WEEK 2

Study Design

2.1 Week 2 Reading Guide: Sampling, Study Design, and Scope of Inference

Textbook Chapter 2: Study Design

Section 2.1: Sampling principles and strategies

Vocabulary

(Target) Population:

Sample:

Anecdotal evidence:

Bias:

Selection bias:

Non-response bias:

Response bias:

Convenience sample:

Simple Random Sample:

Non-response rate:

Representative:

Notes

Ideally, how should we sample cases from our target population? Using what sampling method?

Notes on types of sampling bias

- Someone must first be *chosen* to be in a study and refuse to participate in order to have **non-response bias**.
- There must be a valid reason for someone to lie or be untruthful to justify saying **response bias** is present. Yes, anyone could lie at any time to any question. Response bias is when those lies are predictable and systematic based on outside influences.

True or False: Convenience sampling tends to result in non-response bias.

True or False: Volunteer sampling tends to result in response bias.

True or False: Random sampling helps to resolve selection bias, but has no impact on non-response or response bias.

Section 2.2 & 2.3: Study Design

Reminders from Section 1.2

Explanatory variable: The variable researchers think *may be* affecting the other variable. What the researchers control/assign in an experiment. If comparing groups, the explanatory variable puts the observational units into groups.

Response variable: The variable researchers think *may be* influenced by the other variable. This variable is always observed, never controlled or assigned.

Vocabulary

Observational study:

Observational data:

Prospective study:

Retrospective study:

Confounding variable:

Experiment:

Randomized experiment:

Blocking:

Treatment group:

Control group:

Placebo:

Placebo effect:

Blinding:

Scope of inference:

Generalizability:

Causation:

Notes

What are the four principles of a well-designed randomized experiment?

Section 2.4: Scope of inference

Fill in the appropriate scope of inference for each study design.

	Study Design	
Selection of Cases	Randomized experiment	Observational study
Random sample (and no other sampling bias)		
Non-random sample (or other sampling bias)		

True or False: Observational studies can show an association between two variables, but cannot determine a causal relationship.

True or False: In order for an experiment to be valid, a placebo must be used.

True or False: If random sampling of the target population is used, and no other types of bias are suspected, results from the sample can be generalized to the entire target population.

True or False: If random sampling of the target population is used, and no other types of bias are suspected, results from the sample can be inferred as a causal relationship between the explanatory and response variables.

2.2 Lecture Notes Week 2: Study Design

Sampling Methods: Section 2.1 in the course textbook

The method used to collect data will impact

- Target population: all ______________________ or ____________________ of interest
- Sample:________________________ or ________________________ from which data is collected

Example: Many high schools moved to partial or fully online schooling in Spring of 2020. Did students who graduated in 2020 tend to have a lower GPA during freshman year of college than the previous class of college freshmen? A nationally representative sample of 1000 college students who were freshmen in AY19-20 and 1000 college students who were freshmen in AY20-21 was taken to answer this question.

- What is the target population?
- What is the sample?

Good vs. bad sampling

GOAL: to have a sample that is ______________________ of the _____________________ ______________________ on the variable(s) of interest

- Unbiased sample methods:

    Simple random sample

- Biased sampling method:

Types of Sampling Bias

- Selection bias:

Example: Newspaper article from 1936 reported that Landon won the presidential election over Roosevelt based on a poll of 10 million voters. Roosevelt was the actual winner. What was wrong with this poll? Poll was completed using a telephone survey and not all people in 1936 had a telephone. Only a certain subset of the population owned a telephone so this subset was over-represented in the telephone survey. The results of the study, showing that Landon would win, did not represent the target population of all US voters.

- Non-response bias:

- To calculate the non-response rate:

$$\frac{\text{number of people who do not respond}}{\text{total number of people selected for the sample}} \times 100\%$$

- For non-response bias to occur must first select people to participate and then they choose not to.

Example: Selected to complete review of online purchase but choose to not respond.

- Response bias:

Example(s): Police officer pulls you over and asks if you have been drinking. Expect people to say no, whether they have been drinking or not.

- Need to be able to predict how people will respond.

Words of caution:

- Convenience samples: gathering data for those who are easily accessible; online polls

  Selection bias?

  Non-response bias?

  Response bias?

