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CMED 305

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# Introduction to Study Designs

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**Learning Objectives:** By end of this session students will be able to:

1

List differences between descriptive and analytical study designs

2

Describe main types of study designs and their uses

3

Identify different study designs with examples



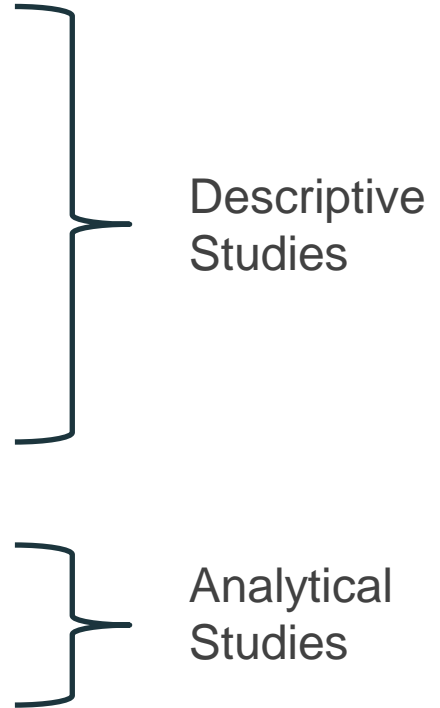
# **1 Study Design: Definition & The Five Ws**

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

# The Five Ws of Epidemiological Studies

- What = Diagnosis or Clinical Information
  - Who = Person
  - Where = Place
  - When = Time
- 

- Why / How = Causes / Risk Factors /  
Mode of Transmission



# { 2 The Study “Design Tree” }

# Remember PICOT ?

**ALL** research questions (**Descriptive AND Analytical**) have the below similar components:

- A **defined population (P)** from which groups of subjects are studied
- **Outcomes (O)** that are measured
- **Time (T)** frame

**ANALYTICAL** research questions have the additional two components:

- **Intervention (I)** that is applied to a groups of subjects
- **Comparison (C)** group without the intervention



