CMED 305

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

                                                                                       Descriptive Studies

- Why / How   = Causes / Risk Factors / Mode of Transmission   Analytical Studies
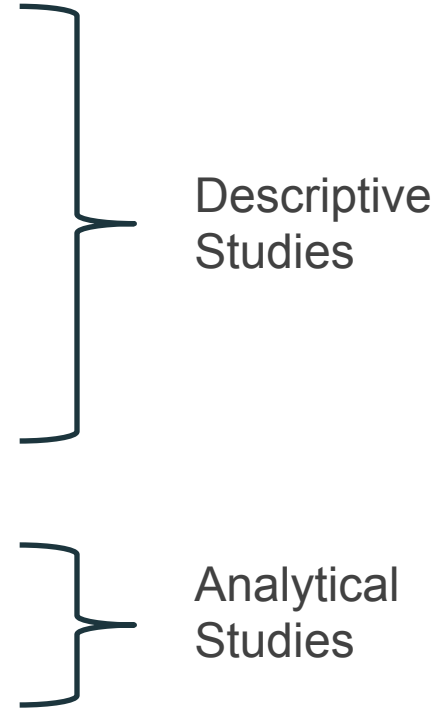
{ 2 } The Study "Design Tree"

Remember PICOT ?

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

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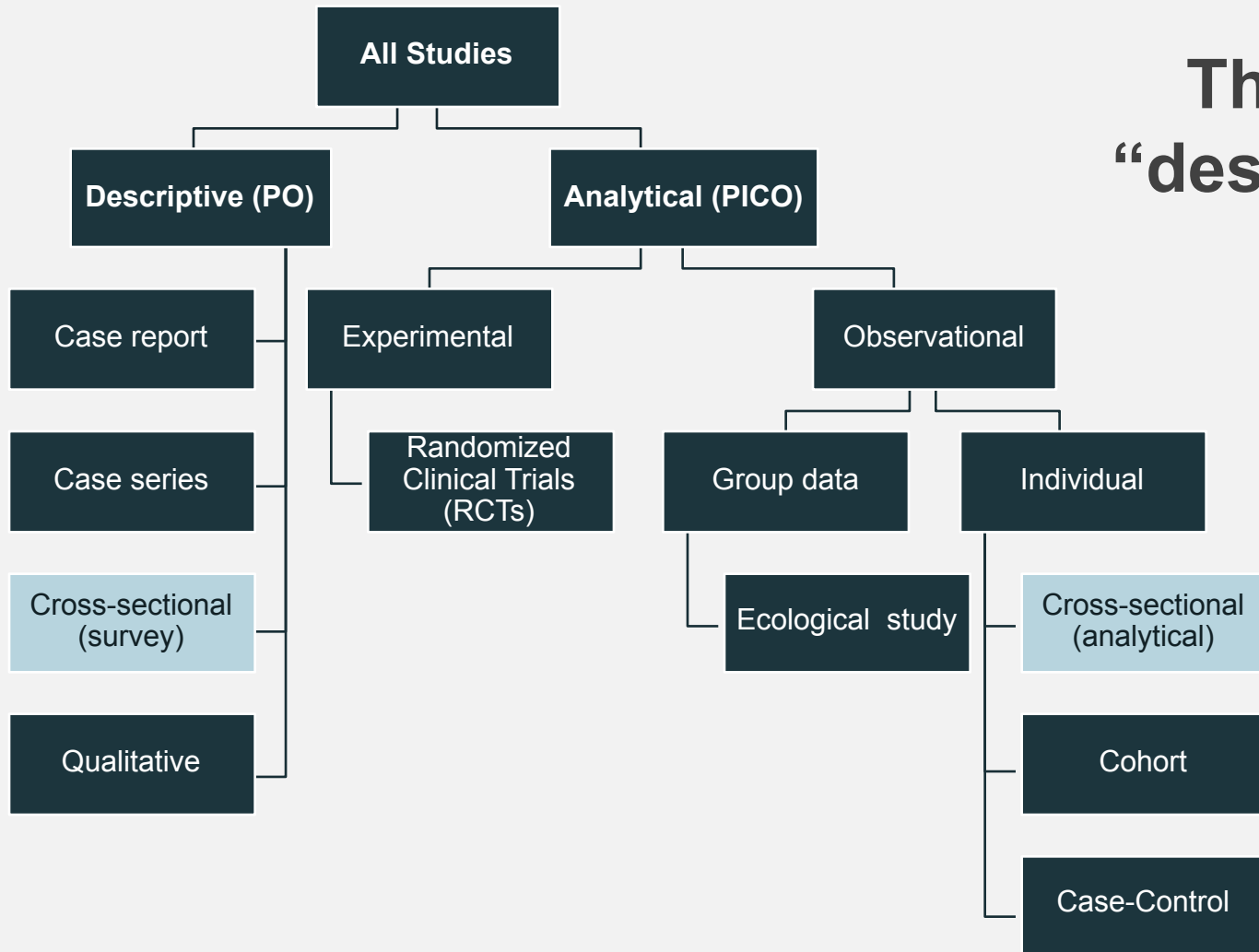- **Outcomes (O)** that are measured
- **Time (T)** frame