- Random sampling reduces ________________________ bias, but has no impact on ________________________ or ____________________ bias.

Examples

A radio talk show asks people to phone in their views on whether the United States should pay off its debt to the United Nations.

- Selection?

- Non-response?

- Response?

The Wall Street Journal plans to make a prediction for the US presidential election based on a survey of its readers and plans to follow-up to ensure everyone responds.

- Selection?

- Non-response?

- Response?

A police detective interested in determining the extent of drug use by high school students, randomly selects a sample of high school students and interviews each one about any illegal drug use by the student during the past year.

- Selection?

- Non-response?

- Response?

Observational studies, experiments, and scope of inference: Sections 2.2 – 2.4 in the course textbook

- Review
  - Explanatory variable: the variable researchers think *may be* effecting the other variable.
  - Response variable: the variable researchers think *may be* influenced by the other variable.
- Confounding variable:
  - associated with both the explanatory and the response variable
  - explains the association shown by the data

Example:

Study design

- Observational study:
- Experiment:

Principles of experimental design

- Control
- Randomization
- Replication
- Blocking

Example: It is well known that humans have more difficulty differentiating between faces of people from different races than people within their own race. A 2018 study published in the Journal of Experimental Psychology: Human Perception and Performance investigated a similar phenomenon with gender. In the study, volunteers were shown several pictures of strangers. Half the volunteers were randomly assigned to rate the attractiveness of the individuals pictured. The other half were told to rate the distinctiveness of the faces seen. Both groups were then shown a slideshow of faces (some that had been rated in the first part of the study, some that were new to the volunteer) and asked to determine if each face was old or new. Researchers found people were better able to recognize faces of their own gender when asked to rate the distinctiveness of the faces, compared to when asked to rate the attractiveness of the faces.

- What is the study design?

Example: In the Physician's Health Study, male physicians participated in a study to determine whether taking a daily low-dose aspirin reduced the risk of heart attacks. The male physicians were randomly assigned to the treatment groups. After five years, 104 of the 11,037 male physicians taking a daily low-dose aspirin had experienced a heart attack while 189 of the 11,034 male physicians taking a placebo had experienced a heart attack.

- What is the study design?

- Assuming these data provide evidence that the low-dose aspirin group had a lower rate of heart attacks than the placebo group, is it valid for the researchers to conclude the lower rate of heart attacks was caused by the daily low-dose aspirin regimen?

Scope of Inference

1. How was the sample selected?

- Random sample with no sampling bias:

- Non-random sample with sampling bias:

2. What is the study design?

- Randomized experiment:

- Observational study:

Scope of Inference Table:

	Study Design	
Selection of Cases	Randomized experiment	Observational study
Random sample (and no other sampling bias)		
Non-random sample (or other sampling bias)		

Example: It is well known that humans have more difficulty differentiating between faces of people from different races than people within their own race. A 2018 study published in the Journal of Experimental Psychology: Human Perception and Performance investigated a similar phenomenon with gender. In the study, volunteers were shown several pictures of strangers. Half the volunteers were randomly assigned to rate the attractiveness of the individuals pictured. The other half were told to rate the distinctiveness of the faces seen. Both groups were then shown a slideshow of faces (some that had been rated in the first part of the study, some that were new to the volunteer) and asked to determine if each face was old or new. Researchers found people were better able to recognize faces of their own gender when asked to rate the distinctiveness of the faces, compared to when asked to rate the attractiveness of the faces.

- What is the scope of inference for this study?

Purpose of random assignment:

Purpose of random selection:

2.3 Out-of-Class Activity Week 2: American Indian Address

2.3.1 Learning outcomes

- Explain why a sampling method is unbiased or biased.
- Identify biased sampling methods.
- Explain the purpose of random selection and its effect on scope of inference.

2.3.2 Terminology review

In this activity, we will examine unbiased and biased methods of sampling. Some terms covered in this activity are:

- Random sample
- Unbiased vs biased methods of selection
- Generalization

To review these concepts, see Section 1.3 in the textbook.

