

Clinical Trials vs. Observational Studies

In a *New York Times* article about hormone therapy for women, reporter Denise Grady wrote about randomized clinical trials that in-



involve subjects who were randomly assigned to a treatment group and another group not given the treatment. Such

randomized clinical trials are often referred to as the “gold standard” for medical research. In contrast, observational studies can involve patients who decide themselves to undergo some treatment. Subjects who decide themselves to undergo treatments are often healthier than other subjects, so the treatment group might appear to be more successful simply because it involves healthier subjects, not necessarily because the treatment is effective. Researchers criticized observational studies of hormone therapy for women by saying that results might appear to make the treatment more effective than it really is.

• **Experiment:** In the largest public health experiment ever conducted, 200,745 children were given a treatment consisting of the Salk vaccine, while 201,229 other children were given a placebo. The Salk vaccine injections constitute a treatment that modified the subjects, so this is an example of an experiment.

Whether one is conducting an observational study or an experiment, it is important to select the sample of subjects in such a way that the sample is likely to be representative of the larger population. In Section 1-2 we saw that in a voluntary response sample, the subjects decide themselves whether to respond. Although voluntary response samples are very common, their results are generally useless for making valid inferences about larger populations. The following definition refers to one common and effective way to collect sample data.

DEFINITION A **simple random sample** of n subjects is selected in such a way that every possible *sample of the same size n* has the same chance of being chosen. (A simple random sample is often called a random sample, but strictly speaking, a random sample has the weaker requirement that all members of the population have the same chance of being selected. That distinction is not so important in this text.)

Throughout, we will use various statistical procedures, and we often have a requirement that we have collected a *simple random sample*, as defined above.

The definition of a simple random sample requires more than selecting subjects in such a way that each has the same chance of being selected. Consider the selection of three students from the class of six students depicted below. If you use a coin toss to select a row, randomness is used and each student has the same chance of being selected, but the result is not a simple random sample. The coin toss will produce only two possible samples; some samples of three students have *no chance* of being selected, such as a sample consisting of a female and two males. This violates the requirement that all samples of the same size have the same chance of being selected. Instead of the coin toss, you could get a simple random sample of three students by writing each of the six different student names on separate index cards, which could then be placed in a bowl and mixed. The selection of three index cards will yield a simple random sample, because every different possible sample of three students now has the same chance of being selected.

Heads: 

Tails: 

With random sampling we expect all components of the population to be (approximately) proportionately represented. Random samples are selected by many different methods, including the use of computers to generate random numbers. Unlike careless or haphazard sampling, random sampling usually requires very careful planning and execution. Wayne Barber of Chemeketa Community College is quite correct when he tells his students that “randomness needs help.”

Other Sampling Methods In addition to simple random sampling, here are some other sampling methods commonly used for surveys. Figure 1-3 illustrates these different sampling methods.