

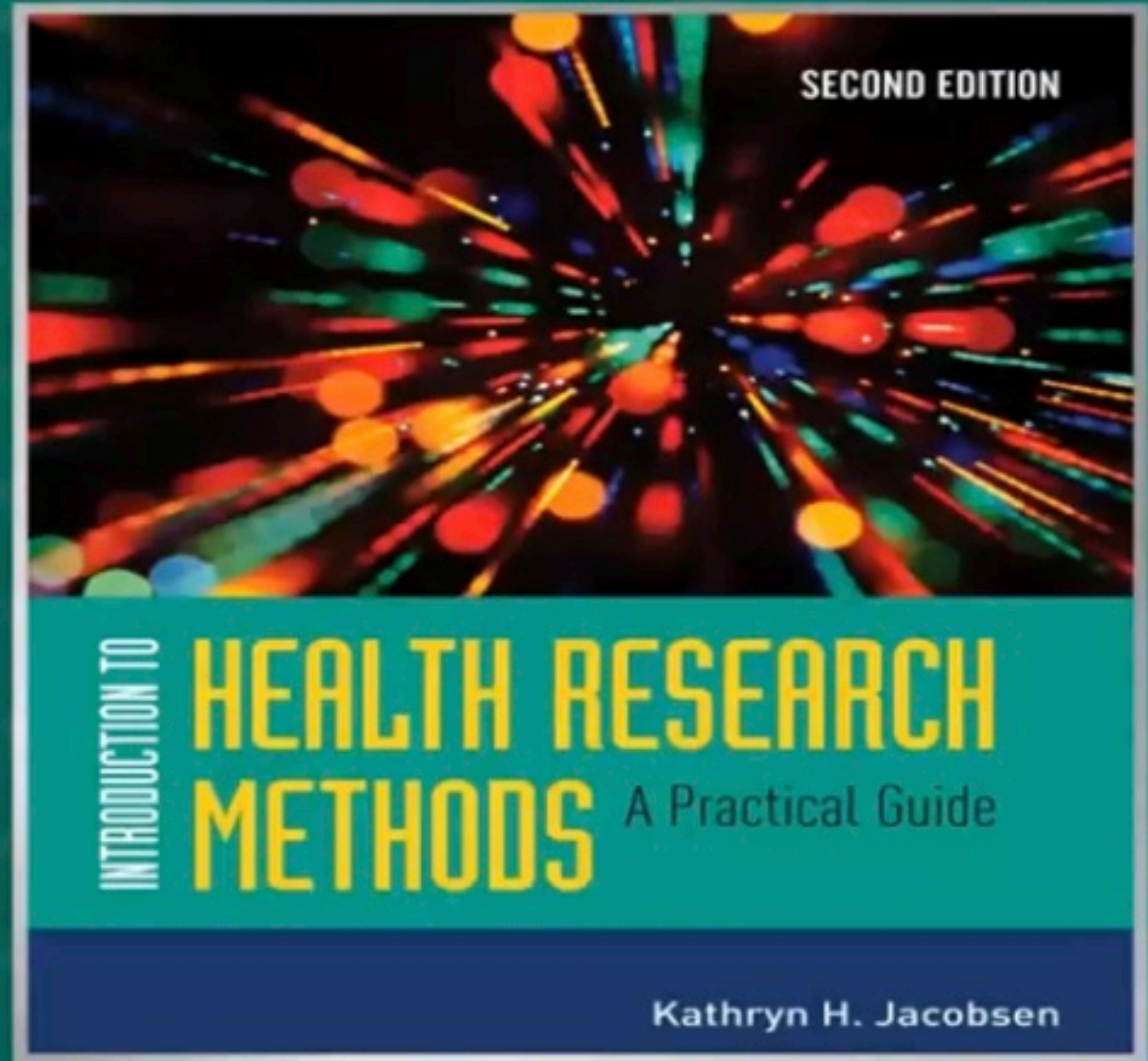
# **Medical Research**

## **Week 3**



# The Health Research Process

## Chapter 7





## 7.1 Types of Study Approaches

- There are many valid study approaches (Eight are highlighted in your book).
- The design selected must be appropriate to the study goals.



