جامعة الملك سعود
King Saud University

CMED 305

Introduction to Study Designs

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Learning Objectives: By the 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.

Remember??

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

There are 2 main categories of epidemiological study designs:

1. Descriptive studies
2. Analytical studies

The Five Ws of Epidemiological Studies

- What = Outcome of interest (Diagnosis)
- Who = Population of interest
- Where = Place
- When = Time

Descriptive Studies

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

Analytical Studies

{2 The Study “Design Tree”}

Remember PICOT ?

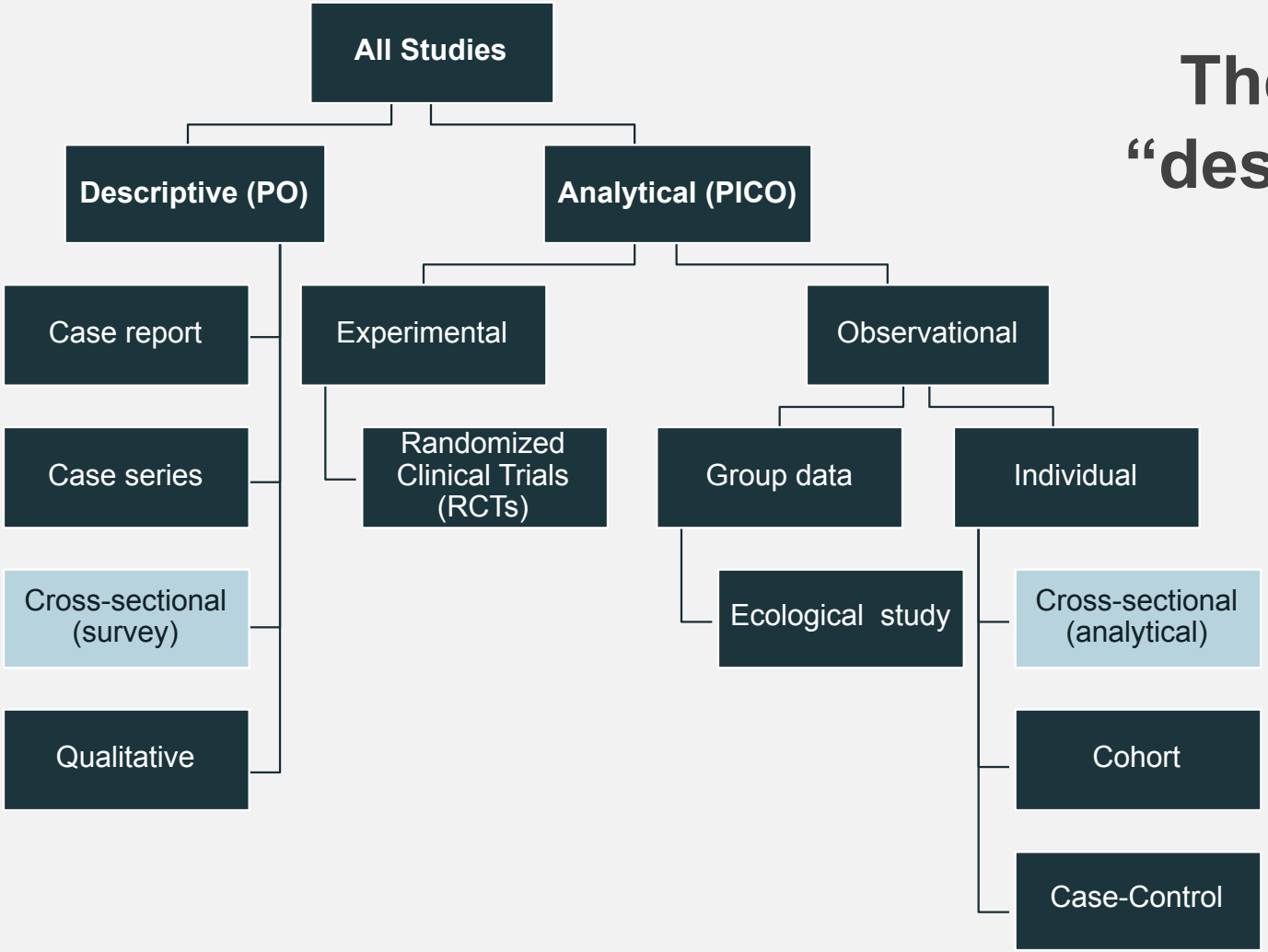
ALL research questions **(Descriptive AND Analytical)** have the below similar components:

