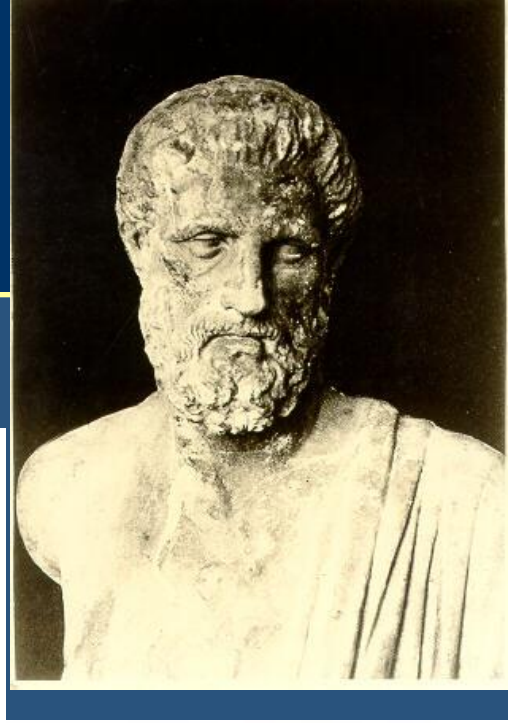
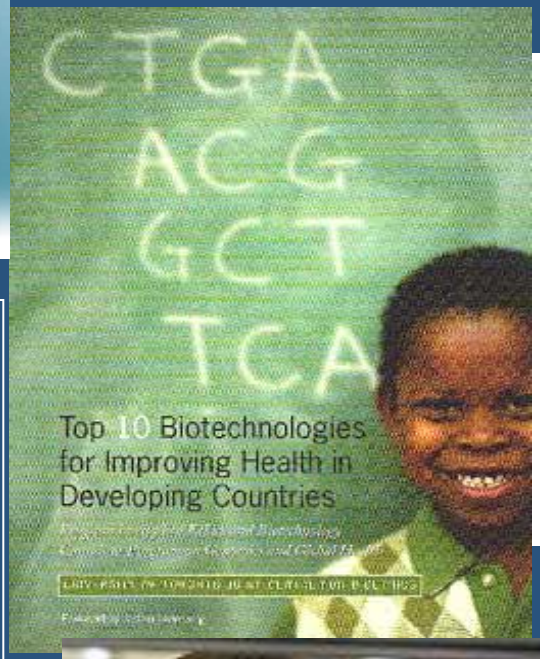
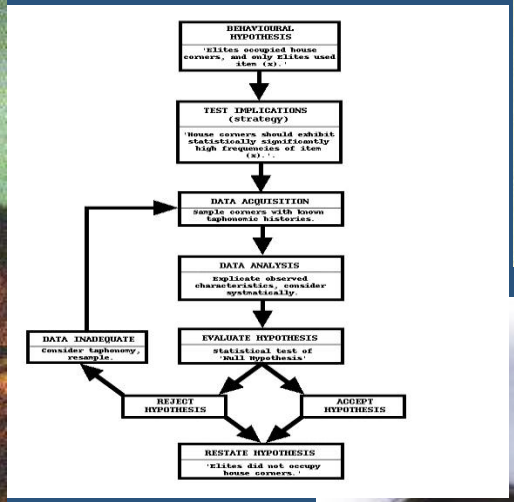
Critical Appraisal of Research Protocol







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Today's presentation

- Definition of epidemiology, brief history and classical studies
- Uses of epidemiology
- The evidence pyramid
- Introduction to research study designs
- Prospective versus retrospective
- Observational versus experimental
  - Cohort, Case control, RCT, Cross- sectional, Meta-analysis, Ecological

Brief introduction to Epidemiology

- **Epidemiology** is derived from a Greek word ***Epi*** meaning on or upon, ***Demos*** meaning people and ***Logos*** meaning the study of.

- *Epidemiology* pertains to the study of the distribution, dynamics, and determinants of disease. (DDD)

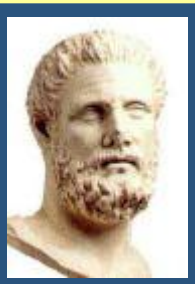
Determinants

- It includes all those factors that influence the distribution.
- **Primary:** Causative agent of the disease or disorder. (Virus, parasite)
-
- **Secondary:** Multitude of factors that influence the disease. (SES, Environment influencing causation of respiratory infections)

Brief introduction to Epidemiology

- **History**
  - Plagues, Cholera, pneumonia, influenza.
- ***Hippo crates*** (340-400 B.C) " *No disease is sent by devils or demons, but is the result of natural cause*".

Epidemiology: Hippocrates (340 BC)

