Study Designs in Health Research: An Overview

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Objectives of the session

- By the end of the session the students should be able to comprehend:
- What is Health research
- Classification of study designs
- Differentiate between Qualitative & Quantitative methods
- How to select an appropriate study design for your research question

Study designs direct how the investigation is conducted

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

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 that 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.**

What designs exist to identify and investigate factors in disease?

Study Designs: Types

- Quantitative
  - Experimental
  - Observational
- Qualitative

QUANTITATIVE STUDY DESIGNS

Descriptive

Examples:

Case-report
Case of 1 scorpion sting

Case series
Treatment of 30 scorpion stings

Analytical

Experimental

Researcher compares Outcomes through intervention

Examples:

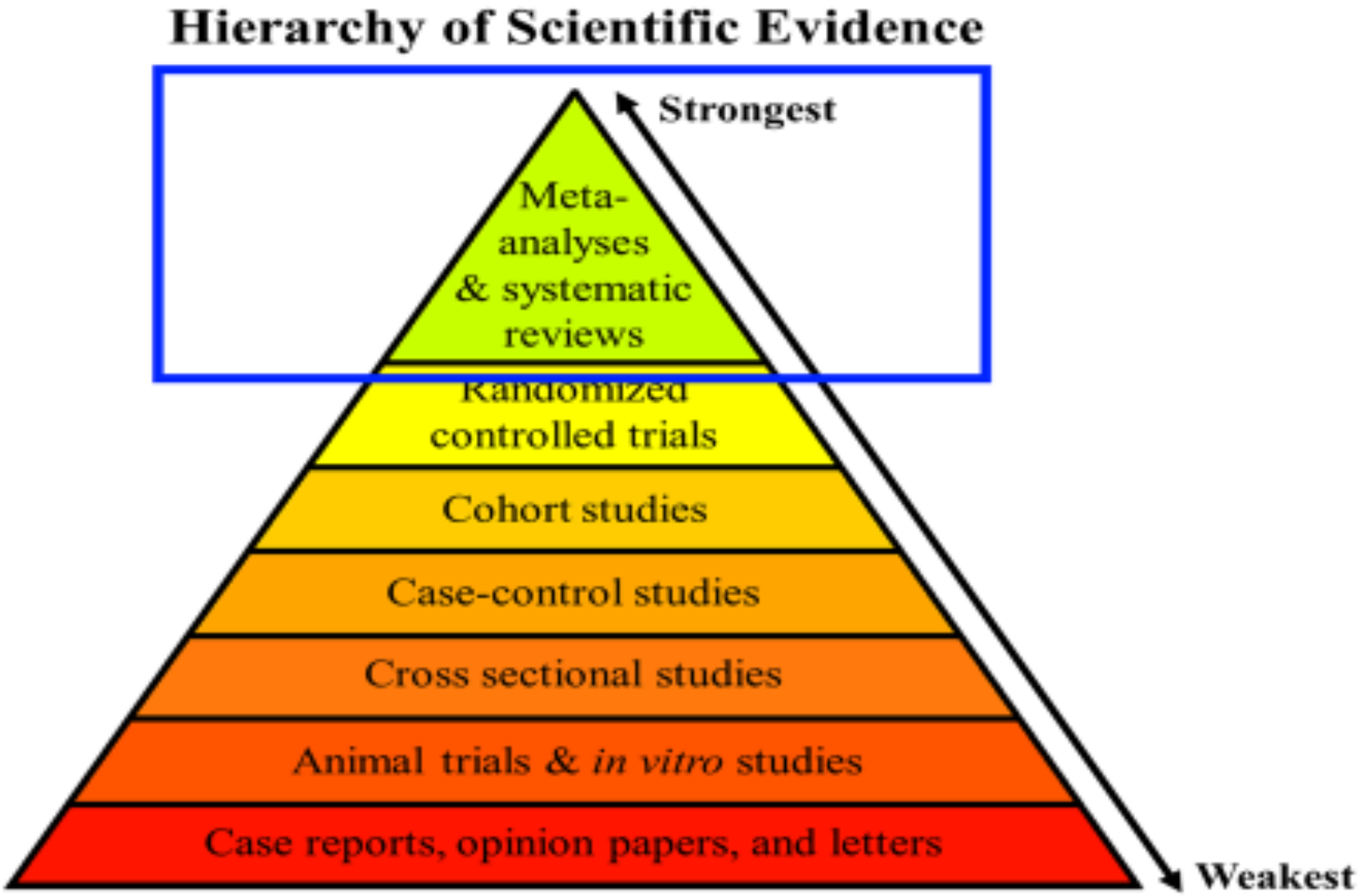
- **Clinical trials**
  Comparison of effectiveness of 2 anti-convulsants
- **Educational intervention**
  assessment using OSCE
  Compared to "long case"