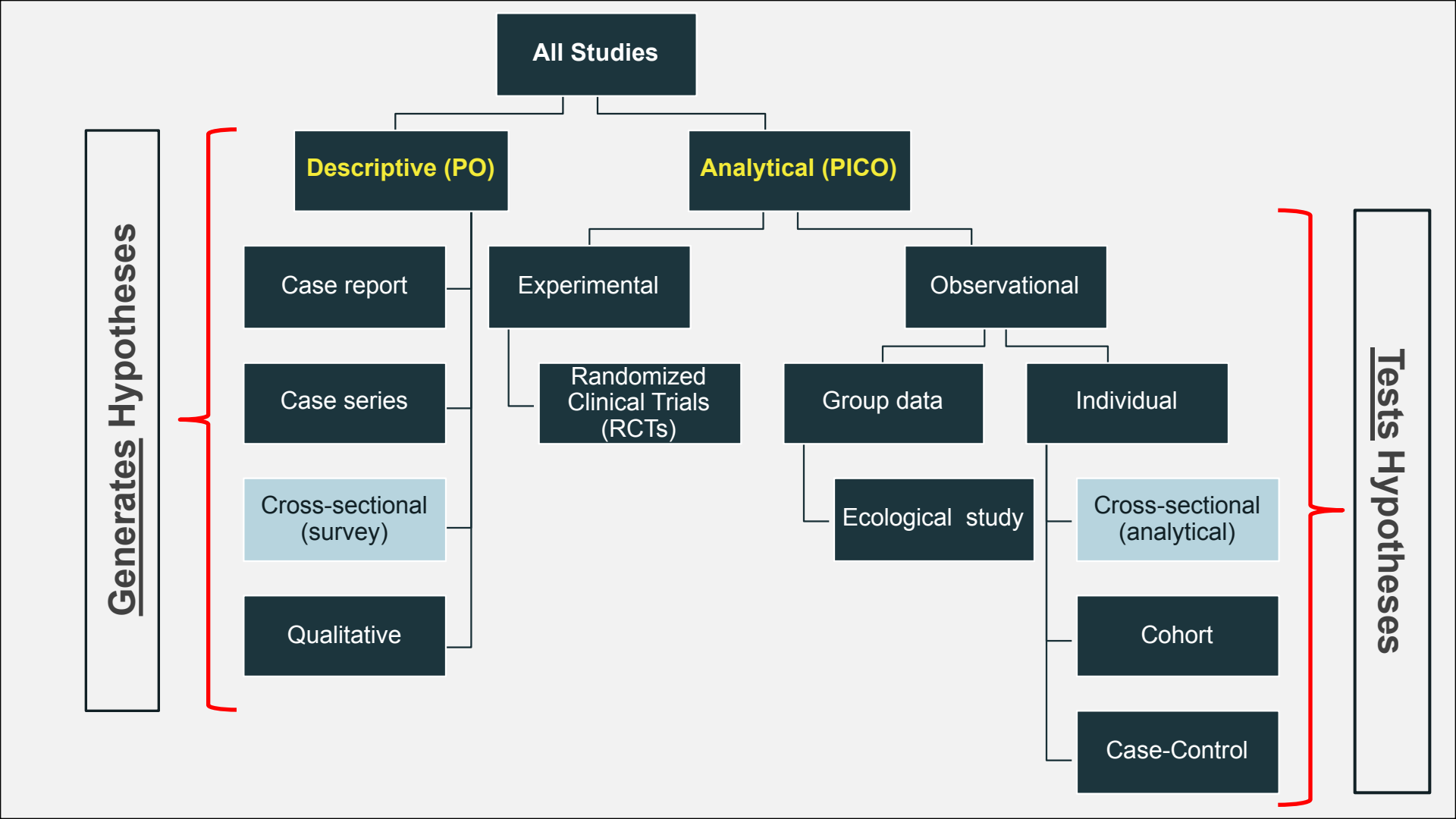
- A **defined population (P)** from which groups of subjects are studied
- **Outcomes (O)** that are measured
- **Time (T)** frame