**FIGURE 7-1**     **Summary of Study Approaches**

<b>Study Approach</b>	<b>Goal</b>
Case series	Describe a group of individuals with a disease
Cross-sectional survey	Describe exposure and/or disease status in a population
Case-control study	Compare exposure histories in people with disease (cases) and people without diseases (controls)
Cohort study	Compare rates of new (incident) disease in people with different exposure histories or follow a population forward in time to look for incident diseases
Experimental study	Compare outcomes in participants assigned to an intervention or control group
Qualitative study	Seek to understand how individuals and communities perceive and make sense of the world and their experiences
Correlational (ecological) study	Compare average levels of exposure and disease in several populations
Review/meta-analysis	Synthesize existing knowledge

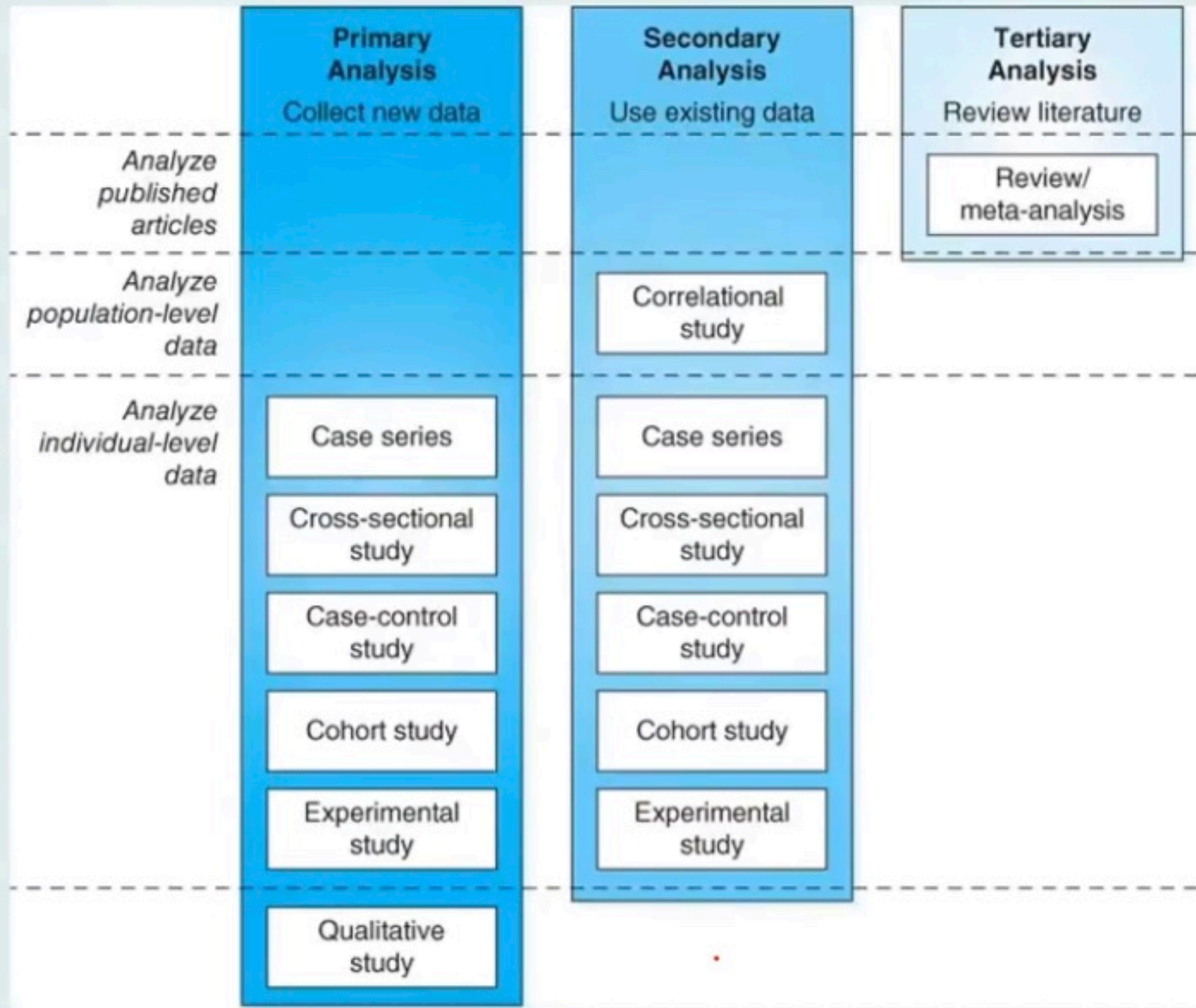


## 7.2 Primary, Secondary, & Tertiary Studies

- The first critical decision is whether to conduct a primary, secondary, or tertiary study.