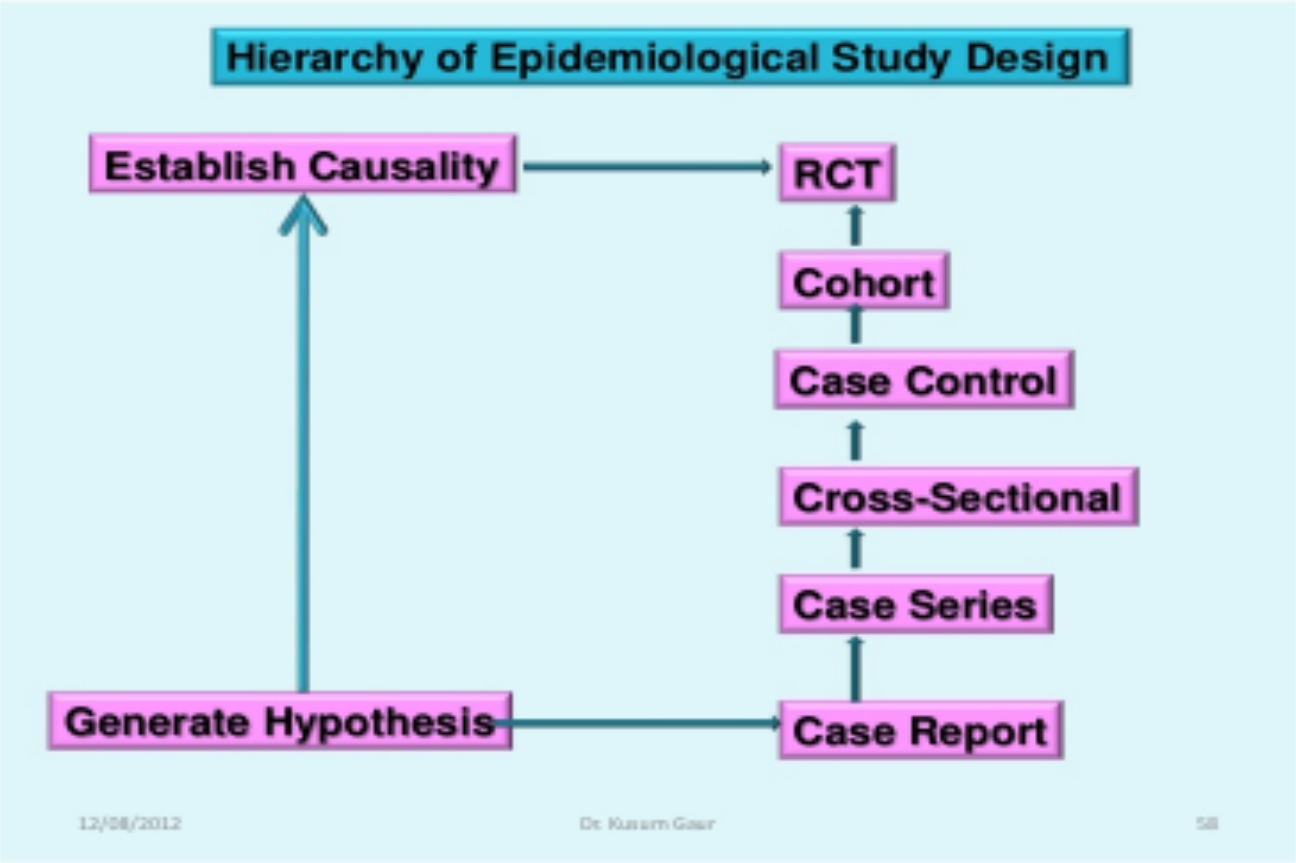
Observational

Researcher compares outcomes through observation

Examples:

- **Case-control (Retrospective)**
  Smoking and lung ca
- **Cohorts (Follow-up)**
  Alcohol use and liver cirrhosis
- **Cross-sectional**
  Obesity among teenagers


Hierarchy of Scientific Evidence
Strongest
Meta-analyses & systematic reviews
Randomized controlled trials
Cohort studies
Case-control studies
Cross sectional studies
Animal trials & *in vitro* studies
Case reports, opinion papers, and letters
Weakest
thelogicofscience.com


