

DESIGN STRATEGIES IN EPIDEMIOLOGIC RESEARCH (BASIC CONCEPTS)

COM 126

PART-I

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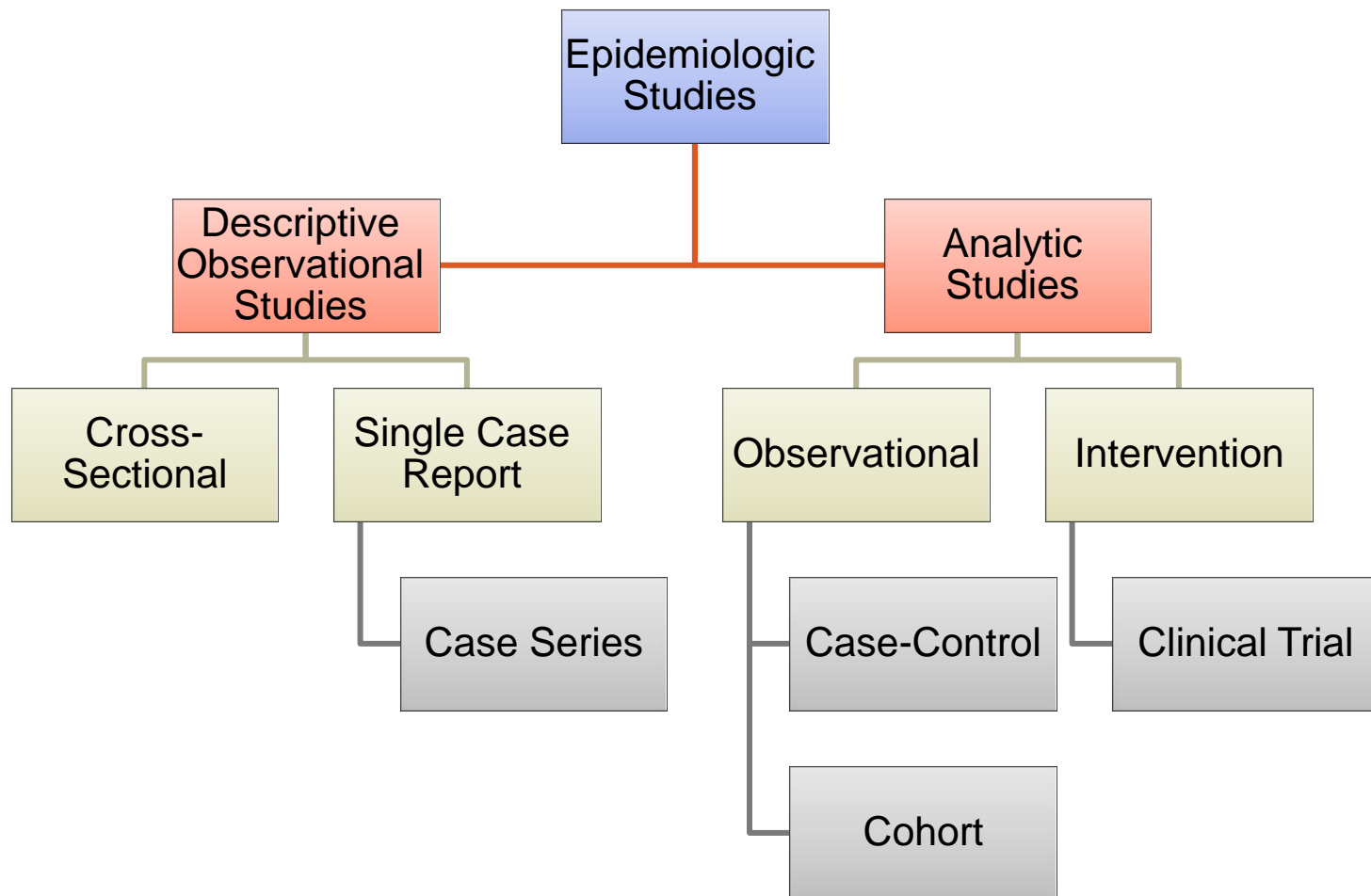
ALFAISAL COLLEGE OF MEDICINE

OBJECTIVES

- **Categorise research design into descriptive or analytical types of studies**
- **Describe the features and give examples of each of the following**
 - Case reports
 - Case series
 - Cross sectional studies
 - Case-control studies
 - Cohort studies
 - Clinical trials
- **Calculate and interpret measurement of association**
 - Odds ratio
 - Relative risk