2.3.3 American Indian Address

For this activity, you will read a speech given by Jim Becenti, a member of the Navajo American Indian tribe, who spoke about the employment problems his people faced at an Office of Indian Affairs meeting in Phoenix, Arizona, on January 30, 1947 (Moquin and Van Doren 1973). His speech is below:

It is hard for us to go outside the reservation where we meet strangers. I have been off the reservation ever since I was sixteen. Today I am sorry I quit the Santa Fe [Railroad]. I worked for them in 1912–13. You are enjoying life, liberty, and happiness on the soil the American Indian had, so it is your responsibility to give us a hand, brother. Take us out of distress. I have never been to vocational school. I have very little education. I look at the white man who is a skilled laborer. When I was a young man I worked for a man in Gallup as a carpenter's helper. He treated me as his own brother. I used his tools. Then he took his tools and gave me a list of tools I should buy and I started carpentering just from what I had seen. We have no alphabetical language.

We see things with our eyes and can always remember it. I urge that we help my people to progress in skilled labor as well as common labor. The hope of my people is to change our ways and means in certain directions, so they can help you someday as taxpayers. If not, as you are going now, you will be burdened the rest of your life. The hope of my people is that you will continue to help so that we will be all over the United States and have a hand with you, and give us a brotherly hand so we will be happy as you are. Our reservation is awful small. We did not know the capacity of the range until the white man come and say "you raise too much sheep, got to go somewhere else," resulting in reduction to a skeleton where the Indians can't make a living on it. For eighty years we have been confused by the general public, and what is the condition of the Navajo today? Starvation! We are starving for education. Education is the main thing and the only thing that is going to make us able to compete with you great men here talking to us.

By eye selection

1. Circle ten words in Jim Becenti's speech which are a representative sample of the length of words in the entire text. Describe your method for selecting this sample.

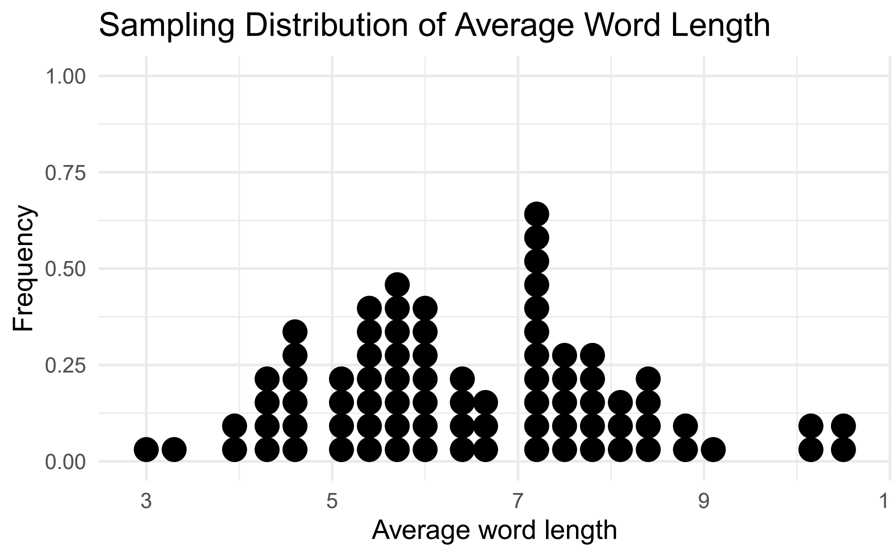
2. Fill in the table below with your selected words from the previous question and the length of each word (number of letters/digits in the word):

Observation	Word	Length
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

3. Calculate the mean (average) word length in your selected sample. Is this value a parameter or a statistic?

A dot plot and summary statistics of the "by-eye" average word lengths from a Spring 2023 class is provided.

```
#>   min  Q1 median  Q3  max     mean       sd  n missing
#> 1   3 5.3    6.3 7.5 10.6 6.479268 1.631309 82       0
```



4. Based on the plot and summary statistics of sample mean word lengths above, what is your best guess for the average word length of the population of all 359 words in the speech?

5. The true mean word length of the population of all 359 words in the speech is 3.95 letters. Is this value a parameter or a statistic?

   Where does the value of 3.95 fall in the plot above? Near the center of the distribution? In the tails of the distribution?

6. If the class samples were truly representative of the population of words, what proportion of sample means would you expect to be below 3.95?

7. Using the graph created above, estimate the proportion of students' computed sample means that were lower than the true mean of 3.95 letters?

