

# 13

## Testing Medicines: A Clinical Trial

INVESTIGATION

3 CLASS SESSIONS

### ACTIVITY OVERVIEW

#### NGSS CONNECTIONS

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In this investigation, students analyze and interpret data about a simulated clinical trial of a headache medicine. They use the evidence from their analysis to engage in an argument about the potential use of this medicine. They begin to think about how body system interactions may need to be considered when developing new medicines for human use. This activity provides an opportunity to apply MS-LS1-3.

#### NGSS CORRELATIONS

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##### Performance Expectations

*Applying MS-LS1-3:* Use argument supported by evidence for how the body is a system of interacting subsystems composed of groups of cells.

##### Disciplinary Core Ideas

*MS-LS1.A Structure and Function:* In multicellular organisms, the body is a system of multiple interacting subsystems. These subsystems are groups of cells that work together to form tissues and organs that are specialized for particular body functions.

##### Science and Engineering Practices

*Engaging in Argument from Evidence:* Use an oral and written argument supported by evidence to support or refute an explanation or a model for a phenomenon.

*Analyzing and Interpreting Data:* Analyze and interpret data to determine similarities and differences in findings.

##### Crosscutting Concepts

*Cause and Effect:* Cause and effect relationships may be used to predict phenomena in natural systems.

*Systems and System Models:* Systems may interact with other systems; they may have subsystems and be a part of larger complex systems.

*Connections to Nature of Science: Science Is a Human Endeavor:* Scientists and engineers are guided by habits of mind, such as intellectual honesty, tolerance of ambiguity, skepticism, and openness to new ideas.

### Common Core State Standards—ELA/Literacy

*RST.6-8.3:* Follow precisely a multistep procedure when carrying out experiments, taking measurements, or performing technical tasks.

*WHST.6-8.1:* Write arguments focused on discipline-specific content.

## WHAT STUDENTS DO

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Students simulate a clinical trial to investigate how medicines are tested. In this model, students participate in a taste test to simulate the clinical trial of a new headache medicine. The class pools results and draws conclusions based on their data.

## MATERIALS AND ADVANCE PREPARATION

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### ■ For the teacher

- 1 tube of edible red food coloring
- 1 measuring cup (2-cup)
- 1 measuring cup (1/2-cup)
- 1 dropper
- 1 Visual Aid 13.1, “Results of a Clinical Trial”
- 1 Visual Aid 13.2, “Analysis of Class Data”
- \* 1 large stirring spoon
- \* 1 permanent ink marker
- \* 1 container (2-quart)
- \* 2 containers (1-quart)
- 1 Scoring Guide: ANALYZING AND INTERPRETING DATA (AID)
- 1 Scoring Guide: EVIDENCE AND TRADEOFFS (E&T)

### ■ For the class

- 1 packet of unsweetened powdered lemon drink mix
- \* 1/2 cup of sugar
- \* 2 quarts of water

### ■ For each group of four students

- 2 tall plastic cups (7-oz.)

■ *For each student*

- 1 small tasting cup
- 1 Student Sheet 13.1, “Analysis of Clinical Trial”
- 1 Science Skills Student Sheets 3a and 3b, “Bar Graphing Checklist” (optional)
- 1 Scoring Guide: ANALYZING AND INTERPRETING DATA (AID) (optional)
- 1 Scoring Guide: EVIDENCE AND TRADEOFFS (E&T) (optional)

*\*not included in kit*

Be certain all containers, cups, etc., are completely clean, because students will use them to taste drinks.

By following the directions on the next page, you will end up with 1 quart of lightly sweetened yellow lemon drink, 1/2 quart of lightly sweetened pink lemon drink, and 1/2 quart of more highly sweetened pink lemon drink. This is enough for one class of 32 students. Prepare the lemon drink samples as follows:

1. Yellow Lemon Drink (representing the headache)

In a 2-quart container, mix the following ingredients, making sure that all of the drink-mix powder has dissolved.

- 1 packet of unsweetened lemon drink mix
- 1/4 cup of sugar
- 2 quarts of water

2. Pink Lemon Drink without Sugar (representing the placebo)

Pour 1 quart (4 cups) of the yellow lemon drink into another container and add 2 drops of edible red food coloring. If using a gel food coloring, add just enough coloring to make the drink a light pink color. Stir thoroughly.

3. Pink Lemon Drink with Sugar (representing the medicine)

Pour 2 cups of the pink lemonade into a third container. Then add another 1/4 cup of sugar to this third container and stir thoroughly.

