An Introduction to Research Designs and Developing SRH Research Projects

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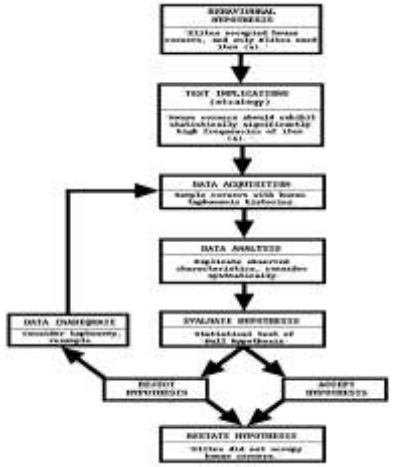

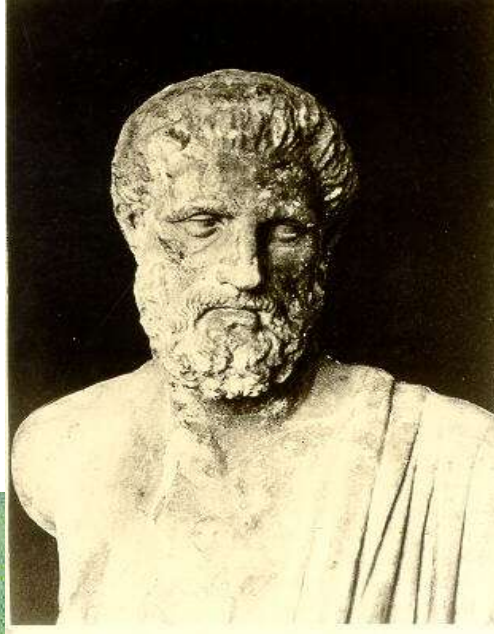

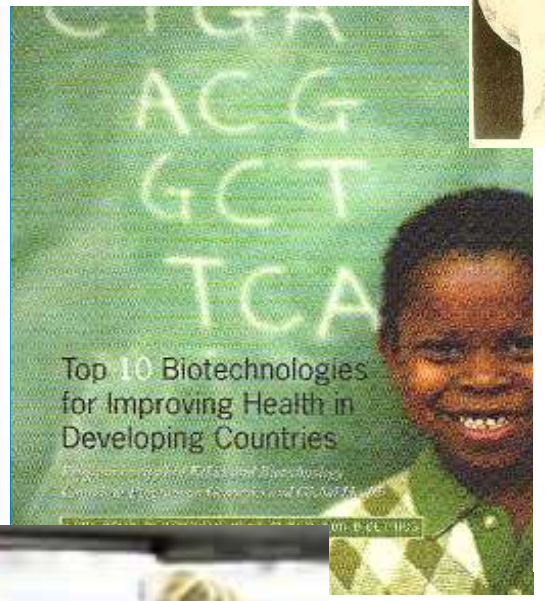

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Introduction

- Definition of epidemiology
- Brief history of epidemiology and classical studies
- Uses of Epidemiology
    - Disease Surveillance
    - Risk Assessment
    - Policy Development
    - Evaluation of Interventions
- The Evidence Pyramid
- Introduction to Research Study Designs
- Types of Epidemiological Studies

Epidemiology

- The term **epidemiology** is derived from Greek words:
  - **Epi** meaning "on" or "upon"
  - **Demos** meaning "people"
  - **Logos** meaning "study"
- Epidemiology is the study of the **distribution**, **dynamics**, and **determinants** of health-related events in populations.

- **Determinants of Disease:**
- These are the **causative agents** of disease or disorder. Examples include:
  - **Biological agents**: Viruses, bacteria, fungi, parasites.
  - **Physical agents**: Radiation, extreme temperatures.
  - **Chemical agents**: Toxins, pollutants.

Brief introduction to Epidemiology

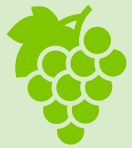
- Throughout history, diseases such as plagues, cholera, pneumonia, and influenza have shaped public health.

- Hippocrates (c. 340-400 B.C.) asserted, "No disease is sent by devils or demons, but is the result of natural causes."

