporal ambiguity; several outcomes could be studied at the same time; suitable for incidence estimation
- **Limitations (of prospective type):** expensive; time-consuming; inefficient for rare diseases; may not be feasible
- **Effect measure:** Risk Ratio (Relative Risk) \pm CI

Cohort Design





Experimental Designs

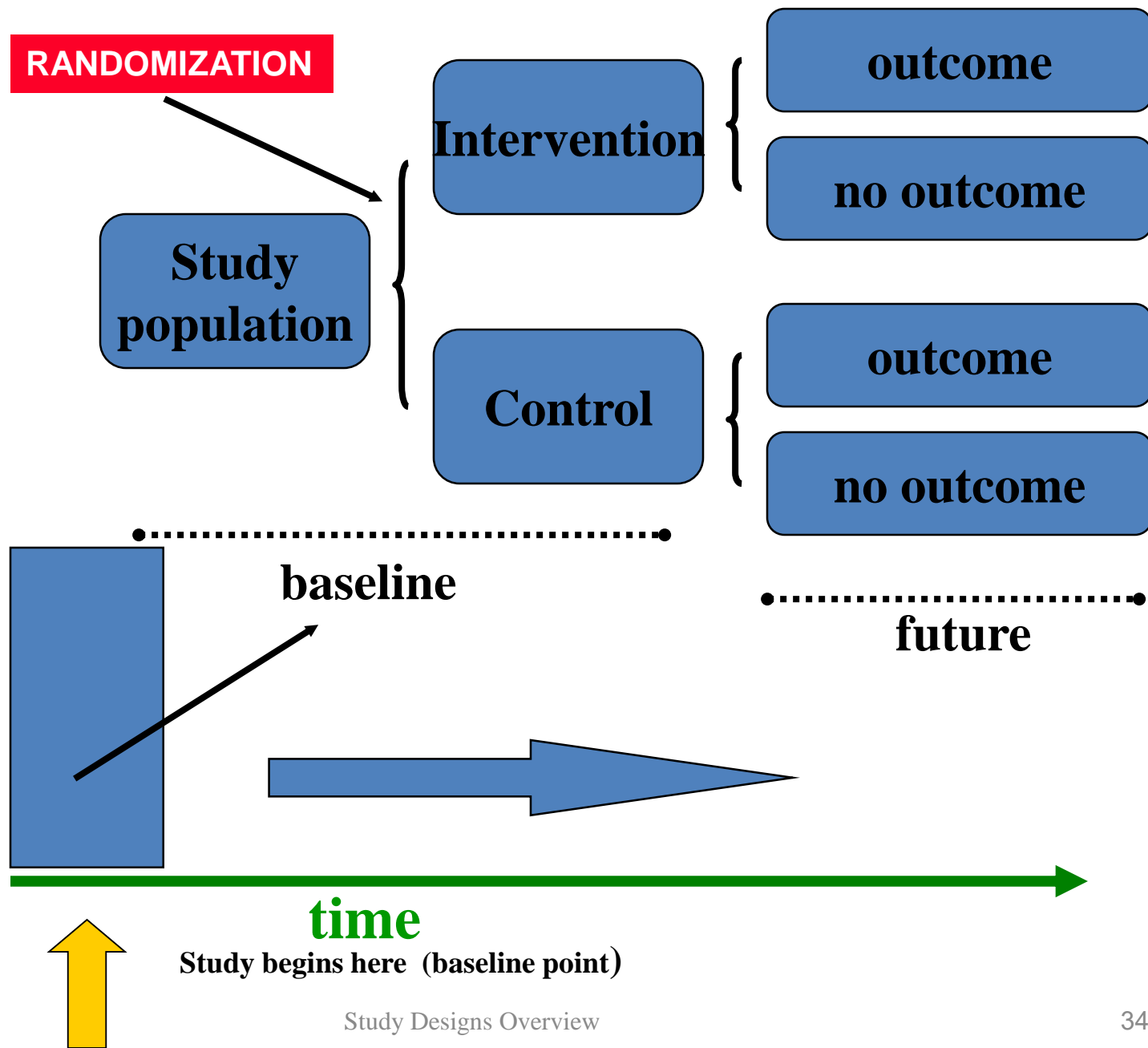
Experimental Study Design

A study in which a population is selected for a planned trial of a regimen, whose effects are measured by comparing the outcome of the regimen in the **experimental** group versus the outcome of another regimen in the **control** group. Such designs are differentiated from observational designs by the fact that there is **manipulation of the study factor** (exposure), and **randomization** (random allocation) of subjects to treatment (exposure) groups.