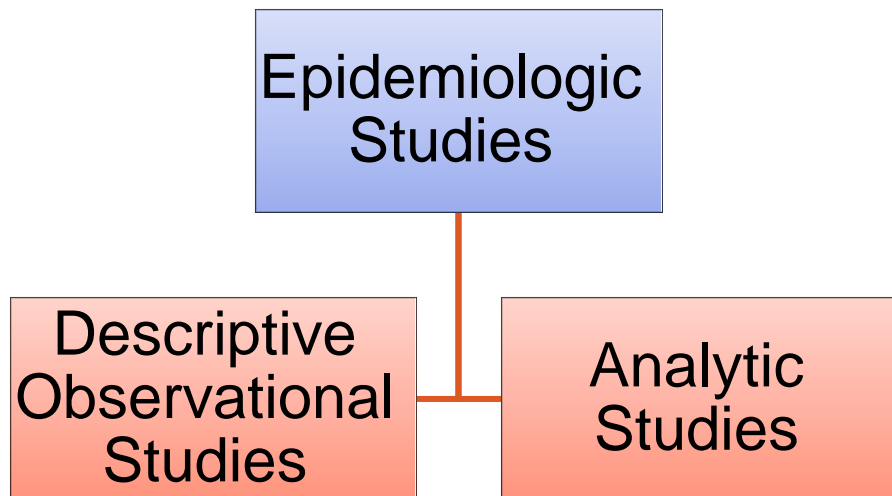
INTRODUCTION

Two categories of epidemiologic studies



TYPES OF STUDY DESIGNS

- **Epidemiology: distributions and determinants of disease frequency in human populations**
 - Epidemiologic researches use **design strategies**
 - Describing the distributions of disease
 - **Descriptive epidemiology**
 - Elucidating the determinants of disease
 - **Analytic epidemiology**



DESCRIPTIVE EPIDEMIOLOGY

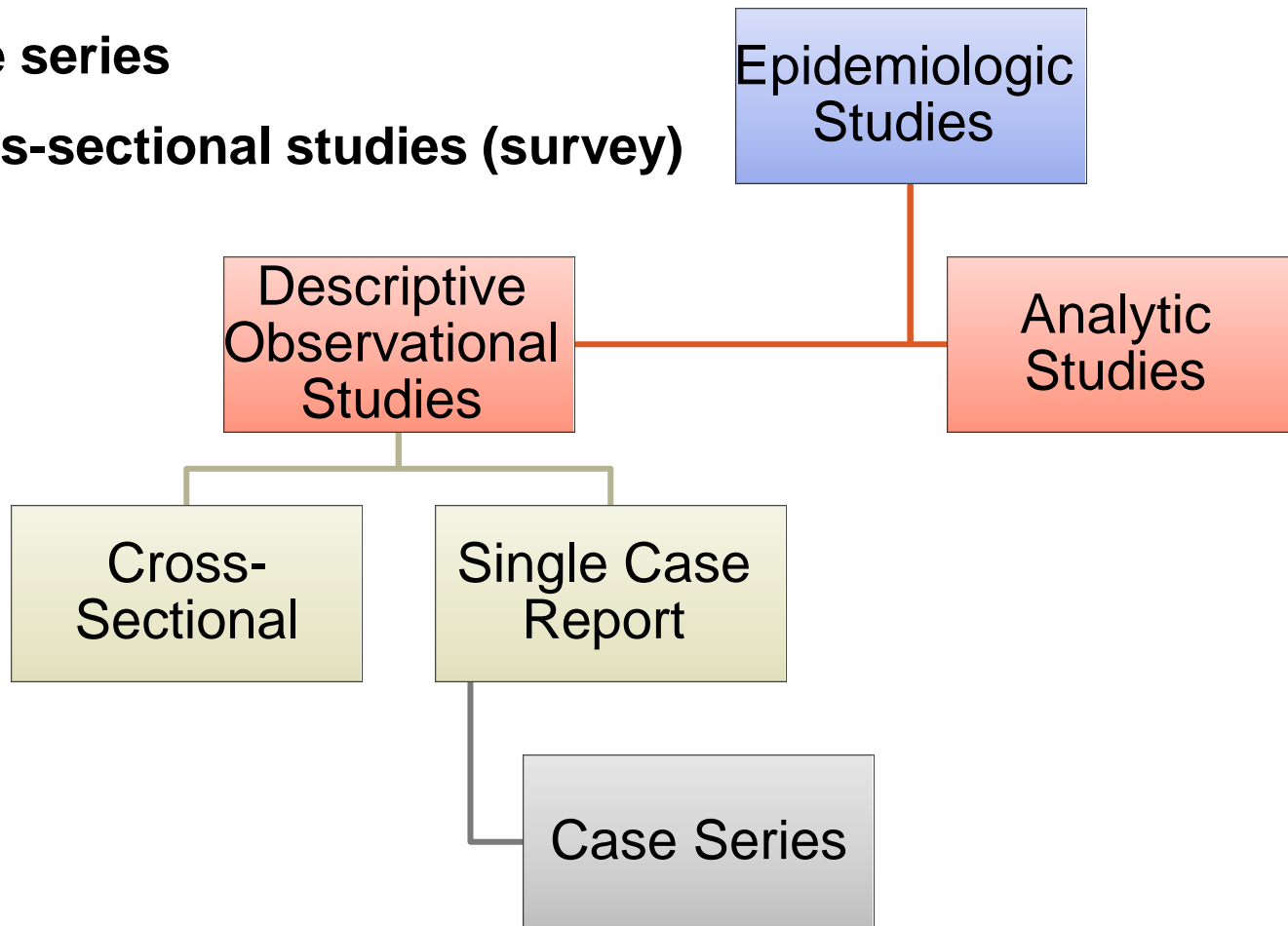
- **Concerned with the distribution of disease**
 - Person
 - Who was affected?
 - Basic demographic factors (age, sex, race, marital status, occupation, SES)
 - Life-style variables (consumption of foods, medication use)
 - Place
 - Where did the event occur?
 - International / National
 - Urban-Rural differences
 - Time
 - When did the event occur?
- **Allocate resources efficiently and plan effective programs**
- **1st important clues about possible determinants of a disease**
- **Information >>>> Epidemiologic Hypothesis**