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



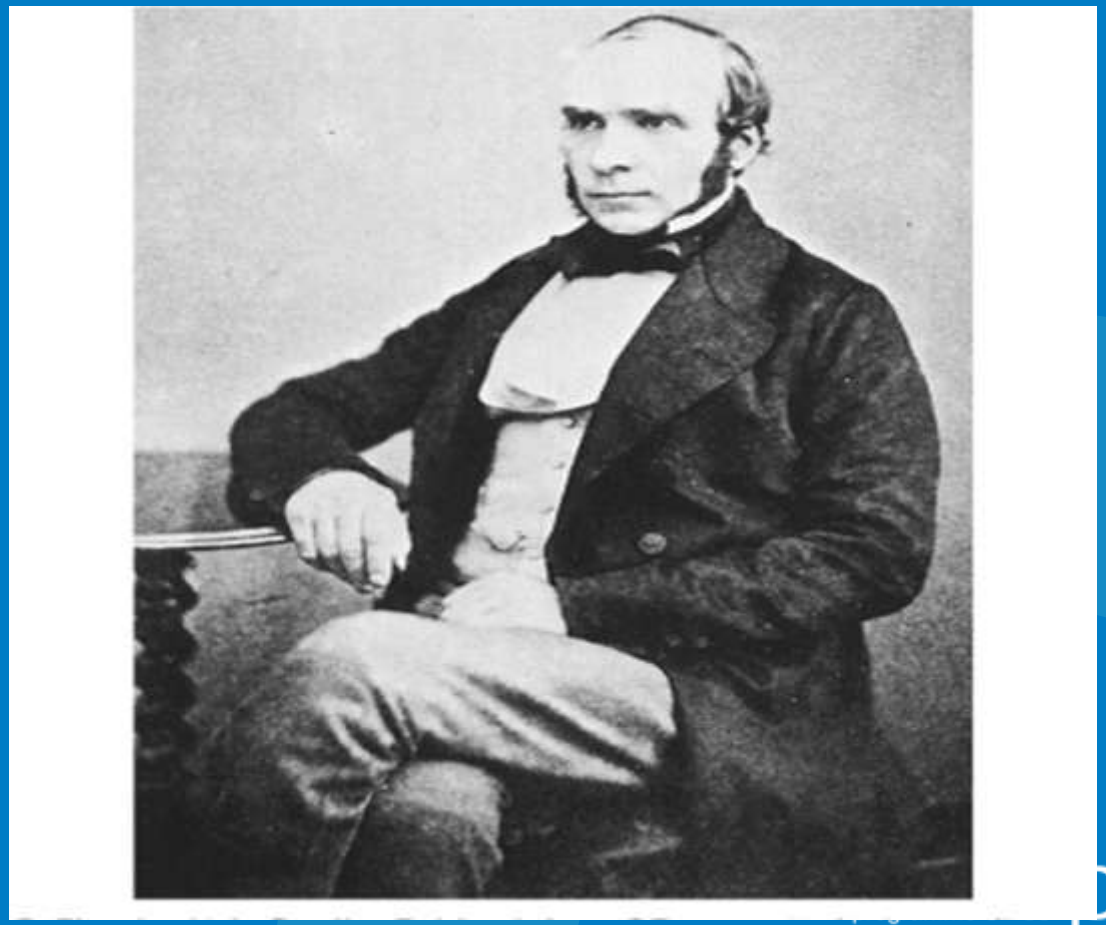
Scurvy Disease (1747): James Lind conducted one of the first clinical trials in 1747, demonstrating that citrus fruits could cure scurvy, a disease caused by vitamin C deficiency

Cholera in London (1854): John Snow's investigation of the 1854 cholera outbreak in London linked the disease to contaminated water from the Broad Street pump, pioneering the field of epidemiology

Nuclear Bombs at Hiroshima and Nagasaki: Studies on survivors of the atomic bombings in 1945 have provided extensive data on the long-term effects of radiation exposure, including increased cancer rates

- **Severe Air Pollution in London** (1952): The Great Smog of 1952 caused a significant increase in deaths from heart and lung diseases, leading to the Clean Air Act of 1956
- **Minamata Disease**: First identified in the 1950s, Minamata disease was caused by the consumption of fish contaminated with methylmercury from industrial wastewater
- **Itai-Itai Disease:** This condition, identified in the mid-20th century in Japan, resulted from consuming rice contaminated with cadmium, leading to severe pain and bone damage
- **Legionnaires' Disease**: An infectious disease caused by Legionella bacteria, often spread through ventilation systems and water supplies in large buildings

