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Or, not as catchy but perhaps more accurate:

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Or, not as catchy but perhaps more accurate:

Fancy analysis can't fix a poorly designed study.



Producing Data

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Statistically designed studies obtain data using a pre-specified plan that ensures that specific questions of interest are answered in a scientifically valid way.



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As the name suggests, in an exploratory analysis investigators explore the data to find patterns that might suggest specific questions about the phenomena under study.

Exploratory analysis cannot establish scientific validity, however. For this, statistically designed studies are needed. A good strategy is to use exploratory data analysis to identify specific questions that can then be answered by targeted statistically designed studies.





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For example, a manufacturing company that produces bronze bushings found that the surface roughness on the bushings was unacceptably variable.

To identify possible reasons, they did an **exploratory** analysis of historical production data (an example of available data). This analysis identified four process conditions that seemed to be strongly associated with surface roughness measurements: lathe operator, cutting speed, feed rate, and tool type.

With this information, they **designed** a study purposely varying these four conditions to see what the effects were on surface roughness.

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Controlled Experiments

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- Observational Studies

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All use **observational units**: entities on which measurements or observations can be made.

These observational units are often selected from a larger population of such units. When discussing their selection, we call them **sampling units**.





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- Quantify how far from the population results our sample results are likely to be.



Selecting Sampling Units

• Target Population:

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- Target Population: A collection of sampling units about which we want to draw conclusions
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- **Sample:** A subset of the target population from which conclusions about the target population will be drawn



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Example 1

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- Sampling Design: There are a large number of choices, as we will see below.
- Sampling Plan: Operational plan for deciding whom to interview, how to get them to do the interview, what to do if they can't be found, or won't talk, etc.



Probability Sampling Methods

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In addition, many samples are taken in stages, using any of the above methods at any stage. Such sampling is called **Multistage Sampling**.

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One large study conducted monthly by the US Census Bureau is the Current Population Survey, which estimates such things as unemployment and schooling by taking a multistage cluster sample of 100,000 people in 60,000 households.



Example 2

Suppose you want to estimate the average amount spent by first term sophomores at WPI for textbooks, and that you can interview 10 students for your study. How would you choose the 10 students if:



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- (b) You believe that textbook expenses for engineering students are substantially higher than for other majors. Stratify into two strata: engineers and others. Then take a stratified random sample.
- (c) You want to be certain to obtain an estimate for humanities majors, as well as other majors. Stratify so that one stratum is humanities majors. Then take a stratified random sample.





Errors in Selecting Sampling Units

• Sampling Error

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One type of nonsampling error is **Selection Bias**:

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In statistics, a bias is a distortion of the results of a statistical procedure.

Selection bias is a bias introduced to the results because the sampling method to at least some extent misses certain segments of the population.



Some Possible Errors in Selecting Sampling Units for the WPI Election Survey

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• Sampling Error: The extent to which the sample is unrepresentative of the population, by chance alone.

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Some Possible Errors in Selecting Sampling Units for the WPI Election Survey

- Sampling Error: The extent to which the sample is unrepresentative of the population, by chance alone.
- Selection Bias: Selection bias might occur if the survey were conducted in class. In that case, the survey would miss those who don't come to class. This would result in a bias if the views of those who come to class and of those who do not come to class differ.



An Extreme Example of Selection Bias

On July 25, 2017 CNN reported:

Chronic traumatic encephalopathy, known as CTE, was found in 99% of deceased NFL players' brains that were donated to scientific research, according to a study published Tuesday in the medical journal JAMA. . . . Out of 202 deceased former football players total – a combination of high school, college and professional players – CTE was neuropathologically diagnosed in 177, the study said.

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Why is this an extreme example of selection bias?

Answer: Brains donated to scientific research are overwhelmingly from individuals exhibiting symptoms of brain damage.





Note:

If the sampling units are selected by some non-probability method (convenience, for example), the results of the study are, strictly speaking, only applicable to the sampling units in the study. In order to have results of the study apply to the target population, sampling units must be selected from that target population using an appropriate probability sampling design.



