## Overview of Epidemiologic Study Designs

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### **Objectives**

- Describe the different purposes of descriptive and analytic studies
- Describe the main feature that distinguishes analytic from descriptive studies
- Discuss the essential design features and major advantages/disadvantages of the two main types of analytic studies

## **Definition of Epidemiology**

"Epidemiology is the study of the distribution and determinants of health related states or events in specified populations, and the application of this study to control of health problems."

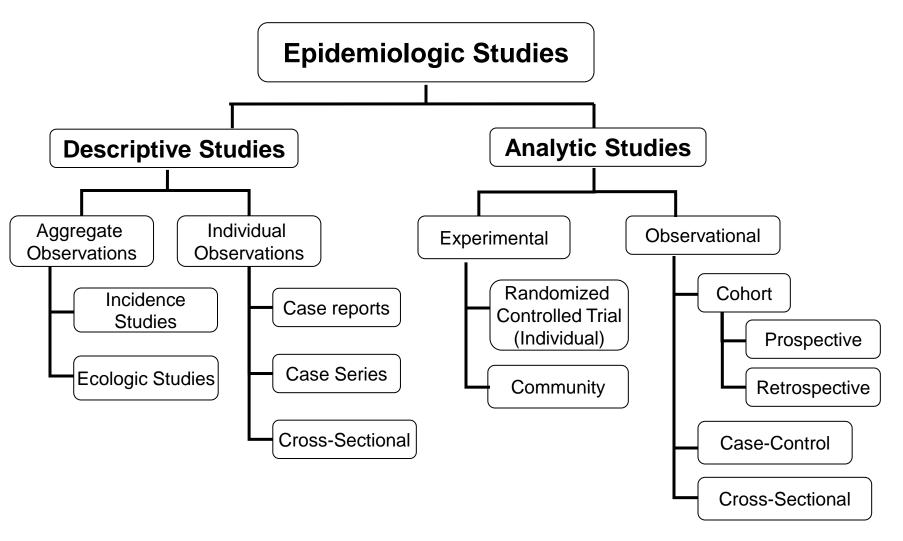
- Last's Dictionary of Epidemiology

### **Study Designs**

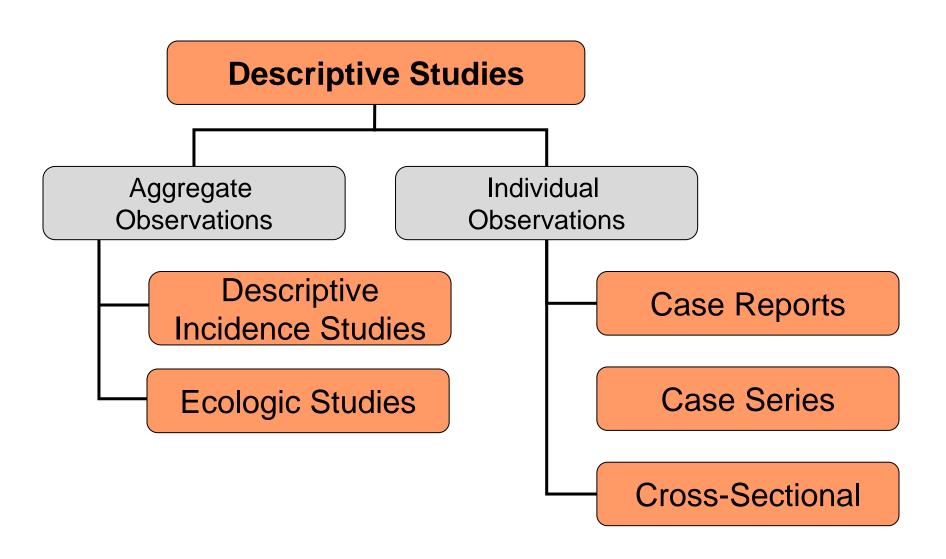
Distribution → descriptive studies

Determinants → analytic studies

## Taxonomy of Epidemiologic Studies: Descriptive vs. Analytic Studies



## **Descriptive Study Designs**



## Case Report (also known as Case Study)

- Simplest type of descriptive study
- Describes a single case of illness, often an unusual or distinctive case
  - New diseases or health hazards
  - New clinical manifestations or syndromes
  - New modes of disease transmission
  - New treatments
- Can be interface of medicine and epidemiology
- May lead to new hypotheses