# Remember??

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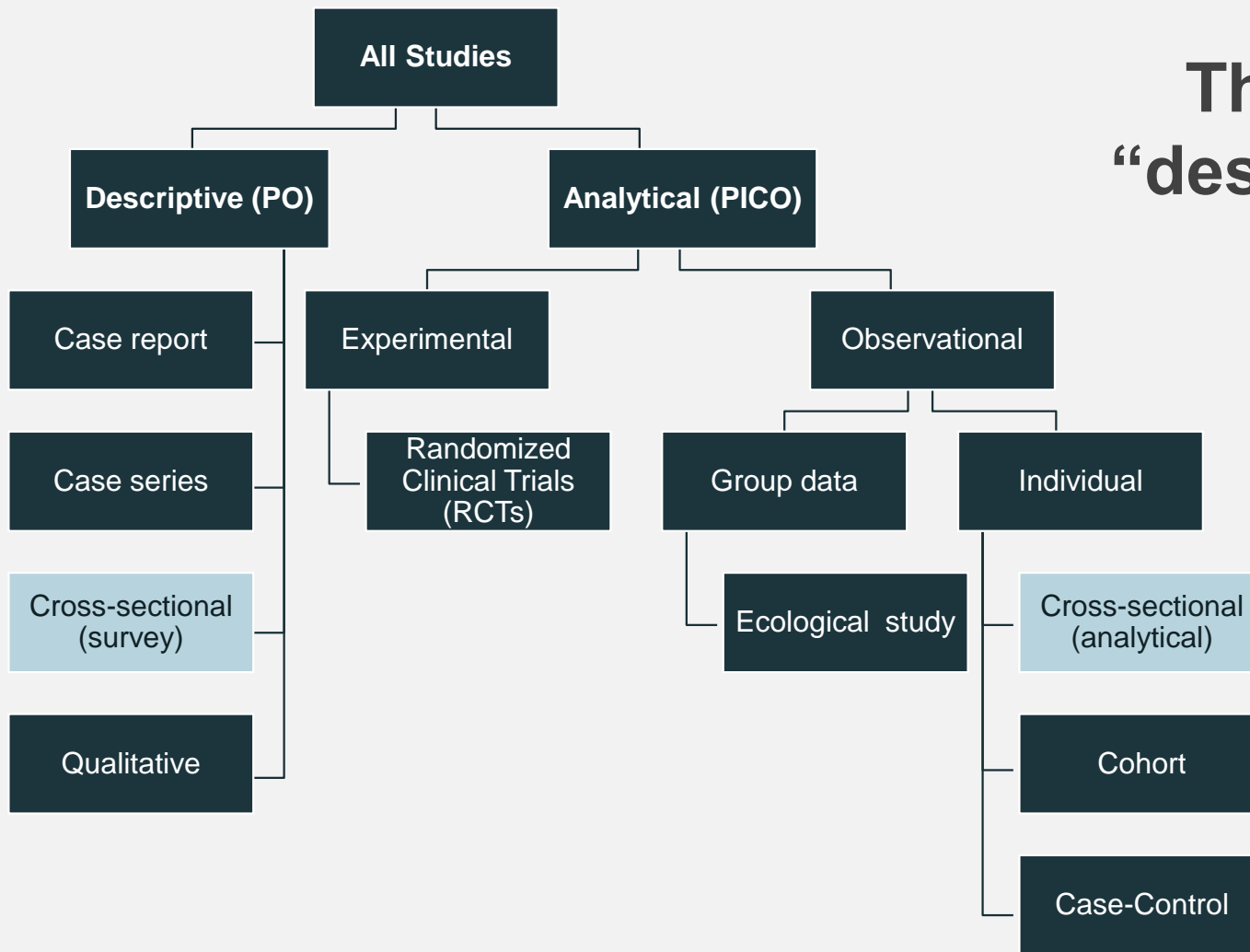
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