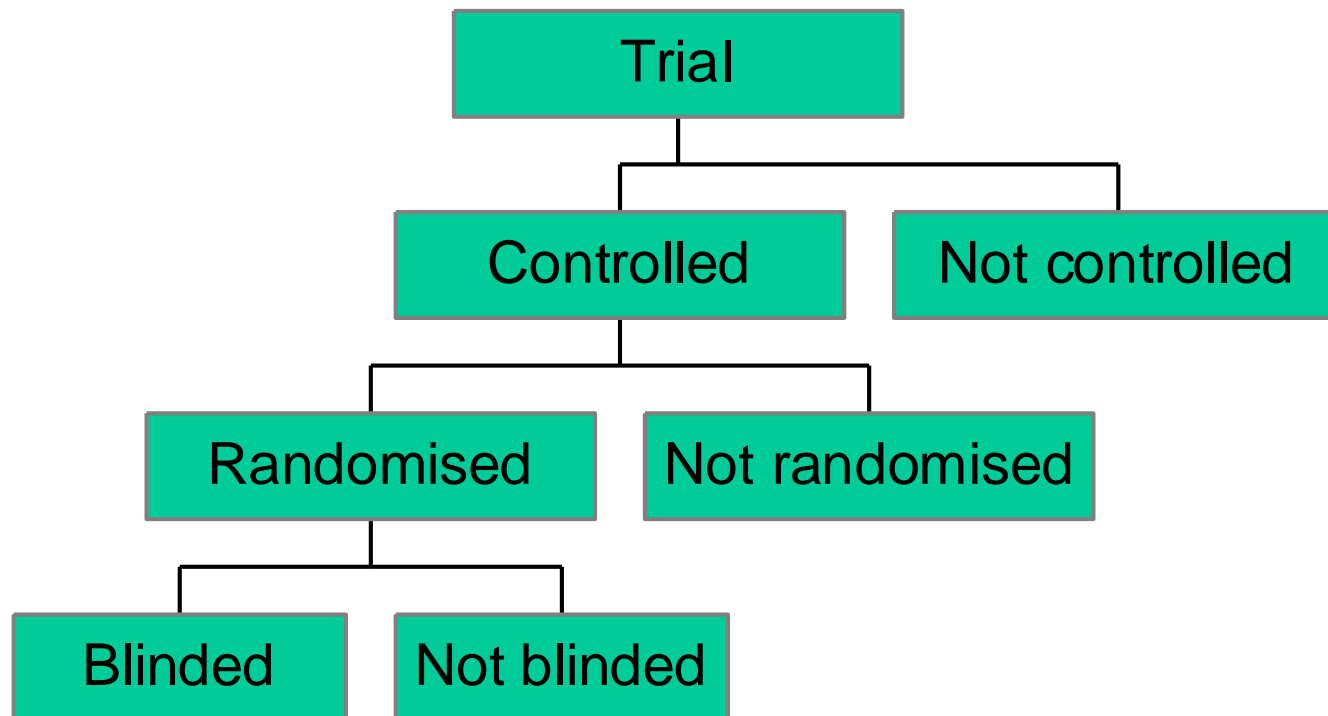
Why Performed ?

1. Provide stronger **evidence** of the effect (outcome) compared to observational designs, with maximum confidence and assurance
2. Yield more **valid results**, as variation is minimized and bias controlled
3. Determine whether experimental treatments are safe and effective under “**controlled environments**” (as opposed to “natural settings” in observational designs), especially when the margin of expected benefit is doubtful / narrow (10 - 30%)

Experimental Design



Types of trials



Choice of Design (I)

Depends on:

- Research Questions
- Research Goals
- Researcher Beliefs and Values
- Researcher Skills
- Time and Funds

Choice of design (II)

It is also related to:

- Status of existent knowledge
- Occurrence of disease
- Duration of latent period
- Nature and availability of information
- Available resources

Conclusion

- **Qualitative designs are complementary to quantitative designs, are important in study of social determinants of health problems**
- **Quantitative designs have a common goal to understand the frequency and causes of health-related phenomena**
- **Seeking causes starts by describing associations between exposures (causes) and outcomes**

Headlines

- **Health research**
- **Classification of designs**
- **Qualitative methods**
- **Quantitative methods**
- **Choice of design**

References

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*Thanks for your kind attention
and listening*