Research
442

Revised by
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Introduction to study designs

Lecture No. 7

Objectives:

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.

~ This lecture was presented by **Dr. Kholood Altassan**
~ It is included in the **Midterm Exam**
~ We highly recommended reading the **Ayah** in the first page

Slides

Color code

Original text
Dr. Notes
Important
Golden note
Extra

Editing file

Study Design: Definition & The Five Ws

1

Definition

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: A clear research question facilitates choosing the optimal study design.

سُورَةُ العَنكبُوت

وَٱلَّذِينَ جَٰهَدُواْ
فِينَا لَنَهۡدِيَنَّهُمۡ سُبُلَنَاۚ وَإِنَّ ٱللَّهَ لَمَعَ ٱلۡمُحۡسِنِينَ ٦٩

المختصر في التفسير

والذين جاهدوا أنفسهم ابتغاء مرضاتنا لنوفقنهم لإصابة الطريق المستقيم، وإن الله مع المحسنين بالعون والنصر والهداية.

Study Design Categories

There are 2 main categories of epidemiological study designs:

- Descriptive Studies
- Analytical Studies

The question your asking, helps determine the best type of study you need to conduct.

Descriptive epidemiologic studies are used to **assess and monitor the health of communities** and **identify health problems and priorities.** They also lend (يعيرون) 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**, ultimately seeking to reach **causal conclusions.**

The five Ws of Epidemiological Studies [1]

Who	Where	When	What	Why/How
=Population of interest	=Place	=Time	=Outcome of interest	=Exposures/Risk Factors/Mode of transmission