Hierarchy of Epidemiological Study Design
Establish Causality
RCT
Cohort
Case Control
Cross-Sectional
Case Series
Case Report
Generate Hypothesis
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Dr. Kusum Gaur
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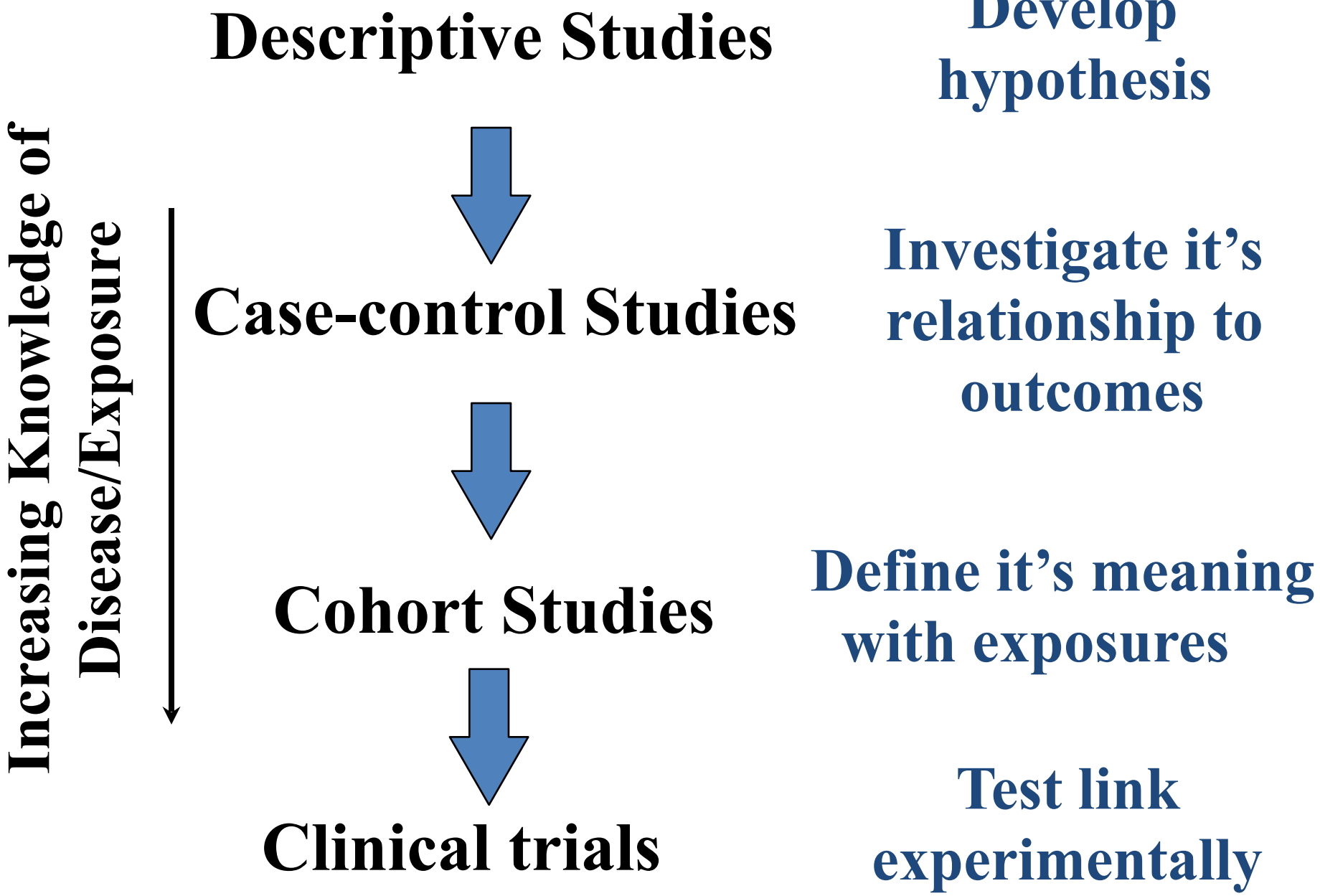
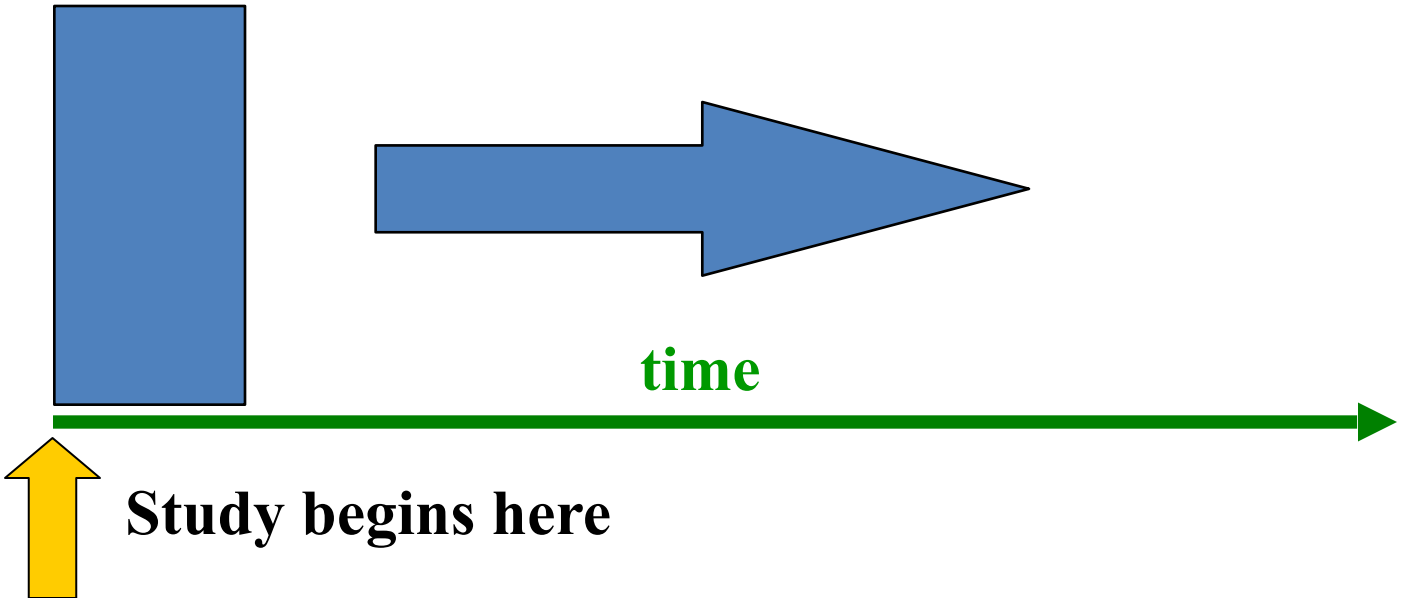

Descriptive Studies
Develop hypothesis
Increasing Knowledge of Disease/Exposure
Case-control Studies
Investigate it's relationship to outcomes
Cohort Studies
Define it's meaning with exposures
Clinical trials
Test link experimentally