Now that we have acquired a sample, what do we do with it?

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That depends on what kind of study we are conducting.



Recall:

Types of Designed Studies

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- Controlled Experiment
- Observational Study

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Before we can discuss controlled experiments, we need some terminology:

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• Experimental Unit:

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Before we can discuss controlled experiments, we need some terminology:

- Experimental Unit: A sampling unit selected for use in a controlled experiment.
- Response: A measurement or observation of interest that is made on an experimental unit.



• Factor:

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 - o Nuisance Factor:

- Factor: Something thought to influence the response.
 - Experimental Factor: A factor that is purposely varied by the experimenter.
 - O Nuisance Factor: A factor that cannot be controlled by the experimenter. Nuisance factors may or may not be known to the experimenter.



• Level:

• Level: A value assumed by a factor in an experiment.

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- Treatments:

- Level: A value assumed by a factor in an experiment.
- Treatments: The combinations of levels of experimental factors for which the response will be observed.



We are now ready to define **Controlled Experiment**:

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A Controlled Experiment is a study in which treatments are imposed on experimental units in order to observe a response.



Example 3

A printing company is having trouble with ink overflow on printed documents. After much brainstorming and discussion, they have narrowed the possible causes to two printing machine settings: the pressure plate setting and the ink flow rate setting. They design and run a controlled experiment to evaluate the effect of these settings on the finished product. They decide on three settings, low, medium and high, for the pressure plate and two settings, low and high, for the ink flow rate. The response is the improperly inked area on a test sheet. The data are (in (mm)²):

Ink flow				
setting	Pressure plate setting			
	Low	Medium	High	
Low	25.300	27.100	19.700	
	21.600	24.200	21.900	
High	31.100	25.600	26.600	
	29.500	23.100	23.900	

For this experiment:

Experimental units:

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• Experimental units: paper sheets.

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- Response:

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- Response: improperly inked area.

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- Experimental units: paper sheets.
- Response: improperly inked area.
- Experimental factors: pressure plate setting, ink flow setting.
- Nuisance factors: variation in paper characteristics, environmental factors (temperature, humidity, etc.), ink supplier, etc.
- Factor levels: low, medium, high for pressure plate; low, high for ink flow rate.

- Experimental units: paper sheets.
- Response: improperly inked area.
- Experimental factors: pressure plate setting, ink flow setting.
- Nuisance factors: variation in paper characteristics, environmental factors (temperature, humidity, etc.), ink supplier, etc.
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- Treatments:

- Experimental units: paper sheets.
- Response: improperly inked area.
- Experimental factors: pressure plate setting, ink flow setting.
- Nuisance factors: variation in paper characteristics, environmental factors (temperature, humidity, etc.), ink supplier, etc.
- Factor levels: low, medium, high for pressure plate; low, high for ink flow rate.
- Treatments: pressure plate & ink flow rate combinations.





This is a controlled experiment because treatments (pressure plate & ink flow rate combinations) are imposed on experimental units (paper sheets) in order to observe a response (improperly inked area).



Here are some further quantities and concepts of importance in controlled experiments:

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o **Effect:** The change in the average response between two factor levels or between two combinations of factor levels. Here are some effects from example 3:



Ink flow				Row
setting	Pressure plate setting			Mean
	Low	Medium	High	
Low	25.300	27.100	19.700	
	21.600	24.200	21.900	
Mean	23.450	25.650	20.800	23.300
High	31.100	25.600	26.600	
	29.500	23.100	23.900	
Mean	30.300	24.350	25.250	26.633
Column				
Mean	26.875	25.000	23.025	24.967

The effect of high ink flow over low ink flow is 26.633 - 23.300 = 3.333.



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	Low	Medium	High	
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Mean	30.300	24.350	25.250	26.633
Column				
Mean	26.875	25.000	23.025	24.967

The effect of high pressure plate setting over medium pressure plate setting is 23.025 - 25.000 = -1.975.