8. Based on your answers to questions 6 and 7, would you say the sampling method used by the class is biased or unbiased? Justify your answer.

9. If the sampling method is biased, what type of sampling bias (selection, response, non-response) is present? What is the direction of the bias, i.e., does the method tend to overestimate or underestimate the population mean word length?

10. Should we use results from our "by eye" samples to make a statement about the word length in the population of words in Becenti's address? Why or why not?

Types of bias

11. To determine if the proportion of out-of-state undergraduate students at Montana State University has increased in the last 10 years, a statistics instructor sent an email survey to 500 randomly selected current undergraduate students. One of the questions on the survey asked whether they had in-state or out-of-state residency. She only received 378 responses.

    Sample size:

    Sample taken:

    Target population:

    Variable:

    Type of Variable: categorical quantitative

    Justify why there is non-response bias in this study.

12. A television station is interest in predicting whether or not a local referendum to legalize marijuana for adult use will pass. It asks its viewers to phone in and indicate whether they are in favor or opposed to the referendum. Of the 2241 viewers who phoned in, forty-five percent were opposed to legalizing marijuana.

    Sample size:

    Sample taken:

    Target population:

    Variable:

    Type of Variable: categorical quantitative

    Justify why there is selection bias in this study.

13. To gauge the interest in a new swimming pool, a local organization stood outside of the Bogart Pool in Bozeman, MT, during open hours. One of the questions they asked was, “Since the Bogart Pool is in such bad repair, don’t you agree that the city should fund a new pool?”

    Sample size:

    Sample taken:

    Target population:

    Variable:

    Type of Variable: categorical quantitative

    Justify why there is response bias in this study.

    Justify why there is selection bias in this study.

14. The Bozeman school district was interested in surveying parents of students about their opinions on returning to in-person classes following the COVID-19 pandemic. They divided the school district into 10 divisions based on location and randomly surveyed 20 households within each division. Explain why selection bias would be present in this study design.

2.3.4 Take-home messages

1. There are three types of bias to be aware of when designing a sampling method: selection bias, non-response bias, and response bias.
2. When we use a biased method of selection, we will over or underestimate the parameter.
3. To see if a method is biased, we compare the distribution of the estimates to the true value. We want our estimate to be on target or unbiased. When using unbiased methods of selection, the mean of the distribution matches or is very similar to our true parameter.
4. If the sampling method is biased, inferences made about the population based on a sample estimate will not be valid.

2.3.5 Additional notes

Use this space to summarize your thoughts and take additional notes on today's activity and material covered.

2.4 Activity 2: American Indian Address (continued)

2.4.1 Learning outcomes

- Explain the purpose of random selection and its effect on scope of inference.
- Select a simple random sample from a finite population using a random number generator.
- Explain why a sampling method is unbiased or biased.
- Explain the effect of sample size on sampling variability.

2.4.2 Terminology review

In today's activity, we will examine unbiased and biased methods of sampling. Some terms covered in this activity are:

- Random sample
- Unbiased vs biased methods of selection
- Generalization

To review these concepts, see Section 2.1 in the textbook.

Random selection

Today we will return to the American Indian Address introduced in the out-of-class activity. Suppose instead of attempting to select a representative sample by eye (which did not work), each student used a random number generator to select a simple random sample of 10 words. A **simple random sample** relies on a random mechanism to choose a sample, without replacement, from the population, such that every sample of size 10 is equally likely to be chosen.

To use a random number generator to select a simple random sample, you first need a numbered list of all the words in the population, called a **sampling frame**. You can then generate 10 random numbers from the numbers 1 to 359 (the number of words in the population), and the chosen random numbers correspond to the chosen words in your sample.

1. Use the random number generator at https://istats.shinyapps.io/RandomNumbers/ to select a simple random sample from the population of all 359 words in the speech.

- Set "Choose Minimum" to 1 and "Choose Maximum" to 359 to represent the 359 words in the population (the sampling frame).
- Set "How many numbers do you want to generate?" to 10 and ensure the "No" option is selected under "Sample with Replacement?"
- Click "Generate".