Each group of students should receive one large cup, approximately half-full, of yellow lemon drink.

Each group of students should also receive one of the two pink lemon drink samples: half of the groups should receive a large cup (approximately half full) of the lightly sweetened pink lemon drink while the other half of the groups should receive a large cup (approximately half full) of the more highly sweetened pink lemon drink. Important: Students must not know that there is more than one kind of pink lemon drink. Code the cups by numbering them: odd-numbered cups

can contain the less sweet pink lemon drink that represents the placebo; even-numbered cups can contain the more sweet pink lemon drink that represents the medicine.

### **SAFETY NOTE**

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Make sure all student work areas and materials being used for the activity are clean and free of any unnecessary equipment or other materials not being used. Check that students are not allergic to lemons or other citrus fruits, juice drinks, or sugar, or have any other health issue, such as diabetes, that limits what they can eat. If students in your class have any such conditions, do not allow them to taste the drink samples in the activity.

### **TEACHING SUMMARY**

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#### **GET STARTED**

1. Prepare students to simulate a clinical trial.
  - a. Introduce the clinical trial scenario.
  - b. Explain the model of a clinical trial.
  - c. Have students read the introduction, which includes a scenario of a clinical trial, either to themselves or aloud.

#### **DO THE ACTIVITY**

2. Students simulate a clinical trial.
  - a. Review the directions.
  - b. Have students complete the Procedure and turn in their responses.
3. Discuss the class's results, and introduce the use of a control (placebo) group.
  - a. Record student responses on Visual Aid 13.1, "Results of a Clinical Trial."
  - b. Explain to students that only some of the groups got the "real medicine."
  - c. Develop the concept of a control by asking, "Why was it important to have a group that did not receive the medicine?"
  - d. Sort the class data based on which groups received the "medicine" (additional sugar) and which did not.
  - e. Use the second table on Visual Aid 13.2 to summarize data from several classes.

**BUILD UNDERSTANDING**

4. (AID ASSESSMENT; E&T ASSESSMENT) Discuss the Analysis items and summarize key points of the activity.
  - a. Review the data students collected in the investigation.
  - b. Have the class summarize what they focused on in terms of safety and effectiveness of the headache medicine.
  - c. Assess students' abilities to analyze and interpret data, and explain evidence and trade-offs.

**TEACHING STEPS****GET STARTED**

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1. Prepare students to simulate a clinical trial.
  - a. Introduce the clinical trial scenario.

Ask students to imagine the following: You work for a company that develops medicines. You have developed a medicine for severe headaches and have tested it on rats and mice to see if it has any negative effects. The tests on animals showed no harmful effects, even at much higher doses than you plan to use on humans. Now it is time to test the medicine on human volunteers in a clinical trial. What could happen to these volunteers after they take the medicine? (Some people might feel better, whereas some might not improve or might even feel worse or display side effects.) If necessary, review with students what side effects are. For example, one possible side effect of taking aspirin is an upset stomach. Ask students to respond in their science notebooks to the question, "How would you test the medicine to be sure it is safe and improves the health of headache patients?" Give students 5 minutes to work on this, and then discuss their responses.
  - b. Explain the model of a clinical trial.

Tell students that they will participate in a model of the trials that are used to determine whether medicines are effective and safe for people. Review with them the meaning of the word model. In this case, a model is an experience that is meant to mimic, or be like, another experience.
  - c. Have students read the introduction, which includes a scenario of a clinical trial, either to themselves or aloud.

Review the reasons for simulating a clinical trial rather than completing an actual test of a medicine, which would not be an appropriate classroom

activity. Be sure that students understand that in this model, a taste test represents the trial of a new headache medicine. Use the figure in the introduction of the activity to review the relationship between the tasting of the lemon drinks and the model. The taste of the yellow lemon drink represents the headache. A perception that the pink lemon drink tastes better than the yellow lemon drink represents feeling better. A perception that the pink lemon drink tastes the same as the yellow lemon drink represents no change in the headache. A perception that the pink lemon drink tastes worse than the yellow lemon drink represents an improvement in the headache but with side effects.

### DO THE ACTIVITY

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2. Students simulate a clinical trial.

- a. Review the directions.

Important: Do not let students know that there is more than one kind of pink lemon drink. Also review the Safety Note. Be sure students understand that eating and drinking are not usually allowed in the science classroom; use this activity to emphasize routine safety rules. Students should wash their hands before they do the activity. Emphasize the need to keep track of the individual tasting cups and not to contaminate the larger cups of lemon drink. The lemon drink should be poured from the larger cups into the tasting cups. Do not allow students to dip their tasting cups into the larger cup.