## **Case Report Example**

- 35-year-old woman presented with 3 weeks fever, persistent vomiting, progressive weight loss, vague abdominal pain and swelling not responsive to medications
- Ultrasound revealed right ovarian mass 11.8cm x
   19cm, resulting in diagnosis of ovarian cancer
- Histology of excised lesion showed tuberculous granuloma
- Conclusion: TB of ovary can masquerade as ovarian cancer, especially in HIV+ patients, so rule out TB before performing extensive surgery

#### **Case Series**

- Series of case reports with common elements
  - Similar clinical features
  - Suspected common exposures
  - Similar geographic area
- Based on
  - Unexpected cases
  - Planned series
- Early evidence for association between disease and exposures

## **Case Series Examples**

Case series	Eventually found association with
5 cases of <i>Pneumocystis</i> pneumonia in previously health young men	HIV / AIDS
Cases of microcephaly in Brazil	Maternal infection with Zika virus
Cases of Nodding Syndrome in Uganda	???
17 cases of cholangiocarcinoma among young workers in Japan	Chemicals used at printing company

## Case Reports and Case Series Publications

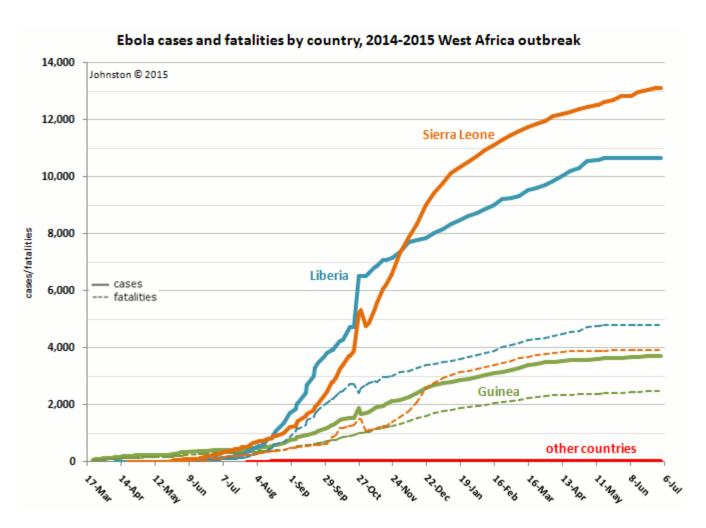
- The link between clinical practice and epidemiology
- Helps to gain a better understanding of new or re-emerging health threats
- Usually published in medical journals
- Represent nearly one third of all publications



## **Descriptive Incidence Study**

- Patterns in occurrence of incident cases (often from surveillance data)
- Defined population (denominators from census)
- Specified period of time
- Optionally, distribution of cases by factors of interest