Ink flow				Row
setting	Pressure plate setting			Mean
	Low	Medium	High	
Low	25.300	27.100	19.700	
	21.600	24.200	21.900	
Mean	23.450	25.650	20.800	23.300
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Mean	30.300	24.350	25.250	26.633
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The effect of low ink flow and high pressure plate settings over high ink flow and medium pressure plate settings is 20.800 - 24.350 = -3.55.



o **Confounding:** Two or more factors are **confounded** if it is impossible to separate their individual effects.

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Here is an example of how confounding might occur in the ink flow experiment:

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Here is an example of how confounding might occur in the ink flow experiment:

Suppose that the experimenters ran the trials for the low and high ink flow settings with different kinds of paper. Then paper type and ink flow would be confounded: any observed effect of ink flow could have been due to paper type instead.



By helping ensure that the experimental units receiving different treatments are similar in all other respects, random assignment of treatments to experimental units protects against unsuspected biases. Random assignment is beneficial in at least two other ways.



 Random assignment of treatments to experimental units provides the foundation for statistical inference, on which many scientific applications of statistics depend. We will study statistical inference in chapters 5 and 6.

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- The most compelling reason to conduct a controlled experiment is to establish causality: that is, to show that changing the treatment will cause a change in the response. Randomization "washes out" or "evens out" the effects of unsuspected nuisance factors, which is essential to establishing causality.

- Random assignment of treatments to experimental units provides the foundation for **statistical inference**, on which many scientific applications of statistics depend. We will study statistical inference in chapters 5 and 6.
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Controlled experiments in which treatments are assigned at random to experimental units are called randomized controlled experiments.



Suppose we want to test two different teaching methods in MA2611 labs. To do so, we select two lab sections, one at 8am and the other at 3pm. We randomly assign one of the methods to be used in the 8am lab and the other method in the 3 pm lab. Later, we compare scores for the two sections.

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- Is this a randomized controlled experiment? Yes.
- Is this a good design? Why or why not?

Suppose we want to test two different teaching methods in MA2611 labs. To do so, we select two lab sections, one at 8am and the other at 3pm. We randomly assign one of the methods to be used in the 8am lab and the other method in the 3 pm lab. Later, we compare scores for the two sections.

- Is this a randomized controlled experiment? Yes.
- Is this a good design? Why or why not? It is not the best, because it confounds time of lab with treatment. Students in the 8am might differ in meaningful ways from those in the 3pm. So observed differences in scores might be confounded with the times of the labs.

Assigning Treatments to Experimental Units: Two Commonly-Used Designs

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Completely Randomized Design (CRD)

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- Completely Randomized Design (CRD) Treatments assigned to experimental units completely at random. Works well if units are homogeneous.
- Randomized Complete Block Design (RCBD)
 Experimental units grouped into blocks and treatments are assigned at random within each block. Effective if units within each block are more homogeneous than all units taken as a whole.



Two Different Designs for the Ink Overflow Experiment Recall there are 6 treatments (2 ink flow, 3 pressure plate settings) and two sheets used for each, for a total of 12 experimental runs giving a total of 12 observations.

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Two Different Designs for the Ink Overflow Experiment Recall there are 6 treatments (2 ink flow, 3 pressure plate settings) and two sheets used for each, for a total of 12 experimental runs giving a total of 12 observations.

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 For a completely randomized design, assign all 12 runs to the two machines at random. So, for example, machine 1 might get both treatments at high ink flow setting and high pressure plate setting. Of course the order of the runs should also be randomized. This kind of design makes sense if the machines act very much the same.

For a randomized complete block design, assign one complete set of six treatments to machine 1 and the other to machine 2. The units assigned to each machine form a block, so there are two blocks. Run each set of treatments in random order. This kind of design makes sense if there are substantial differences between the machines.



More on Blocking

More on Blocking

Here is another example of blocking:

25 pleasure boats around the country are available to test two types of marine paint. Make each boat a block by applying both types of paint to each. This (a) reduces boat-to-boat variation and variation due to such things as environment, and (b) makes the results of the study applicable to a wider range of environments and boat types.



Another Example, Continued

How might you modify the design of the study of two teaching methods in MA2611 labs to improve it?