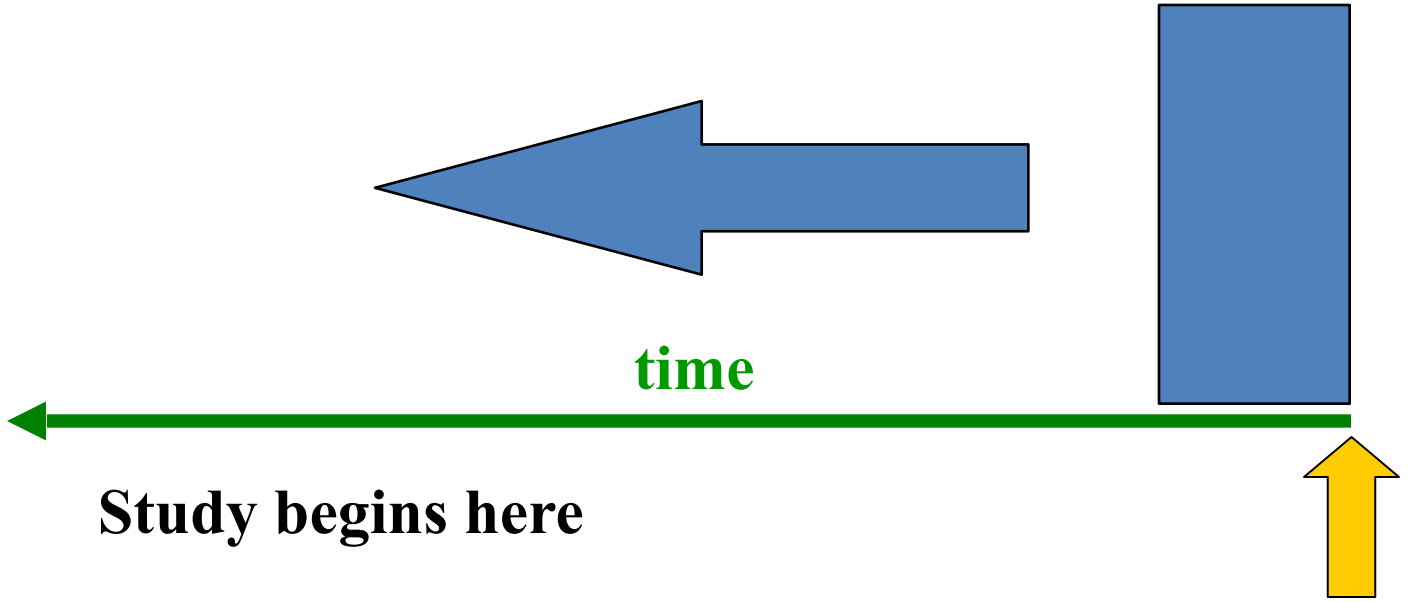
Timeframe of Studies

- Prospective Study - looks forward, looks to the future, examines future events, follows a condition, concern or disease into the future



Timeframe of Studies

- Retrospective Study - "to look back", looks back in time to study events that have already occurred

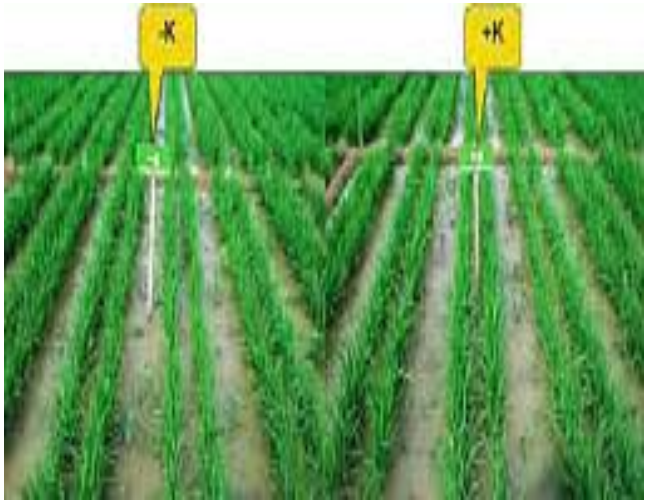


Quantitative designs

- 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

Observational Situations

SITUATION:

People Watching People

EXAMPLE:

Observers stationed in supermarkets watch consumers check out their groceries. The purpose is to see how much “prepared” vs. “fresh” food is purchased.

Observation Methods

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

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.

Example – Observing participation in an after school program

- **Who** you will observe: youth attending the program
- **What** you will observe:
  - Age, gender
  - Length of time student stays in the program
  - Involvement in activities: which activities
    - Level of involvement
  - Interactions with other youth; with staff
- **When** you will observe: all hours the program is open for one week each month during 2007