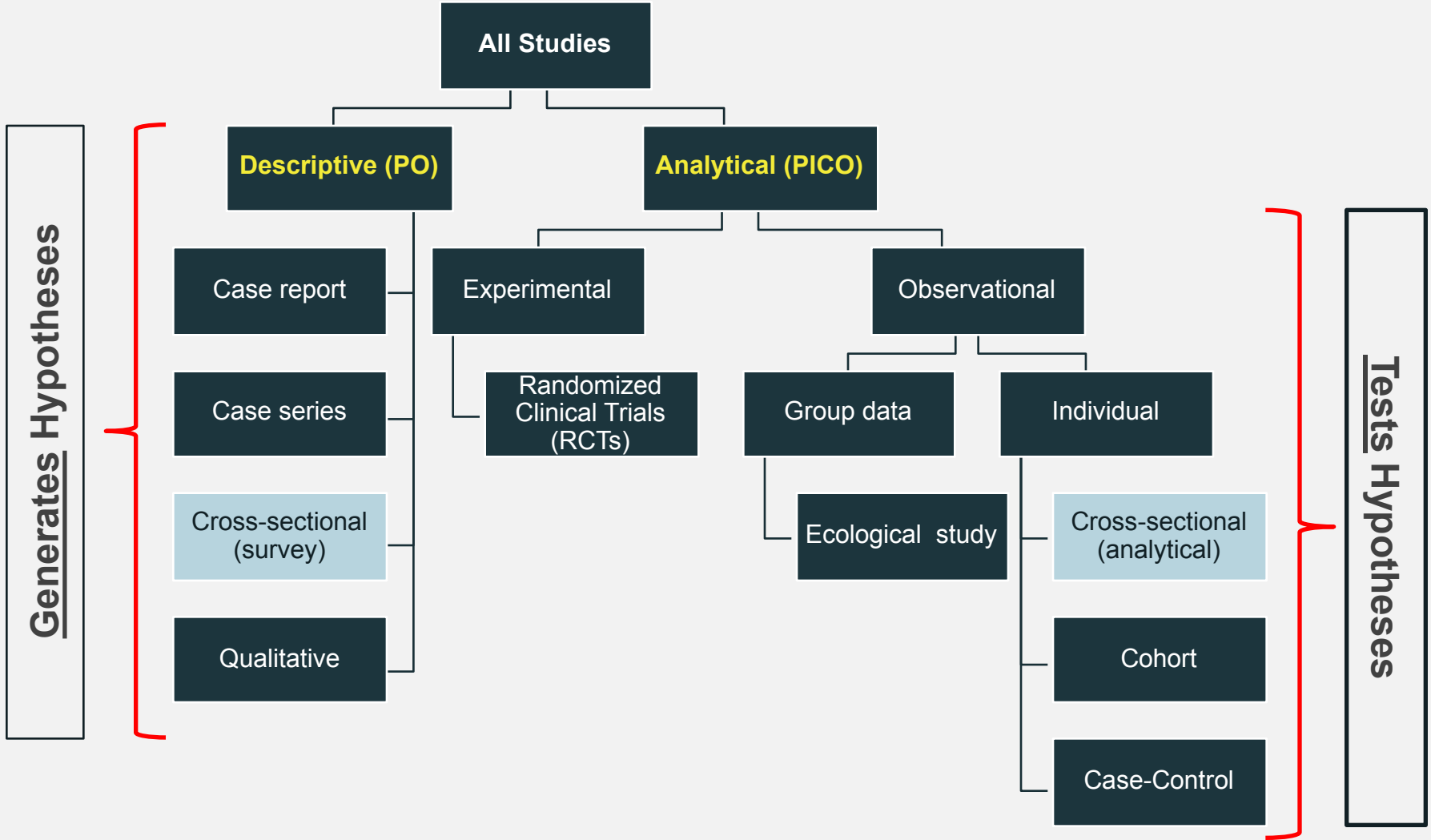**ANALYTICAL** research questions have the additional two components:

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

Remember??

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

The study "designs tree"

All Studies

Descriptive (PO)

- Case report
- Case series
- Cross-sectional (survey)
- Qualitative

Analytical (PICO)

Experimental
- Randomized Clinical Trials (RCTs)

Observational

Group data
- Ecological study

Individual
- Cross-sectional (analytical)
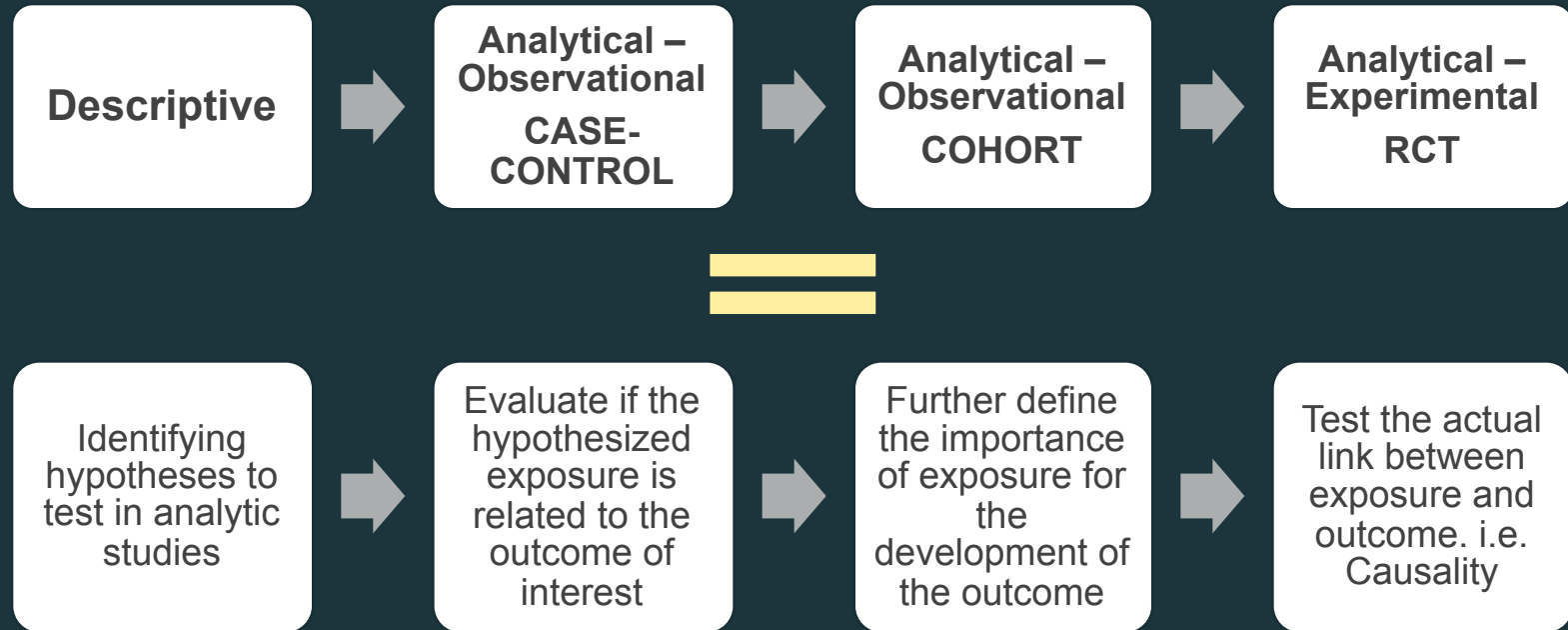- Cohort
- Case-Control

