# 05

# INTRODUCTION TO STUDY DESIGNS

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## ACKNOWLEDGMENTS

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# LECTURE **OBJECTIVES**


**By the end of this lecture, I am able to:**

- List differences between descriptive and analytical study designs
- Describe main types of study designs and their uses
- Identify different study designs with examples

# INTRODUCTION

## Definition

Definitions Are Important

A study design is a detailed plan or approach for systematically collecting, analyzing, and interpreting data; it is a formal approach of scientific investigation.

## 5-Ws Of Epidemiological Studies

- Study designs in epidemiology are **classified** as either descriptive or analytic.
- **Descriptive epidemiologic studies** are used to assess and monitor the health of communities and identify health problems and priorities according to person, place, and time.
- **Descriptive epidemiologic studies** also lend support to more definitive evaluation using analytic methods.
- **Analytic epidemiologic studies** employ comparison groups and are used to test one or more predetermined hypotheses about associations between exposure and outcome variables.
- **Analytic epidemiologic studies** provide information on how and why a health-related state or event occurred.

| Descriptive | | | | Analytical |
|---|---|---|---|---|
| **What** | **Who** | **Where** | **When** | **When & How** |
| Diagnosis or clinical information | Person | Place | Time | Causes<br>Risk Factors<br>Modes Of Transmission |