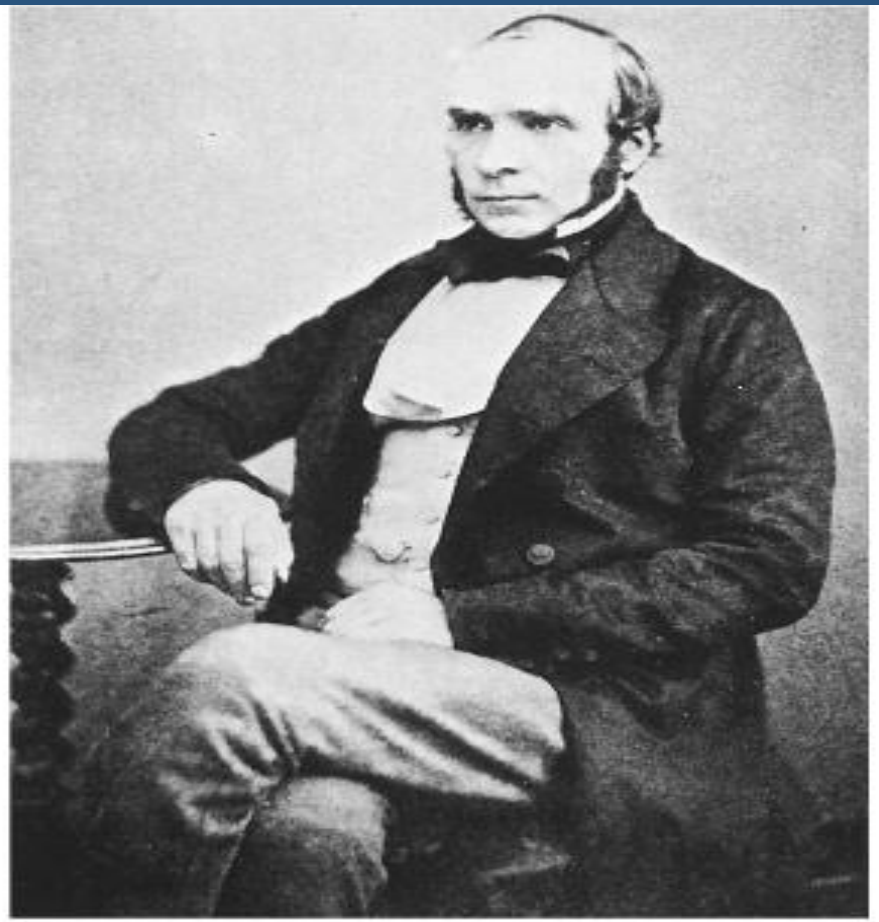


- “Whoever wishes to investigate medicine properly should proceed thus; When he comes into a strange city, he ought to consider its situation, how it lies to the wind and sun, and consider the waters the people use. For if he knows these things well, he cannot miss knowing the diseases peculiar to the place”.

Classical studies

- Scurvy disease (1747)
- Cholera in London and its relationship to water supply location for different households (Snow, 1854)
- Nuclear bombs at Hiroshima and Nagasaki- studies of radiation effects among bombs survivors
- Severe air pollution in London led to a epidemic of deaths from heart and lung diseases (1952)
- Minamata disease- consumption of fish contaminated with methyl mercury
- Itai-Itai disease- consumption of rice contaminated with cadmium
- Legionnaires disease- infectious disease spread through ventilation system

