**Section 1.6 The Design of Experiments**

**Objectives**

1. Describe the Characteristics of an Experiment
2. Explain the Steps in Designing an Experiment
3. Explain the Completely Randomized Design
4. Explain the Matched-Pairs Design

*Watch the video for a review of the language used in observational studies.*

**Review the definitions of cross-sectional studies, case-control studies, and cohort studies.**

* **In observational studies, we cannot make statements of *causality* between the explanatory variable(s) and the response variable.**
* **The response variable measures the outcome of the study.**
* **The explanatory variable is the variable whose impact we want to see has on the response variable.**

So let's define experiment and look

at all the different characteristics

that experiments have.

An experiment is a controlled study.

**so that's the big difference between it**

**and an observational study.**

It's a controlled study conducted

to determine the effect of varying,

meaning changing, one or more explanatory variables.

And in an experimental design sense,

instead of saying explanatory variables,

you'll often hear us say factors.

Factors and explanatory variables

are synonymous, as on a response variable.

Any combination of values and factors

is going to be called a **treatment.**

**So when you have only one explanatory variable,**

**the factors and the treatments are one in the same.**

**But sometimes we might have more than one explanatory variable.**

Let's say we say smoking versus non-smoking is one variable,

and then we might say low protein diet and high protein

diet.

There the treatments would be non-smoker, low protein,

non-smoker, high protein.

Smoker, low protein, and then smoker, high protein.

There's 4 treatments, basically, that

are the combination of factors.

**The experimental unit** is a person, object,

or some other well defined item upon which

a treatment is applied.

Typically we use experimental unit

when we're not talking about humans.

When we're talking about **humans,** we refer to them as **subjects**,

because it sounds better, I guess.

In a design experiment, you're always

going to have a control group.

**A control group serves as a baseline treatment**

**that can be used to compare other treatments.**

**Like if I was going to be highly unethical**

**and have this smoking experiment,**

my control group would probably be the nonsmokers,

and then the other group would be hey,

I'm going to make you smoke a pack of cigarettes every day

for the next 30 years and see what happens.

Again, a highly unethical experiment

that hopefully conveys the idea.

**A placebo** is another word used in experimental designs.

A placebo is an innocuous medication,

such as a sugar tablet, that looks, tastes, and smells

like the experimental medication.

So maybe I'm trying to do an experiment

to see the impact of alcohol on reaction time.

My placebo there would have to be something

that looks, tastes, and smells like alcohol,

but does not have the effects that alcohol has.

**Blinding** refers to nondisclosure of the treatment

an experimental unit is receiving.

So I'm doing an experiment where I'm

trying to see the impact alcohol has on reaction time,

I'm not going to tell you hey, you're getting the real alcohol

and over there, you're getting the placebo.

That would kind of ruin the experiment.

**There are two types of blinding that exist.**

**A single blind**

experiment is one where the experimental unit

does not know the treatment he or she is receiving,

but the researcher or the individual administering

the treatment does.

Those are dicey.

Sometimes it's necessary to do this,

but more times, experiments are done

as a

**double blind experiment**.

Meaning the experimental unit doesn't

know the treatment they're receiving,

nor does the individual administering

the treatment know which treatment the experimental unit

is receiving.

So obviously there needs to be a third party in the background

that does know, but is not involved directly

with the experimental units.

And the reason double blinding is important,

especially in medical studies, is

let's say I am doing an experiment on human subjects

where it's a new medication for the treatment of, say, cancer.

Some type of cancer.

I might, if I know that Bob over here

is getting the new medication, I might, knowingly

or unknowingly, treat Bob different than John

over here who is getting the placebo.

Maybe I'm not a very good poker player

and I show my hands to Bob, and I may also

show my hand to John, and John's like, oh man,

I'm getting the placebo.

I can tell by the way he's acting towards me.

Because there's all kinds of psychosomatic stuff

that oftentimes happens in these medical studies.

And if John knows he's getting a placebo

he might get all down on himself,

and it might be the psychosomatic results that

are impacting the cancer treatment as opposed

to the experimental drug.