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).
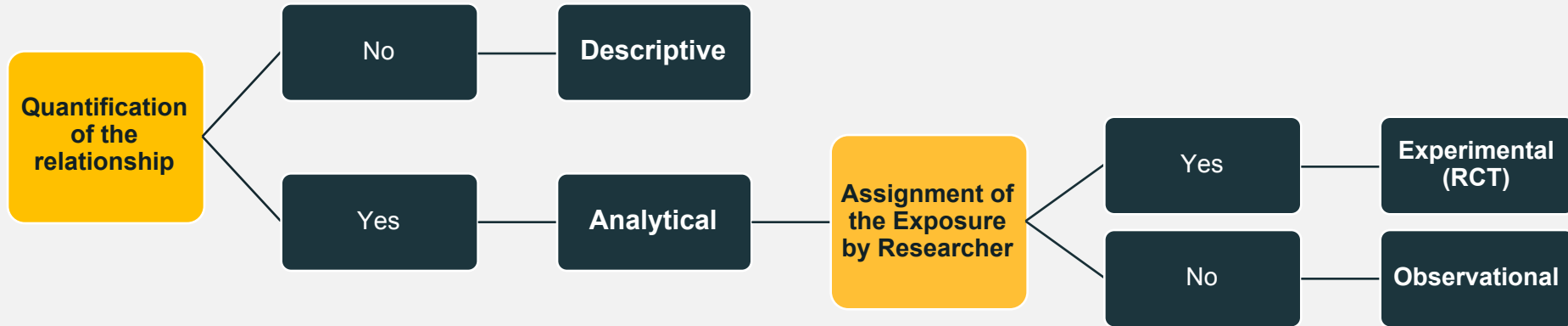
Sequence of Study Design

Increasing Knowledge of Exposure / Outcome (Strength of Evidence) →

Descriptive	Analytical – Observational CASE-CONTROL	Analytical – Observational COHORT	Analytical – Experimental RCT

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Identifying hypotheses to test in analytic studies	Evaluate if the hypothesized exposure is related to the outcome of interest	Further define the importance of exposure for the development of the outcome	Test the actual link between exposure and outcome. i.e. Causality

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

1- Quantification of Relationship between Exposure and Outcome

2- Researcher Assignment (Manipulation) of Exposure

	Descriptive Studies			
Study Design	**Case Report**	**Case-Series**	**Cross-Sectional (Survey)**	**Qualitative**
Study Population	Single case			
Primary Use	• Detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an <u>individual patient</u>. • Typically an <u>unusual/novel occurrence</u>			
Advantages	• Detecting novelties • Generating hypotheses • Allowing in-depth understanding • Educational value			
Dis-advantages	• Lack of ability to generalize • No possibility to establish cause-effect relationship • Publication bias			

Analytical Studies

	Experimental	Observational		
Data Level	Individual Data	Group Data	Individual Data	
Study Design	RCT			
Study Population	Highly selected population, Highly controlled environment. Allocation of exposure is made by the researcher.			
Directionality	Exposure is assigned BEFORE Outcome is measured			
Primary Use	Efficacy of an intervention / Causality			

Examples of Analytical Studies

Exposure:
Flu Vaccine

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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