A sketch of a drop of London water

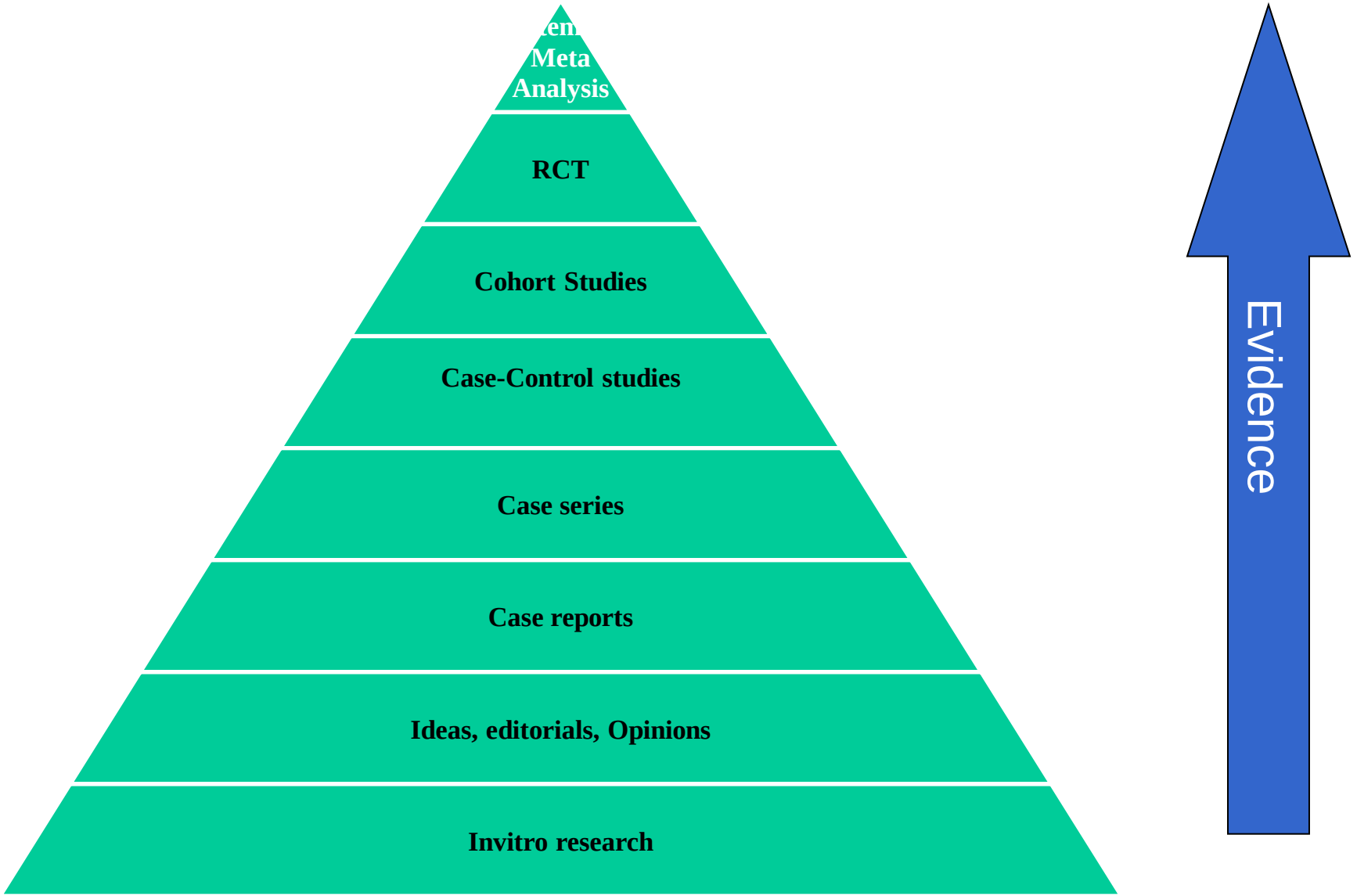


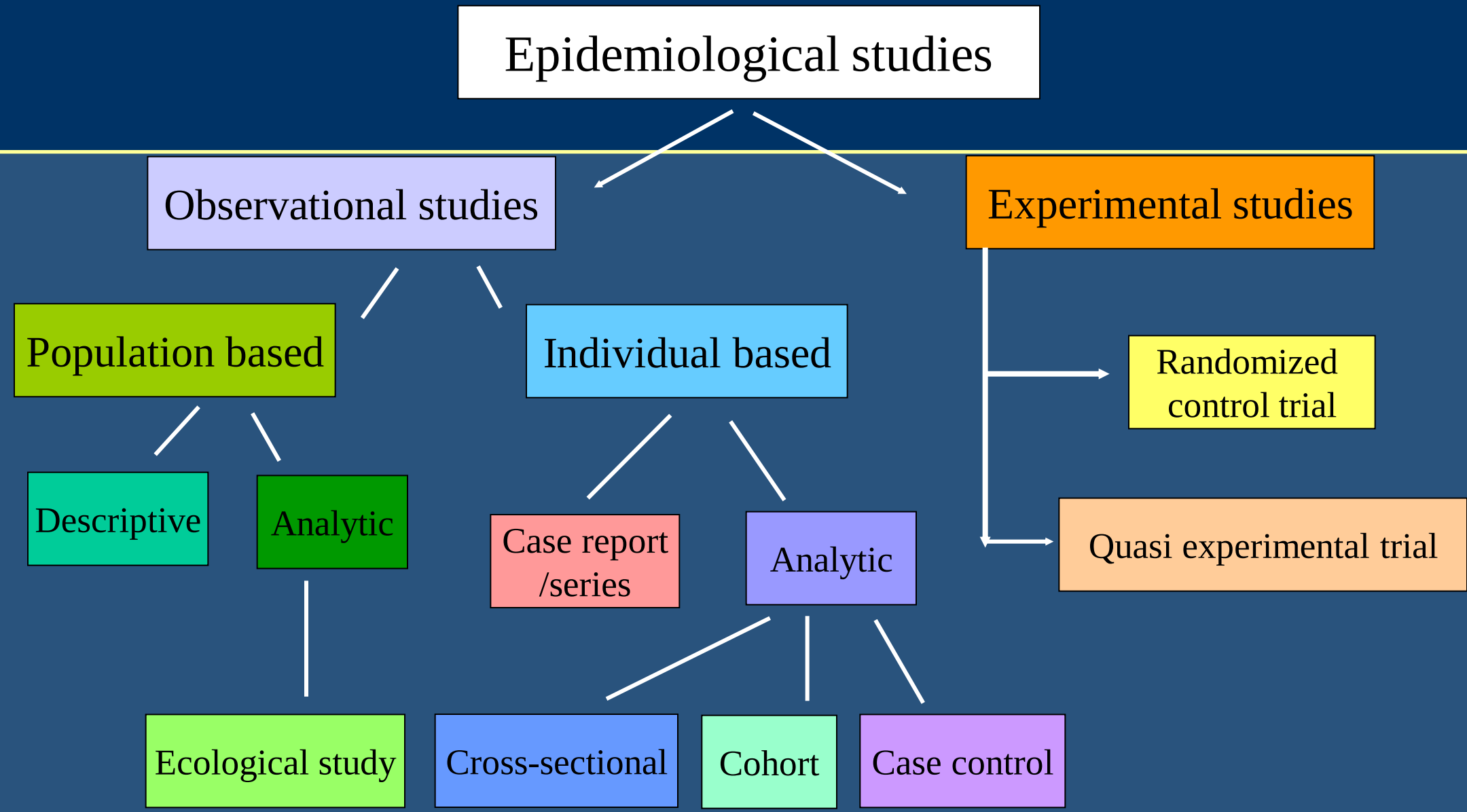
A DROP OF LONDON WATER.

Deaths from Cholera per 10,000 Houses by source of water supply, London (Snow,1854)

Water supply	Number of houses	Cholera deaths	Deaths per 10,000 houses
Southwark & Vauxhall Co.	*40,046*	*1263*	*315*
Lambeth Co.	*26,107*	*98*	*38*
Other districts in London	*256,423*	*1422*	*56*

The Evidence Pyramid




Epidemiological studies
Observational studies
Experimental studies
Population based
Individual based
Randomized control trial
Descriptive
Analytic
Case report /series
Analytic
Quasi experimental trial
Ecological study
Cross-sectional
Cohort
Case control

Study Types

- Study type: on the basis of intervention
- Study type: on the basis of design
- Study type: on the basis of time

Study types: on the basis of intervention

- It divides the studies into two categories

1. Observational studies (no intervention)

2. Experimental studies / Interventional studies

On the basis of intervention: Observational studies

They are further divided into;

- **Descriptive**

Descriptive is further sub divided into

1. Institutional surveys
2. Community surveys (Cross sectional surveys)

- **Analytic**

Analytic is further sub divided into

1. Cohort
2. Case control

On the basis of intervention: Experimental studies

They are analytic type

It is further sub classified into

1. Randomized control trials
2. Community trials (community mass education program, smoking prevention program in schools, dietary intervention at family level)

Study types: on the basis of design

Another way is on the basis of design

- Qualitative study (*Time, place, person*)
- Quantitative study

Qualitative study

- Qualitative field research usually focuses on:
- Meanings = (culture, language, norms)
- Practices = (various kinds of behavior)
- Episodes = (divorce, crime illness)
- Encounters = (2 people meeting and interacting)
- Roles = (positions people occupy. Ethnic groups)
- Relationships = (kinds of behaviors appropriate to pairs or sets of roles: mother-son, lovers, friends)
- Groups => relationships = (work groups, teams)
- Settlements = (small communities, villages, ghettoes, neighborhoods)

