

# INTERPRETING STUDY FINDINGS



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*"After months of hard work collecting data, my sense of accomplishment quickly turned into panic as I realized I now had to interpret my findings. I wasn't sure where to start. It was almost as if the numbers on the spreadsheet were mocking me. A strong foundation on this topic is key."*

—Former PGY1 Pharmacy Practice Resident

## LEARNING OBJECTIVES

- Describe, calculate, and interpret measures of outcome frequency.
- Describe, calculate, and interpret measures of association.
- Describe how to interpret  $p$  values and confidence intervals.

## INTRODUCTION

Once you have completed your statistical analysis (see Chapter 5), you will need to interpret your study findings and make sense of the results. Understanding where the results originated and the methods used to analyze your data will help you interpret the results. This chapter provides an overview of how to calculate and interpret commonly used study outcome measures. This chapter also reviews in detail how to interpret  $p$  values, confidence intervals, and determine if your findings are statistically and/or clinically significant.

## MEASURES OF OUTCOME FREQUENCY

Two of the most common ways to describe study outcomes are risk and rate. *Risk* refers to the probability of experiencing an outcome in a given time (e.g., 5% risk of experiencing a fatal cardiovascular event in a 10-year period). The calculation of risk is simply the number of subjects who experience an outcome divided by the total number of subjects studied. Duration of time is a critical component of risk interpretation, and in fact, risk calculations assume that all study participants are at risk of the outcome for the same duration. Rates also describe the occurrence of

outcomes over time, but do not require equal follow up by each individual (e.g., 3.2 bleeding events per 100 patient-years). This is because the observed duration of follow up is included in the denominator of the rate calculation. *Rates* are calculated by dividing the number of outcomes observed by the sum of time that all patients were at risk of experiencing an event. A beneficial characteristic of rates is that follow-up time can be variable for every patient without producing biased estimates.<sup>1</sup>

## Measures of Association

There are two categories of measures of association—relative measures and absolute measures.<sup>2</sup> *Relative measures*, or the ratio of outcome frequency in one group compared to another, indicate the extent to which an exposure accounts for the increased or decreased occurrence of an outcome. In contrast, *absolute measures*, or the difference in outcome frequency in one group compared to another, describe the greater or lesser occurrence of an outcome that occurs in individuals with the exposure of interest. Both relative and absolute measures are important for providing a complete picture of study results.

Before measures of association can be calculated, it is necessary to set up a 2×2 contingency table (Figure 6-1). The 2×2 contingency table is used to summarize frequencies of outcome and exposure and, therefore, are used to calculate measures of association.

		Outcome		Total
		Yes	No	
Exposure	Yes	A	B	A + B
	No	C	D	C + D
Total		A + C	B + D	

A = number of individuals who are exposed and have the outcome

B = number of individuals who are exposed and do not have the outcome

C = number of individuals who are not exposed and have the outcome

D = number of individuals who are not exposed and do not have the outcome

**FIGURE 6-1. A 2×2 Contingency Table<sup>2</sup>**

### Relative Risk

*Relative risk (RR)* is a measure of association often used in cohort studies and randomized trials. The RR is calculated as the ratio of the risk in the exposed group or proportion of the exposed group with the outcome, divided by the risk in the unexposed group (Figure 6-2).<sup>2</sup> If the risks are equivalent, the RR is 1.0 (i.e., the null value). If the relative risk is greater than 1.0, then the exposure increases the risk of the outcome. Conversely, if the relative risk is less than 1.0, the exposure is protective of the outcome. Similarly, rates can be compared and interpreted in the same manner.<sup>3</sup>

$$\text{relative risk} = \frac{\text{risk of outcome in exposed}}{\text{risk of outcome in unexposed}}$$