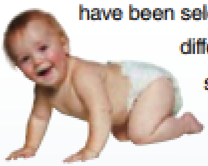
National Children's Study

The National Children's Study, launched in 2009, is designed to follow 100,000 U.S. children from before birth to age 21. Subjects have been selected from 105 different counties so that it will include a good mix of characteristics. Because children are observed from birth into the future, this is a good example of a prospective study. The cost of the study was originally expected to be $3 billion, but it has grown to almost $7 billion. Data are being collected from such varied sources as breast milk and carpet dust. The general goal is to collect data that will enhance our understanding of the effects of genetics and the environment on children. It is hoped that this understanding will lead to improvements in children's health. The National Children's Study is the largest, most expensive, and most comprehensive study of its type ever undertaken. It is being sponsored by several federal organizations, including the Department of Health and Human Services, the National Institutes of Health, and the Environmental Protection Agency.



DEFINITIONS

In a **cross-sectional study,** data are observed, measured, and collected at one point in time, not over a period of time.

In a **retrospective** (or **case-control**) **study,** data are collected from a past time period by going back in time (through examination of records, interviews, and so on).

In a **prospective** (or **longitudinal** or **cohort**) **study,** data are collected in the future from groups that share common factors (such groups are called *cohorts*).

The sampling done in retrospective studies differs from that in prospective studies. In retrospective studies we go back in time to collect data about the characteristic that is of interest, such as a group of drivers who died in car crashes and another group of drivers who did not die in car crashes. In prospective studies we go forward in time by following a group with a potentially causative factor and a group without it, such as a group of drivers who use cell phones and a group of drivers who do not use cell phones.

Designs of Experiments

We begin with Example 3, which describes the largest public health experiment ever conducted, and which serves as an example of an experiment having a good design. After describing the experiment in more detail, we describe the characteristics of randomization, replication, and blinding that typify a good design in experiments.

Example 3 The Salk Vaccine Experiment

In 1954, a large-scale experiment was designed to test the effectiveness of the Salk vaccine in preventing polio, which had killed or paralyzed thousands of children. In that experiment, 200,745 children were given a treatment consisting of Salk vaccine injections, while a second group of 201,229 children were injected with a placebo that contained no drug. The children being injected did not know whether they were getting the Salk vaccine or the placebo. Children were assigned to the treatment or placebo group through a process of random selection, equivalent to flipping a coin. Among the children given the Salk vaccine, 33 later developed paralytic polio, and among the children given a placebo, 115 later developed paralytic polio.

Randomization is used when subjects are assigned to different groups through a process of random selection. The 401,974 children in the Salk vaccine experiment were assigned to the Salk vaccine treatment group or the placebo group via a process of random selection equivalent to flipping a coin. In this experiment, it would be extremely difficult to directly assign children to two groups having similar characteristics of age, health, sex, weight, height, diet, and so on. There could easily be important variables that we might not think of including. The logic behind randomization is to use chance as a way to create two groups that are similar. Although it might seem that we should not leave anything to chance in experiments, randomization has been found to be an extremely effective method for assigning subjects to groups. However, it is possible for randomization to result in unbalanced samples, especially when very small sample sizes are involved.

Replication is the repetition of an experiment on more than one subject. Samples should be large enough so that the erratic behavior that is characteristic of very small samples will not disguise the true effects of different treatments. Replication is used effectively when we have enough subjects to recognize differences resulting from different treatments. (In another context, *replication* refers to the repetition or duplication of an experiment so that results can be confirmed or verified.) With replication, the large sample sizes increase the chance of recognizing different treatment effects. However, a large sample is not necessarily a good sample. Although it is important to have a sample