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

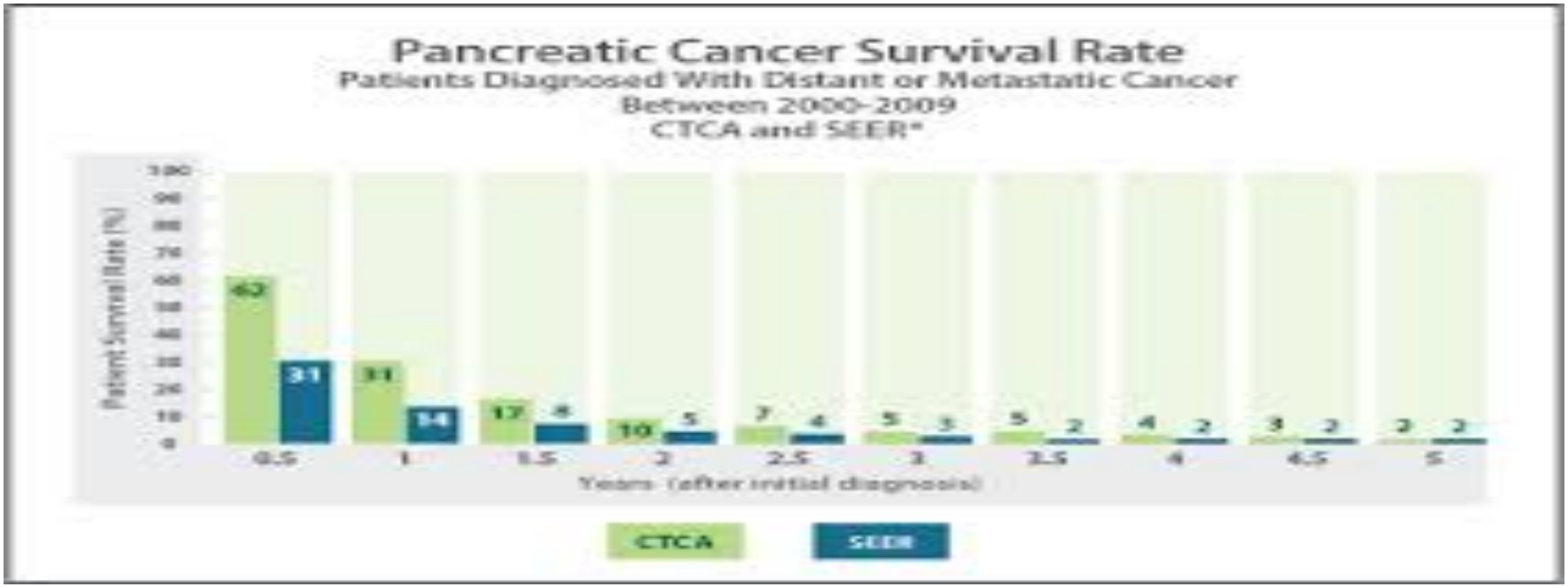
Announcing
PLOS Currents: Outbreaks

Rapid publication of research in infectious disease outbreaks

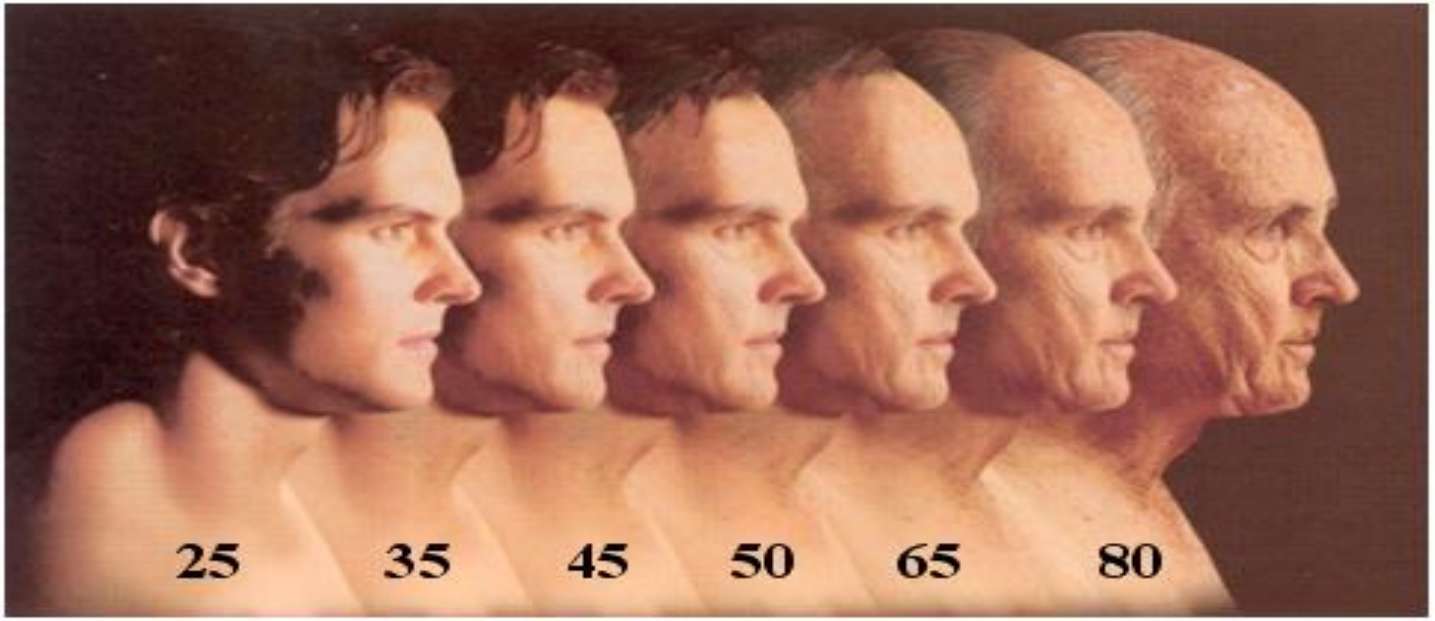
For findings that the world just can't wait to see

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.



Longitudinal Studies



Advantages & Disadvantages of Longitudinal Study Design

The main advantage is that it allows the researcher to measure the pattern of change and obtain factual information, requiring collection on a regular or continuing basis.

The design has the same disadvantages as before-and after design, in addition to:

Conditioning effect: this is a situation where, if the same respondents are contacted frequently, they begin to know what is expected of them and may respond to questions without thought, or they may lose interest in the study.

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: 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 e.g. ozone concentration at ground level and the thickness of the ozone layer in the earth's atmosphere.**