- b. Have students complete the Procedure and record their data for the class results.

3. Discuss the class's results, and introduce the use of a control (placebo) group.

- a. Record student responses on Visual Aid 13.1, "Results of a Clinical Trial."

Fill in the table by listing the number of students within a group that indicated each response. Ask, "Based on these results, does the "medicine" appear to have worked?" It is likely that most members of the odd-numbered groups will report that the pink drink tasted better, thus simulating improvement. But most members of the even-numbered groups are likely to report that they "feel the same."

Some students in both groups will report that the lemon drink tastes worse. This simulates that the medicine worked (even though it may be from the control or placebo group) but that there were side effects. Later in the activity, the severity of side effects and their implications for the clinical trial will be addressed.

- b. Explain to students that only some of the groups got the “real medicine.”

Tell students that as they may have guessed, there were two different kinds of pink lemon drink. All of the lemon drinks were originally the same; however, some students tasted a pink lemon drink that was identical to the yellow lemon drink except for an inactive (in this model, flavorless) ingredient—red food coloring. Other students tasted a sample of the pink lemon drink that also had additional sugar (the “medicine”). Identify which groups had pink lemon drink without the added sugar and which had the pink lemon drink with the added sugar. Only the groups receiving the pink lemon drink with additional sugar actually tested the “medicine.” They were in the “treatment” group. The others got a drink that looked like it had the real medicine in it but didn’t. They were in the “control” group.

- c. Develop the concept of a control by asking, “Why was it important to have a group that did not receive the medicine?”

Begin to develop the idea that a control group allows for comparison and helps investigators evaluate if changes are due to the medicine or to some other factor. You may want to refer back to Dr. Goldberger’s experiments on the prisoners from “The Pellagra Story” activity. Dr. Goldberger did not have a control; in his experiment, he could have included prisoners who continued to receive a healthy diet but underwent all of the other conditions of those who were on the restricted diet.

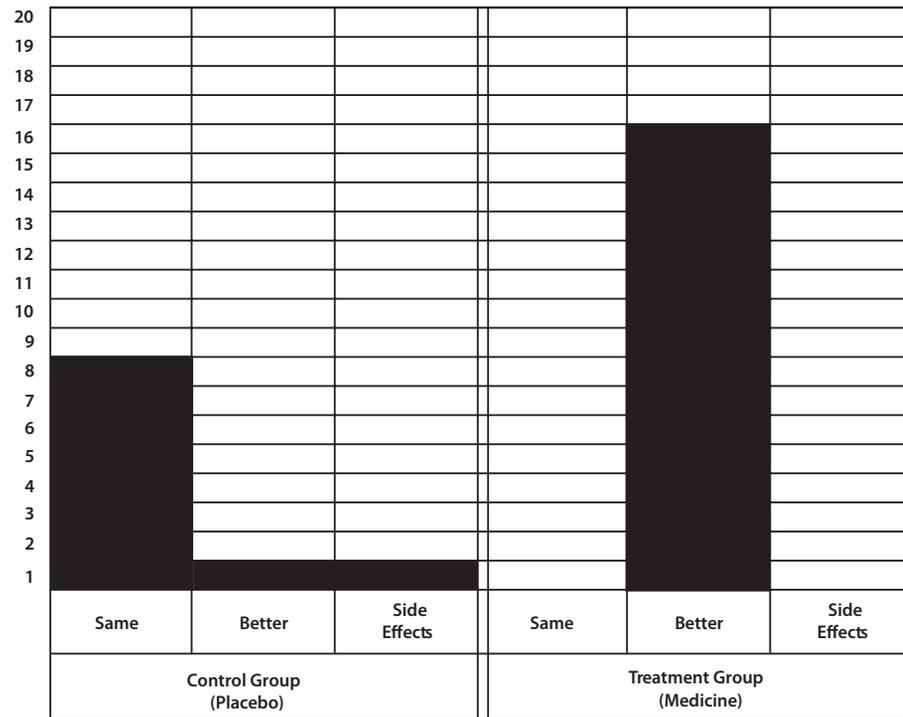
Tell them that a placebo simulates a medicine but doesn’t have the active ingredient in it, so it can be used for the control group. Emphasize that this helps investigators be sure that any improvement is due to the medicine and not to other factors. Explain that in a real test of a medicine, one group receives a pill or liquid containing inactive ingredients, while another group receives a pill or liquid containing the medicine. In this model, the red food coloring represents the idea of taking a pill or liquid, whereas the additional sugar represents the active ingredient in the medicine.