*Define the following terms after watching the video.*

1. **Experiment:**

An experiment is a controlled study.

**so that's the big difference between it**

**and an observational study.**

1. **FACTOR.** And in an experimental design sense,

instead of saying explanatory variables,

you'll often hear us say factors.

Factors and explanatory variables

are synonymous, as on a response variable.

1. **Treatment:** Any combination of values and factors

is going to be called a **treatment.**

The use of [Placebos](https://xlitemprod.pearsoncmg.com/assignment/containerassignmentplayer.aspx#xln-lb-lnk_obj1_2_5173b208-ef2f-afce-2459-46d51b911ca2) in designed experiments is a way to form a [Control group](https://xlitemprod.pearsoncmg.com/assignment/containerassignmentplayer.aspx#xln-lb-lnk_obj1_2_62532bf4-6e16-7e36-8e03-211d1a37ec00) in a designed experiment. Often, placebos take the form of a medication. However, a placebo might also be a procedure that follows the same steps as the experimental procedure, but leaves out a key intervention.

For example, a procedure called **Vertebroplasty** where medical cement is pumped into a spine fracture was tested through a designed experiment. All subjects went through a surgery to repair the spine, but only half received the medical cement. An interesting outcome results from the vertebroplasty experiment. A subject in the placebo group found that the procedure resulted in complete abatement of the back pain even though she did not receive the medical cement! This type of phenomena in an experiment is referred to as the *placebo effect*. A book entitled *Cure* by Jo Marchant explores the **placebo effect**. In the book, she suggests that placebo treatments can have measurable effects. For example, in patients with Parkinson's disease placebos caused an increase of the neurotransmitter dopamine. In a study of 459 migraine sufferers, it was found that the placebo effect accounted for about 60% of the benefit of the drug Maxalt. Of course, the placebo effect will not account for improvements in someone with a tumor or replace insulin with someone with diabetes. However, the Maxalt study suggests that remedies for pain, nausea, or depression rely extensively on the placebo effect.

Recall confounding in a study occurs when the effects of two or more explanatory variables are not separated. In designed experiments, confounding may occur as a result of a confounding variable, which is an explanatory variable that was considered in a study whose effect cannot be distinguished from a second explanatory variable in the study.

The example we used to illustrate the concept of confounding was Professor Egner's study on the effect of online homework versus paper/pencil homework on final exam scores. Professor Egner taught her morning class using online homework and her afternoon class using paper/pencil homework. If the final exam scores for the morning class were higher than the afternoon class, we could not tell whether the higher exam scores are a result of the homework system, or the time the class is offered. Therefore, the explanatory variable homework system is confounded with the explanatory variable time of day.

Well-designed experiments will account for the potential of confounding in a study.

Objective 1, Page 1 (continued)

*Define the following terms after watching the video.*

1. Experimental Unit-----

A​ person, object, or some other​ well-defined item upon which a treatment is applied

B..Treatment

Any combination of the values of the factors​ (explanatory variables)

C. Response Variable

The quantitative or qualitative variable for which the experimenter wishes to determine how its value is affected by the explanatory variable

D. Factor: .A variable whose effect on the response variable is to be assessed by the experimenter

E. Placebo:   
An innocuous​ medication, such as a sugar​ tablet, that​ looks, tastes, and smells like the experimental medication

F. Confounding:   
The effect of two factors​ (explanatory variables on the response​ variable) cannot be distinguished.

Blinding:

Single-blind: **A single blind**

experiment is one where the experimental unit

does not know the treatment he or she is receiving,

but the researcher or the individual administering

the treatment does.

Those are dicey.

Sometimes it's necessary to do this,

but more times, experiments are done

as a

Double-blind:

Objective 1, Page 2

The use of placebos in designed experiments is a way to form a control group in a designed experiment.