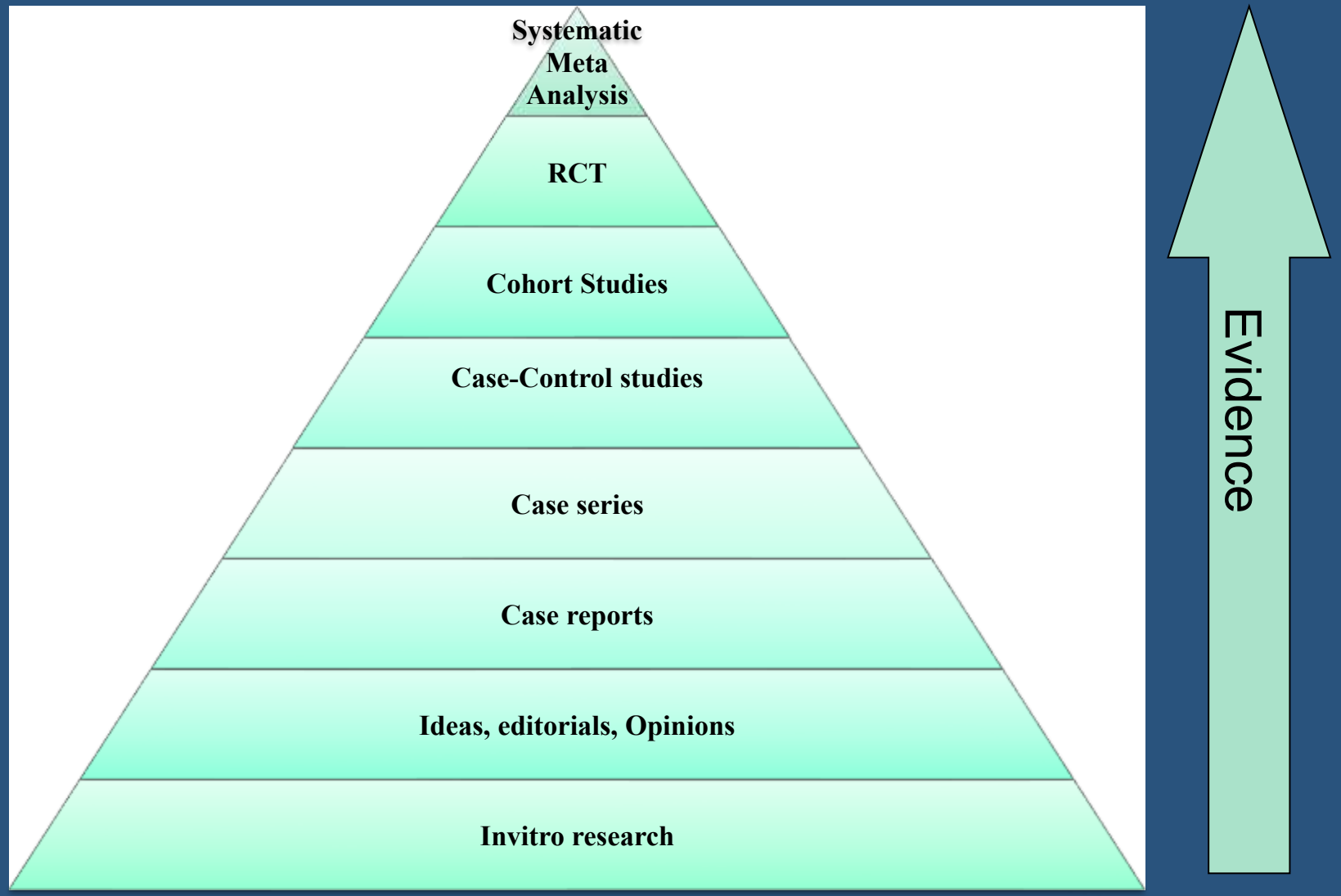
A sketch of water drop - London

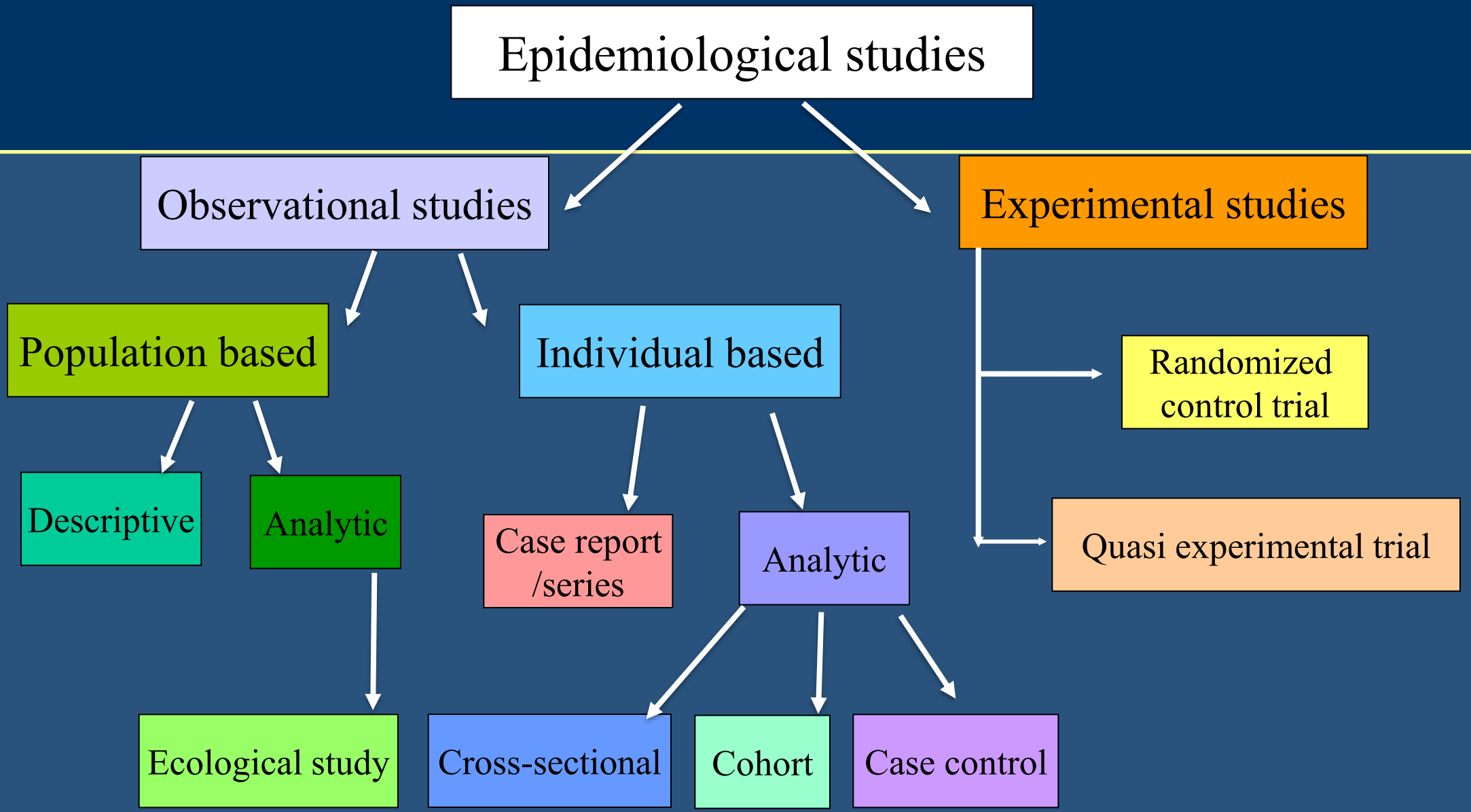


Deaths from Cholera per 10,000 Houses by source of water supply, London (Snow, 1854)