Fill in the table below with the random numbers selected and use the Becenti.csv data file found on D2L to determine each number's corresponding word and word length (number of letters/digits in the word):

Observation	Number	Word	Length
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

“

2. Calculate the mean word length in your selected sample in question 1. Is this value a parameter or a statistic?

3. Report your mean word length to your instructor. Your instructor will guide the class in creating a visualization of the distribution of results generated by your class. Draw a picture of the plot here. Include a descriptive x-axis label.

4. Where does the value 3.95, the true mean word length, fall in the distribution created in question 3? Near the center of the distribution? In the tails of the distribution?

5. How does the plot generated in question 3 compare to the plot generated in the out-of-class activity?

   Which features are similar?

   Which features differ?

   Why didn't everyone get the same sample mean?

One set of randomly generated sample mean word lengths from a single class may not be large enough to visualize the distribution results. Let's have a computer generate 1,000 sample mean word lengths for us.

- Navigate to the "One Variable with Sampling" Rossman/Chance web applet: http://www.rossmanchance.com/applets/2021/sampling/OneSample.html?population=gettysburg.
- Click "Clear" below the text box containing data from the Gettysburg address to delete that data set.
- Download the Becenti.csv file from D2L and open the spreadsheet on your computer.
- Copy and paste the population of word lengths (column C) into the applet from the data set provided making sure to include the header. Click "Use Data". Verify that the mean for the data set is 3.953 with a sample size of 359. If these are not the values you got, check with your instructor for help with copying in the data set correctly.
- Click the check-box for "Show Sampling Options"
- Select 1000 for "Number of samples" and select 10 for the "Sample size".
- Click "Draw Samples".

6. The plot labeled "Statistics" displays the 1,000 randomly generated sample mean word lengths. Sketch this plot below. Include a descriptive x-axis label and be sure to write down the provided mean and SD (standard deviation) of the distribution.

7. What is the center value of the distribution created in question 6?

8. Explain why the sampling method of using a random number generator to generate a sample is a “better” method than choosing 10 words “by eye”.

9. Is random selection an unbiased method of selection? Explain your answer. Be sure to reference your plot from question 6.

Effect of sample size

We will now consider the impact of sample size.

10. First, consider if each student had selected 20 words, instead of 10, by eye. Do you think this would make the plot from the out-of-class activity centered on 3.95 (the true mean word length)? Explain your answer.

11. Now we will select 20 words instead of 10 words at random.

- In the “One Variable with Sampling” Rossman/Chance web applet(http://www.rossmanchance.com/applets/2021/sampling/OneSample.html?population=gettysburg.), change the Sample size to 20.
- Click “Draw Samples”.

The plot labeled “Statistics” displays the 1,000 randomly generated sample mean word lengths. Sketch this plot below. Include a descriptive x-axis label and be sure to write down the provided mean and SD (standard deviation) of the distribution.

12. Compare the distribution created in question 11 to the one created in question 6.

    Which features are similar?

    Which features differ?

13. Compare the spreads of the plots in question 11 and in question 6. You should see that in one plot all sample means are closer to the population mean than in the other. Which plot shows this?

14. Using the evidence from your simulations, answer the following research questions:

    Does changing the sample size impact whether the sample estimates are unbiased? Explain your answer.

    Does changing the sample size impact the variability (spread) of sample estimates? Explain your answer

15. What is the purpose of random selection of a sample from the population?

2.4.3 Take-home messages

1. Random selection is an unbiased method of selection.
2. To determine if a sampling method is biased or unbiased, we compare the distribution of the estimates to the true value. We want our estimate to be on target or unbiased. When using unbiased methods of selection, the mean of the distribution matches or is very similar to our true parameter.
3. Random selection eliminates selection bias. However, random selection will not eliminate response or non-response bias.
4. The larger the sample size, the more similar (less variable) the statistics will be from different samples.
5. Sample size has no impact on whether a *sampling method* is biased or not. Taking a larger sample using a biased method will still result in a sample that is not representative of the population.

2.4.4 Additional notes

Use this space to summarize your thoughts and take additional notes on today's activity and material covered.

2.5 Week 2 Lab: Study Design

2.5.1 Learning outcomes

- Explain the purpose of random assignment and its effect on scope of inference.
- Identify whether a study design is observational or an experiment.
- Identify confounding variables in observational studies and explain why they are confounding.