What is the placebo effect? **placebo effect**. In the book, she suggests that placebo treatments can have measurable effects. For example, in patients with Parkinson's disease placebos caused an increase of the neurotransmitter dopamine. In a study of 459 migraine sufferers, it was found that the placebo effect accounted for about 60% of the benefit of the drug Maxalt. Of course, the placebo effect will not account for improvements in someone with a tumor or replace insulin with someone with diabetes. However, the Maxalt study suggests that remedies for pain, nausea, or depression rely extensively on the placebo effect.

Recall confounding in a study occurs when the effects of two or more explanatory variables are not separated. In designed experiments, confounding may occur as a result of a confounding variable, which is an explanatory variable that was considered in a study whose effect cannot be distinguished from a second explanatory variable in the study.

Lipitor is a cholesterol-lowering drug made by Pfizer. In the Collaborative Atorvastatin Diabetes Study (CARDS), the effect of Lipitor on cardiovascular disease was assessed in 2838 subjects, ages 40 to 75, with type 2 diabetes, without prior history of cardiovascular disease. In this placebo-controlled, double-blind experiment, subjects were randomly allocated to either Lipitor 10 mg daily (1428 subjects) or placebo (1410 subjects) and were followed for 4 years. The response variable was whether there was an occurrence of any major cardiovascular event or not.

**Video Solution**

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Lipitor significantly reduced the rate of major cardiovascular events (83 events in the Lipitor group versus 127 events in the placebo group). There were 61 deaths in the Lipitor group versus 82 deaths in the placebo group.

What does it mean for the experiment to be placebo-controlled?

Solution

The placebo is a medication that looks, smells, and tastes like Lipitor. The placebo control group serves as a baseline against which to compare the results from the group receiving Lipitor. The placebo is also used because people tend to behave differently when they are in a study. By having a placebo control group, the effect of this is neutralized.

What does it mean for the experiment to be double-blind?

Solution

Since the experiment is double-blind, the subjects, as well as the individual monitoring the subjects, do not know whether the subjects are receiving Lipitor or the placebo. The experiment is double-blind so that the subjects receiving the medication do not behave differently from those receiving the placebo and so the individual monitoring the subjects does not treat those in the Lipitor group differently from those in the placebo group.

What is the population for which this study applies? What is the sample?

Solution

The population is individuals from 40 to 75 years of age with type 2 diabetes without a prior history of cardiovascular disease.

The sample is the 2838 subjects in the study

What are the treatments?

Solution

The treatments are 10 mg of Lipitor or a placebo daily

What is the response variable? Is it qualitative or quantitative?

Solution

The response variable is whether the subject had any major cardiovascular event, such as a stroke, or not.

It is a qualitative variable with two possible outcomes—cardiovascular event or not

**Steps in Designing an Experiment**

1. *Identify the Problem to Be Solved.* The statement of the problem should be as explicit as possible and should provide the experimenter with direction. The statement must also identify the response variable and the population to be studied. Often, the statement is referred to as the *claim.*
2. *Determine the Factors That Affect the Response Variable*. The factors are usually identified by an expert in the field of study. In identifying the factors, ask, “What things affect the value of the response variable?” After the factors are identified, determine which factors to fix at some predetermined level, which to manipulate, and which to leave uncontrolled
3. *Determine the Number of Experimental Units*. As a general rule, choose as many experimental units as time and money allow. Techniques exist for determining sample size, provided certain information is available.

*Determine the Level of Each Factor.* There are two ways to deal with the factors, control or randomize.

1. **Control:** There are two ways to control the factors.
   1. Set the level of a factor at one value throughout the experiment (if you are not interested in its effect on the response variable).
   2. Set the level of a factor at various levels (if you are interested in its effect on the response variable). The combinations of the levels of all varied factors constitute the treatments in the experiment.

**Randomize:** Randomly assign the experimental units to treatment groups.  Because it is difficult, if not impossible, to identify all factors in an experiment, randomly assigning experimental units to treatment groups reduces the effect of variation attributable to factors (explanatory variables) not controlled. That is, randomly assigning experimental units to treatment groups tends to "even out" any uncontrolled factors.