# STUDY DESIGN TREE

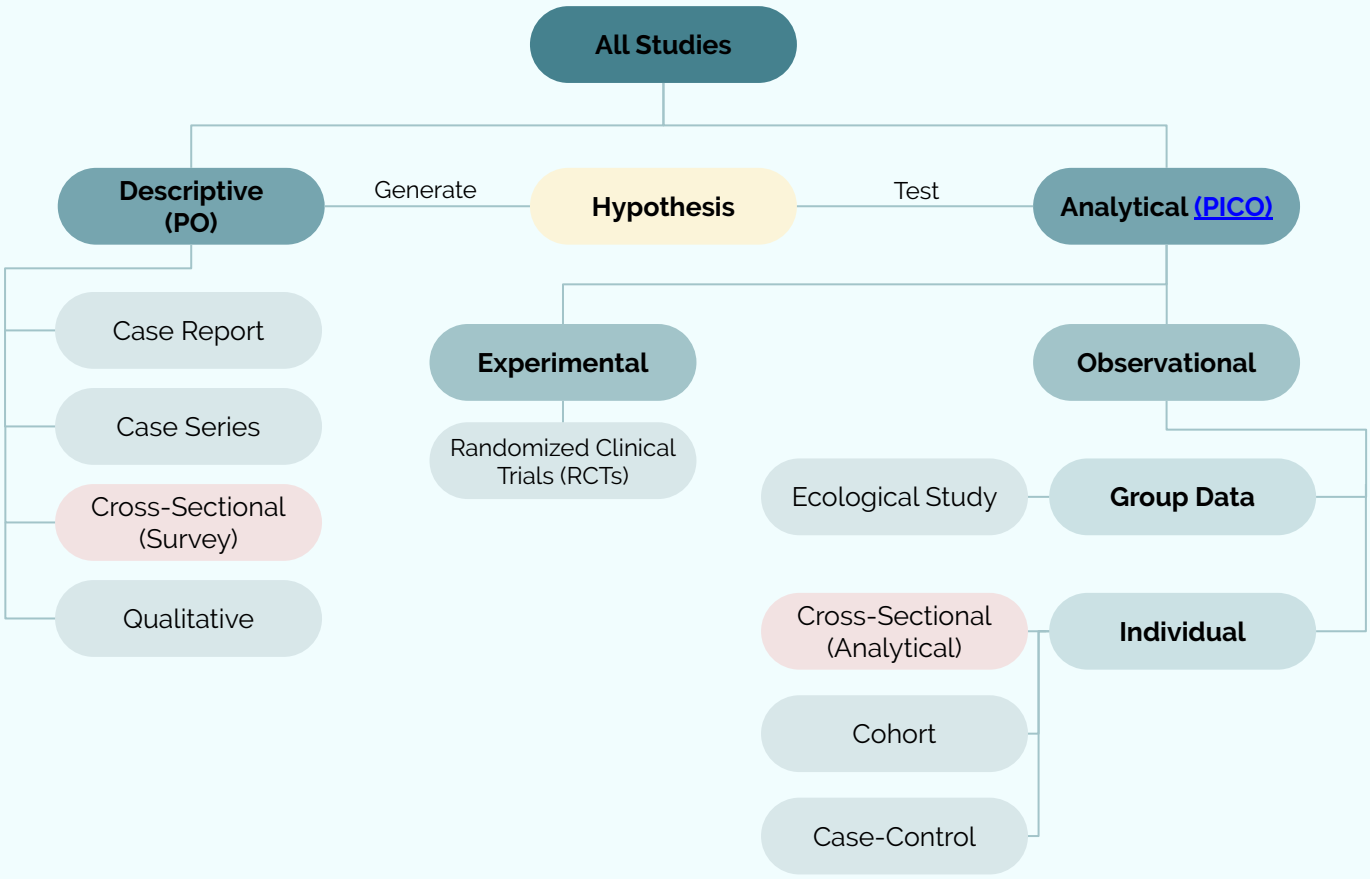
## Remember

- A clear research question facilitates selecting the optimal study design. Sometimes, two groups are conducting the same topic, but the research question and objectives are different between them, and hence, the study design differs accordingly.
- **All research questions, (descriptive and analytical), have the below similar components:**
  1. A defined population **(P)** from which groups of subjects are studied.
  2. Outcomes **(O)** that are measured. 3. Time **(T)** frame.
- **Analytical research questions have the additional two components:**
  1. Intervention **(I)** that is applied to a groups of subjects. 2. Comparison **(C)** group without the intervention.

## Study Design Tree

**Whether a study is hypothesis-testing or hypothesis-generating, that depends on:**

1. Sequence of past studies.
2. Present state of knowledge (i.e. Whether a hypothesis currently under evaluation was suggested by a previous study).




## Sequence Of Study Design

Increasing Knowledge of Exposure / Outcome (Strength of Evidence)

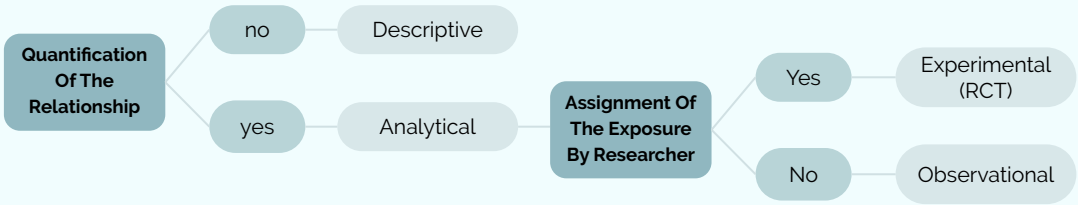
| DESCRIPTIVE | Analytical-Observational CASE-CONTROL | Analytical-Observational COHORT | Analytical-Experimental RCT |
|---|---|---|---|
| Identifying hypotheses to test in analytic studies | Evaluate if hypothesized exposure is related to the outcome of interest | Further define importance of exposure for the development of outcome | Test the actual link between exposure and outcome. i.e. Causality |

- If one seeks to identify **the etiologic factors** (e.g. hyperlipidemia/any causal factor) behind an **outcome** (e.g. an MI), then, **each step in the epidemiologic framework** provides **new and important information.**
- **Descriptive** studies identify **hypotheses** to test in **analytic studies.**
- **Case-control studies** are then usually applied to evaluate if the **hypothesized exposure** is related to the **outcome of interest**.
- Subsequently, **cohort or longitudinal studies** are applied to further define the importance of **exposure to the causal agent** for the development of the **outcome.**