Study types: on the basis of design

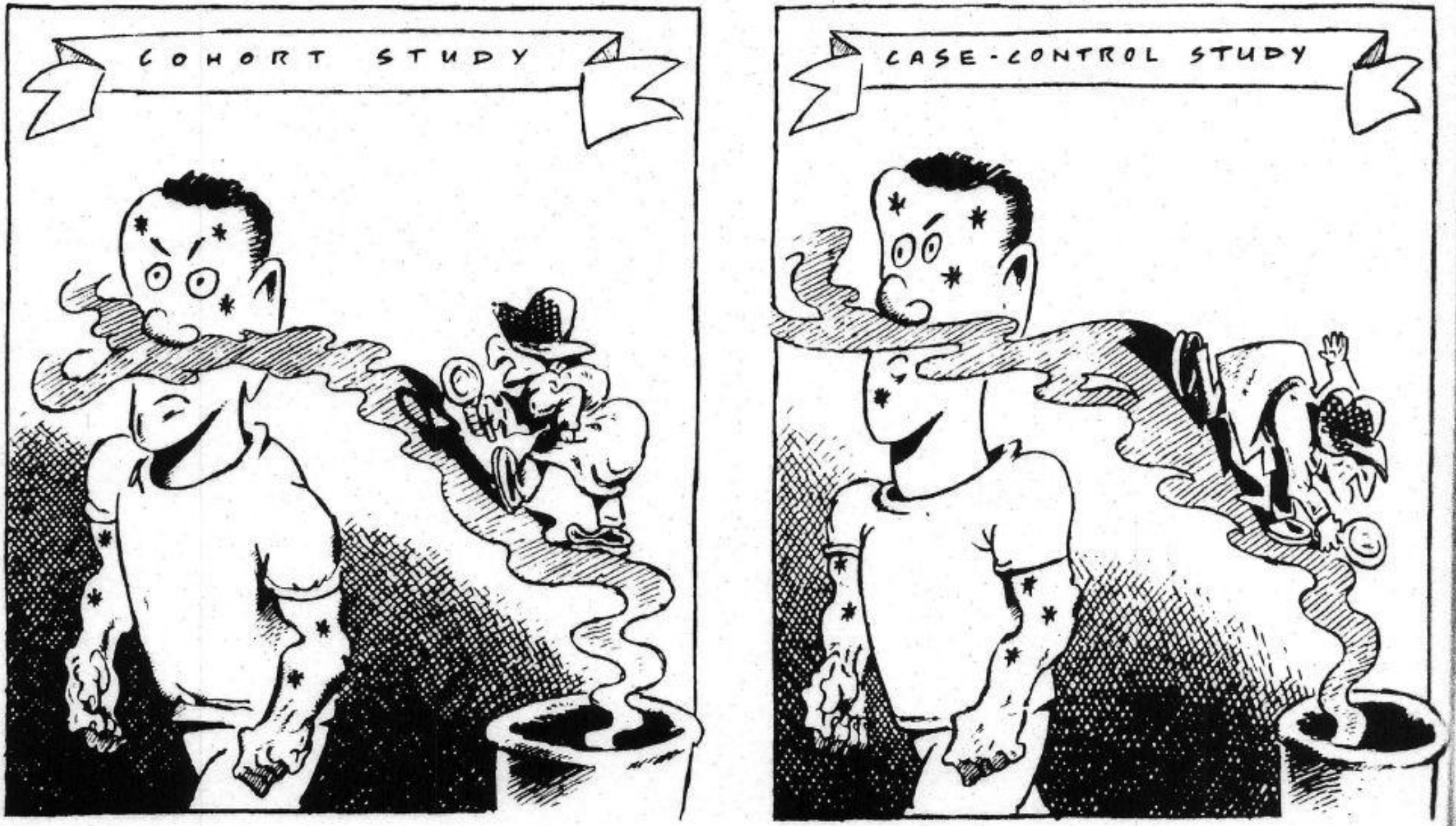
Designs include:

- Descriptive research
- Ecological study
- Ethnography
- Evaluation research
- Experimental research
- Historical research
- Phenomenology
- Quasi experimental research
- Randomized control trials

(The above list is in alphabetical order only)

Study types: on the basis of time

- Before discussing the various study designs, defining a few terms is helpful. The definitions are intentionally left fairly basic.
- **Retrospective** - Any design that looks at data that have already been gathered (e.g. CCS)
- **Prospective** - Any design that collects data on groups of subjects over time, according to a carefully written protocol, beginning at time zero; this design yields data that enable comparisons of groups. (In ancient Rome, a cohort was a group of foot soldiers.)
- **Cross-sectional** - A design that collects data from a variety of subjects (e.g., patients) at a given point in time