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

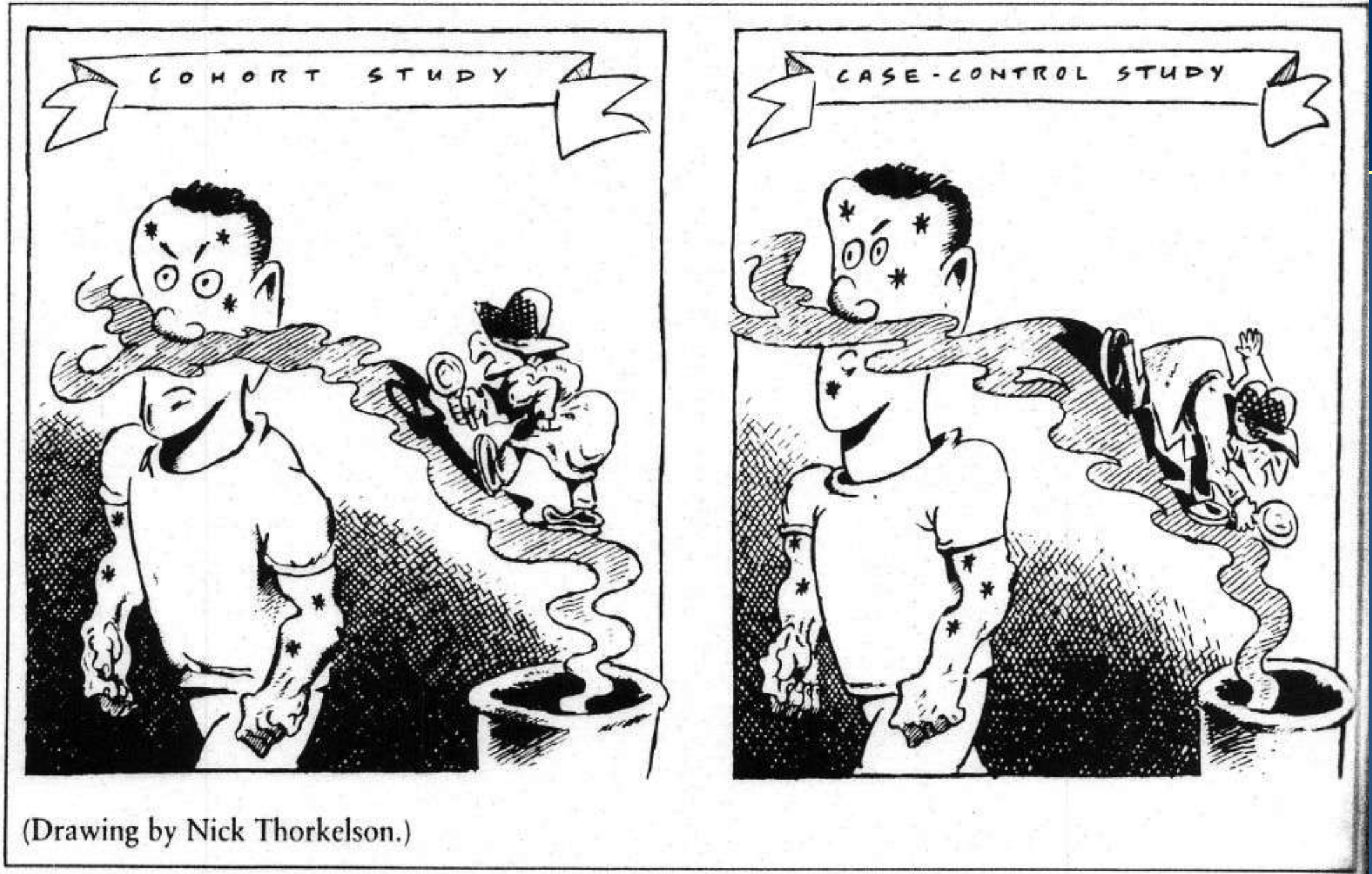
- Qualitative field research usually focuses on:
- Meanings = (culture, language, norms)
- Practices = (various kinds of behavior)
- Episodes = (divorce, crime illness)
- Encounters = (2 people meeting and interacting)
- Roles = (positions people occupy. Ethnic groups)
- Relationships = (kinds of behaviors 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 time

- **Retrospective**: Any design that looks at data that have already been gathered (e.g., Case-Control Study).

- **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

Steps:

1. **Identify and Select Study Population**: Choose a group of individuals to study.
2. **Classify Study Population**: Categorize the population based on exposure status and other risk factors.
3. **Follow Cohort Members Over Time**: Track the cohort over a period to observe health outcomes based on exposure status sub-groups.

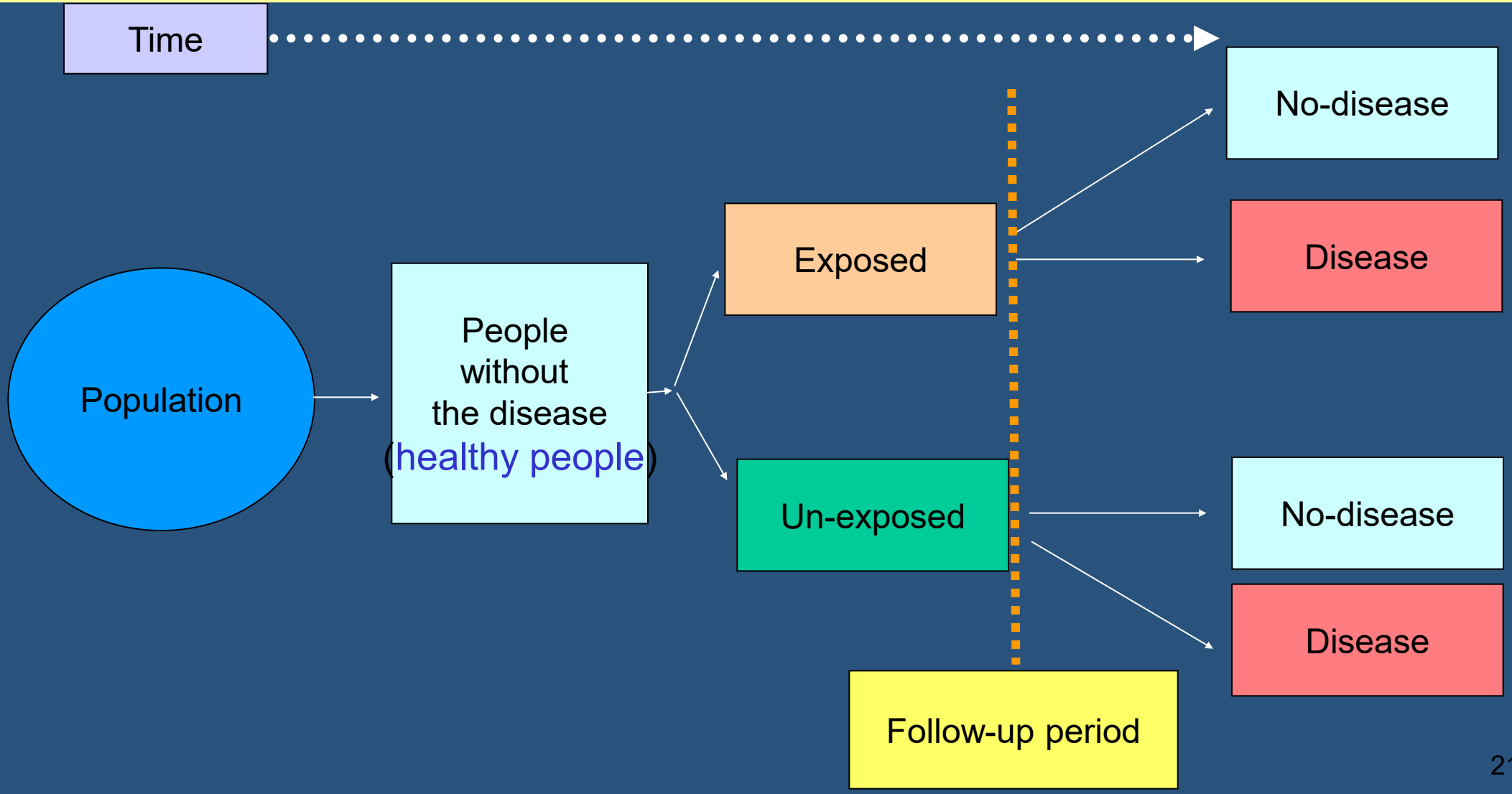
Advantages:

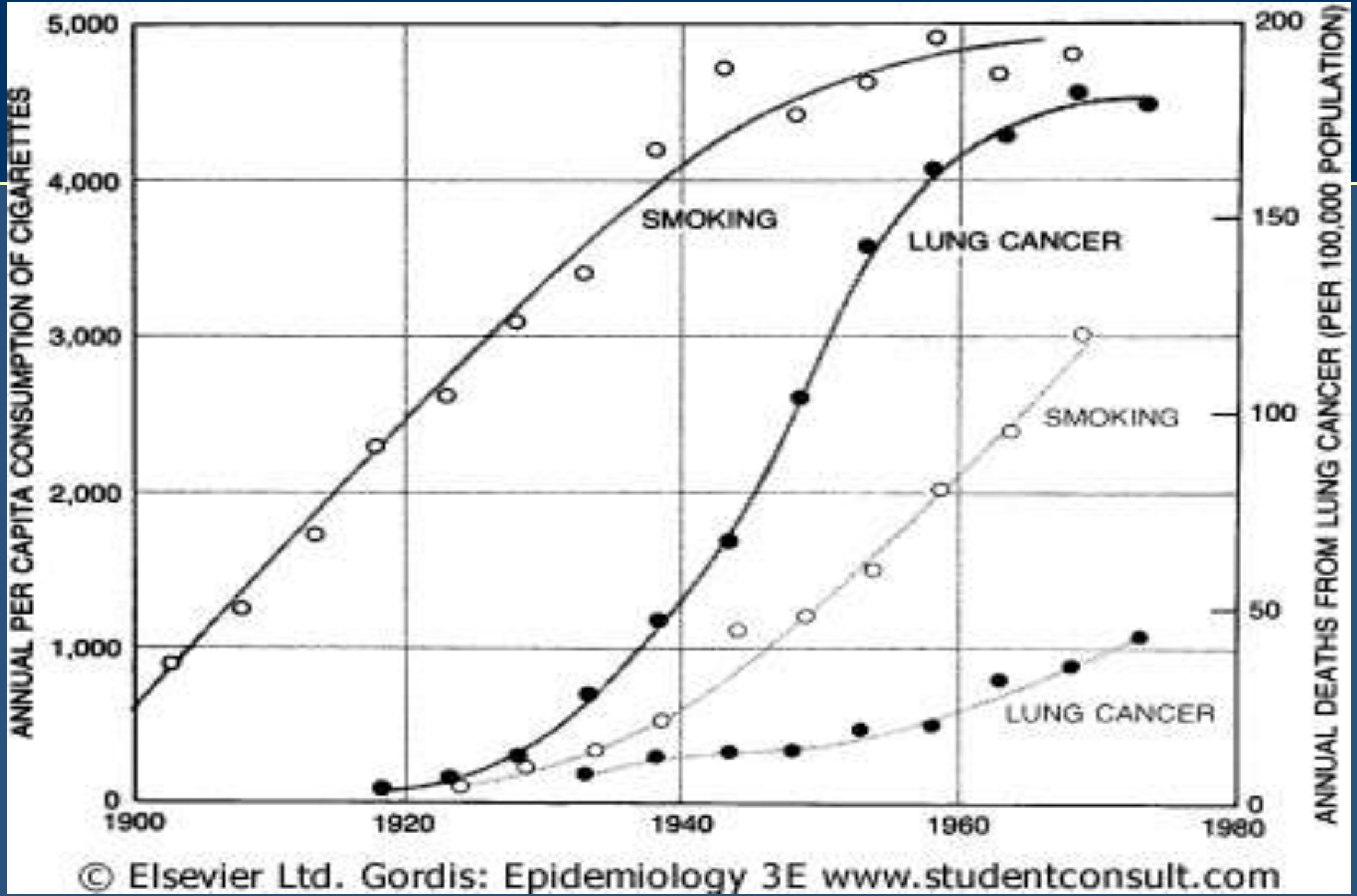
- **Establish Causality**: Helps in determining cause-and-effect relationships.
- **Determine Incidence Rates and Risk**: Useful for calculating the incidence of outcomes and associated risks.
- **Efficient for Studying Rare Exposures**: Particularly beneficial for studying rare exposures such as:
  - Nuclear bomb radiation
  - Radiation for enlarged thymus
  - Chernobyl nuclear accident
  - Minamata disease
  - Toxic chemical exposure (e.g., methyl isocyanides) from industrial accidents like Bhopal, India

Disadvantages:

- **Inefficient**: Requires following many subjects over a long period.
- **Expensive**: High costs associated with long-term studies.
- **Large Sample Size Needed for Rare Exposures**: Requires a large number of participants to study rare exposures effectively.
- **Delayed Results**: Results are not available for a long time due to the extended follow-up period.
- **Bias Due to Attrition and Loss to Follow-Up**: Potential for bias if participants drop out or are lost during the study.