ANALYTICAL research questions have the additional two components:

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

The study “design tree”



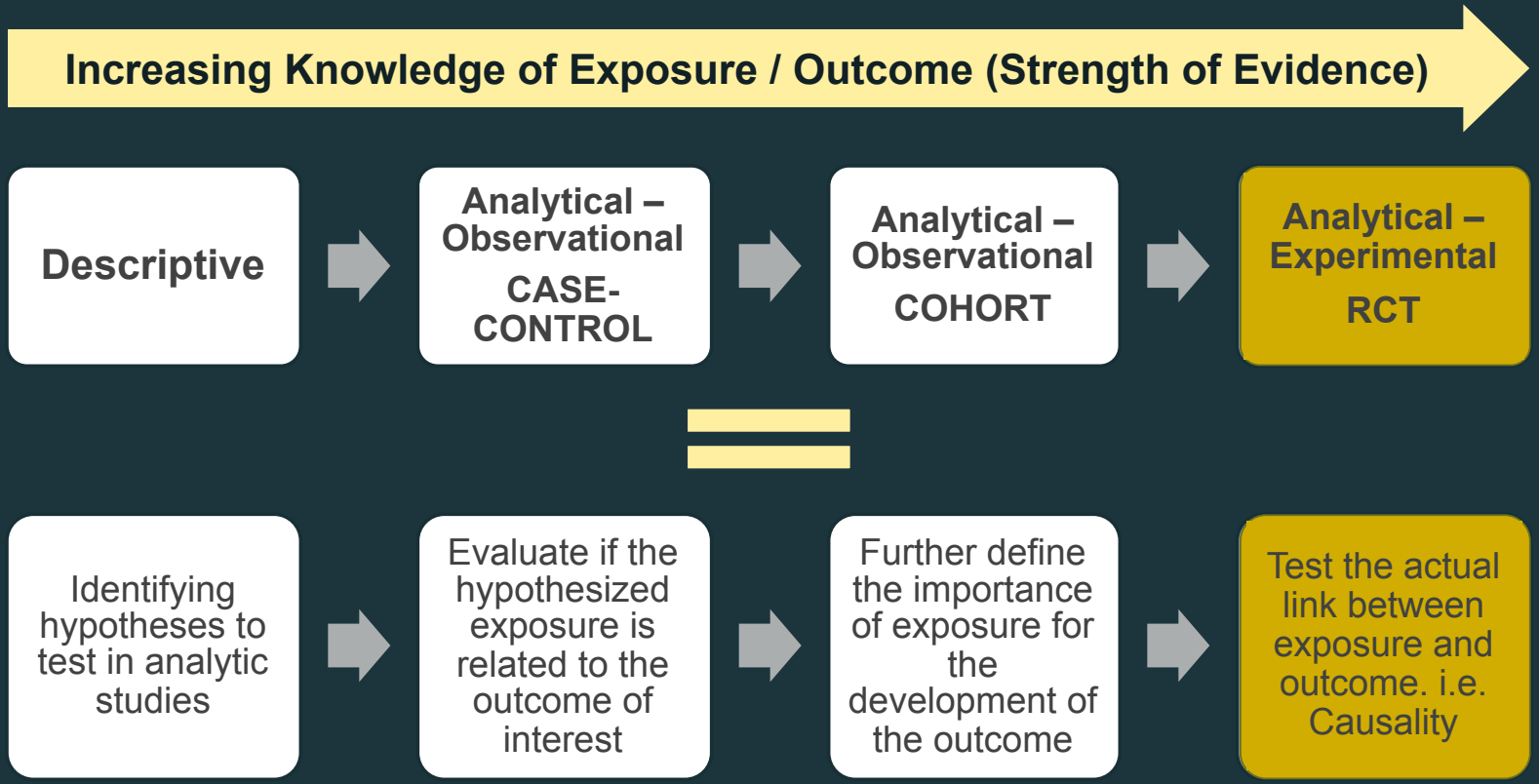

All Studies
Descriptive (PO)
Analytical (PICO)
Case report
Case series
Cross-sectional (survey)
Qualitative
Experimental
Randomized Clinical Trials (RCTs)
Observational
Group data
Individual
Ecological study
Cross-sectional (analytical)
Cohort
Case-Control
Generates Hypotheses
Tests Hypotheses

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

1. What types of studies have already been conducted

2. The present state of knowledge
   - What do we know about the outcome of interest?
   - What if any risk factors have been investigated?

Sequence of Study Design

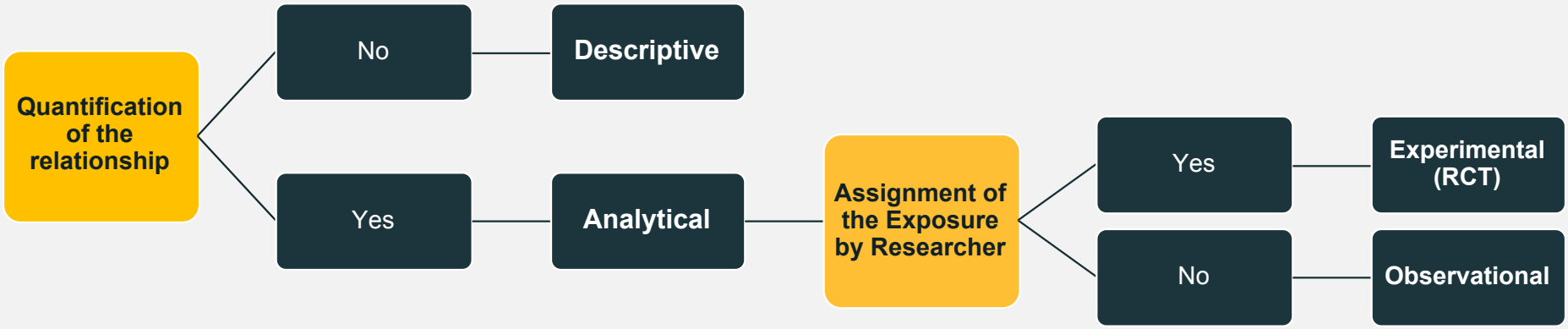


From observational studies we can infer causal relationships, from experimental studies we can confirm causal relationships.

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	Single sample from larger population
Primary Use	• Detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an individual patient. • 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 • Often used to study conditions that are relatively frequent with long duration of expression (nonfatal, chronic conditions)	Answers the 'why?' questions • Interviews • Focus groups
Advantages	• Detecting novelties • Allowing in-depth understanding • Educational value	• Informative for very rare disease with few established risk factors	• Inexpensive and simple. • Ethically safe.	• Provides depth and detail • Creates openness • Simulates people's individual experiences
Dis-advantages	• Lack of ability to generalize • No possibility to establish cause-effect relationship	• Cannot study cause and effect relationships • Cannot assess disease frequency	Not suitable for studying rare or highly fatal diseases or a disease with short duration	• Usually fewer people studied • Difficult to generalize • Dependent on skills of the researcher