## Study Design Distinctive Factors

**Two important distinctive factors in study designs:**

1. **Quantification** of relationship between **exposure** and **outcome.**.
2. Researcher assignment **(manipulation)** of **exposure.**




# TYPES OF STUDIES

## USES, COMPARISONS & EXAMPLES

## Descriptive Studies

| | Case Report | Case-Series | Cross-Sectional (Survey) | Qualitative |
|---|---|---|---|---|
| **Population** | **Single case** | Collection of **similar cases** | **Single sample** from larger population (No comparison) | Process of naturalistic inquiry that seeks in-depth understanding of phenomena within their **natural setting** (Individual, societies, languages) |
| **Primary Use** | • Detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an **individual patient.**<br>• Typically an **unusual/novel occurrence** | Detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of a **group of patients or cases with similar issue.** | • Study **prevalence** of health related events at a **point in time/snapshot.**<br>• Often used to study conditions that are relatively frequent with long duration of expression (nonfatal, chronic conditions) | Answers the **'why?'** questions |
| **Advantages** | • Detecting novelties.<br>• Generating hypotheses.<br>• Allowing in-depth understanding.<br>• Educational value. | • Useful for hypothesis generation.<br>• Informative for very rare disease with few established risk factors. | • Cheap and simple.<br>• Ethically safe. | • Provides depth and detail<br>• Creates openness<br>• Simulates people's individual experiences |
| **Disadvantages** | • Lack of ability to generalize<br>• No possibility to establish cause-effect relationship<br>• Publication bias | • Cannot study cause and effect relationships<br>• Cannot assess disease frequency | Not suitable for studying **rare** or highly fatal diseases or a **disease with short duration** | • Usually fewer people studied<br>• Less easy to generalize<br>• Dependent on skills of the researcher |

## Analytical Studies

| | Experimental | Observational | | | |
|---|---|---|---|---|---|
| | Individual Data | Group Data | Individual Data | | |
| | RCT | Ecological | Cross-Sectional | Cohort | Case-Control |
| **Population** | Highly selected population, Highly controlled environment. Allocation of exposure is made by the researcher. | Population based study (city, country, geographic area). Usually using secondary data. | Single sample from larger population – compares two groups in the sample | Two samples – **Exposed** group and **Not Exposed.** NO allocation of exposure is made by the researcher | Two samples – group **With Outcome** (DISEASE) and group **Without Outcome** (NO DISEASE) |
| **Directionality** | Exposure is **assigned** BEFORE Outcome is **measured** | Exposure and Outcome BOTH **measured** at the SAME TIME at POPULATION level | Exposure and Outcome BOTH **measured** at the SAME TIME at INDIVIDUAL level | Exposure is **measured** BEFORE Outcome is **measured** | Outcome is **measured** BEFORE Exposure is **measured** |
| **Primary Use** | Efficacy of an intervention / **Causality** | Screening hypotheses at population level (BE AWARE of Ecological Fallacy) | Screening hypotheses at individual level, **Prevalence studies** | Assessing associations between exposures and outcomes **over time** | Assessing associations between exposures and **rare outcomes (rare diseases)** |

**Directionality:** When exposure and outcome assigned or measured.

**Ecological fallacy:** refers to drawing inferences incorrectly from data on groups or about individuals in the groups. In an example, researchers found that death rates from breast cancer were significantly increased in countries where fat consumption was high when compared with countries where fat consumption was low. This is an association for aggregate data in which the unit of observation is country. Thus, in countries with more fat in the diet and higher rates of breast cancer, women who eat fatty foods are not necessarily more likely to get breast cancer. One cannot be certain that the breast cancer cases had high fat intakes.