- d. Sort the class data based on which groups received the “medicine” (additional sugar) and which did not.

Summarize the class data in the top table of Visual Aid 13.2, “Analysis of Class Data.” As an example of one set of results, in a class of 26 students, 16 were given the pink lemon drink with sugar (representing the medicine) and 10 were given the pink lemon drink without sugar (representing the placebo). The results of the activity are shown in the table below. This correlates to a slight placebo effect and a very successful

medicine. Such clear results are unusual in real clinical trials. A high number of students preferring the pink lemon drink without additional sugar compared with the yellow lemon drink simulates a significant placebo effect. A high number of students disliking the pink lemon drink without additional sugar compared with the yellow lemon drink simulates a significant placebo effect for improvement with side effects. A significant number of students disliking the drink with sugar simulates a significant group of people with side effects from the actual medicine.

**SAMPLE CLASS RESULTS**



- e. Use the second table on Visual Aid 13.2 to summarize data from several classes.

If you are using this course with multiple classes, have students compare the multiple classes' results to their own class's results. Are they the same? Discuss the fact that not every subgroup will be representative of a larger population. Review reasons why not all people reacted the same to the samples of lemon drink. Use this to reinforce the variation among people and the idea that different people can respond differently to the same stimulus.

**BUILD UNDERSTANDING**

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4. (AID ASSESSMENT; E&T ASSESSMENT) Discuss the Analysis items and summarize key points of the activity.

a. Review the data students collected in the investigation.

You may need to review how to complete a bar graph. If so, you can use Science Skills Student Sheets 3a and 3b, “Bar Graphing Checklist,” to help students construct their graphs and/or refer them to Appendix C in the Student Book. The axes are set up for students on Student Sheet 13.1. To view typical data, see Sample Student Response to Student Sheet 13.1 at the end of this activity.

b. Have the class summarize what they focused on in terms of safety and effectiveness of the headache medicine.

Students will likely mention the following:

Safety:

1. The number of people who reported side effects.
2. The severity of the side effects.
3. The trade-offs of using medicine with side effects.

Effectiveness:

1. The number of people compared with the total who reported improvement.
2. Questioning effectiveness if many people reported side effects.
3. Questioning effectiveness if many people in the placebo group reported improvement.

c. Assess students’ abilities to analyze and interpret data, and explain evidence and trade-offs.

Analysis item 2 in this activity can be assessed using the ANALYZING AND INTERPRETING DATA (AID) Scoring Guide. Analysis item 4 in this activity can be assessed using the EVIDENCE AND TRADE-OFFS (E&T) Scoring Guide. Sample Level-4 responses follow. For more information, see Teacher Resources III, “Assessment.”

For Analysis item 4 you may have to help students distinguish the more serious symptoms in this question from those described in Procedure

Step 10. Use this item to introduce the idea of weighing health benefits vs. side effects. Be sure to use the concept of trade-offs. In this case, the side effects may be severe enough to outweigh the benefits of the medicine, and most people would not be willing to accept this trade-off.

For Analysis item 5, student responses should fit with the evidence collected. For instance, if most people reported improvement from the treatment and very few people reported side effects, this provides evidence that the medicine is likely safe and effective. If many people reported side effects, students should question the safety or note the trade-offs of using a medicine with side effects. If many students in the placebo group reported improvement, students should mention these results and question the effectiveness of the medicine.

### SAMPLE RESPONSES TO ANALYSIS

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1. What body systems are a headache medicine likely to affect? Explain.

*A headache medicine will likely affect the nervous system, because you feel the pain in your head. It might possibly affect the digestive system, because that's where it's absorbed into the bloodstream.*

2. (AID ASSESSMENT) In this activity, what evidence do you have that the medicine does or does not have the desired effect of improving headaches?

Student responses may vary because individual class results will vary. This question can serve as practice for the ANALYZING AND INTERPRETING DATA (AID) Scoring Guide. Students should begin to relate the data from the model to their conclusions.