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Specifically, a completely random design for assigning treatments to experimental units is analogous to simple random sampling for obtaining those units from a population, while a randomized complete block design is analogous to

You might notice parallels between two of the types of sampling we discussed earlier and the two types of random treatment assignment just presented.

Specifically, a completely random design for assigning treatments to experimental units is analogous to simple random sampling for obtaining those units from a population, while a randomized complete block design is analogous to stratified random sampling.



However, don't confuse sampling with treatment assignment. The purpose of the random sampling designs is to obtain a representative sample so that the results of any analysis are applicable to the population. The purpose of the random experimental designs is to remove bias due to nuisance factors and so enable accurate, causal conclusions.

Stratification and blocking are mechanisms to increase the efficiency and precision of the results.



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For example, consider an experiment conducted by a pharmaceutical company to test a new medication designed to lower LDL cholesterol levels. Here are a couple of different ways to design a paired experiment to do this:



 Ten subjects are recruited for the study. Their LDL levels are measured at the beginning of the study. They are then given the medication for one month and their LDL levels measured at the end of that time. Here, subjects are blocks and paired measurements are taken on each.

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- Twenty subjects are recruited for the study in such a way that each subject is paired with another based on gender, age, LDL levels, and other relevant variables. One of each pair is randomly selected to receive the medication; the other does not receive it. After one month their LDL levels are measured. Here the paired subjects form the blocks.

Principles of Experimental Design

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Principles of Experimental Design in the Ink Overflow Experiment

Principles of Experimental Design in the Ink Overflow Experiment

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- Randomize What You Cannot Block. Paper sheets were randomly assigned and order of run was randomized in each machine (block) separately.



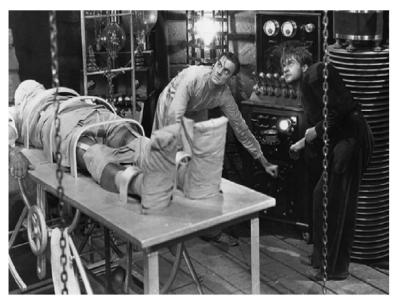
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- Confirm the Results. To verify the results, confirmatory experiments were later run.





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Example: Salk Vaccine Field Trial, p. 108 of the original text, p. 92 of the pdf/local version.





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Example 4

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This study is not a controlled experiment since it merely **observed** the folic acid intake and coronary death outcomes, rather than assigning a folic acid regimen to individuals.





Cohort (aka Prospective) Studies

Also known as quasi-experiments, because they are controlled experiment "wannabees", cohort studies do not control the assignment of treatments to experimental units (e.g., we cannot assign a human subject a certain number of cigarettes per day).

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Also known as quasi-experiments, because they are controlled experiment "wannabees", cohort studies do not control the assignment of treatments to experimental units (e.g., we cannot assign a human subject a certain number of cigarettes per day).

As a result, cohort studies (and, in fact, all observational studies) can only demonstrate association, not cause-effect, between treatments and responses.



In a cohort study, "treatment" and "control" groups (known as **cohorts**) are established based on the hypothesized cause. The pattern of response (i.e., the effect) is then compared for the groups.

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In a study of the relation between smoking and lung cancer, the cohorts might be smokers and non-smokers, and the response might be whether or not the subject develops lung cancer.

If the percentage of smokers who develop lung cancer is substantially different than the percentage of non-smokers who develop lung cancer, we would conclude there is an association between smoking and lung cancer.





Example 4, Continued:

If the Canadian folic acid study assigned individuals to groups based on their reported folic acid intake, followed them for a period of time to observe and compare the incidence of fatal coronary disease for the two groups, then it was a cohort study.



Case-Referent (aka Retrospective) Studies

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If the percentage of smokers among the lung cancer group is substantially different than the percentage of smokers among those who did not develop lung cancer, we would conclude there is an association between smoking and lung cancer.

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Case-Referent studies are particularly useful when

- The time between the hypothesized cause and observed effect is large, or
- The effect occurs rarely.