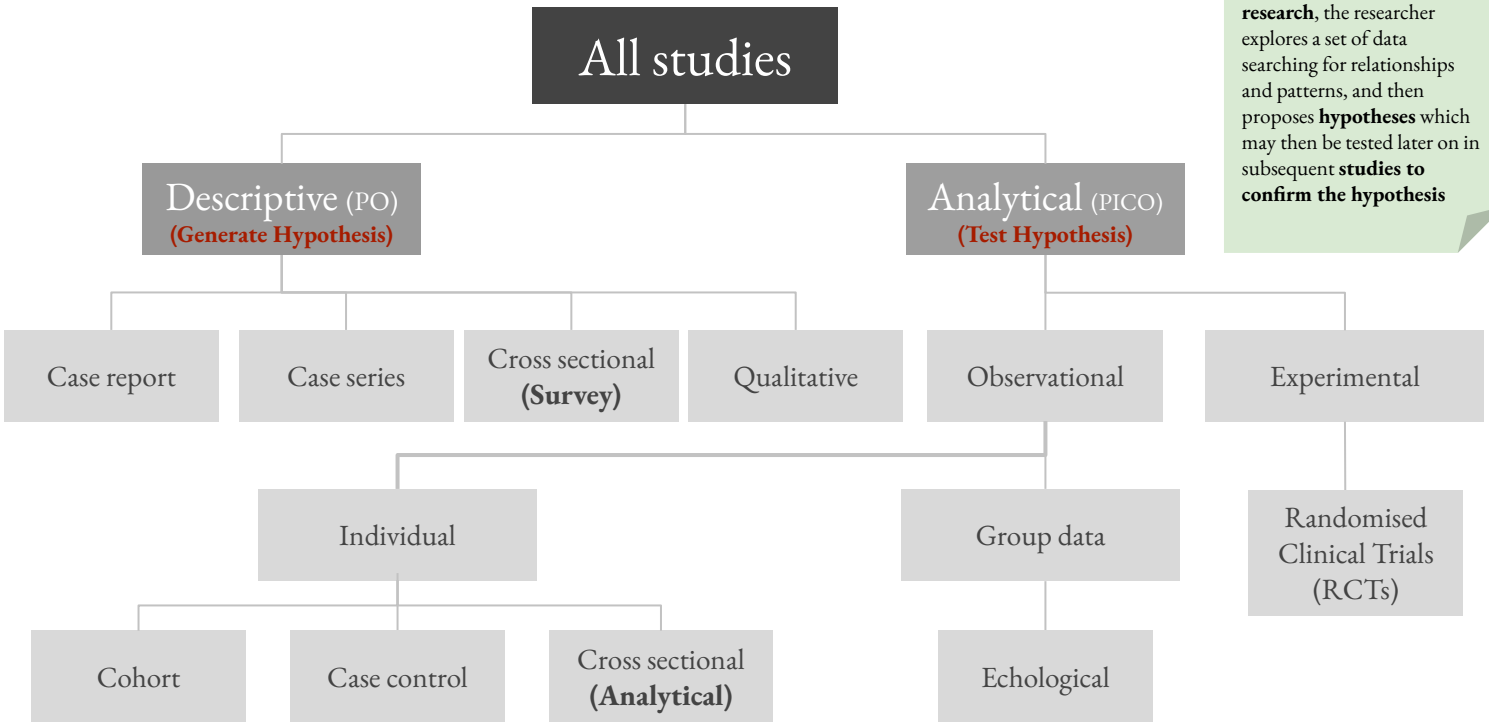
Descriptive studies
The effect

Analytical studies
The cause

[1] WHAT refers to the outcome you're interested in studying. That could be a specific disease entity or diagnosis, for instance stomach cancer, or a biomarker like lead levels in the blood.
WHO is the population of interest. This could be male patients at king khalid university hospital, or adults in the city of Riyadh.
WHERE is the geographical location limiting your study population.
And WHEN is the time frame of the study.
Both descriptive and analytical studies will have these 4. Analytical studies will additionally have the 5th W; WHY which represents the exposure or risk factors that we want to investigate as potentially causing the outcome of interest. For instance, if you're studying coronary artery disease as your outcome of interest, then you might be looking at smoking, obesity, lifestyle factors, demographics as your WHY.
To summarize we study *what, who, where*, and *when*, or in other words, clinical data plus person, place, and time information, through descriptive epidemiology, which investigates the distribution of diseases or conditions.
We study *why and how*, or in other words, causes, risk factors, and modes of transmission, through analytic epidemiology, which investigates the determinants of diseases or conditions.

The Study "Design Tree"

In **hypothesis generating research**, the researcher explores a set of data searching for relationships and patterns, and then proposes **hypotheses** which may then be tested later on in subsequent **studies to confirm the hypothesis**



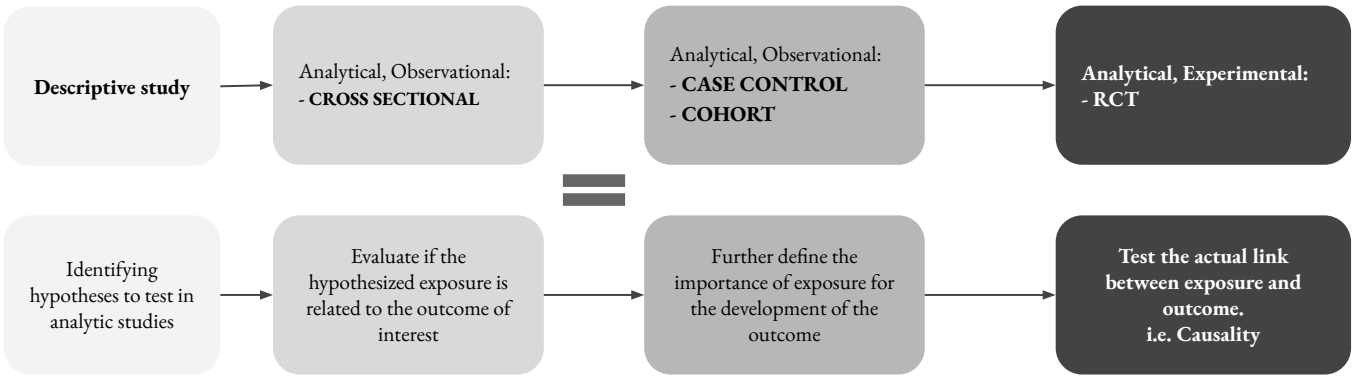
- Whether a topic requires a **hypothesis-testing** or **hypothesis-generating** study, it depends on:

1. What types of **studies** have **already** been **conducted**
2. The **present** state of **knowledge**:
   a. What do we know about the outcome of interest?
   b. What if any risk factors have been investigated?