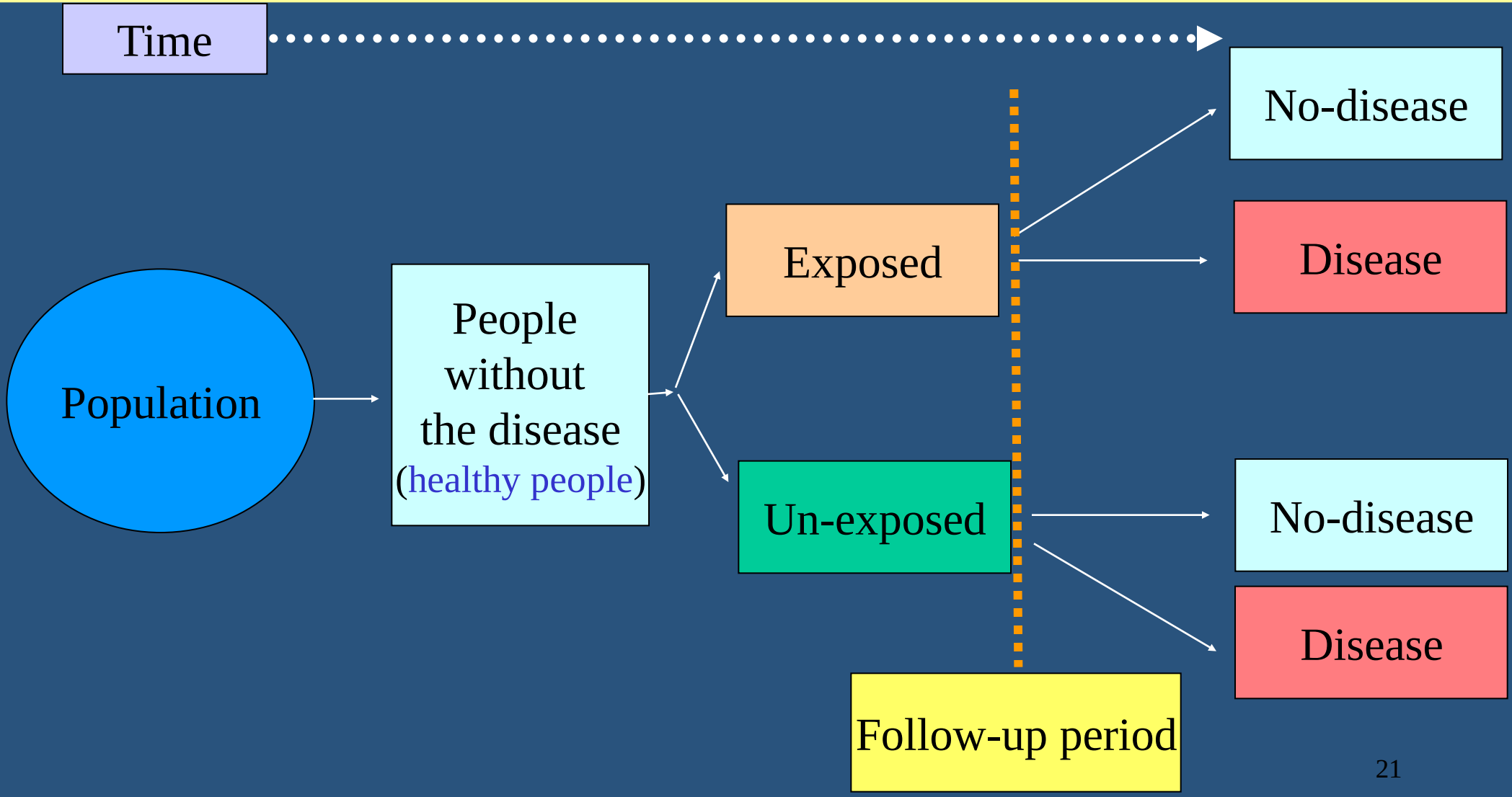


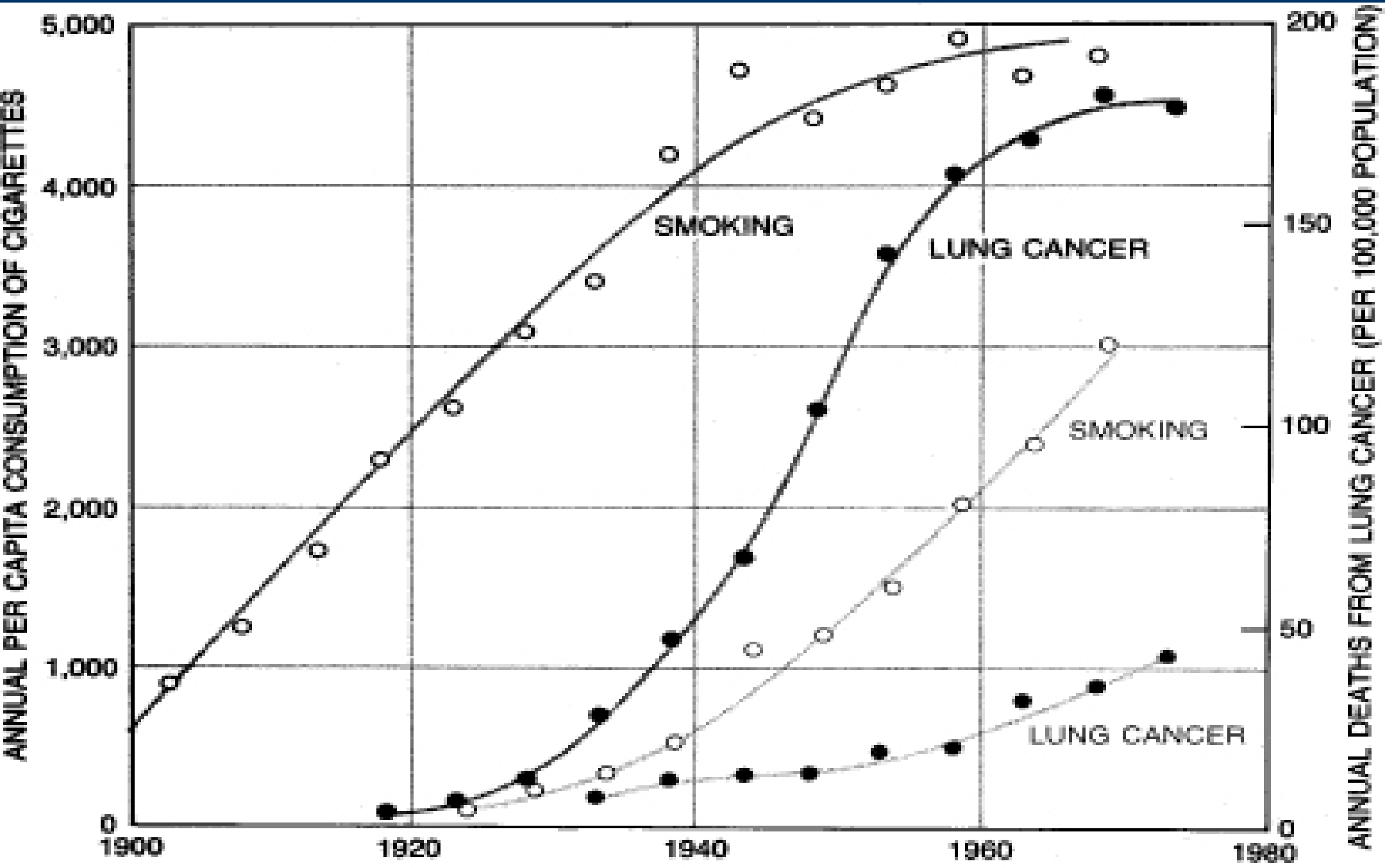
(Drawing by Nick Thorkelson.)

Cohort study: forward in time

- Identify and select study population
- Classify study population according to exposure status ad other risk factors
- Follow cohort members over time to determine health outcome occurrence by exposure status sub-groups
- Advantage:
  - Establish causality
  - Can determine incidence rates and risk
  - Can be efficient for studying rare exposures (Nuclear bomb, radiation for enlarged thymus, Chernobyl nuclear accident, Minamata, toxic chemical (methyl isocyanides) from industry such as Bhopal, India)
- Disadvantages
  - Inefficient, as must follow many subjects (Long period of time)
  - Expensive
  - Rare exposure, need large sample size
  - Results are not available for a long time
  - Bias due to attrition and loss to follow up