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 ± CI

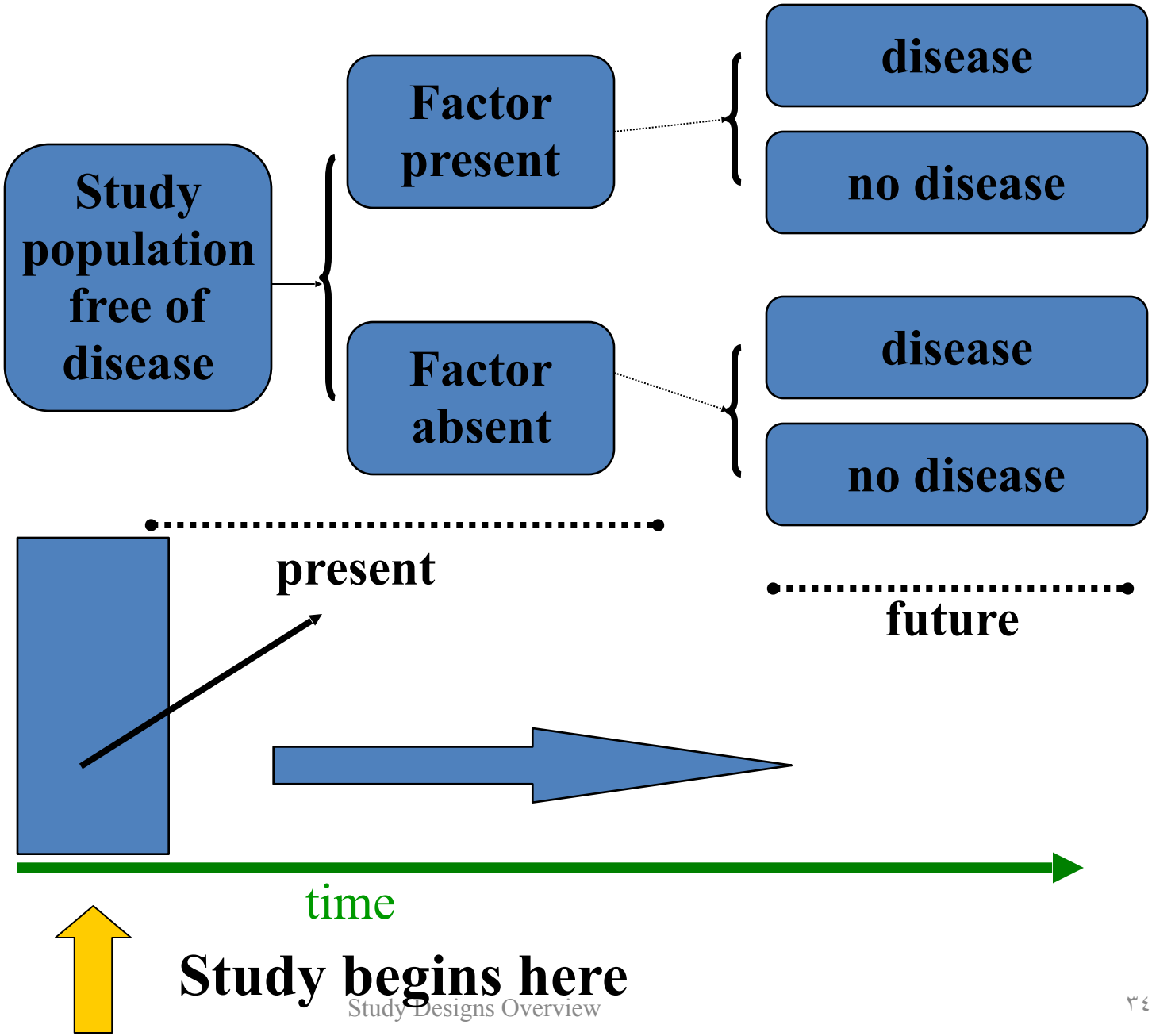
Case - Control Studies

- **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

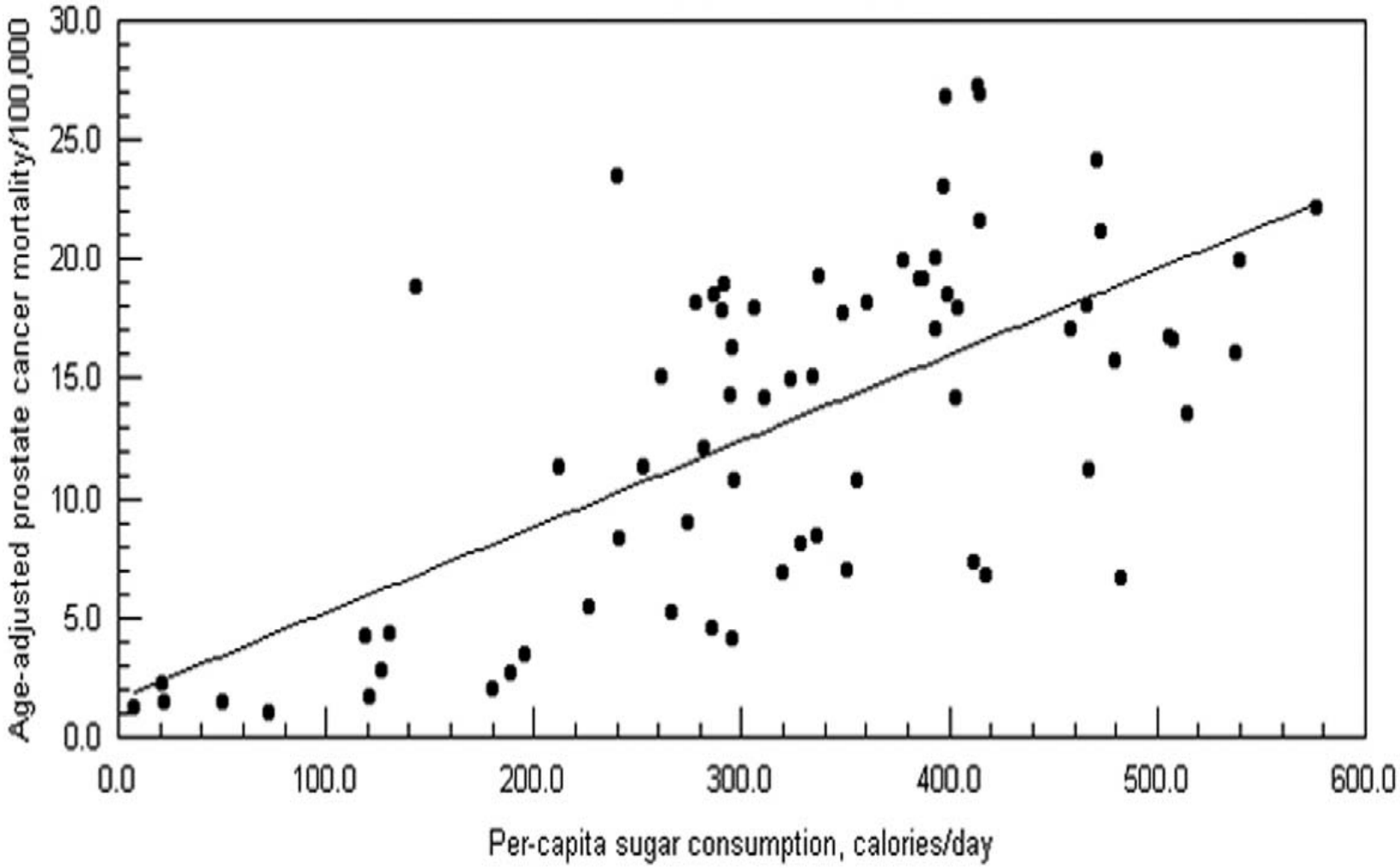


Ecological studies (I)