Sequence of study design [1]

[1] Each step in the framework provides new and important information. **Descriptive** studies are useful for **identifying hypotheses** to later test in analytical studies. **Cross-sectional** studies are then usually applied to **evaluate** if the **hypothesized** exposure is related to the outcome of interest. Subsequently, **case-control and cohort studies** are applied to further **define** the importance of **exposure** for the development of the outcome. Ultimately experimental studies are able to confirm or reject the causal association between exposure and outcome without bias. This is why RCTs are considered the gold standard in epidemiological studies. Until an experimental study is conducted you cannot use the word "causal or causing" to describe the relationship between exposure and outcome. You infer causality but you cannot confirm.

Increasing Knowledge of Exposure/Outcome (Strength of Evidence)

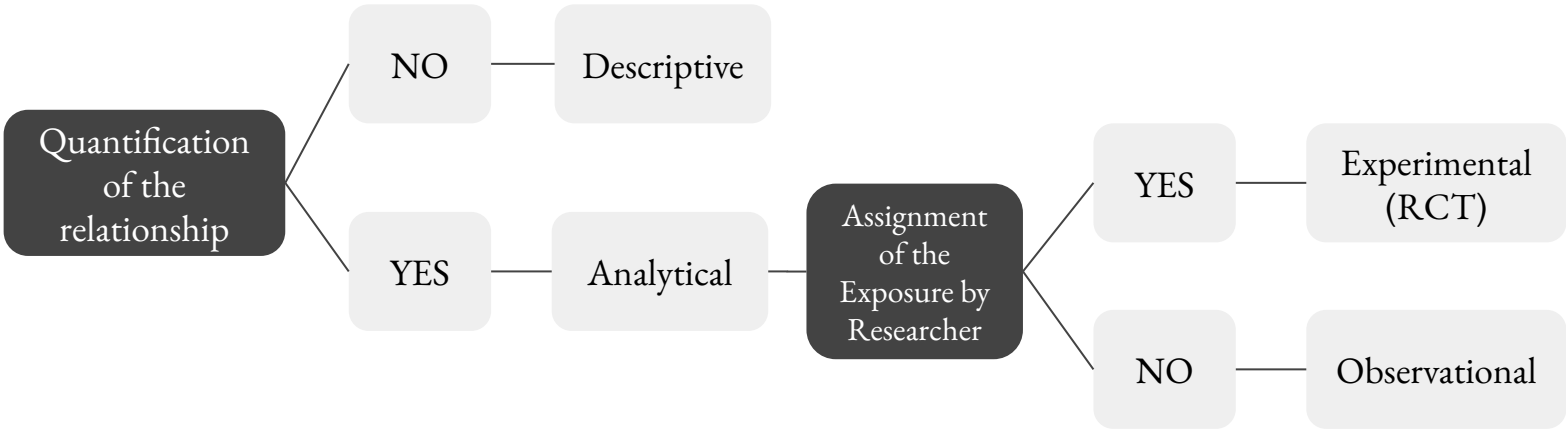


- From **observational** studies we can **infer causal relationships,** from **experimental** studies we can **confirm** causal relationships.

Study design Cont.

Two IMPORTANT DISTINCTIVE Factors in Study Designs:

1. **Quantification** of Relationship between Exposure and Outcome
2. **Researcher Assignment** (Manipulation) **of Exposure**



Another way to look at classification of study designs. There are 2 factors that distinguish study designs:
1. Quantifying the relationship between various exposures and the outcome of interest.
2. Whether or not the exposure was assigned by the researcher.
First looking at quantification of the relationship, if you are not doing any measuring of the association between exposure and outcome, meaning you are not doing any statistical analyses then this would be considered a **descriptive** study.
On the other hand, if you are conducting some type of **data analysis** to quantify the relationship between exposure and outcome, then as the name would suggest this would be an **analytical study.**
Now within analytical studies, we look at assignment of exposure. Are you, the research team, assigning an exposure to one group in your study population? If so, then you are conducting an experiment. If you are just observing the population without you yourself assigning the exposure to individuals, you're just observing without intervention then its an observational study.