Design of a Cohort study





Case-control study: back in time

Steps:

1. **Select Cases**: Identify a group of patients with a particular disease (the cases).
2. **Select Controls**: Choose a comparison group without the disease (the controls).
3. **Assess Prior Exposure Status and Other Risk Factors**: Evaluate the exposure status and other risk factors for both cases and controls.

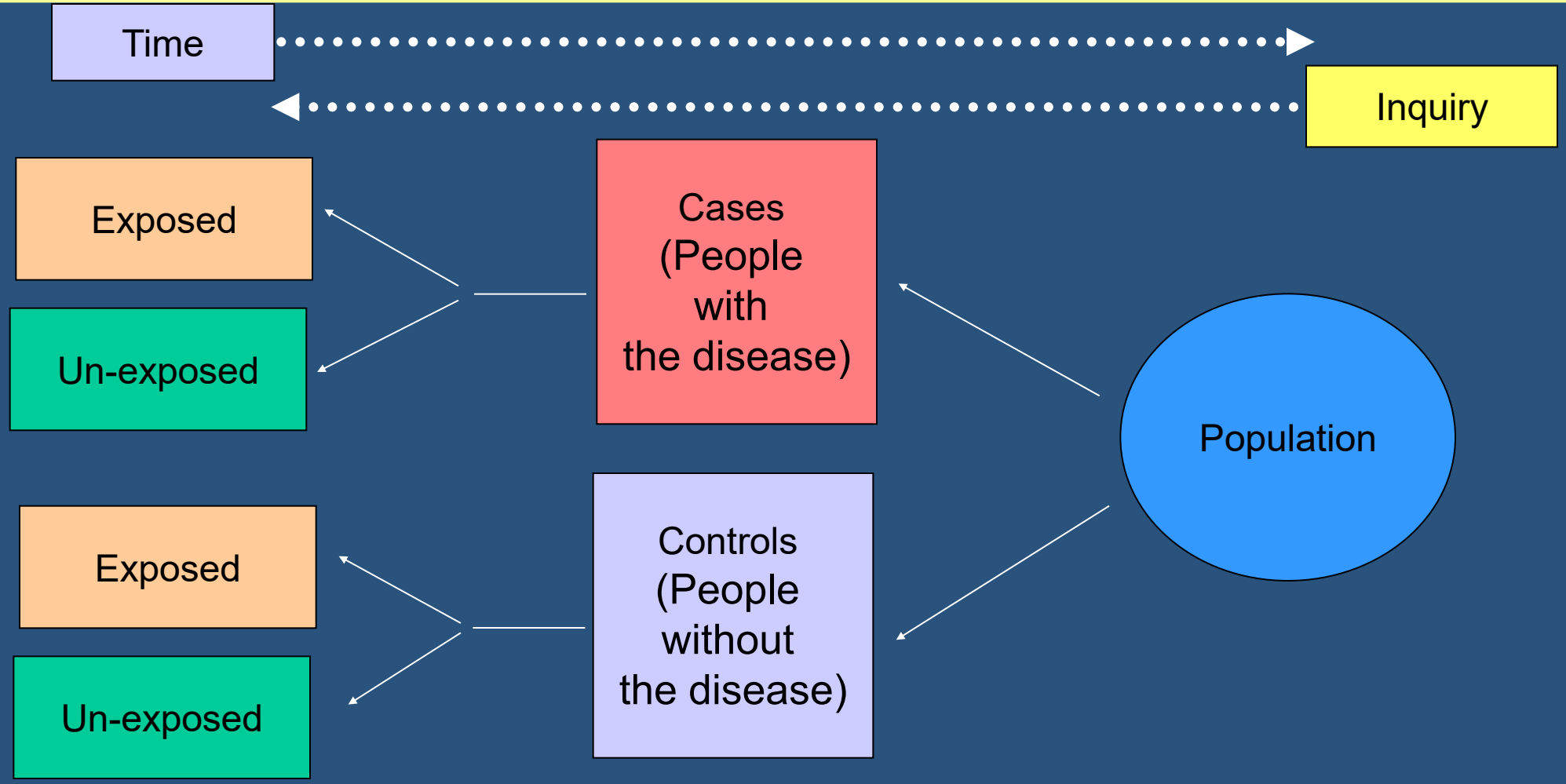
Examples:

- **Lung Cancer and Exposure to Radon**: Studying the relationship between lung cancer and radon exposure.
- **Lung Cancer and Indoor Air Pollution in China**: Investigating the link between lung cancer and indoor air pollution.
- **Leukemia and Radioactive Fallout**: Examining leukemia in individuals exposed to radioactive fallout from nuclear testing in the USA.

Advantages:

- **Inexpensive and Efficient**: Particularly useful for studying rare diseases.
- **Useful for Studying Diseases with Long Latencies**: Effective for diseases that take a long time to develop.
- **Disadvantages:**
- **Difficult to Select Appropriate Comparison Group**: Challenges in finding a suitable control group.
- **Potential Bias in Measuring Exposure**: Risk of recall bias due to the disease affecting memory of past exposures.

Design of a Case - Control study



Main difference between both designs

- **Case-Control Study**
- **Description**: The study begins with two groups of people: those who have the disease (cases) and those who do not have the disease (controls).
- **Steps**:
  - Select cases (diseased individuals).
  - Select controls (non-diseased individuals).
  - Assess prior exposure status and other risk factors for both cases and controls.