ANALYTIC EPIDEMIOLOGY

- **Focuses on the determinants of a disease**
 - Testing the hypotheses
 - Ultimate Goal
 - Does the exposure cause (or prevents) the disease?

DESCRIPTIVE EPIDEMIOLOGIC STUDIES

- Individual case reports
- Case series
- Cross-sectional studies (survey)



CASE REPORTS

- **Most basic type**
- **Single occurrence of a noteworthy health-related incident**
- **Careful, detailed report by one or more clinicians**
- **Case 1.**
 - On December 8, 2007
 - Previously healthy woman
 - 26-year-old
 - Received cosmetic soft-tissue filler injections in her buttocks
 - Experienced headache and vomiting
 - Urine looked like purple blood
 - The woman was diagnosed with acute renal failure and required a two-week hospital stay and hemodialysis

CASE REPORTS

- **Case 2.**

- In 1961, a case report was published of a
- 40-year-old
- Premenopausal woman
- Developed a pulmonary embolism 5 weeks after beginning to use an oral contraceptive to treat endometriosis

- **Note**

- PE is far more common in older, postmenopausal women
- Postulated that the Drug # this rare occurrence (PE)
- **!She had other characteristics accounted for PE!**
- The crucial question is whether women who develop PE are more likely to have used OC than women who did not develop the disease
- This case report was suggestive
 - Not possible to differentiate between various alternative explanations
- Studies were subsequently undertaken and have consistently shown an association between use of OC and risk of PE

CASE SERIES

- **Larger collection of cases of disease**
- **Often grouped and describing characteristics of a number of patients with a given disease**
- **Example 1.**
 - 5 young previously healthy homosexual men
 - Diagnosed with *Pneumocystis carinii* pneumonia at 3 hospitals during a 6-month period in 1980 to 1981
 - Raised the hypothesis:
 - A probable link between the sexual behavior and risk of the disease

CROSS-SECTIONAL SURVEYS

- “Examines the relationship between health-related characteristics and other variables of interest as they exist in a defined population at one particular time.”
- **Snapshot of the prevalence**
 - Status of an individual with respect to the presence or absence of both exposure and disease is assessed in a representative sample at the same point in time
- **Formulate hypotheses that can be followed up in analytic studies**