Design of a Cohort study

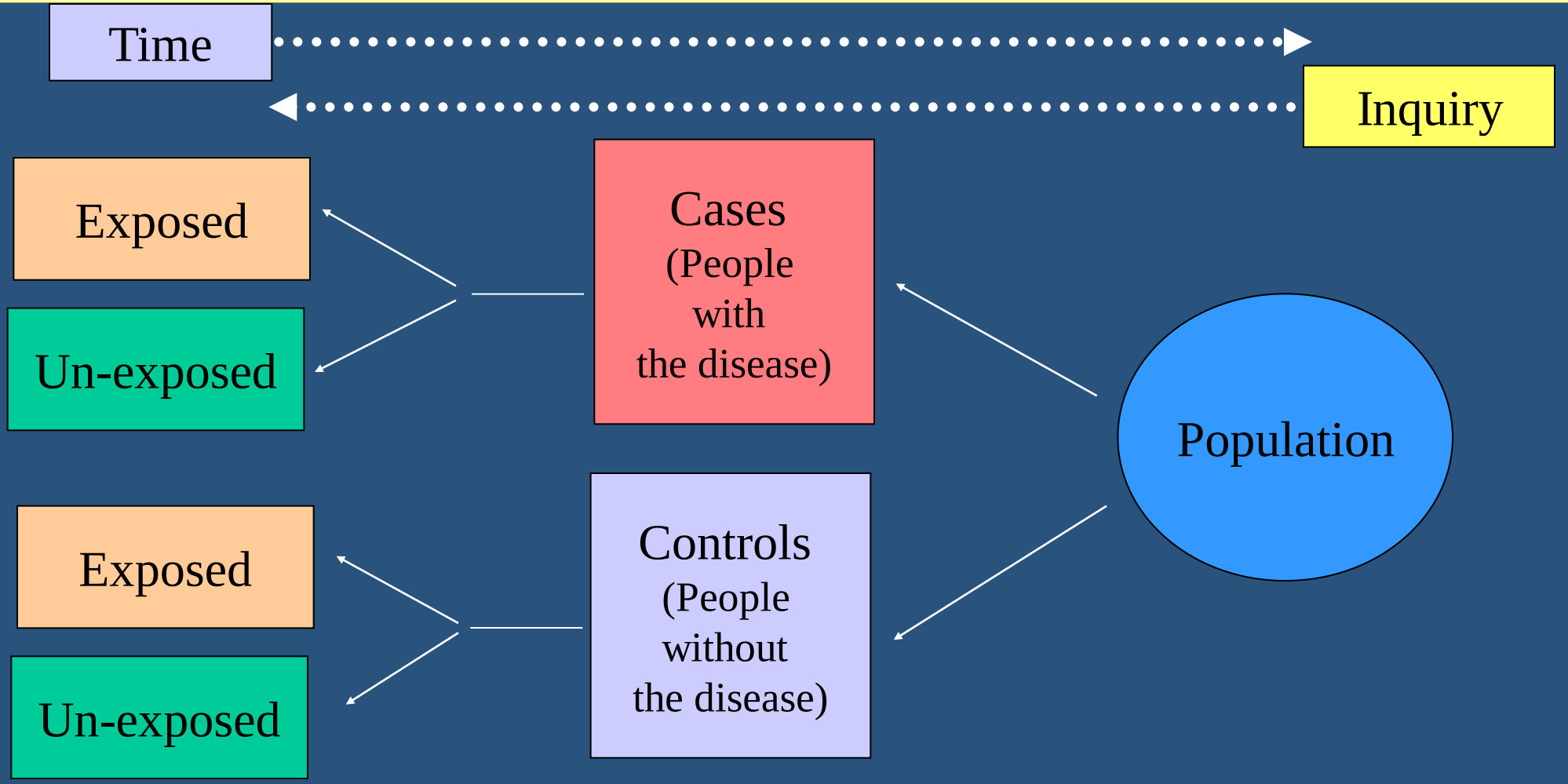




Case-control study: back in time

- In studies of disease etiology, for example, researchers begin by selecting a group of patients (the cases) with a particular disease.
- Assess prior exposure status and other risk factors for cases and controls
- Examples
  - Lung cancer and exposure to Radon
  - Lung cancer and indoor air pollution in China
  - Leukemia in individuals exposed to radioactive fallout form nuclear testing in USA
- Advantages
  - Inexpensive and efficient (specially for rare diseases)
  - Useful for studying diseases with long latencies
- Disadvantages
  - Difficult to select appropriate comparison group
  - Potential bias in measuring exposure (recall bias due to disease)

Design of a Case - Control study



Main difference between both designs

- Case control: The study begins with diseased (cases) and non-diseased (control) people

- Cohort study: The study begins with exposed (healthy) and non-exposed (healthy) people

Cross Sectional / Prevalence study

- It is a also called snap-shot study, as it captures a moment in time.
- Choose sampling frame for selecting study participants
- Measure exposure and health outcome status of the study participants
  - Health outcome are based on prevalence, not incidence

- Limitation
  - Cannot prove cause-effect relationship

Meta-analysis (contd…)

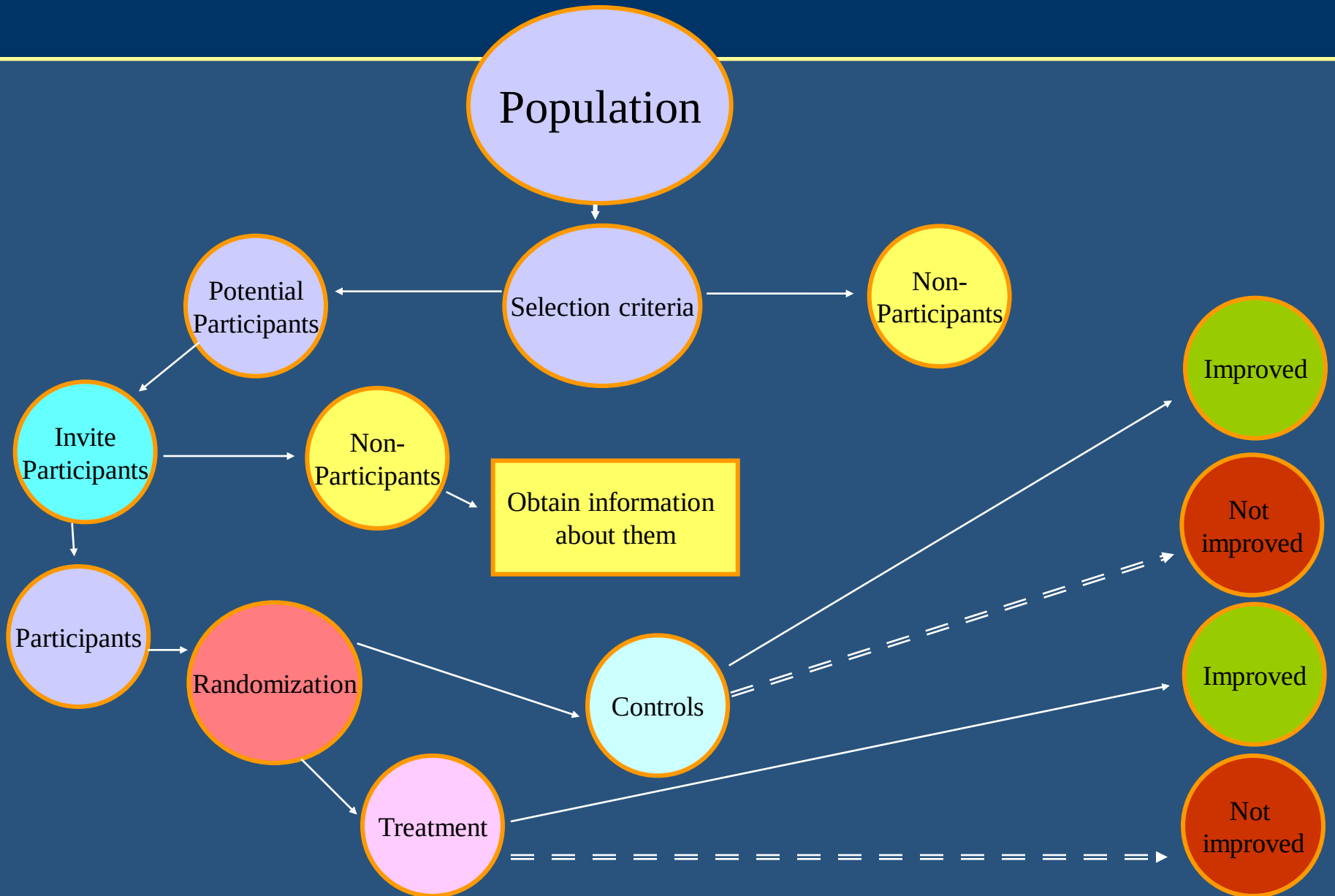
- Meta-analysis also can be defined as a systematic method that uses statistical analyses for combining data from independent studies to obtain a numerical estimate of the overall effect of a particular intervention or variable on a defined outcome.