- **Cohort Study**
- **Description**: The study begins with two groups of healthy people: those who have been exposed to a certain factor (exposed) and those who have not been exposed (non-exposed).
- **Steps**:
  - Identify and select a healthy study population.
  - Classify the population based on exposure status.
  - Follow cohort members over time to determine health outcome occurrence by exposure status sub-groups.

Cross Sectional / Prevalence study

Description: Also called a "snap-shot study," as it captures a moment in time.

Steps:

- **Choose Sampling Frame**: Select a sampling frame for choosing study participants.
- **Measure Exposure and Health Outcome Status**: Assess both the exposure and health outcome status of the study participants at a single point in time.
- **Health Outcomes Based on Prevalence**: Health outcomes are measured based on prevalence (the proportion of individuals with a condition at a specific time), not incidence (the rate of new cases over time).

Limitation:

- **Cannot Prove Cause-Effect Relationship**: This design cannot establish causality between exposure and outcome.

Meta-analysis

Description: A systematic method that uses statistical analyses to combine data from independent studies, providing a numerical estimate of the overall effect of a particular intervention or variable on a defined outcome. This study design aims to overcome much of the subjectivity inherent in narrative literature reviews.

Steps (According to Thacker):

1. **Define the Problem and Criteria for Admission of Studies**: Clearly outline the research question and establish criteria for including studies in the analysis.
2. **Locate Research Studies**: Conduct a comprehensive search to find relevant studies that meet the inclusion criteria.
3. **Classify and Code Study Characteristics**: Systematically categorize and code the characteristics of each study.
4. **Quantitatively Measure Study Characteristics on a Common Scale**: Use statistical methods to measure study characteristics in a standardized way.
5. **Analyze, Interpret, and Report the Results**: Perform statistical analyses, interpret the findings, and report the results.

Example:

- **Streptokinase Use in Myocardial Infarction (MI)**: Combining data from multiple studies to evaluate the overall effectiveness of streptokinase in treating myocardial infarction.

Randomized Clinical Trials

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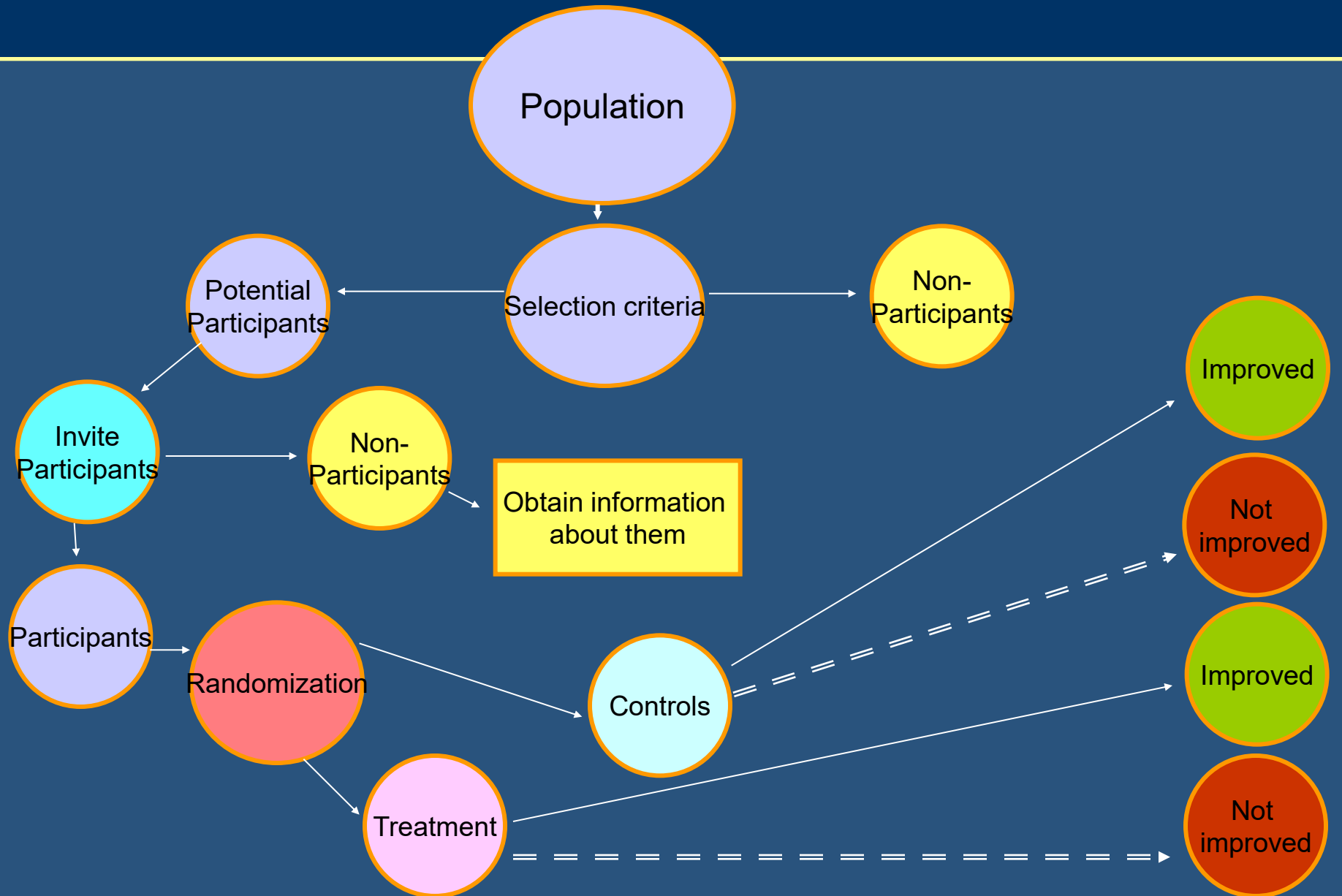
Randomized Clinical Trials



Randomized Clinical Trials

- **Description**: RCTs have become the accepted standard for evaluating therapeutic efficacy. These trials are performed in a prospective fashion to allow as much control of variables as possible.