CROSS-SECTIONAL SURVEYS

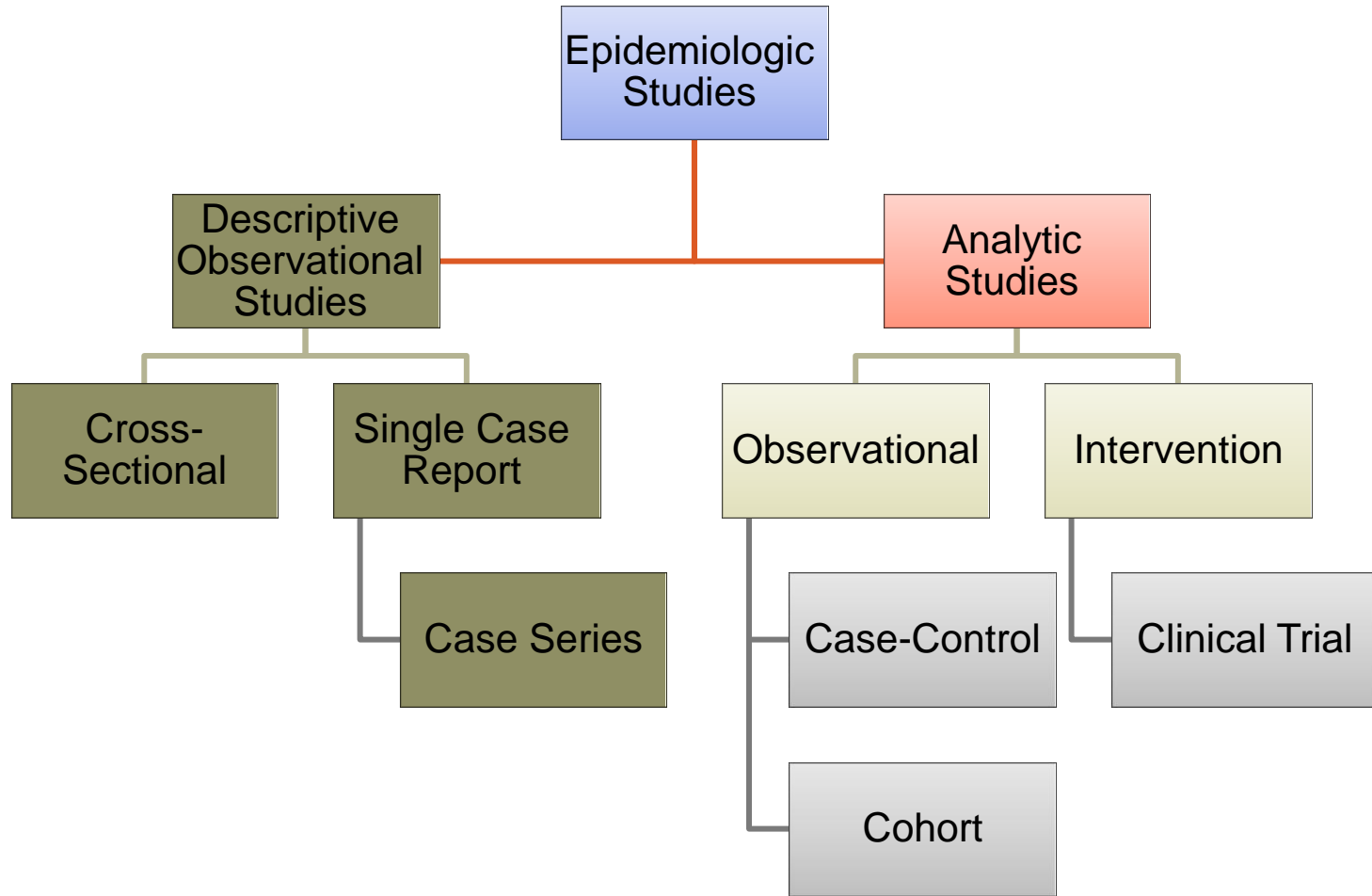
Example

- **A national cross-sectional study**
- **Questionnaire from a representative sample**
 - Demographic characteristics
 - Illnesses
 - Health habits
 - Utilization of health care resources
- **Frequencies of diseases, injuries, other health outcomes are calculated and examined in relation to age, sex, race SES, medication use, smoking, other risk factors**
- **Great value to public health administrators in assessing the health status and health care needs of the population**

CROSS-SECTIONAL SURVEYS

Exposure and disease are assessed at the same point in time

- **Did the exposure precede the development of the disease or the presence of the disease affected the individual's level of exposure**
- **Example:**
 - Cross-sectional studies >>> individuals with cancer have significantly lower levels of serum β -carotene than healthy individuals (age and sex).
 - Not possible to determine whether the observed low levels preceded the cancer (etiologic role) or because of the disease itself (dietary changes or the effects of cancer)
- **Doses the exposure cause (or prevents) the disease?**