## Examples Of Analytical Studies

**Exposure: Flu Vaccine** → **Outcome: Flu**

| Experimental RCT | Observational COHORT | Observational CASE-CONTROL | Observational CROSS-SECTIONAL | Observational ECOLOGICAL |
|---|---|---|---|---|
| Study of a new flu vaccine | Study of who have received flu vaccine, and did they get ill | Study of who has flu, and if they were vaccinated | Study of how many cases of flu in females, and males | Compares cases of flu and air quality in two countries |

# SPOTTING OF THE STUDY DESIGN

## 3 Issues Of The Design Tree

**The type of study can be spotted by looking at three issues as per the "Design Tree":**

**Q1 What was the aim of the study?**

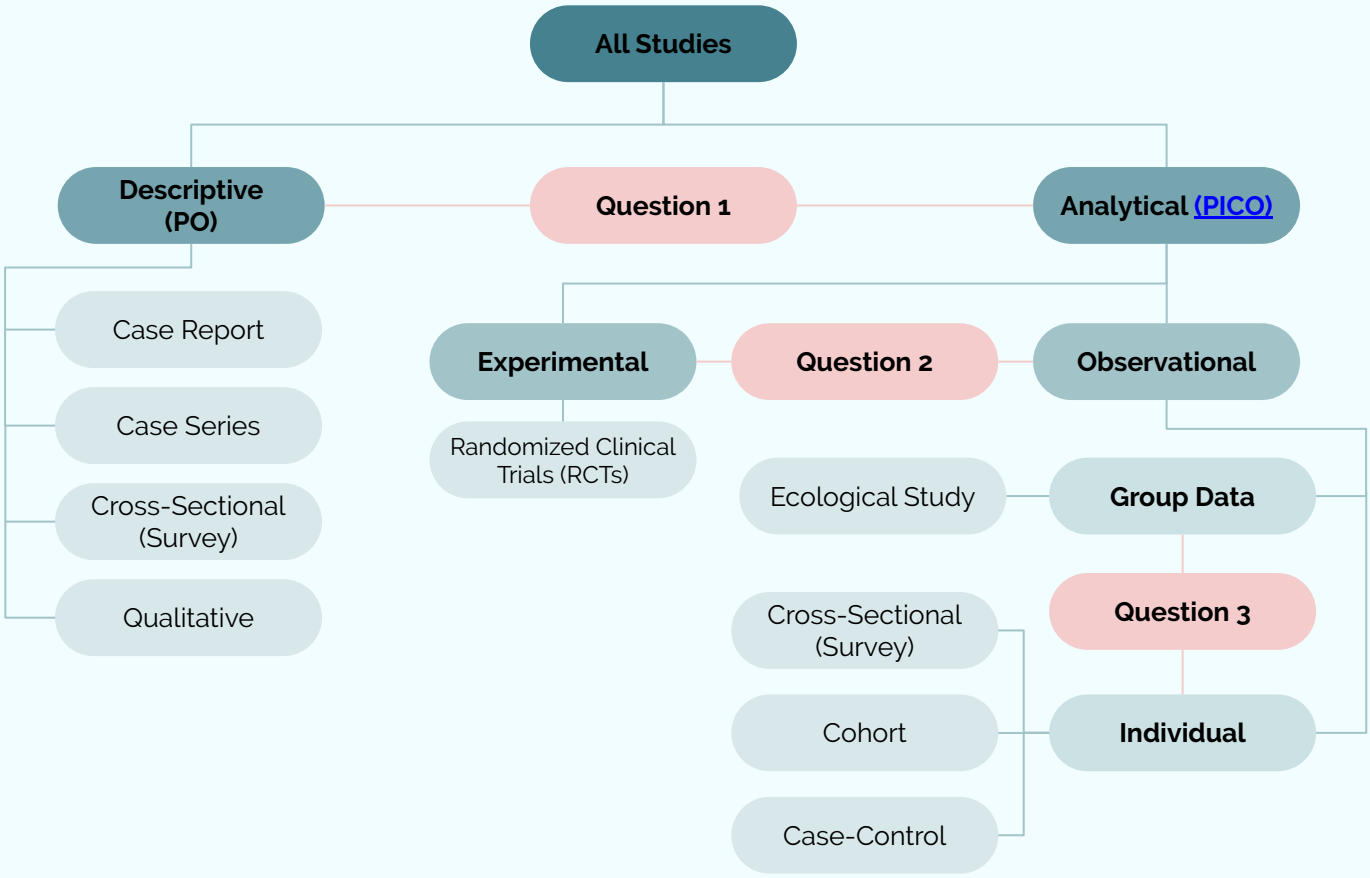
1. To simply describe a population (PO questions) → Descriptive
2. To quantify the relationship between exposure & outcome (PICO questions) → Analytic