Example 4, Continued

If the Canadian folic acid study classified individuals into groups based on whether or not they died of coronary disease, and compared the pattern of folic acid intake for the two groups, then it was a case-referent study.



Caution

Some students get the mistaken idea that if the study was done in the past, or done using data taken in the past, it is case-referent. Case-referent refers only to the fact that the groups are formed based on the outcome and then differences in potential causal factors are sought. The case group is the group that gets the positive outcome (e.g., cancer) and the referent group the group that gets the negative outcome (e.g., no cancer).



While it is true that outcomes must be observed prior to analyzing a case-referent study, studies based on data taken in the past can also be cohort studies if groups are established based on characteristics observed prior to observing the outcomes.



For example, suppose the researchers conducted the Canadian folic acid study by randomly selecting 5000 patient records which included folic acid intake, and whether they suffered fatal coronary disease by the end of a 5 year period. Even though the data were taken in the past, if they formed comparison groups based on folic acid intake and compared outcomes, the study is a cohort study.



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The biggest difference between controlled experiments and observational studies, such as cohort and case-referent studies, that attempt to show cause-effect, is the idea of **control**: the ability of the experimenter to assign treatments to experimental units. It is the control in controlled experiments that validates cause-effect conclusions and the lack of control in observational studies that casts doubt on cause-effect conclusions.

Applicability of Study Results

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However, there is nothing in the conduct of such studies that requires such sampling: even if the units used in the study are not selected from the target population in an appropriate way, the results of the study can still be valid for the units in the study.



Sampling Studies

In contrast, sampling studies always rely on data obtained by sampling from a larger target population. The most familiar sampling study is the sample survey.

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Sample surveys

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Sample surveys

- Use a sample of sampling units obtained from a population to obtain information about the whole population.
- Have as their primary goals description of various aspects of the population from which the sample is obtained, or comparison of subgroups from that population (not establishment of association).

The study described in Example 1, in which a sample of 20 WPI students was interviewed to estimate the outcome of an election is an example of a survey.

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Another is the Current Population Survey, conducted monthly by the US Census Bureau. The CPS questions about 100,000 people in some 60,000 households nationwide, and uses the results to estimate measures of the state of the nation such as income, unemployment, and schooling.



Note also that sample surveys are not confined to samples from human populations.

 A survey of wildlife populations might consist of monitoring a sample of habitat parcels (perhaps using capture-recapture methods).

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- Landsat surveys use satellite imagery to estimate land use characteristics worldwide.
- Many manufacturers sample incoming materials or outgoing product to assess quality.
- Election monitors take samples of election ballots to evalulate the fairness of elections.





Recall our earlier discussion of sampling error (and how it's not really an "error") and selection bias which is one variety of nonsampling error.

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Unless a study obtains responses from the entire target population (in which case it is called a census), sampling error is certain to occur. Selection bias may also occur.



Studies of human populations in which individuals are asked to respond to questions, verbally or in writing, are subject to other nonsampling errors, such as

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- **Nonresponse bias:** Bias due to failure to obtain responses from some subjects.
- **Response bias:** Bias due to erroneous responses from some subjects.



Example 4, Continued

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Here are some possible non-sampling errors in the Canadian Folic Acid Study:

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 Nonresponse bias might occur if certain individuals refuse to supply their medical histories.

Example 4, Continued

Here are some possible non-sampling errors in the Canadian Folic Acid Study:

- Nonresponse bias might occur if certain individuals refuse to supply their medical histories.
- Response bias might occur if the subject doesn't tell the truth about his or her health history because of concerns that giving information about poor health will adversely affect future insurability.



• The role of statistics in producing and analyzing data

- The role of statistics in producing and analyzing data
- Selecting sampling units

- The role of statistics in producing and analyzing data
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 - O Sampling designs

- The role of statistics in producing and analyzing data
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 - o Sampling designs
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 - o Designing sampling plans



• Controlled experiments

- Controlled experiments
 - o Principles of experimental design

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 - ${\it o}\,$ Experimenting with human subjects

- Controlled experiments
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 - o Experimenting with human subjects
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- Non-sampling Errors in Studies of Human Populations