#### SAMPLE LEVEL-4 RESPONSE

*In our class, 16 people received the pink lemon drink with sugar, which represented the medicine. Of those 16 people, 14 thought it tasted better than the yellow lemon drink. One person thought it tasted the same, and one thought it tasted worse. This means that 15 out of 16 people felt better after taking the medicine (although one suffered side effects). This shows that the medicine works to improve headaches.*

3. Who was the control group in this model of a clinical trial? Why is a control group included in clinical trials?

*In this model the control group is the people who got the drink with red food coloring added, but no additional sugar, because the sugar represented the medicine. A control group is included because members' results can be compared with the treatment group, so the researcher can tell if the medicine is working or if there is something else happening to make people feel better.*

4. (E&T ASSESSMENT) In this activity, if a person finds that the sweetened pink lemon drink (the medicine) tastes worse than the yellow lemon drink, the headache is gone, but there are side effects. If the side effects were serious, such as a risk of serious heart problems, would you recommend selling the medicine to people suffering from headaches? Explain your decision. What are the trade-offs involved in your decision?

**SAMPLE LEVEL-4 RESPONSE**

*If the medicine had a serious side effect, like the risk of serious heart problems, I would not recommend selling the medicine to people. Heart problems are too risky, and someone might die from them. The trade-off is that they would still have headaches, but that is better than possibly having serious heart problems or dying from a heart condition.*

5. In this activity, if a person finds that the medicine tastes better or worse than the yellow lemon drink, the headache is gone. Review the results of this model. Think about whether the medicine works and how often side effects occur. What would you conclude about the safety and effectiveness of this medicine for treating headaches? Support your conclusion with evidence.

Student results may vary. One sample response is shown here:

*Fifteen out of 16 people reported an improvement. (They thought the pink lemon drink with sugar tasted better or worse than the yellow lemon drink.) Of those 15 people, one person reported a side effect because she thought it tasted worse than the original drink. The medicine is effective because most people reported an improvement, and it is safe because only one person had a side effect.*

6. How do the effects of the medicines described in this activity demonstrate interactions between body systems?

*In this activity, a medicine that you drink helps with a headache. This demonstrates that the digestive system, where the medicine was taken, interacts with the circulatory system because that is the only way it could get to your head to stop the headache.*

**EXTENSION**

For a larger sample size, you can add your students' data to those gathered by other classes from other schools. Visit the *SEPUP Third Edition Body Systems* page of the SEPUP website at [www.sepuplhs.org/middle/third-edition](http://www.sepuplhs.org/middle/third-edition) to see data from other classes and for instructions on how to post your class's data.

### **REVISIT THE GUIDING QUESTION**

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How are medicines tested during a clinical trial?

Review with students what data had to be collected in the clinical trial and why a control group was important. Foreshadow the final activity by asking students to brainstorm what other questions they might have before deciding if a medicine should be sold to the public.

### **ACTIVITY RESOURCES**

#### **KEY VOCABULARY**

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clinical trial

control

evidence

trade-off

Name \_\_\_\_\_ Date \_\_\_\_\_

## STUDENT SHEET 13.1

### ANALYSIS OF CLINICAL TRIAL

#### Response to Treatment vs. Placebo (our class)

	Same as Yellow Lemon Drink (Headache the Same)	Better Than Yellow Lemon Drink (Headache Better)	Worse Than Yellow Lemon Drink (Headache Better, but Side Effects)
Control Group (Received placebo)			
Treatment Group (Received medicine)			

**Figure 1: Graph of Class Data**

20						
19						
18						
17						
16						
15						
14						
13						
12						
11						
10						
9						
8						
7						
6						
5						
4						
3						
2						
1						
	Same	Better	Side Effects	Same	Better	Side Effects
	Control Group (Placebo)			Treatment Group (Medicine)		