- 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



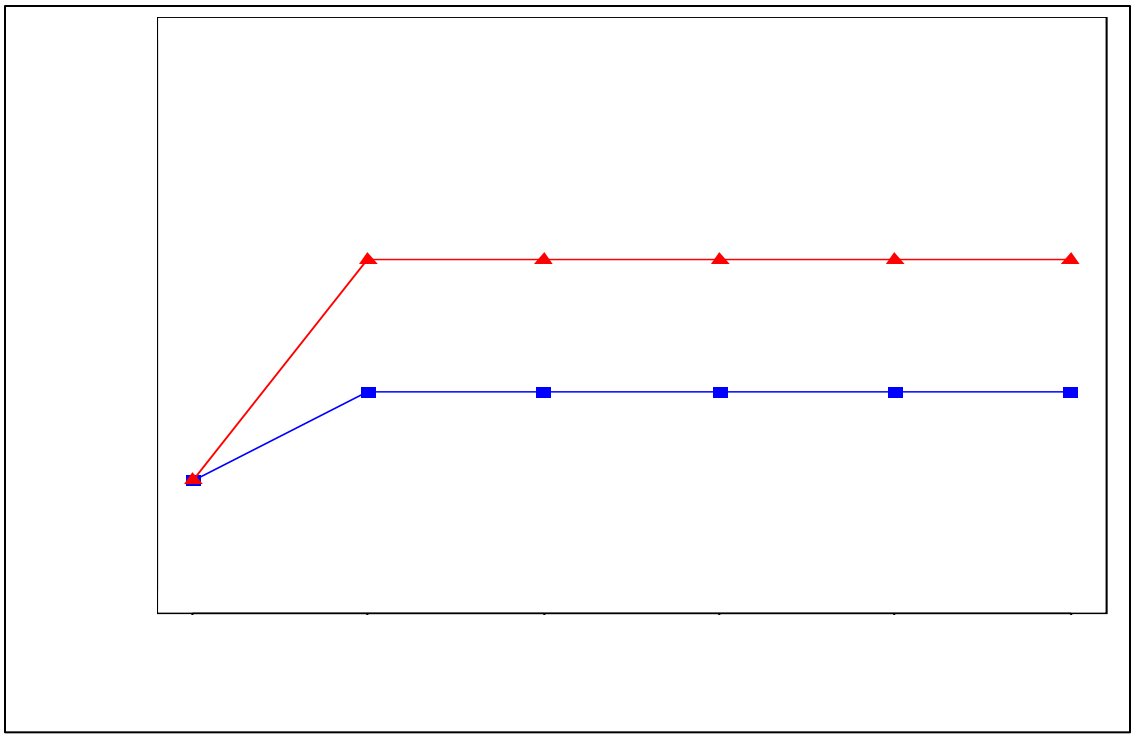
Administrative data: group data at country level, not individual based