**Q2 If analytic, was the intervention randomly allocated (assigned by the researcher)?**

1. Yes → RCT
2. No → Observational

**Q3 If Observational, When were the outcomes determined (measured)?**

1. Some time after the exposure (intervention) è Cohort study
2. At the same time as the exposure (intervention) è Cross-sectional
3. Before the exposure was measured è Case-Control



# EXAMPLES

"Primary spontaneous pneumothorax is a common disorder occurring in young adults without underlying lung disease. Although tobacco smoking is a well-documented risk factor for spontaneous pneumothorax, an association between electronic cigarette use (that is, vaping) and spontaneous pneumothorax has not been noted. We report a case of spontaneous pneumothoraces correlated with vaping"

Study design: Descriptive – Case Report

"Fourteen patients were treated for electronic cigarette burns between 2012 and 2016. Burn size ranged from <1% to 6% total body surface area. Most patients suffered burns to their thighs because the battery or device exploded in their pocket. The majority suffered partial thickness burns while four patients had full thickness burns. Three patients required excision and autografting, all of which were full thickness burns. The average time to recovery was 24.5 days"

**Study design:** Descriptive – Case Series

"We conducted 12 focus groups and two individuals interviews with youg adult nonusers e-cigarette vapers, cigarette smokers, and dual users to assess beliefs about the effects of e-cigarettes. After a series of open-ended questions,follow-up questions assessed reactions to domains previously examined in expectancy measures for cigarette smoking and e-cigarette vaping. The constant comparative method was used to derive themes from transcripts"

Study design: Descriptive - Qualitative

"A survey of 6902 German students (mean age 13.1 years, 51.3% male) recruited in six German states was performed. Exposure to e-cigarette advertisements was measured with self-rated contact frequency to three advertising images. Multilevel mixed-effect logistic regression models were used to assess associations between exposure to e-cigarette advertisement and use of e-cigarettes, combustible cigarettes and hookahs (ever and past 30 days)"

**Spot the design! Three questions:**
Q1: Analytical (association)
Q2: Observational (exposure was not randomly allocated)
Q3: Cross-sectional (Exposure & Outcome at the same time)

"Adult smokers (≥18 years old) making thewir first purchase at local participating vape shops were asked by professional retail staff to complete a form with their basic demographic and smoking history details together with scoring of their level of nicotine dependence by a questionnaire. Participants were instructed how to charge, fill, activate and use their e-cigs. Key troubleshooting was addressed and phone numbers were supplied for technical assistance. Participants were encouraged to use these products in the anticipation of reducing the number of cig/day smoked. Their cigarette consumption was followed-up at 6 and 12 months"

**Spot the design! Three questions:**
Q1: Analytical (association)
Q2: Observational (exposure was not randomly allocated)
Q3: Cohort study (Exposure is measured BEFORE Outcome is measured)

“We randomly assigned adults attending U.K. National Health Service stop-smoking services to either nicotine-replacement products of their choice or an e-cigarette starter pack with a recommendation to purchase further e-liquids of the flavor and strength of their choice. Treatment included weekly behavioral support for at least 4 weeks. The primary outcome was sustained abstinence for 1 year, which was validated biochemically at the final visit”

**Spot the design! Three questions:**

Q1: Analytical (association)

Q2: Experimental (exposure was randomly allocated) - RCT

Q3: Not Applicable