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3. ***Conduct the Experiment.***
4. Replication occurs when each treatment is applied to more than one experimental unit. Using more than one experimental unit for each treatment ensures the effect of a treatment is not due to some characteristic of a single experimental unit. It is a good idea to assign an equal number of experimental units to each treatment.
5. Collect and process the data. Measure the value of the response variable for each replication. Then organize the results. The idea is that the value of the response variable for each treatment group is the same before the experiment because of randomization. Then any difference in the value of the response variable among the different treatment groups is a result of differences in the level of the treatment.
6. *Test the Claim*. This is the subject of **inferential statistics**. Inferential statistics is a process in which generalizations about a population are made on the basis of results obtained from a sample. Provide a statement regarding the level of confidence in the generalization
   1. To help understand the steps in designing an experiment, let's review [Example 1](https://xlitemprod.pearsoncmg.com/assignment/containerassignmentplayer.aspx#xln-lb-lnk_obj2_2_a0c604ad-5b50-fa67-9c74-c382df6b6d1d).

*Identify the Problem to Be Solved*. The problem to be solved is to determine whether 10 mg of Lipitor daily reduces the likelihood of having a major cardiovascular event in 40- to 75-year old subjects with type 2 diabetes.

* 1. *Determine the Factors That Affect the Response Variable*. Some factors that may affect whether one has a cardiovascular event are diet, exercise, family history, and level of cholesterol.

*3.Determine the Number of Experimental Units.* There were 2838 subjects in the study.

*4.Determine the Level of Each Factor.* The factor of interest is the drug, which was set at two levels: placebo and 10 mg of Lipitor. Although not stated, the researchers likely fixed the diet of the subjects and fixed an exercise regimen. Family history cannot be controlled, so the random assignment of the subjects to two groups will average out a bad family history of heart disease. For example, we would not expect all subjects with a poor history of heart health to end up in the placebo (control) group.

*5. Conduct the Experiment.* The subjects were randomly assigned to either the placebo or Lipitor group. There were 2838 replications of the experiment.

*6. Test the Claim*. The inferential statistics suggest that the Lipitor group had a lower rate of major cardiovascular events

e now concentrate on the simplest type of experiment.

**DEFINITION**

A **completely randomized design** is one in which each experimental unit is randomly assigned to a treatment.

The study from Example 1 is a completely randomized design because each experimental unit (the 2838 subjects) was randomly assigned to either the placebo group or Lipitor group

Problem

A farmer wishes to determine the optimal level of a new fertilizer on his soybean crop. Design an experiment that will assist him.

**Video Solution**

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Approach

Follow the [steps](https://xlitemprod.pearsoncmg.com/assignment/containerassignmentplayer.aspx#xln-lb-lnk_obj3_2_fcab5ca6-ac0a-bdc3-ea57-3afa4f9b30d5) for designing an experiment.

Solution

**Step 1. Identify the Problem to Be Solved** The farmer wants to identify the optimal level of fertilizer for growing soybeans. We define *optimal* as the level that maximizes yield. So, the response variable will be crop yield.

**Determine the Factors** Some factors that affect crop yield are fertilizer, precipitation, sunlight, method of tilling the soil, type of soil, plant, and temperature.

**Determine the Number of Experimental Units** In this experiment, we will plant 60 soybean plants (experimental units).

**Determine the Level of Each Factor** List the factors and their levels.

* **Fertilizer.** This factor is the explanatory variable of interest. So, it will be controlled and set at three levels. We wish to measure the effect of varying the level of this variable on the response variable, yield. We will set the treatments (level of fertilizer) as follows:
  + Treatment A: 20 soybean plants receive no fertilizer.
  + Treatment B: 20 soybean plants receive 2 teaspoons of fertilizer per gallon of water every 2 weeks.
  + Treatment C: 20 soybean plants receive 4 teaspoons of fertilizer per gallon of water every 2 weeks.
* **Precipitation.**The amount of rainfall cannot be controlled, but the amount of watering done can be controlled. Each plant will receive the same amount of precipitation.
* **Sunlight.** This uncontrollable factor will be roughly the same for each plant.
* **Method of tilling.**Control this factor using the round-up ready method of tilling for each plant.
* **Type of soil.**Certain aspects of the soil, such as level of acidity, can be controlled. In addition, each plant will be planted within a 1-acre area, so it is reasonable to assume that the soil conditions for each plant are equivalent.
* **Plant.** There may be variation (in terms of ability to generate yield) from plant to plant. To account for this, we randomly assign the plants to a treatment.
* **Temperature.** This factor is uncontrollable, but will be the same for each plant.

