

15. a) This is an observational study.
- b) The study is retrospective. Results were obtained from pre-existing medical records.
 - c) The subjects in this study were 981 women who lived near the site of dioxin release.
 - d) The parameter of interest is the incidence of breast cancer.
 - e) As there is no random assignment, there is no way to know that the dioxin levels caused the increase in breast cancer. There may have been lurking variables that were not identified.
16. a) This is an observational study.
- b) The study is retrospective. Results were obtained from pre-existing church records.
 - c) The subjects of the study are women in Finland. The data were collected from church records dating 1640 to 1870, but the selection process is unknown.
 - d) The parameter of interest is difference in average lifespan between mothers of sons and daughters.
 - e) For this group, having sons was associated with a decrease in lifespan of an average of 34 weeks per son, while having daughters was associated with an unspecified increase in lifespan. As there is no random assignment, there is no way to know that having sons caused a decrease in lifespan.

21. a) This is an experiment. Hopefully, dogs are randomly assigned to different treatment groups.
b) The subjects are inactive dogs.
c) There is 1 factor (type of dog food), at 2 levels (low-calorie and standard). One possible difficulty with this experiment is that some owners might feed their dogs more food than others. We will assume that the dog food company has given the owners specific instructions about the quantity of food required, based on the size of each dog.
d) 1 factor, at 2 levels, results in 2 treatments.
e) The response variable is the weight of the dogs.
f) The experiment uses blocking by size of breed. Blocking by size reduces variation in weight that may be due to overall size of the dog.
g) Assuming that the dog owners do not know which type of dog food their dog is receiving, the experiment is blinded.
h) Assuming the dog owners followed the prescribed feeding levels, there could be a conclusion as to whether or not the dog food helped the dogs maintain a healthy weight.
22. a) This is an experiment. Athletes were randomly assigned to one of two exercise programs.
b) The subjects are athletes suffering hamstring injuries.
c) There is one factor (type of exercise), at 2 levels (static stretching, and agility and trunk stabilization).
d) 1 factor, at 2 levels, results in 2 treatments.
e) The response variable is the time before the athletes were able to return to sports.
f) The experiment is completely randomized.
g) The experiment employs no blinding. The subjects know what kind of exercise they do.

But Is It Ethical?

- Is it OK to experiment on animals?
- How much pain is ethical to inflict upon animals?
Upon humans?
- Some psychological questions involve mental stress. Is it ethical to subject humans to emotional stress?
- There are no easy answers to these questions. Most researchers have to submit their research ideas to an ethics board for approval.

- Researchers intentionally give rats cancer to explore how tumors grow and what kinds of treatments may slow the progress of or cure the disease. Is it okay to inflict cancer in rats to improve medical care for humans?
- Because their hearts closely resemble ours, pigs are often used in research on heart disease. In fact, many pigs are killed so that their heart valves can be transplanted to humans whose own valves have failed. Do you think this is ethical?
- Our closest genetic relatives are monkeys, making them desirable subjects for many medical experiments. In addition to whatever suffering these animals may experience, often they must be killed and dissected to evaluate the effectiveness of the treatments under investigation. Are these sacrifices justifiable if they help save the life of someone you love?
- Even if you are okay with the use of animal subjects in medical experiments, what about other research? Cosmetics companies test makeup to be sure it's safe for human use. In the Draize test, for example, caustic substances are placed in the eyes of conscious rabbits to see if they cause damage to sensitive eye tissues. Is it ethical to induce pain in animals so that humans can look prettier?
- Many experiments use human subjects. Parkinson's disease involves neural malfunctions deep in the brain. In one possible treatment under investigation, doctors drill a small hole in the patient's skull to insert an instrument that injects new nerve cells, hoping these may grow and replace the damaged ones. Some subjects got "placebo holes" without any injections, so that the experiment could be double-blind. Is it ethical to just drill a hole in someone's skull, even if not doing so interferes with the researcher's ability to evaluate the effectiveness of the treatment?

Would you volunteer for an experiment not knowing whether the treatment would work—or even be safe—and knowing you might only receive the placebo? What if you were paid, or had no health insurance and were offered free medical care? Suppose you were told that your condition was life-threatening and there were no other options? Do human subjects participate out of desperation, or out of a genuine desire to help others who may suffer from the same condition?

Salk Polio Vaccine Trials:

- 1940's-1950's polio epidemic
- Killed many children and crippled others (FDR)
- Parents were afraid for their children's lives
- Parents were asked for approval to try and experimental vaccine on their 2nd grade children
- Two experiments performed:
 - > Double-blind:
 - 600,000 children received 2 shots, one month apart
 - half received vaccine, half placebo
 - Students who received vaccines had a considerable decrease in the number of polio cases
 - > Voluntary:
 - Parents who chose to participate had their children vaccinated
 - Children of those who refused to consent weren't vaccinated; they became the control group
 - Results were not as dramatic because it is believed that the students who came from parents who consented to the vaccine came from better, cleaner home-life.
 - Children from less clean homes had the opportunity to be infected by a milder form of polio creating a natural immunity.
 - As a result, those vaccinated children were MORE likely to contract polio to begin with (without the vaccine.)

How do you think it felt to be the parents during those times?

How do you think it felt to be the children during those times?

What Can Go Wrong?

- Don't give up just because you can't run an experiment.
 - If we can't perform an experiment, often an observational study is a good choice.
- Beware of confounding.
 - Use randomization whenever possible to ensure that the factors not in your experiment are not confounded with your treatment levels.
 - Be alert to confounding that cannot be avoided, and report it along with your results.

What have we learned?

- We can recognize sample surveys, observational studies, and randomized comparative experiments.
 - These methods collect data in different ways and lead us to different conclusions.
- We can identify retrospective and prospective observational studies and understand the advantages and disadvantages of each.
- Only well-designed experiments can allow us to reach cause-and-effect conclusions.
 - We manipulate levels of treatments to see if the factor we have identified produces changes in our response variable.



What have we learned? (cont.)

- We know the principles of experimental design:
 - Identify and control as many other sources of variability as possible so we can be sure that the variation in the response variable can be attributed to our factor.
 - * Try to equalize the many possible sources of variability that cannot be identified by randomly assigning experimental units to treatments.
 - Replicate the experiment on as many subjects as possible.
 - Consider blocking to reduce variability from sources we recognize but cannot control.

What have we learned? (cont.)

- We've learned the value of having a control group and of using blinding and placebo controls.
- We can recognize problems posed by confounding variables in experiments and lurking variables in observational studies.

Homework:

Start Review - Do Multiple Choice

Packet pg. 45-47 #1-14