{ 3 Spotting the Study Design }
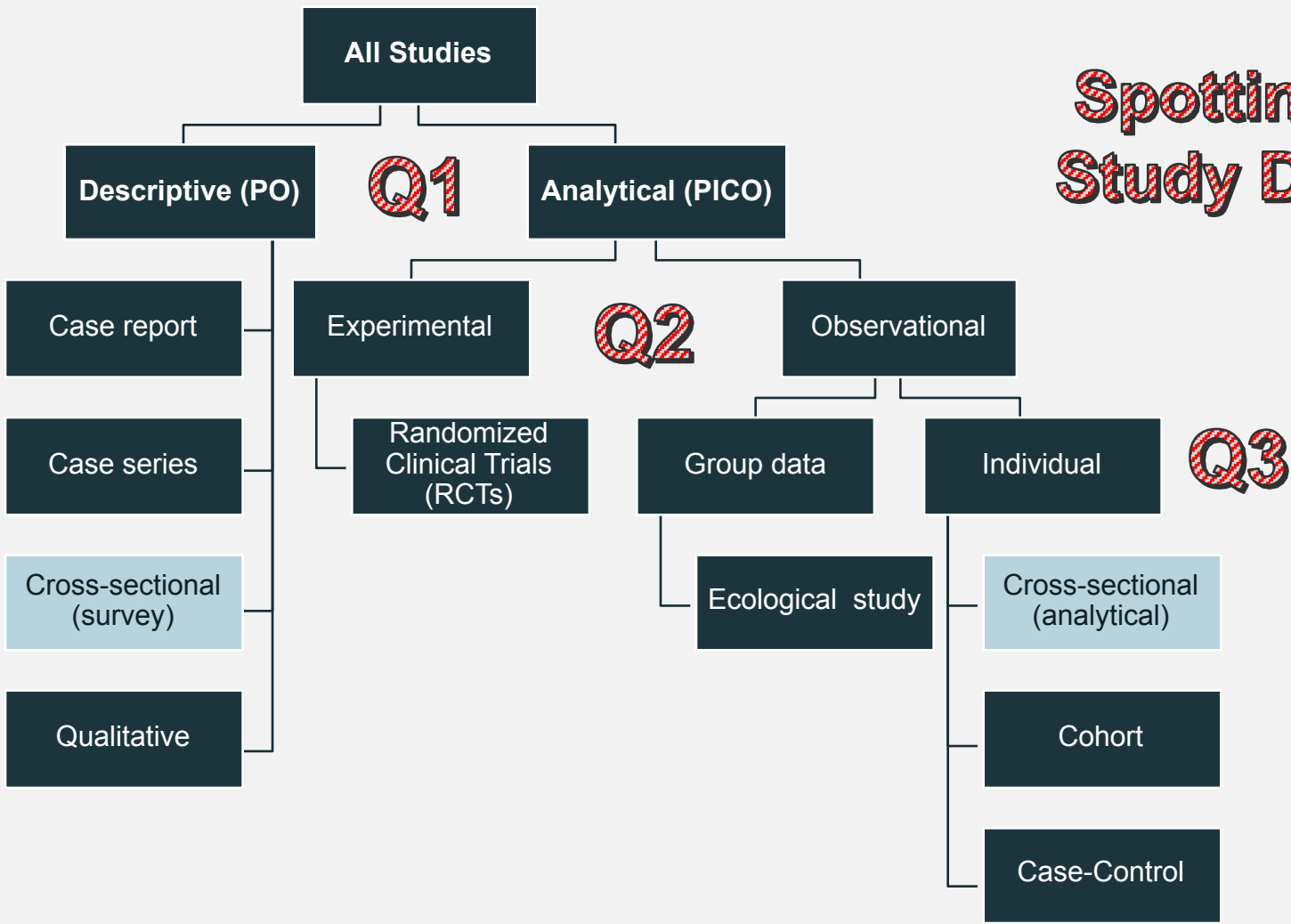
The type of study canbe spotted by looking at **three issues** as per the "Design Tree":

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 <u>after</u> the exposure (intervention) ➔ Cohort study
2. At the <u>same time</u> as the exposure (intervention) ➔ Cross-sectional
3. <u>Before</u> 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)

Hansen, Julia, Reiner Hanewinkel, and Matthis Morgenstern. "Electronic cigarette marketing and smoking behaviour in adolescence: a cross-sectional study." *ERJ open research* 4, no. 4 (2018): 00155-2018.

"Adult smokers (≥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)

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.

"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.

Check the Video Here

Thank you!

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References:

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- Hulley, Stephen B., ed. Designing clinical research. Lippincott Williams & Wilkins, 2007.

- Haynes, R. Brian. Clinical epidemiology: how to do clinical practice research. Lippincott williams & wilkins, 2012.

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