Now, Let's put them together



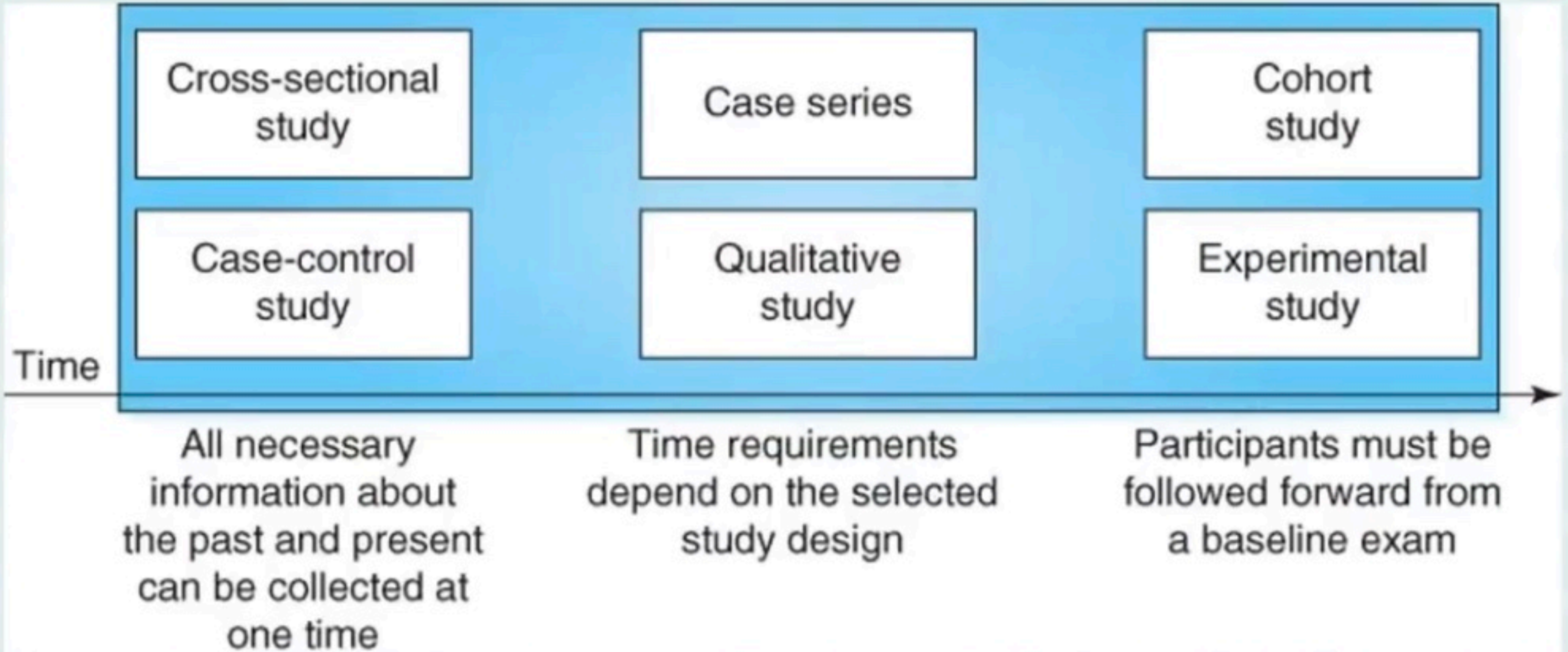


## 7.3 Study Duration

- Primary studies usually take longer than secondary or tertiary studies.