- **Key Feature**: The outstanding feature of RCTs 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 outcomes observed among treatment groups tend to result from treatment effects and not from inherent differences among the groups.

Randomized Clinical Trials

- Randomized Clinical Trials (RCTs) are often challenging to conduct. Many clinicians and patients are reluctant to accept randomization, especially if one of the proposed interventions is particularly desirable or undesirable, raising ethical considerations

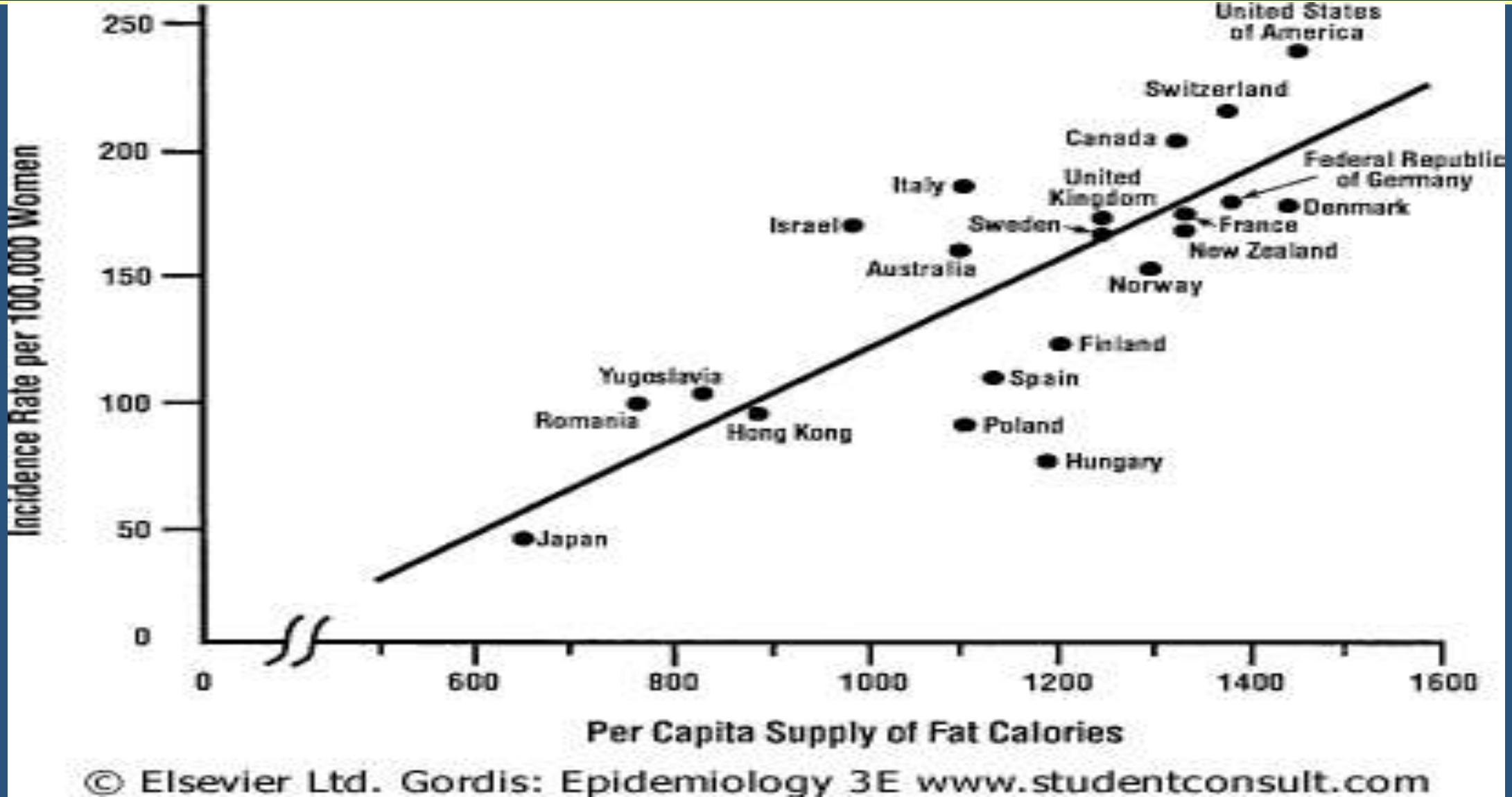
- Additionally, large numbers of patients may be required if the disease prevalence is low, necessitating the involvement of multiple institutions, which increases complexity and cost

For example:

- **Breast Cancer and Tamoxifen**: RCTs have shown that tamoxifen significantly reduces the risk of recurrence in patients with ductal carcinoma in situ (DCIS) who undergo breast-conserving surgery

- **Hypertension Monitoring and Policy**: RCTs in hypertension have demonstrated the effectiveness of blood pressure-lowering interventions in reducing cardiovascular events, influencing clinical guidelines and policies

Breast cancer and fat intake



Ecological study

In ecological studies, the unit of analysis is a group or population (e.g., schools, factories, nations) rather than individuals. These studies compare aggregate measures of health outcomes with aggregate measures of exposure, typically using existing data.

Advantages

- **Quick and Inexpensive**: These studies can be conducted rapidly and at a low cost

Range of Exposure: They may identify associations by examining a broader range of exposure levels

Disadvantages

- **Ecological Fallacy**: It is not possible to link exposure with disease in individuals, leading to potential misinterpretations

Confounding Factors: Controlling for confounding factors is challenging, which can affect the validity of the findings

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 affected? How do the affected people behave? What do we know think or believe about the problem and its causes?	**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**

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