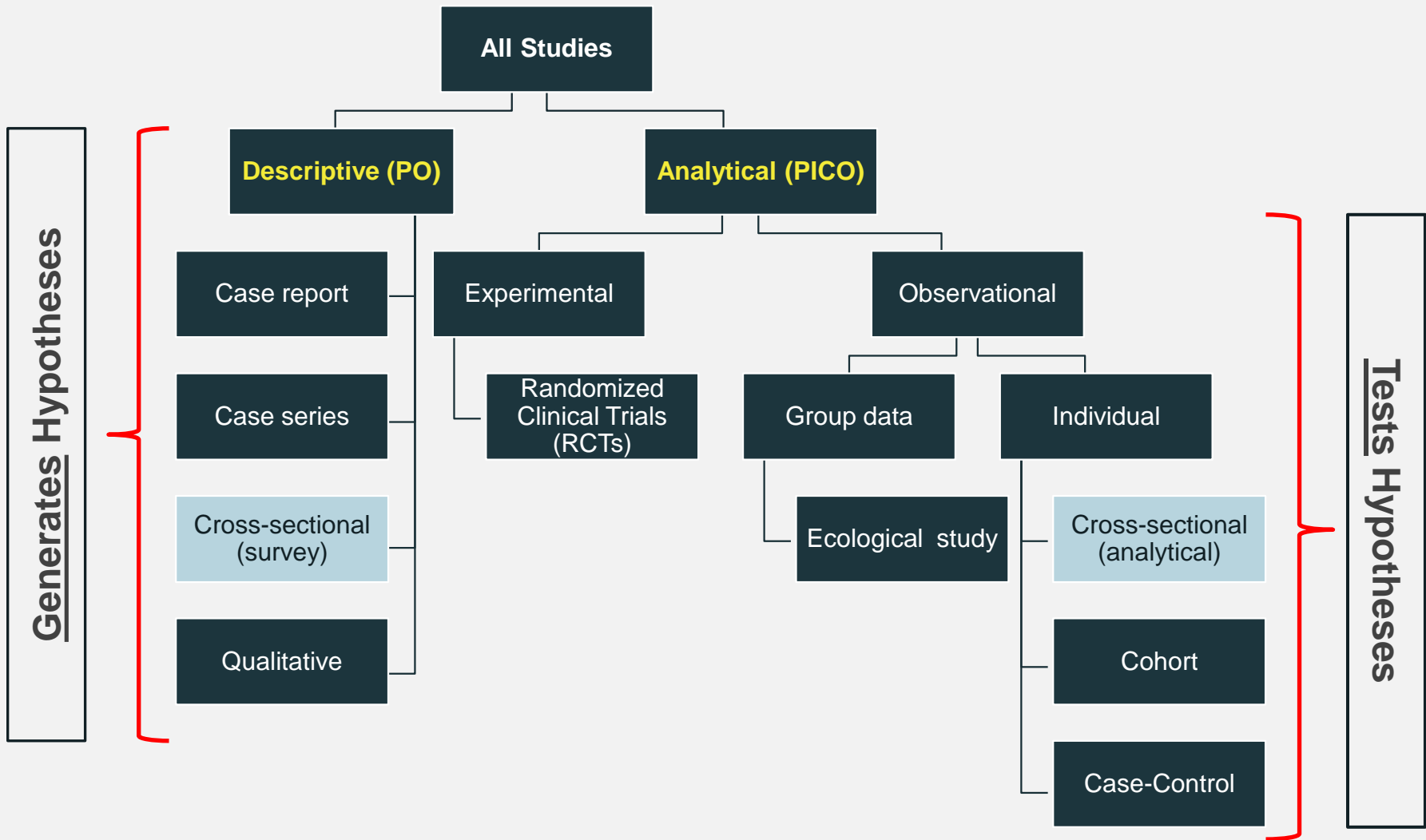
clear research question facilitates  
choosing the optimal **study design**