Hypothesis Generating

Analytical Studies

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

Hypothesis Testing

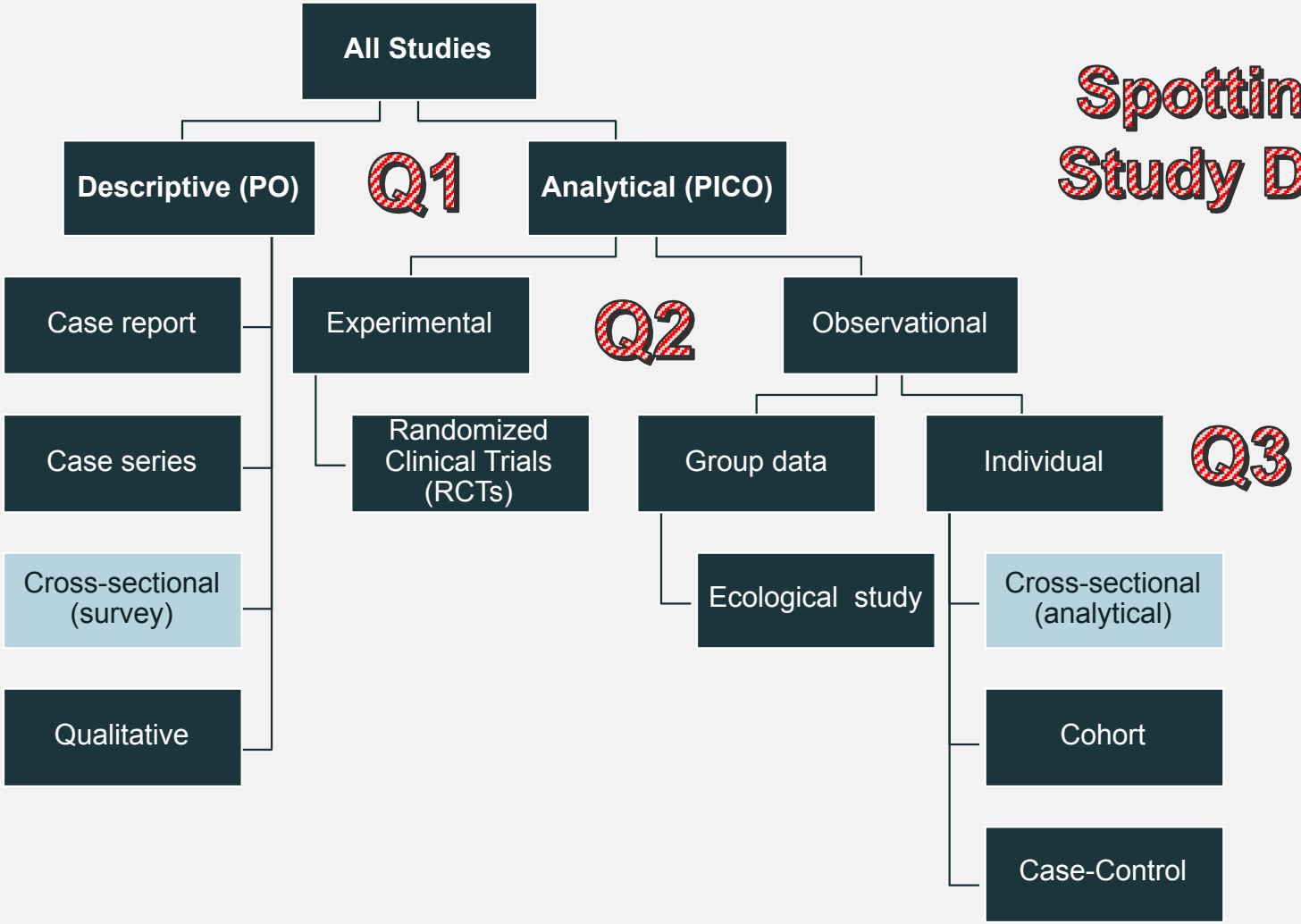
Examples of Analytical Studies

Strength of Evidence

Ecological	• Compares cases of flu and flu vaccine in two countries
Cross-Sectional	• KKUH hospital flu cases and vaccination status in females vs males
Case-Control	• Comparing a group of flu cases to non-cases based on vaccination status
Cohort	• Following vaccinated and non-vaccinated groups over time to see if they get the flu
Experimental – RCT	• Same as cohort but researcher randomly allocates the flu vaccine

{3 Spotting the Study Design }

Spotting the Study Design



The type of study can be determined by looking at **three factors** (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 ➔ Experimental
2. No ➔ Observational

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

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


Case Studies

“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.”

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.

For further educational resources Here

Thank you

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