**Conduct the Experiment**

1. Assign each plant to a treatment group. First, number the plants from 1 to 60 and randomly generate 20 numbers. The plants corresponding to these numbers get treatment A. Next number the remaining plants 1 to 40 and randomly generate 20 numbers. The plants corresponding to these numbers get treatment B. The remaining plants get treatment C. Now till the soil, plant the soybean plants, and fertilize according to the schedule prescribed.
2. At the end of the growing season, determine the crop yield for each plant.

**Test the Claim.**Determine any differences in yield among the three treatment groups

gure 2 illustrates the experimental design from Example 2 on the previous screen.

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| An experimental design. |  |
| Figure 2 | |

Example 2 is a completely randomized design because the experimental units (the plants) were randomly assigned to the treatments. It is the most popular experimental design because of its simplicity, but it is not always the best.

OBJECTIVE 4 Explain the Matched-Pairs Design

Another type of experimental design is called a *matched-pairs design*.

**DEFINITION**

A **matched-pairs design** is an experimental design in which the experimental units are paired up. The pairs are selected so that they are related in some way (that is, the same person before and after a treatment, twins, husband and wife, same geographical location, and so on). There are only two levels of treatment in a matched-pairs design.

In matched-pairs design, one matched individual will receive one treatment and the other receives a different treatment. The matched pair is randomly assigned to the treatment using a coin flip or a random-number generator. We then look at the difference in the results of each matched pair. One common type of matched-pairs design is to measure a response variable on an experimental unit before and after a treatment is applied. In this case, the individual is matched against itself. These experiments are sometimes called before–after or pretest–posttest experiments.

A Matched-Pairs Design

Problem

An educational psychologist wants to determine whether listening to music has an effect on a student’s ability to learn. Design an experiment to help the psychologist answer the question.

**Video Solution**

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Approach

Use a matched-pairs design by matching students according to IQ and gender (just in case gender plays a role in learning with music).

Solution

Match students according to IQ and gender. For example, match two females with IQs in the 110 to 115 range.

For each pair of students, flip a coin to determine which student is assigned the treatment of a quiet room or a room with music playing in the background.

Each student will be given a statistics textbook and asked to study Section 1.1. After 2 hours, the students will enter a testing center and take a short quiz on the material in the section. Compute the difference in the scores of each matched pair. Any differences in scores will be attributed to the treatment. Figure 3 illustrates the design.

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| [Alt-Text](https://xlitemprod.pearsoncmg.com/assignment/containerassignmentplayer.aspx)A matched-pairs design.  Figure 3 |  |

The experimental design is based on how the subjects are grouped. Different types of experimental designs and studies are explained below.

A completely randomized design is one in which each experimental unit is randomly assigned to a treatment.

A​ matched-pairs design is an experimental design in which the experimental units are paired up. The pairs are selected so that they are related in some way​ (that is, the same person before and after a​ treatment, twins, husband and​ wife, same geographical​ location, and so​ on).

A randomized block design is used when the experimental units are divided into homogeneous groups called blocks. Within each​ block, the experimental units are randomly assigned to treatments.

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Case-control studies are retrospective​ studies, meaning that they require individuals to look back in time or require the researcher to look at existing records. In​ case-control studies, individuals who have a certain characteristic may be matched with those who do not.

An experiment is a controlled study conducted to determine the effect varying one or more explanatory variables or factors has on a response variable. Any combination of the values of the factors is called a treatment.