# Example: West Africa Ebola Epidemic by Time



## Example: West Africa Ebola Epidemic by Place

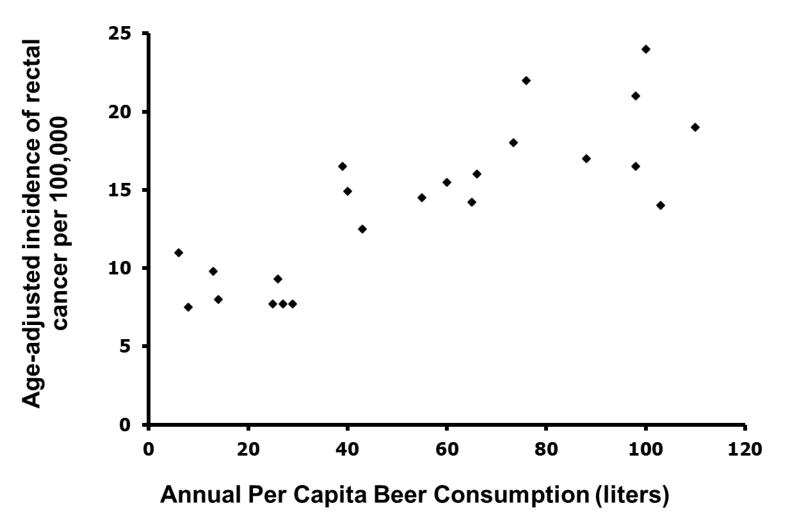


https://www.cdc.gov/vhf/ebola/outbreaks/ 2014-west-africa/distribution-map.html

## **Ecologic (Correlational) Study**

- Exposure and outcome at aggregate (e.g., country) level
- Data from groups not individuals
  - Aggregate measures
  - Global measures
- Unit of observation is a population
- Types
  - Geographic comparisons
  - Time comparisons

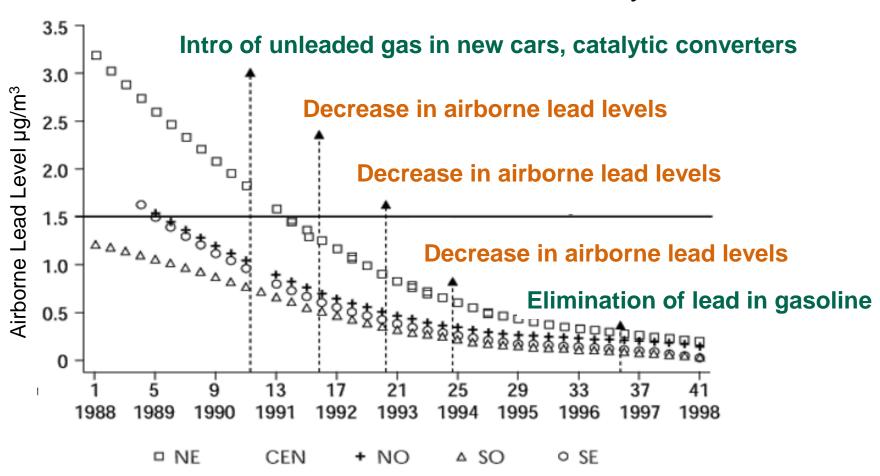
## Ecologic Study Example 1: Rectal Cancer Incidence by Beer Consumption



Armstrong & Doll. Int J Cancer 1975; 15(4): 617-631.

## Ecologic Study Example 2: Time Comparison

Trends in airborne lead levels, Mexico City, 1988-1998



## Ecological Study — Advantages

- Quick use routinely collected data
- Inexpensive
- Simple
- Generate new hypotheses about the causes of a disease or condition
- Identify new potential risk factors

## Ecological Study — Major Disadvantage

#### Ecological Fallacy

An error in **inference** that occurs when association observed between variables at the *group level* are assumed to exist at an *individual level*.

## **Ecological Fallacy Example**

- At the population level, schools with higher female dropout rates have higher adolescent pregnancy rate
- At the individual level, not all girls in these schools have higher risk of pregnancy
- A group level association may not be present at the individual level, and may not indicate a true cause-and-effect relationship