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# The study “designs tree”



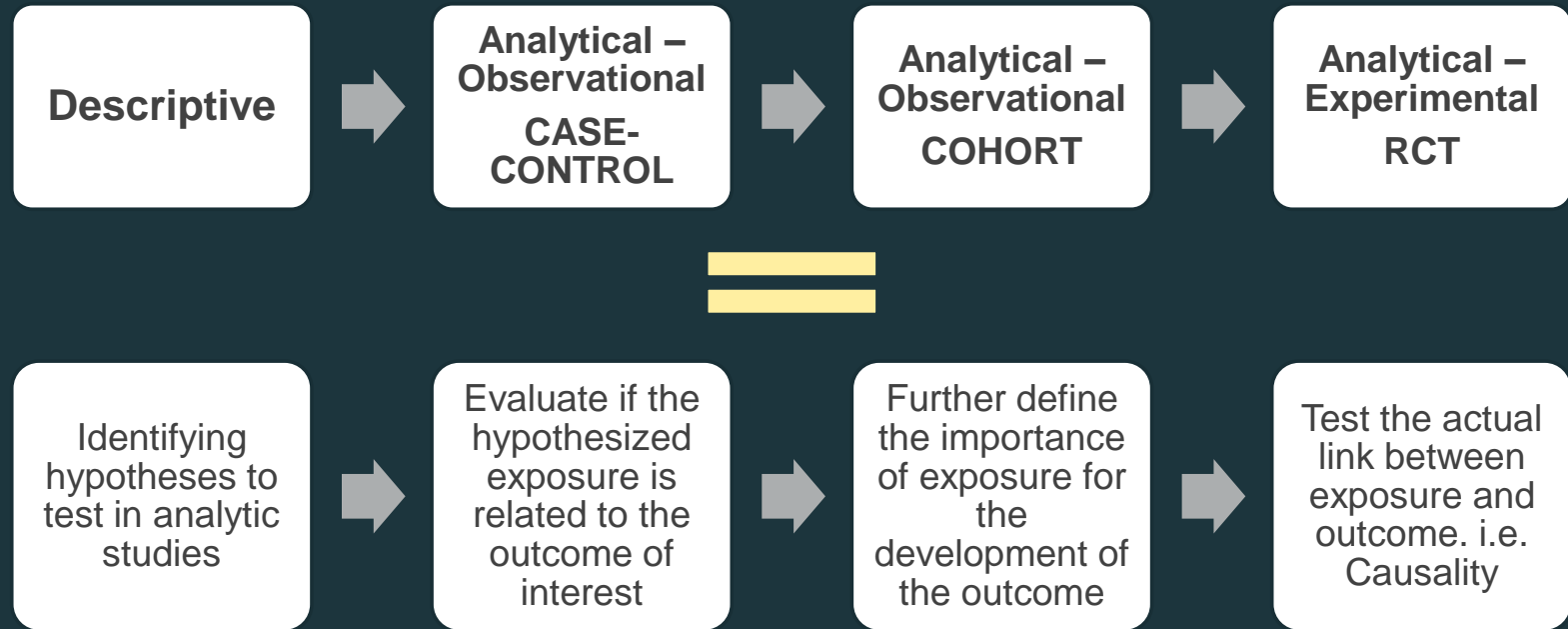


Whether a study is **hypothesis-testing** or **hypothesis-generating** depends on:

1. The sequence of past studies; and
2. The present state of knowledge (i.e., whether a hypothesis currently under evaluation was suggested by a previous study).

# Sequence of Study Design

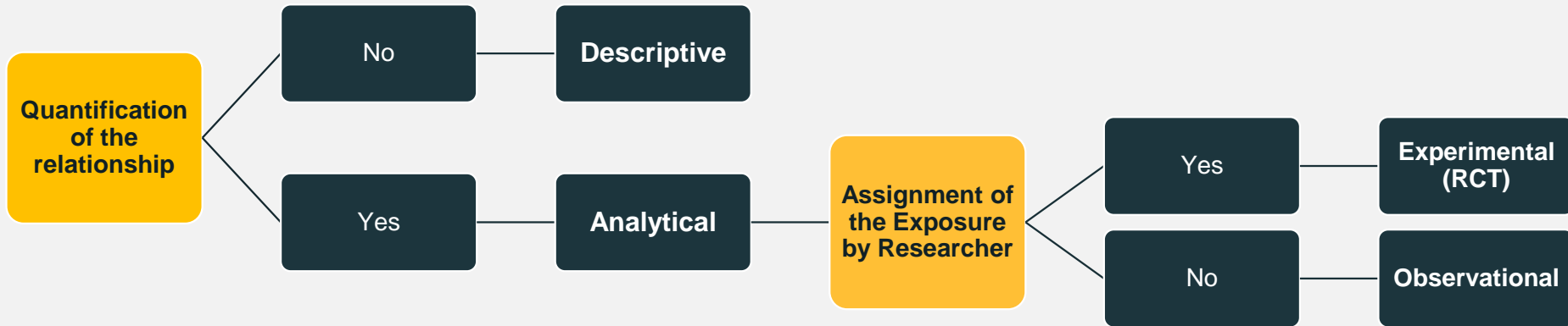
Increasing Knowledge of Exposure / Outcome (Strength of Evidence)



Two **IMPORTANT DISTINCTIVE Factors** in Study Designs:

1- **Quantification of Relationship** between Exposure and Outcome

2- **Researcher Assignment** (Manipulation) of Exposure



# { 3 Types of Studies: Uses, Comparisons and Examples }

## Descriptive Studies

Study Design	Case Report	Case-Series	Cross-Sectional (Survey)	Qualitative
Study 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	<ul style="list-style-type: none"> <li>Detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an <u>individual patient</u>.</li> <li>Typically an <u>unusual/novel occurrence</u></li> </ul>	Detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of a <u>group of patients or cases with similar issue</u> .	<ul style="list-style-type: none"> <li>Study <u>prevalence</u> of health related events at a <u>point in time/snapshot</u></li> <li>Often used to study conditions that are relatively frequent with long duration of expression (nonfatal, chronic conditions)</li> </ul>	Answers the 'why?' questions
Advantages	<ul style="list-style-type: none"> <li>Detecting novelties</li> <li>Generating hypotheses</li> <li>Allowing in-depth understanding</li> <li>Educational value</li> </ul>	<ul style="list-style-type: none"> <li>Useful for hypothesis generation</li> <li>Informative for very rare disease with few established risk factors</li> </ul>	<ul style="list-style-type: none"> <li>Cheap and simple.</li> <li>Ethically safe.</li> </ul>	<ul style="list-style-type: none"> <li>Provides depth and detail</li> <li>Creates openness</li> <li>Simulates people's individual experiences</li> </ul>
Dis-advantages	<ul style="list-style-type: none"> <li>Lack of ability to generalize</li> <li>No possibility to establish cause-effect relationship</li> <li>Publication bias</li> </ul>	<ul style="list-style-type: none"> <li>Cannot study cause and effect relationships</li> <li>Cannot assess disease frequency</li> </ul>	Not suitable for studying <u>rare</u> or highly fatal diseases or a <u>disease with short duration</u>	<ul style="list-style-type: none"> <li>Usually fewer people studied</li> <li>Less easy to generalize</li> <li>Dependent on skills of the researcher</li> </ul>



