CHOOSING A STUDY DESIGN

Yardlee S. Kauffman and Daniel M. Witt

"Formulating the study design was likely the most challenging step in the residency research project as I tried to predict and address any challenges early on. I strived for a prospective study to produce results likely to be published; however, I learned that a retrospective study also offers promising data. I had to be realistic and remember that there's only 1 year to complete this."

—Former PGY2 Ambulatory Care Resident

LEARNING OBJECTIVES

- Identify considerations for study sample and subject selection criteria.
- Describe the difference between observational and experimental study designs.
- Distinguish between internal and external validity.
- Describe important factors that may impact study design selection.

INTRODUCTION

The type of study design selected by a researcher is determined by a variety of factors such as the frequency of the outcome of interest, the availability of study subjects, and the method and timing of data collection. Carefully examining your research question can be helpful in deciding what research design and methods to use. For example, if your research question aims to evaluate the impact of a given "exposure" on the incidence or prevalence of an outcome, you could use a survey, retrospective chart review, or prospective trial to answer this question. Many resident research projects attempt to describe the current state of a given situation, such as how your health system is performing on a quality metric or the outcomes associated with current clinical practice. Such descriptive studies can help identify situations that could benefit from a new clinical intervention. If the research question seeks to understand the way people feel or behave in certain situations, this could suggest a qualitative research design.[1]

DOI 10.37573/9781585285617.002

This chapter will help you identify a study design based on your research question. For more information, consult with your preceptors and researchers at your residency site to determine what type of study design will be best for your project.

SELECTION OF A STUDY DESIGN

The design of a study is guided by the study objectives. **Figure 2-1** and **Table 2-1** provide an overview of study designs. First, you must determine if your study is descriptive or analytic. *Descriptive studies* measure frequencies, incidence rates, prevalence, central tendency (mean, median), and the distribution of data and/or describe the natural history of a disease or outcome. Descriptive studies help to generate a preliminary hypothesis about the relationship between an exposure and disease.

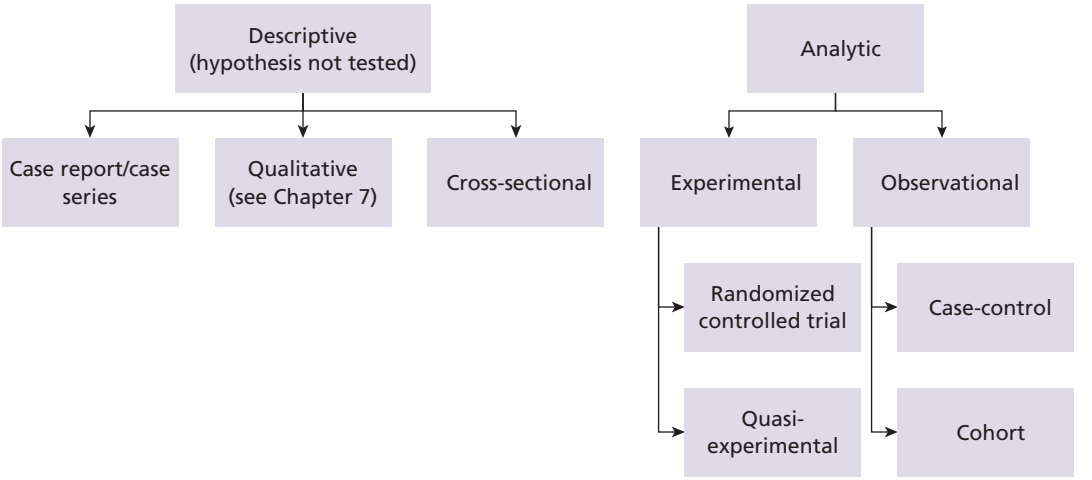

FIGURE 2-1. Study Designs[2]

TABLE 2-1. Overview of Study Designs[1,2]

Study Definition	Advantages	Disadvantages	Example
Case Report/Case Series			
• Presents details of a single case or small number of cases. • Reports a new or unique finding. • Can provide clues in identification of a new disease or adverse effects of exposures.	• May identify rare events. • Highlights possible mechanisms of disease and treatment. • Generates hypothesis.	• Can represent isolated events; presence of any risk factor may be purely coincidental. • Is subject to bias and confounding. • Has no comparison group. • Cannot be used to test for presence of a valid statistical association.	Dos Santos T, Rodriguez A, Almiron M, et al. Zika virus and the Guillain-Barré syndrome—case series from seven countries. *N Engl J Med.* 2016;375:1598–1601