### **Ecological Fallacy Example**

Schools with higher female dropout rate

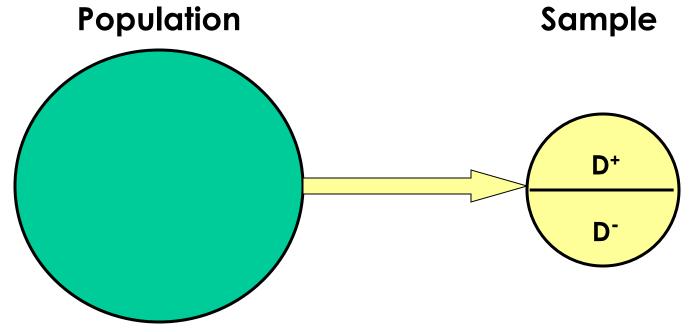
Higher adolescent pregnancy rate

Attending a school with a high female drop-out rate



More likely to get pregnant

### **Descriptive Cross-Sectional Studies**



#### **Examples:**

- (1) Chloramphenicol-resistant Salmonella among patients with enteric fever in Waybargi Hospital in 2017
- (2) Prevalence of hypertension in Yangon Region in 2017

## **Descriptive Cross-Sectional Studies**

 Study population: Well-defined population or a sample of a larger population

#### Uses:

- Calculate prevalence of a disease (or exposure)
- Survey of knowledge, attitudes, and behaviors
- Assess needs for public health resources
- Generate hypotheses about causes of disease

## Cross-Sectional Studies: Advantages and Disadvantages

#### Advantages

- Simple
- Inexpensive
- Timely
- Good for chronic illnesses

#### Disadvantages

- Low participation → Poor generalizability to your source population
- Limited usefulness for acute illnesses
  - Prevalence of salmonellosis?

## **Example: Descriptive Cross-Sectional Study**

- Study design: Descriptive cross-sectional study of sexual behaviors of women ages 18-49 at 25 health clinics in Limpopo Province, South Africa
- Study population: Convenience sample of women aged 18-49 years who reported sexual activity and attended clinic on that survey day
- Study time frame: Surveys conducted in 2012

## Example: Descriptive Cross-Sectional Study

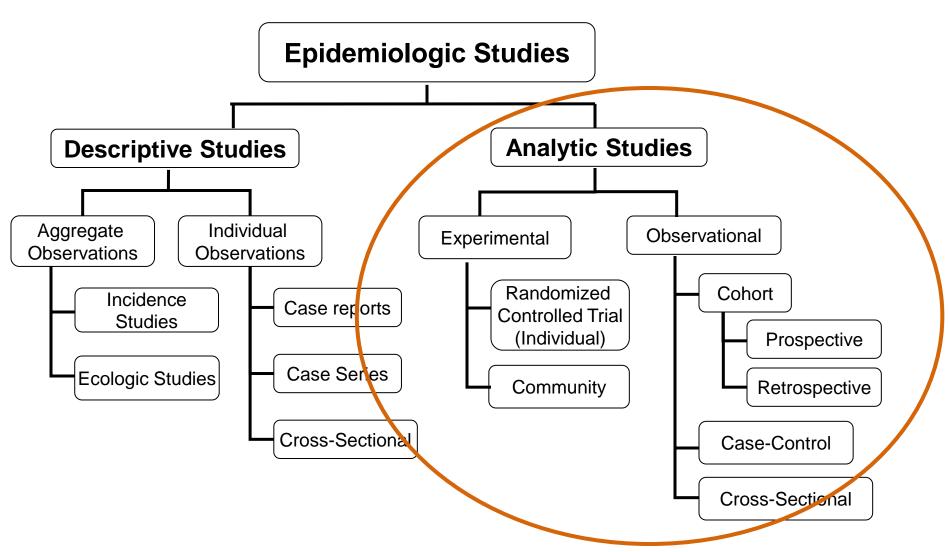
Study results: 570 surveys (95%) of 600 completed

- Median respondent age: 30 years
- 31% HIV-positive, 53% single, 75% unemployed
- Sexual risk behaviors:
  - 36.1% used condoms at last sex
  - 15.3% had concurrent sexual partners
  - 22.1% had a sexual partner >10 years older
  - 23.9% reported sexual coercion

## **Descriptive Studies - Summary**

- Describe patterns of occurrence
- Four main types:
  - Case reports and case series
  - Descriptive incidence studies
  - Cross-sectional (prevalence) studies
  - Ecologic (correlational) studies
- Generate hypotheses for analytic study

