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Chapter 4: Designing Studies

Section 4.3

Using Studies Wisely

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Scope of Inference

What type of inference can be made from a particular study? The answer depends on the design of the study.

Well-designed experiments randomly assign individuals to treatment groups. However, most experiments don't select experimental units at random from the larger population. That limits such experiments to inference about cause and effect.

Observational studies don't randomly assign individuals to groups, which rules out inference about cause and effect. Observational studies that use random sampling can make inferences about the population.

		Were individuals randomly assigned to groups?	
		Yes	**No**
Were individuals randomly selected?	**Yes**	Inference about the population: YES Inference about cause and effect: YES	Inference about the population: YES Inference about cause and effect: NO
	No	Inference about the population: NO Inference about cause and effect: YES	Inference about the population: NO Inference about cause and effect: NO

Example 1: A small-town dentist wants to know if a daily dose of 500 milligrams (mg) of vitamin C will result in fewer canker sores in the mouth than taking no vitamin C.

The dentist is considering the following four study designs:

Design 1: Get all dental patients in town with appointments in the next two weeks to take part in a study. Give each patient a survey with two questions: (1) Do you take at least 500 mg of vitamin C each day? (2) Do you frequently have canker sores? Based on patients' answers to Question 1, divide them into two groups: those who take at least 500 mg of vitamin C daily and those who don't.

Design 2: Get all dental patients in town with appointments in the next two weeks to take part in a study. Randomly assign half of them to take 500 mg of vitamin C each day and the other half to abstain from taking vitamin C for three months.

Design 3: Select a random sample of dental patients in town and get them to take part in a study. Divide the patients into two groups as in Design 1.

Design 4: Select a random sample of dental patients in town and get them to take part in a study. Randomly assign half of them to take 500 mg of vitamin C each day and the other half to abstain from taking vitamin C for three months.
For whichever design the dentist chooses, suppose she compares the proportion of patients in each group who complain of canker sores. Also suppose that she finds a statistically significant difference, with a smaller proportion of those taking vitamin C having canker sores.

What can the dentist conclude for each design?

Design 1: Because the patients were not randomly selected, the dentist cannot infer that this result holds for a larger population of dental patients. This was an observational study because no treatments were deliberately imposed on the patients. With no random assignment to the two groups, no inference about cause and effect can be made. The dentist just knows that for these patients, those who took vitamin C had fewer canker sores than those who didn't.

Design 2: As in Design 1, the dentist can't make any inference about this result holding for a larger population of dental patients. However, the treatments were randomly assigned to the subjects. Assuming proper control in the experiment, she can conclude that taking vitamin C reduced the chance of getting canker sores in her subjects.

Design 3: Because the patients were randomly selected from the population of dental patients in the town, the dentist can generalize the results of this study to the population. Because this was an observational study, no inference about cause and effect can be made. The dentist would conclude that for the population of dental patients in this town, those taking vitamin C have fewer canker sores than those who don't. She can't say whether the vitamin C causes this reduction or some other confounding variable.

Design 4: As in Design 3, the random sampling allows the dentist to generalize the results of this study to the population of dental patients in the town. As in Design 2, the random assignment would allow her to conclude (assuming proper control in the experiment) that taking vitamin C reduced the chance of getting canker sores. So the dentist would conclude that for the population of dental patients in this town, those taking vitamin C will tend to have fewer canker sores than those who don't due to the vitamin C.

The Challenges of Establishing Causation

A well-designed experiment tells us that changes in the explanatory variable cause changes in the response variable.

Lack of realism can limit our ability to apply the conclusions of an experiment to the settings of greatest interest.

Example 2: Do those high center brake lights, required on all cars sold in the United States since 1986, really reduce rear-end collisions? Randomized comparative experiments with fleets of rental and business cars, done before the lights were required, showed that the third brake light reduced rear-end collisions by as much as 50%. But requiring the third light in all cars led to only a 5% drop.

What happened? Most cars did not have the extra brake light when the experiments were carried out, so it caught the eye of following drivers. Now that almost all cars have the third light, they no longer capture attention.

In some cases it isn't practical or ethical to do an experiment. Consider these questions:

Does texting while driving increase the risk of having an accident?
Does going to church regularly help people live longer?
Does smoking cause lung cancer?

What are the criteria for establishing causation when we can't do an experiment?

Example 3: Doctors had long observed that most lung cancer patients were smokers. Comparison of smokers and similar nonsmokers showed a very strong association between smoking and death from lung cancer. Could the association be due to some other variable? Is there some genetic factor that makes people both more likely to get addicted to nicotine and to develop lung cancer? If so, then smoking and lung cancer would be strongly associated even if smoking had no direct effect on the lungs. Or maybe confounding is to blame. It might be that smokers live unhealthy lives in other ways (diet, alcohol, lack of exercise) and that some other habit confounded with smoking is a cause of lung cancer. How were these objections overcome?

The association is strong. The association between smoking and lung cancer is very strong.

The association is consistent. Many studies of different kinds of people in many countries link smoking to lung cancer. That reduces the chance that a lurking variable specific to one group or one study explains the association.

Larger values of the explanatory variable are associated with stronger responses. People who smoke more cigarettes per day or who smoke over a longer period get lung cancer more often. People who stop smoking reduce their risk.

The alleged cause precedes the effect in time. Lung cancer develops after years of smoking. The number of men dying of lung cancer rose as smoking became more common, with a lag of about 30 years. Lung cancer kills more men than any other form of cancer. Lung cancer was rare among women until women began to smoke. Lung cancer in women rose along with smoking, again with a lag of about 30 years, and has now passed breast cancer as the leading cause of cancer death among women.

The alleged cause is plausible. Experiments with animals show that tars from cigarette smoke do cause cancer.