- This study design attempts to overcome much of the subjectivity of the narrative literature review. According to Thacker, the steps are as follows:
  - Define the problem and criteria for admission of studies
  - Locate research studies
  - Classify and code study characteristics
  - Quantitatively measure study characteristics on a common scale
  - Analyze, interpret, and report the results

  - E.g. streptokinase use in myocardial infraction (MI)

Randomized Clinical Trials

Randomized Clinical Trials



Randomized clinical trials (contd…)

- RCT has become the accepted standard for evaluating therapeutic efficacy.
- Randomized trials are performed in a prospective fashion to allow as much control of variables as possible.
- The outstanding feature of such trials is the use of randomization to help prevent bias in the assignment of subjects to specific intervention groups.
- If randomization is carried out properly, differences in outcome that are observed among treatment groups tends to result from treatment effects and not from inherent differences among the groups.

Randomized clinical trials

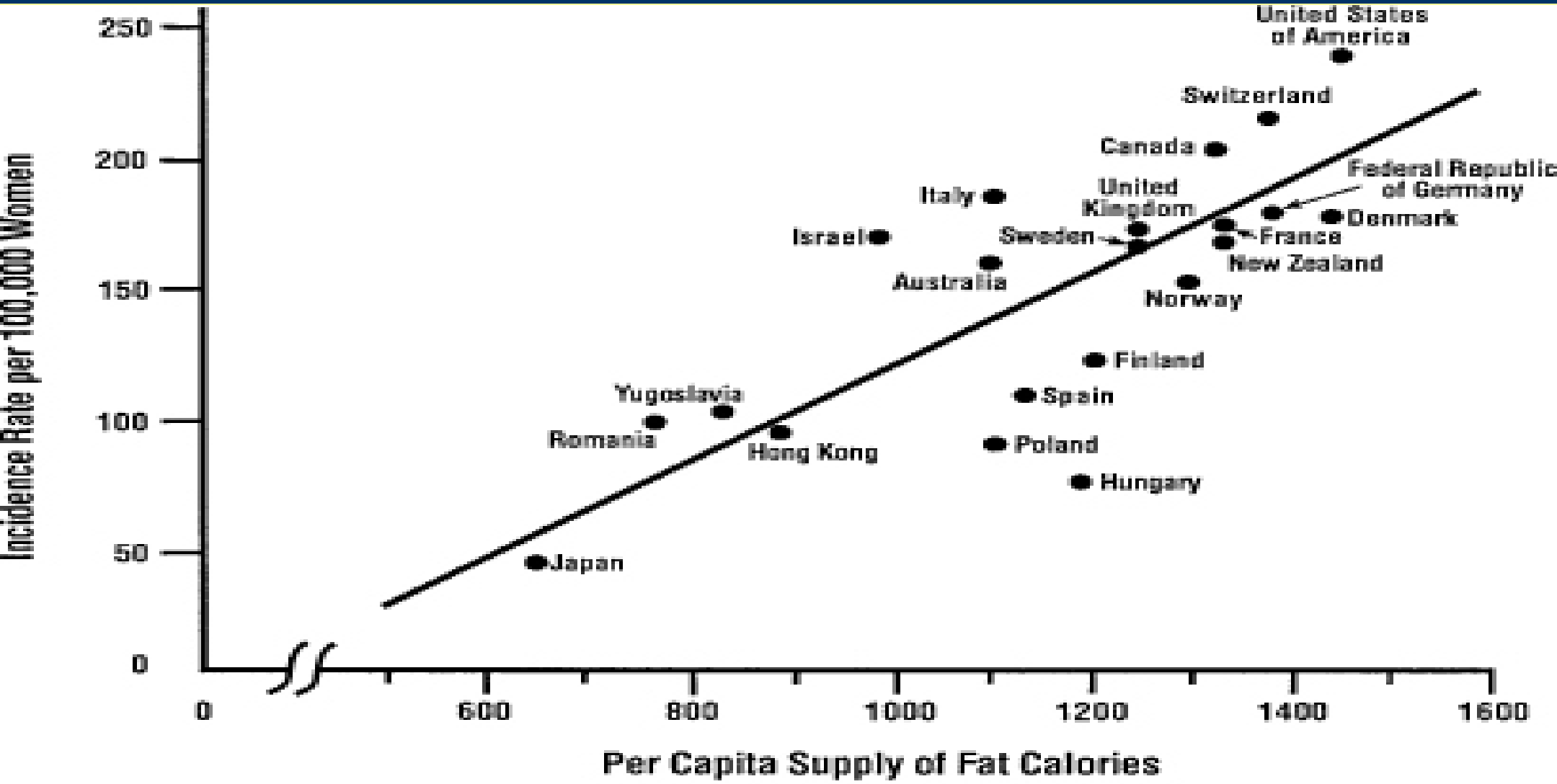
- RCTs are often difficult to conduct. Many clinicians and patients are reluctant to accept randomization, especially if one of the proposed interventions is particularly desirable or undesirable.
- This may be an ethical consideration.
- Furthermore, large numbers of patients may be required if the disease prevalence is low.
- This may necessitate the involvement of multiple institutions, which may increase its complexity and cost.
- E.g.:
  - Breast cancer and Tamoxifen
  - Hypertension monitoring and policy