## Taxonomy of Epidemiologic Studies: Descriptive vs. Analytic Studies



## **Analytic Studies – Overview**

- Goal: to determine the relationship between exposure and disease
  - Assess determinants of disease
  - Focus on risk factors, causes
- Used for
  - Testing hypotheses
  - Looking for / quantifying associations

## **Analytic Studies – Hallmark**

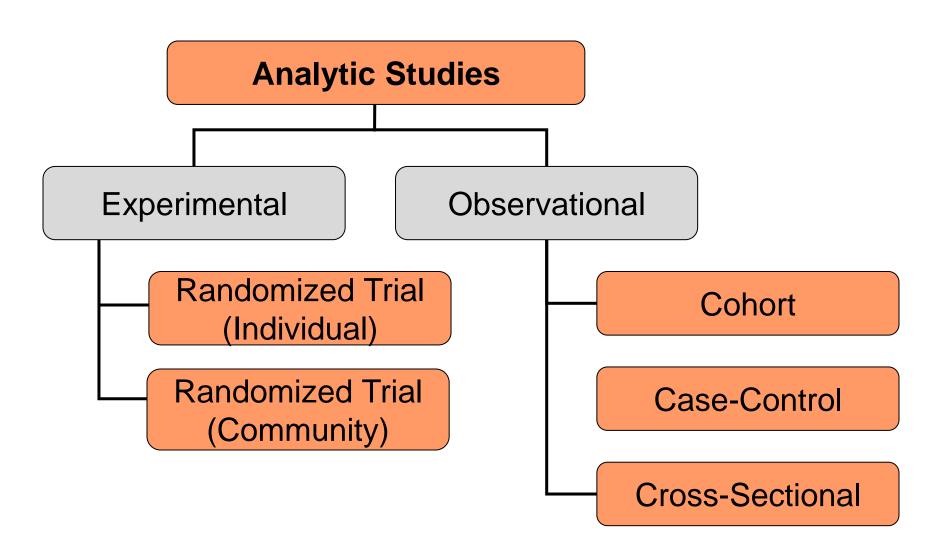
Q. What is the hallmark feature that distinguishes an analytic study from a descriptive study?

## **Analytic Studies - Hallmark**

Q. What is the hallmark feature that distinguishes an analytic study from a descriptive study?

### A. Comparison Group

## **Analytic Study Designs**



## **Experimental Studies**

- Assign exposure randomly, follow over time and monitor for disease
- Types:
  - Clinical trial
  - Community trial
- "Gold standard"
- Ethical issues

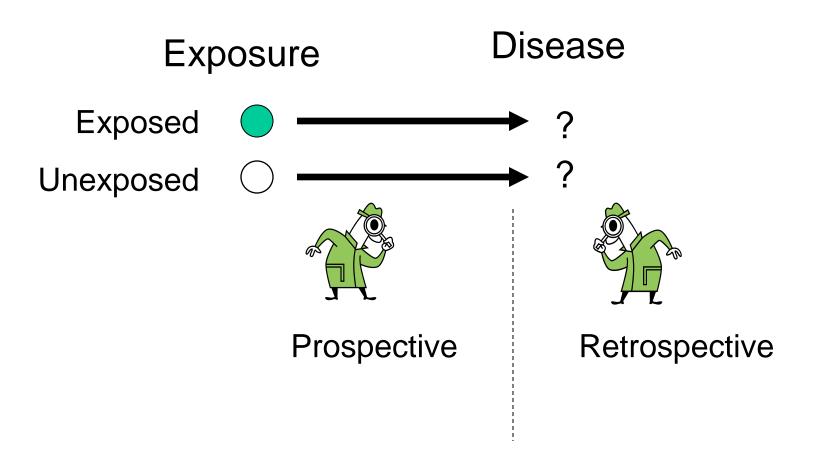
## **Observational Analytic Studies**

- Nature prevails
- Main types:
  - Cohort
  - Case-control
  - Cross-sectional (analytic)
- Dimensions:
  - Directionality, timing