# Time Frame for Primary Data Collection



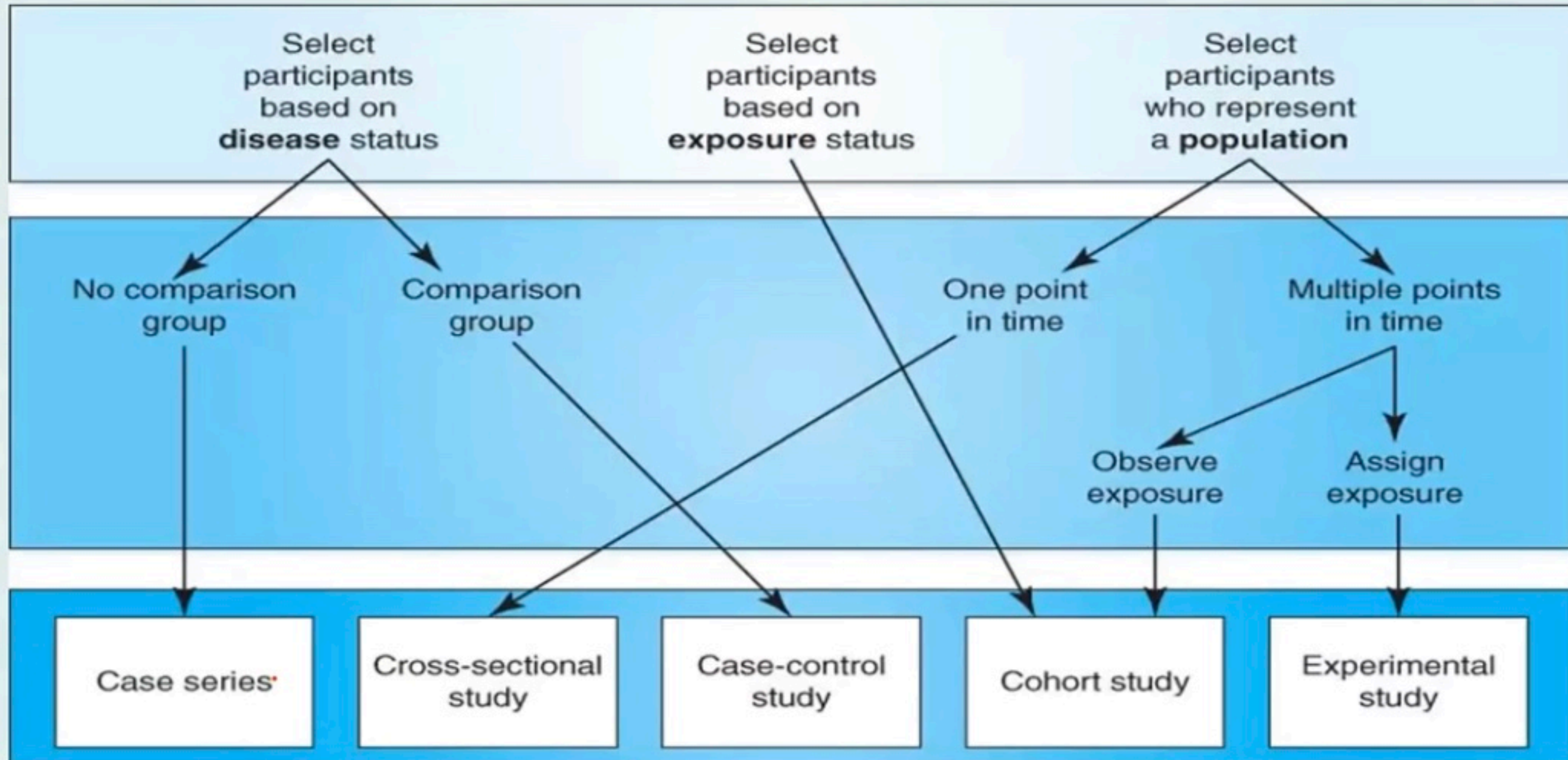


## 7.4 Primary Focus: Exposure, Disease, or Population?

- Primary study designs can be selected based on which EDP is the major motivation for the study.



# Population Selection for Each Study Approach





## 8.1 Overview

- A ***case report*** describes one patient.
- A ***case series*** describes a group of individuals with the same disease or who have undergone the same procedure.



## FIGURE 8-1 Key Characteristics of a Case Series

Objective	Describe a group of individuals with a disease
Primary study question	What are the key characteristics of the cases in this study population?
Population	All individuals in the study must have the same disease or be undergoing the same procedure.
When to use this approach	A source of cases is available, and no comparison group is required or available.
Requirement	An appropriate source of cases is available.
First steps	<ol style="list-style-type: none"><li>1. Specify what new and important information the analysis will provide.</li><li>2. Identify a source of cases.</li><li>3. Assign a case definition.</li><li>4. Select the characteristics of the study population that will be described.</li></ol>
What to watch out for	A lack of generalizability
Key statistical measure	Only descriptive statistics are required.



## 8.2 Case Definitions

- A clear ***case definition*** spells out inclusion & exclusion criteria.
- ***ICD codes*** can be helpful.
- Include person, place, and time (PPT) characteristics.



**FIGURE 8-2     Sample Case Definitions**

<b>Category</b>	<b>Example 1</b>	<b>Example 2</b>
Disease/ procedure Person	Whooping cough (ICD-10 code A37)  Any person with a confirmed case of whooping cough, defined as an acute cough of any duration with isolation of Bordatella pertussis from a clinical specimen or a cough lasting 2 or more weeks with paroxysms of coughing, inspiratory “whoop,” or posttussive vomiting and contact with a laboratory-confirmed case of pertussis	Liver transplantation  Adult patients (ages 18 and older at the time of transplant), excluding those who were not receiving their first liver transplant and those who received multi-organ transplants
Place	Residents of Big City whose diagnoses were reported to the Big City Health Department (which requires notification of all diagnoses of pertussis)	Patients who had transplant surgery at the Oakville Regional University Medical Center
Time	First sought clinical care between January 1 and March 31, 2016	Recipients of liver transplants between January 1, 2006, and December 31, 2014, who were followed for a minimum of 2 years post-transplant



## 8.3 Special Considerations

- Use a “questionnaire” to extract information from medical charts.
- Remember that missing information does not mean that a symptom or sign was not present, just that it was not recorded in the file.
- Ethical approval is required, and great care must be taken to protect the identities of study subjects.
- Photographs can only be used with written permission from the patient.



## 8.4 Analysis

- Few numbers are required for most case series studies.
- Some may report percentages such as:
  - Case fatality rate.
  - Mortality rate.
  - Proportionate mortality rate.
- With sufficient sample size, comparisons can be made between subpopulations of cases



# Thank You