# Analytical Studies

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

## Examples of Analytical Studies

**Exposure:**  
Flu  
Vaccine



**Outcome:**  
Flu

Experimental - RCT

- Study of a new flu vaccine

Observational –  
Cohort

- Study of who have received flu vaccine and did they get ill

Observational –  
Case-Control

- Study of who has flu and if they were vaccinated

Observational –  
Cross-Sectional

- Study of how many cases of flu in females and males

Observational –  
Ecological

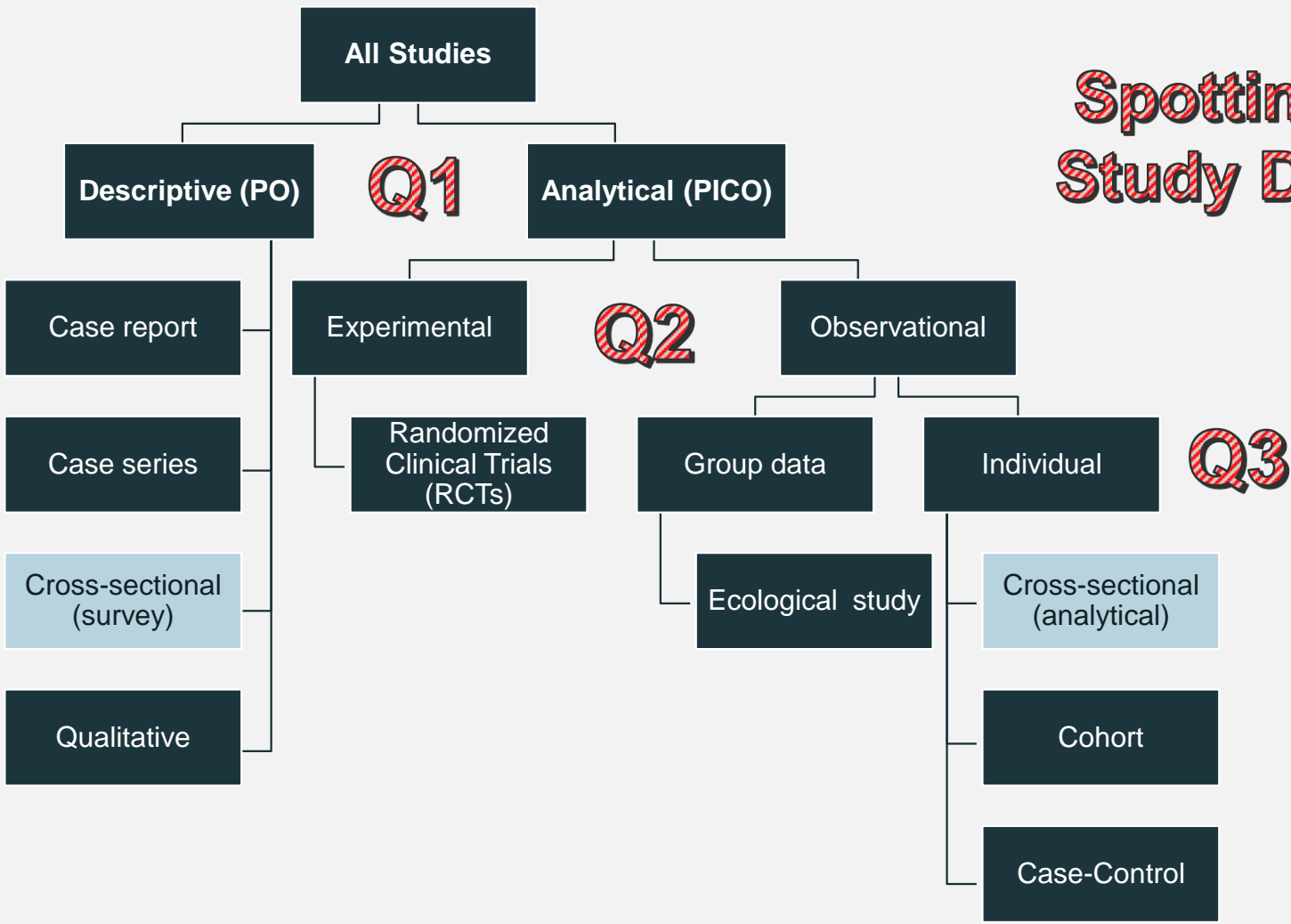
- Compares cases of flu and air quality in two countries

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**Spotting the Study Design**

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# Spotting the Study Design



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



“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**

Bonilla, Alex, Alexander J. Blair, Suliman M. Alamro, Rebecca A. Ward, Michael B. Feldman, Richard A. Dutko, Theodora K. Karagounis, Adam L. Johnson, Erik E. Folch, and Jatin M. Vyas. "Recurrent spontaneous pneumothoraces and vaping in an 18-year-old man: a case report and review of the literature." *Journal of Medical Case Reports* 13, no. 1 (2019): 1-6.

“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

Gibson, Cameron JS, Niknam Eshraghi, Nathan A. Kemalyan, and Charles Mueller. "Electronic cigarette burns: A case series." Trauma 21, no. 2 (2019): 103-106.



“We conducted 12 focus groups and two individual interviews with young 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

Harrell, Paul T., Thomas H. Brandon, Kelli J. England, Tracey E. Barnett, Laurel O. Brockenberry, Vani N. Simmons, and Gwendolyn P. Quinn. "Vaping Expectancies: A Qualitative Study among Young Adult Nonusers, Smokers, Vapers, and Dual Users." *Substance abuse: research and treatment* 13 (2019): 1178221819866210.

“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 ( $\geq 18$  years old) making their 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

Polosa, Riccardo, Pasquale Caponnetto, Fabio Cibella, and Jacques Le-Houezec. "Quit and smoking reduction rates in vape shop consumers: a prospective 12-month survey." *International journal of environmental research and public health* 12, no. 4 (2015): 3428-3438.

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**Check the Video Here**

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# Thank you!

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via email):**

Mondays & Wednesdays

11 AM – 1 PM

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