## **Cohort Study**

- Different from experiment
  - Investigator does not dictate exposure
- Similar to experiment
  - Enroll or enroll all members of a group, then classify by exposure (less commonly, enroll subjects based on exposure status)
  - Follow subjects over time and record occurrence of health event (outcome of interest)
  - Compare rates of disease occurrence among exposed and unexposed groups of persons

## **Cohort Studies - Timing**

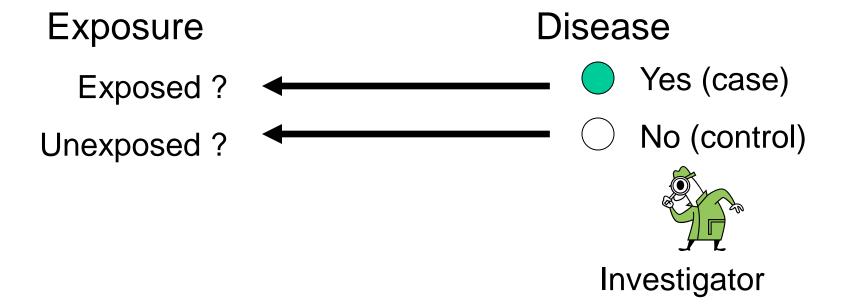


## **Case-Control Study**

#### Observational analytic study that enrolls

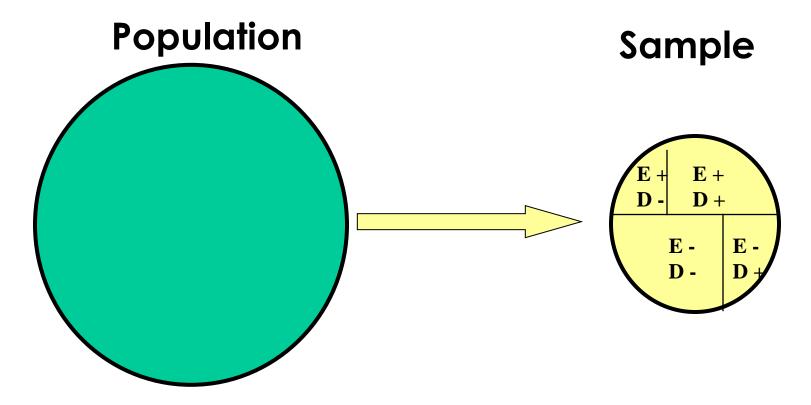
- one group of people with a certain disease, chronic condition, or type of injury ("cases" or "case-patients"), and
- a group of people from the same population but without the health problem ("controls"), and
- compares exposures, behaviors and other characteristics to identify differences
- to identify and quantify associations, test hypotheses, and identify causes

### Case-Control Studies — Timing



## **Analytic Cross-Sectional Study**

## **Analytic Cross-Sectional Study**



Example: Smoking and Hypertension in Adult Male Population

## **Analytic Cross-Sectional Study**

- Descriptive cross-sectional studies: Examine the <u>prevalence</u> of disease (or exposure) in a defined population at one point in time
- Analytic cross-sectional studies: Examine the <u>relationship</u> between exposure and outcome in a defined population at one point in time



## **Summary (1/3)**

- Case reports and case series are the simplest types of descriptive studies and are the interface between clinical medicine and epidemiology
- Ecologic studies use group-level measures to compare health trends over time and between different geographic regions, but associations at the group level may not apply to individuals ("ecologic fallacy")

## **Summary (2/3)**

- The hallmark of an analytic study is inclusion of a comparison group
- Cohort studies proceed from exposure to disease, either prospectively (like an experiment) or retrospectively
- Case-control studies enroll a case group and a comparison "control" group, and compare exposure experience of each

## **Summary (3/3)**

 Cross-sectional studies can be either descriptive or analytic, depending on the presence of a comparison group, but both use data captured at a single point in time