Ecological study

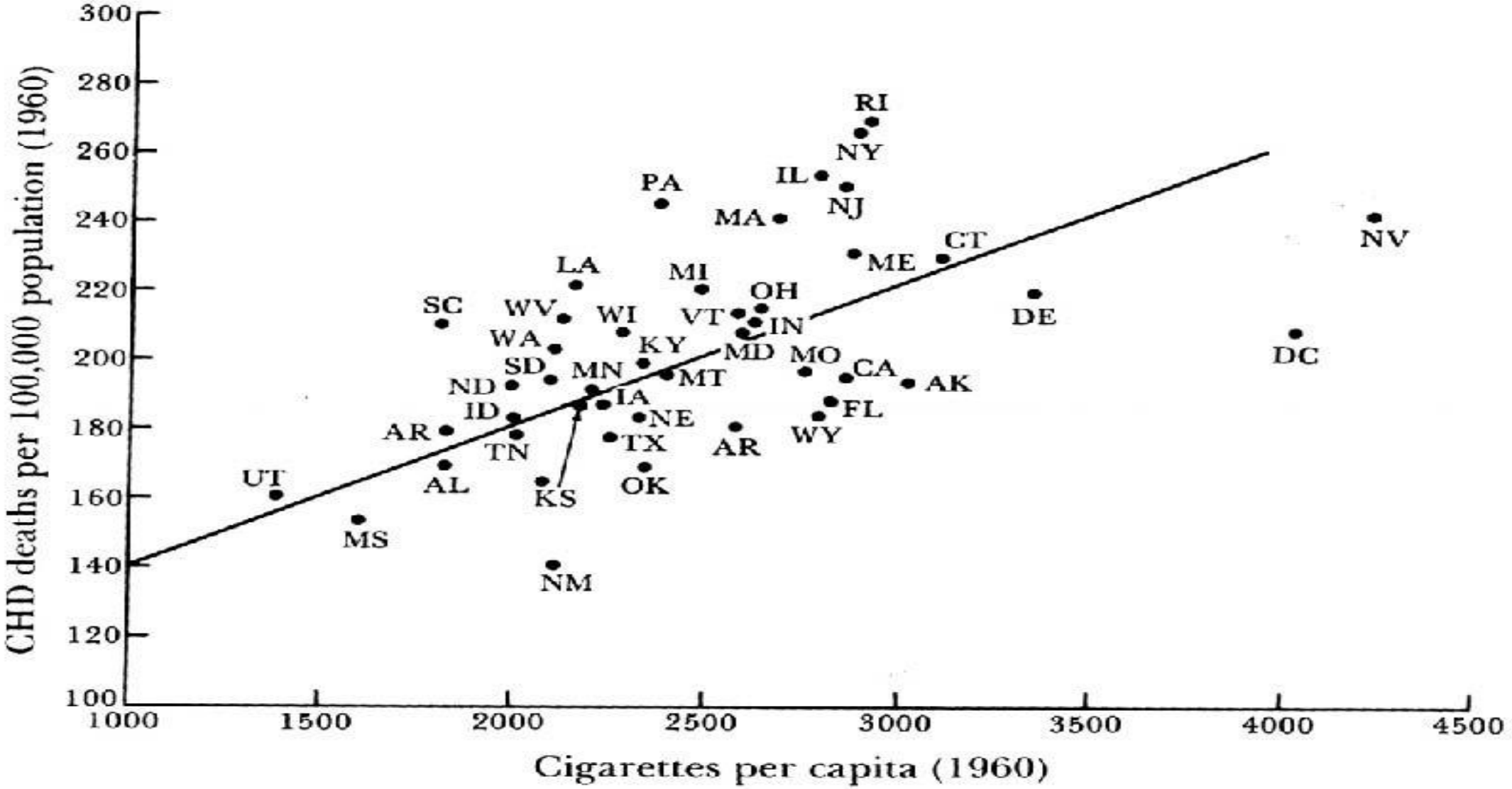
- Unit of analysis is group or population, rather than individuals (schools, factories, nations)
- Compare aggregate measure of health outcome with aggregate measure of exposure
- Generally based on existing data

- Advantages
  - Can be done quickly and inexpensively
  - May be able to identify associations by examining greater range in exposure
- Disadvantages
  - Ecological fallacy: Cannot link exposure with disease in individuals
  - Difficult to control confounding factors

Breast cancer and fat intake



CHD mortality rate by cigarette consumption in USA counties



Research question and study type
(*Reference: Leon Gordis*)

State of the knowledge of the problem	Type of research questions	Type of study
Knowing that a problem exists but knowing little about its characteristics or possible causes	What is the nature/ magnitude of the problem? Who is effected? How do the effected people behave? What do the know think or believe about the problem and its	**Exploratory studies *or* Descriptive studies** •**Descriptive case studies** •**Cross sectional surveys**

Research question and study type

State of the knowledge of the problem	Type of research questions	Type of study
Suspecting that certain factors contribute to the problem	Are certain factors indeed associated with the problem? (e.g. is low fiber diet related to carcinoma of large intestine?)	**Analytical studies:** • **Cross sectional comparative studies** • **Case-control studies** • **Cohort studies**

Research question and study type

State of the knowledge of the problem	Type of research questions	Type of study
Having established that certain factors are associated with the problem: desiring to establish the extent to which a particular factor causes or contributes to the problem.	What is the cause of the problem? Will the removal of particular factor prevent or reduce the problem (e.g., stopping smoking, providing safe water etc)	**Cohort studies** **Experimental or quasi experimental studies**

Research question and study type

State of the knowledge of the problem	Type of research questions	Type of study
Having sufficient knowledge about causes to develop and assess an intervention that would prevent, control or solve the problem	What is the effect of a particular intervention/strategy? (e.g., treating with a particular drug, being exposed to a certain type of health education) Which of the two alternate strategies give better results? Which strategy is most cost-effective	**Experimental or** **Quasi-experimental studies**

Thank you. Have a nice day