ANALYTIC EPIDEMIOLOGY

- **According to the role played by the investigator**

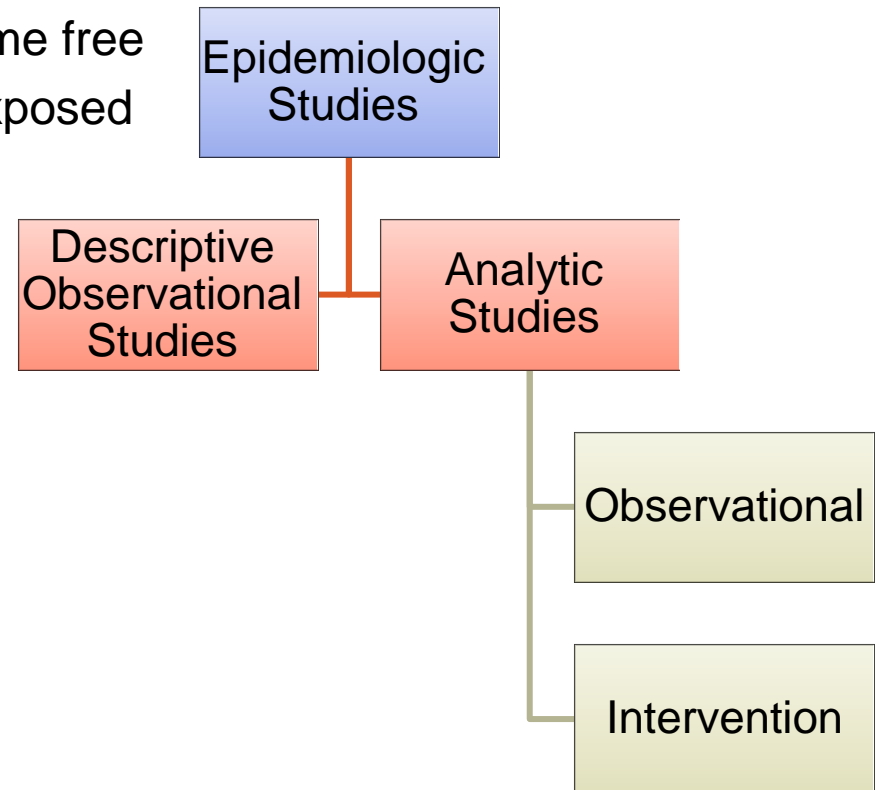
- **Observational**

- Simply observes the natural course of events

- Outcome and outcome free
- Exposed and non-exposed

- **Intervention**

- Allocate the exposure
- Follow the subjects



OBSERVATIONAL ANALYTIC STUDIES

- **Two basic types**
 - Case-control study
 - Cohort study
- **Certain advantages and disadvantages**
- **Which one to use**
 - Features of the exposure and disease
 - Current state of knowledge
 - Logistic (time and resources)

CASE-CONTROL STUDIES

- **Subjects are defined on the basis of the presence or absence of an outcome of interest**
- **Cases = individuals who have the outcome or disease of interest**
- **Controls = individuals who are disease free**
- **Matched case-control study:**
 - Cases and controls have been matched according to one or more criteria such as sex, age, race, or other variables

CASE-CONTROL STUDIES

Example

- **?? An association between consumption of artificial sweeteners and risk of bladder cancer**
 - Cases = 592 patients hospitalized with bladder cancer
 - Controls = 536 subjects without bladder cancer (selected at random from the general population)
 - All were interviewed to obtain information on their history of consumption of artificially sweetened beverages and food, use of sugar substitutes
 - Similar proportion of individuals who had used artificial sweeteners among cases of bladder cancer and controls

MEASURE OF ASSOCIATION USED IN CASE-CONTROL STUDIES

- **Odds ratio (OR)**
 - The measure of the association between frequency of exposure and frequency of outcome
 - $OR = (A/C) \div (B/D)$
 - (A/C) = the odds in favor of exposure among the cases
 - (B/D) = the odds in favor of exposure among the controls

	Disease status	
Exposure status	Yes (Cases)	No (Controls)
Yes	A	B
No	C	D
Total	A + C	B + D

ODDS RATIO

OR	Interpretation
> 1	Suggests a (+) association between the exposure and the outcome
$= 1$	No association between exposure and outcome
< 1	Indicates that the exposure might be a protective factor

ODDS RATIO

Example:

	Lung cancer	
Smoking	Yes (Cases)	No (Controls)
Yes	9	4
No	95	88
Total	104	92

- $OR = AD/BC = (9 \times 88) / (4 \times 95) = 2.08$
- Interpretation: the odds of the disease are about two times higher among the exposed persons than among the non-exposed persons

END OF PART 1

REFERENCES

- Friis, R. H. (2010). *Epidemiology 101.* : Jones & Bartlett Learning.
- Hennekens, C. H. & Burnig, J. E., *Epidemiology in medicine.* : Lippincott Williams & Wilkins.

Any questions?