Descriptive studies

Descriptive Studies

	Case Report	Case-Series	Cross-Sectional (Survey)	Qualitative
Study Population	Single case	Collection of similar cases	Single sample from larger population	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 relatively frequent conditions with long duration of expression (nonfatal, chronic conditions or behaviors)	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 • Cant establish cause-effect relationship	• Cannot assess disease frequency • Cannot establish cause-effect relationship	• Not suitable for studying rare or highly fatal diseases or a disease with short duration • Can't establish cause-effect relationship	• Fewer people studied • Difficult to generalize • Dependent on skills of the researcher • Can't establish cause-effect relationship

Qualitative: take a sample from small population and investigate with depth.

The CMED-305 faculty did it to change the course from the second year to be on the third year 😔.

Prevalence and incidence assess the frequency

Types of Studies: Uses, Comparisons and Examples

Analytical studies

Analytical Studies

	Observational *(NO allocation of exposure is made by the researcher)				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 – collects data on exposure and outcome; 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.	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 (retrospective)	Exposure is measured BEFORE Outcome is measured (prospective) or AFTER (retrospective)	Exposure is assigned BEFORE Outcome is measured (prospective)
Primary Use	Screening hypotheses at population level (BEWARE 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

Case-control always retrospective.

In cohort we **start** with the **exposure** or risk, then to see the the outcome, this helps to differentiate from **case-control**, which starts from the **outcome.**

Examples of analytical studies

Strength of Evidence

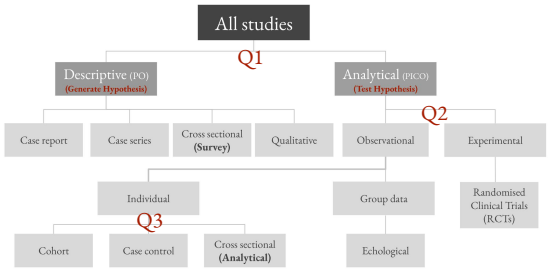
- **Ecological** Compares cases of COVID and COVID vaccination rates in two countries.
- **Cross-Sectional Survey** to KKUH patients about COVID vaccination status and history of COVID.
- **Case-Control** Comparing a group of covid cases to non-cases based on vaccination status.
- **Cohort** Following vaccinated and non-vaccinated groups over time to see if they get COVID.
- **Experimental (RCT)** Same as cohort but researcher randomly allocates the COVID vaccine.

Exposure: **COVID Vaccination**

Outcome: **COVID**

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?
To simply describe a population; **Descriptive**.
To quantify the relationship between exposure & outcome; **Analytic**.

Q2. If analytic, was the intervention/exposure randomly allocated (assigned by the researcher)?
Yes; **Experimental**.
No; **Observational**.

***Q3. If Observational, When were the outcomes determined (measured)?**
At the same time as the exposure (intervention); **Cross-sectional.**
Before the exposure was measured; **Case-Control or retrospective Cohort.**
Some time after the exposure (intervention); **Cohort study.**

The best way to differentiate between case-control and cohort is by looking at how the sample was grouped:

- Grouped based on **outcome** status (cases vs non-cases) → case-control
- Grouped based on **exposure** status (exposed vs unexposed) → cohort

This helps delineate the difference even when you're try to differentiate between a retrospective cohort and a case-control.

For a prospective cohort it is obvious as soon as you see there is **follow-up over time.**

Case studies

1- "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

2- "Fourteen patients were treated for electronic cigarette burns between 2012 and 2016. Burn size ranged from <1% to 6% of 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

3- “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

4- “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)

5- “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)

6- “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

القادة:

نواف التركي عبدالله الشهري لمتحمي

ريان الغنامي وهى ا

الأعضاء:

عبدالله التركي	عبدالله المياح	رغد النظيف
محمد الزير	عبدالله النجرس	ريما الجريبة
عثمان الدريهم	تركي العتيبي	شهد البخاري
عبدالعزيز القحطاني	عبدالله القرني	نوف الضلعان
ناصر الغيث	عامر الغامدي	أثير الاحمري
سعد السهلي	سعد الاحمري	وعد ابو نخاع
رائد الماضي	معاذ آل صلام	ثراء الهويش
سعود الشعلان	محمد الحصيني	في الدوسري
		منار الزهراني