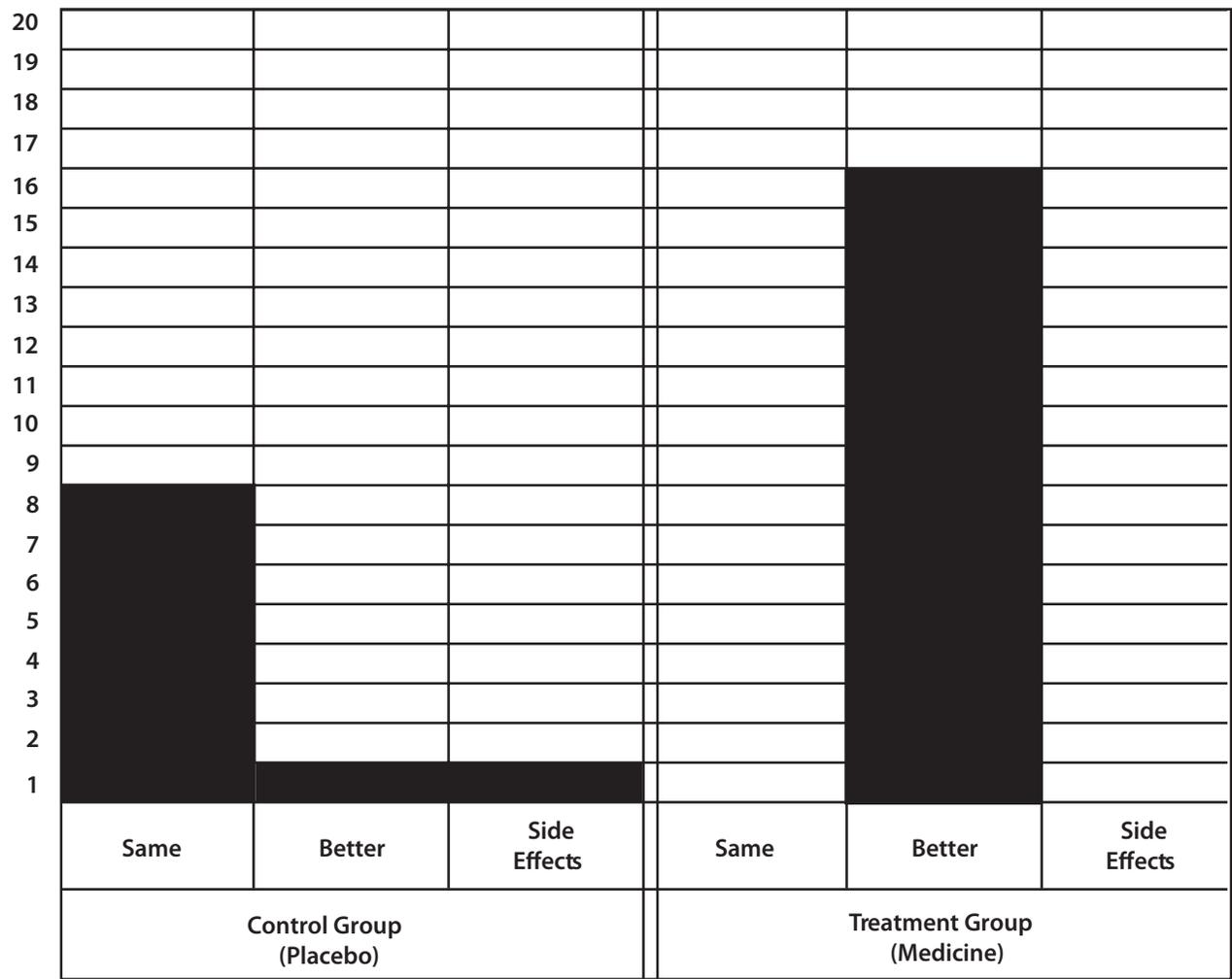
## STUDENT SHEET 13.1

### ANALYSIS OF CLINICAL TRIAL

#### Response to Treatment vs. Placebo (our class)

	Same as Yellow Lemon Drink (Headache the Same)	Better Than Yellow Lemon Drink (Headache Better)	Worse Than Yellow Lemon Drink (Headache Better, but Side Effects)
Control Group (Received placebo)	8	1	1
Treatment Group (Received medicine)	0	16	0

**Figure 1: Graph of Class Data**



# VISUAL AID 13.1

## RESULTS OF A CLINICAL TRAIL

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Cup number	Same as Yellow Lemon Drink	Better Than Yellow Lemon Drink	Worse Than Yellow Lemon Drink
1			
2			
3			
4			
5			
6			
7			
8			
Total			

## VISUAL AID 13.2

### ANALYSIS OF CLASS DATA

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#### Response to Treatment vs. Placebo (our class)

	Same as Yellow Lemon Drink (Headache the Same)	Better Than Yellow Lemon Drink (Headache Better)	Worse Than Yellow Lemon Drink (Headache Better, but Side Effects)
Control Group (Received placebo)			
Treatment Group (Received medicine)			

#### Response to Treatment vs. Placebo (all classes)

	Same as Yellow Lemon Drink (Headache the Same)	Better Than Yellow Lemon Drink (Headache Better)	Worse Than Yellow Lemon Drink (Headache Better, but Side Effects)
Control Group (Received placebo)			
Treatment Group (Received medicine)			