2.5.2 Terminology review

In this activity, we will examine different study designs, confounding variables, and how to determine the scope of inference for a study. Some terms covered in this activity are:

- Scope of inference
- Explanatory variable
- Response variable
- Confounding variable
- Experiment
- Observational study

To review these concepts, see Sections 2.2 through 2.5 in the textbook.

2.5.3 General information labs

At the end of each module you will complete a lab. Questions are selected from each lab to be turned in on Gradescope. The questions to be submitted on Gradescope are bolded in the lab. As you work through the lab have the Gradescope lab assignment open so that you can answer those questions as you go.

2.5.4 Atrial fibrillation

Atrial fibrillation is an irregular and often elevated heart rate. In some people, atrial fibrillation will come and go on its own, but others will experience this condition on a permanent basis. When atrial fibrillation is constant, medications are required to stabilize the patient's heart rate and to help prevent blood clots from forming. Pharmaceutical scientists at a large pharmaceutical company believe they have developed a new medication that effectively stabilizes heart rates in people with permanent atrial fibrillation. They set out to conduct a trial study to investigate the new drug. The scientists will need to compare the proportion of patients whose heart rate is stabilized between two groups of subjects, one of whom is given a placebo and the other given the new medication.

1. Identify the explanatory and response variable in this trial study.

   Explanatory variable:

   Response variable:

Suppose 24 subjects with permanent atrial fibrillation have volunteered to participate in this study. There are 16 subjects that self-identified as male and 8 subjects that self-identified as female.

2. One way to separate into two groups would be to give all the males the placebo and all the females the new drug. Explain why this is not a reasonable strategy.

3. Could the scientists fix the problem with the strategy presented in question 2 by creating equal sized groups by putting 4 males and 8 females into the drug group and the remaining 12 males in the placebo group? Explain your answer.

4. A third strategy would be to **block** on sex. In this type of study, the scientists would assign 4 females and 8 males to each group. Using this strategy, what **proportion** of males out of the 12 individuals would be in each group?

5. **Assume the scientists used the strategy in question 4, but they put the four tallest females and eight tallest males into the drug group and the remaining subjects into the placebo group. They found that the proportion of patients whose heart rate stabilized is higher in the drug group than the placebo group.**

   Could that difference be due to the sex of the subjects? Explain your answer.

   Could it be due to other variables? Explain your answer.

While the strategy presented in question 5 controlled for the sex of the subject, there are more potential **confounding variables** in the study. A confounding variable is a variable that is *both*

1. associated with the explanatory variable, *and*
2. associated with the response variable.

When both these conditions are met, if we observe an association between the explanatory variable and the response variable in the data, we cannot be sure if this association is due to the explanatory variable or the confounding variable—the explanatory and confounding variables are "confounded."

Random assignment means that subjects in a study have an equally likely chance of receiving any of the available treatments.

6. You will now investigate how randomly assigning subjects impacts a study's scope of inference.

- Navigate to the "Randomizing Subjects" applet under the "Other Applets" heading at: http://www.rossmanchance.com/ISIapplets.html. This applet lists the sex and height of each of the 24 subjects. Click "Show Graphs" to see a bar chart showing the sex of each subject. Currently, the applet is showing the strategy outlined in question 3.
- Click "Randomize".

In this random assignment, what proportion of males are in group 1 (the placebo group)?

What proportion of males are in group 2 (the drug group)?

What is the difference in proportion of males between the two groups (placebo - drug)?

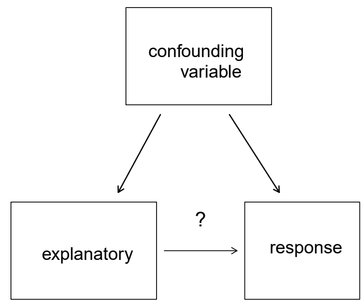
7. Notice the difference in the two proportions is shown as a dot in the plot at the bottom of the web page. Un-check the box for Animate above "Randomize" and click "Randomize" again. Did you get the same difference in proportion of males between the placebo and drug groups?

8. Change "Replications" to 998 (for 1000 total). Click "Randomize" again. Sketch the plot of the distribution of difference in proportions from each of the 1000 random assignments here. Be sure to include a descriptive x-axis label.