Ecological fallacy: example

- **INCOME .....related 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.**



Experimental Designs

Experimental Study Design

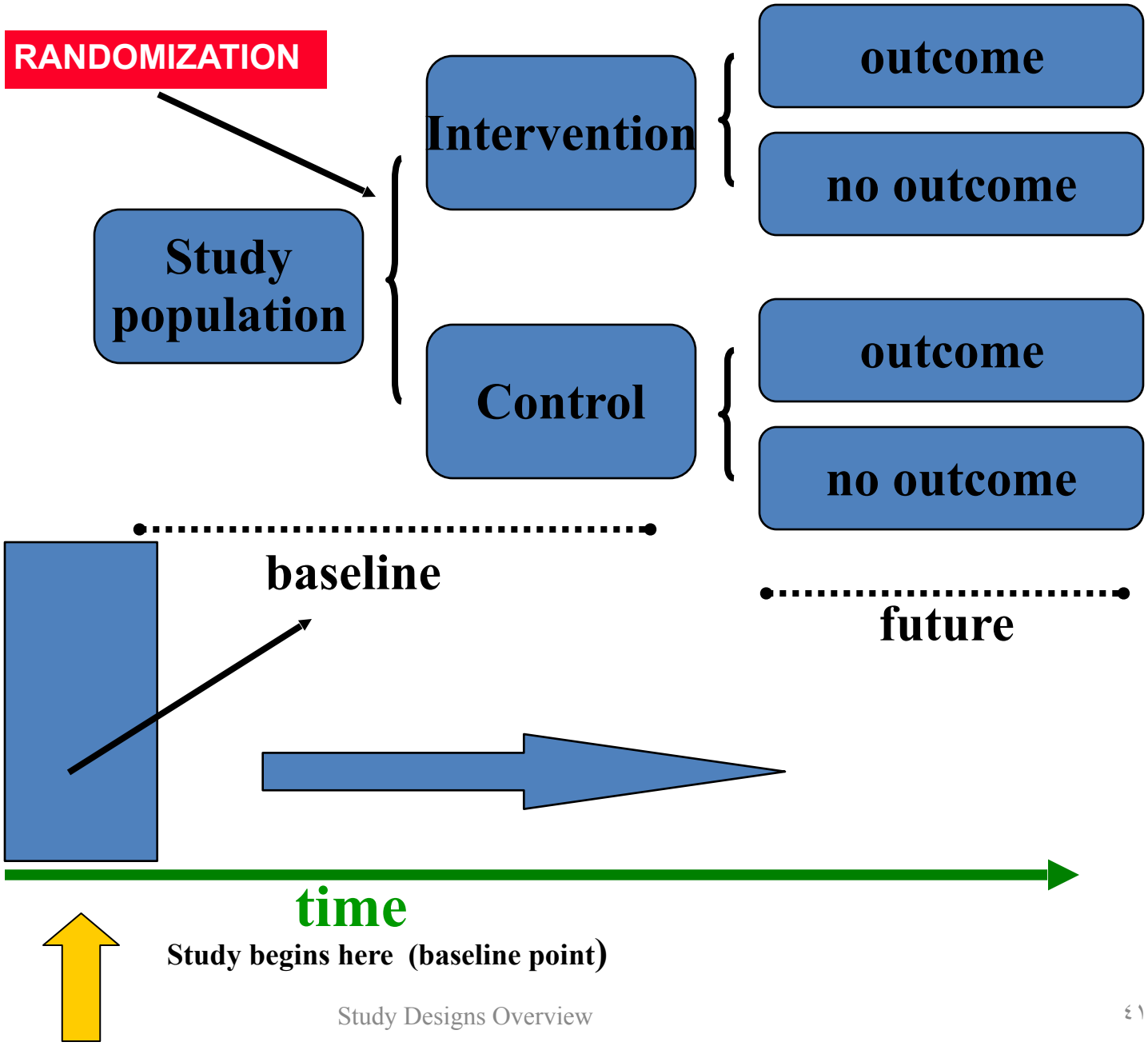
A study in which a population is selected for a planned trial of a regimen, whose effects are measured by comparing the outcome of the regimen in the experimental group versus the outcome of another regimen in the control group. Such designs are differentiated from observational designs by the fact that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

Why Performed ?

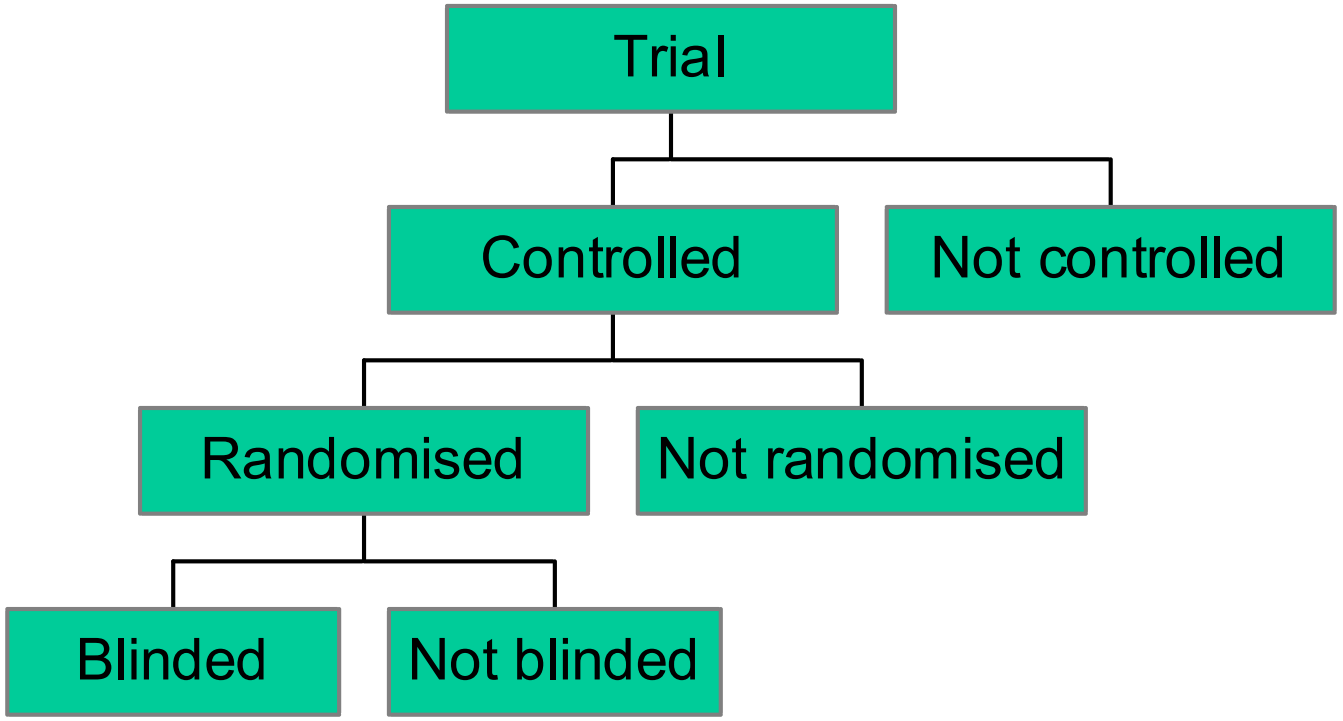
1. Provide stronger evidence of the effect (outcome) compared to observational designs, with maximum confidence and assurance
2. Yield more valid results, as variation is minimized and bias controlled
3. Determine whether experimental treatments are safe and effective under "controlled environments" (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



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 infomants
- Video / Text and Image analy (documents, media data)
- Surveys
- User testing

Involves Skills of

- Observing

- Conversing

- Participating
- Interpreting

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**

References

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Thanks for your kind attention and listening