9. **Does random assignment *always* balance the placebo and drug groups based on the sex of the participants? Does random assignment *tend* to make the placebo and drug groups *roughly* the same with respect to the distribution of sex? Use your plot from question 8 to justify your answers.**

10. Change the drop-down menu below Group 2 from "sex" to "height". The applet now calculates the average height in the placebo and drug groups for each of the 1000 random assignments. The dot plot displays the distribution of the difference in mean heights (placebo - drug) for each random assignment. Based on this dot plot, is height distributed equally, on average, between the two groups? Explain how you know.

The diagram below summarizes these ideas about confounding variables and random assignment. When a confounding variable is present (such as sex or height), and an association is found in a study, it is impossible to discern what caused the change in the response variable. Is the change the result of the explanatory variable or the confounding variable? However, if all confounding variables are *balanced* across the treatment groups, then only the explanatory variable differs between the groups and thus *must have caused* the change seen in the response variable.



11. **What is the purpose of random assignment of the subjects in a study to the explanatory variable groups?** Cross out the arrow in the figure above that is eliminated by random assignment.

12. Suppose in this study on atrial fibrillation, the scientists did randomly assign groups and found that the drug group has a higher proportion of subjects whose heart rates stabilized than the placebo group. Can the scientists conclude the new drug *caused* the increased chance of stabilization? Explain your answer.

13. Is the sample of subjects a simple random sample or a convenience sample?

14. **Both the sampling method (which we covered last week) and the study design will help to determine the *scope of inference* for a study: To *whom* can we generalize, and can we conclude *causation or only association*? Use your answers to question 12 and 13 and the table on the next page to determine the scope of inference of this trial study described in question 12.**

Scope of Inference: If evidence of an association is found in our sample, what can be concluded?

	Study Type	
Selection of cases	**Randomized experiment**	**Observational study**
Random sample (and no other sampling bias)	Causal relationship, **and** can generalize results to population.	Cannot conclude causal relationship, **but** can generalize results to population.
No random sample (or other sampling bias)	Causal relationship, **but** cannot generalize results to a population.	Cannot conclude causal relationship, **and** cannot generalize results to a population.

Inferences to population can be made

Can only generalize to those similar to the sample due to potential sampling bias

Can draw cause-and-effect conclusions

Can only discuss association due to potential confounding variables

2.5.5 Study design

The two main study designs we will cover are **observational studies** and **experiments**. In observational studies, researchers have no influence over which subjects are in each group being compared (though they can control other variables in the study). An experiment is defined by assignment of the treatment groups of the *explanatory variable*, typically via random assignment.

For the next exercises identify the study design (observational study or experiment), the sampling method, and the scope of inference.

15. The pharmaceutical company Moderna Therapeutics, working in conjunction with the National Institutes of Health, conducted Phase 3 clinical trials of a vaccine for COVID-19 in the Fall of 2021. US clinical research sites enrolled 30,000 volunteers without COVID-19 to participate. Participants were randomly assigned to receive either the candidate vaccine or a saline placebo. They were then followed to assess whether or not they developed COVID-19. The trial was double-blind, so neither the investigators nor the participants knew who was assigned to which group.

    Study design:

    Sampling method:

    Scope of inference:

16. **In another study, a local health department randomly selected 1000 US adults without COVID-19 to participate in a health survey. Each participant was assessed at the beginning of the study and then followed for one year. They were interested to see which participants elected to receive a vaccination for COVID-19 and whether any participants developed COVID-19.**

    Study design:

    Sampling method:

    Scope of inference:

2.5.6 Take-home messages

1. The study design (observational study vs, experiment) determines if we can draw causal inferences or not. If an association is detected, a randomized experiment allows us to conclude that there is a causal (cause-and-effect) relationship between the explanatory and response variable. Observational studies have potential confounding variables within the study that prevent us from inferring a causal relationship between the variables studied.

2. Confounding variables are variables not included in the study that are related to both the explanatory and the response variables. When there are potential confounding variables in the study we cannot draw causal inferences.

3. Random assignment balances confounding variables across treatment groups. This eliminates any possible confounding variables by breaking the connections between the explanatory variable and the potential confounding variables.

4. Observational studies will always carry the possibility of confounding variables. Randomized experiments, which use random assignment, will have no confounding variables.

2.5.7 Additional notes

Use this space to summarize your thoughts and take additional notes on today's activity and material covered.