

Activity 13: Testing Medicines: A Clinical Trial

Guiding Question: How are medicines tested during a clinical trial?

Key Words: *clinical trial, control, evidence, trade-off*

Get Started:

1. 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? Record your thoughts in the space provided.

2. How would you test the medicine to be sure it is safe and improves the health of headache patients?

3. Read the introduction and Guiding Question to Activity 13, “Testing Medicines: A Clinical Trial,” in your Student Book.

Do the Activity:

1. Read Procedure Steps 1-10.

2. Your class performed this simulation of a clinical trial while you were absent. Below are data from an example group.

Results of Treatment

	<i>Same as yellow lemon drink</i>	<i>Better than yellow lemon drink</i>	<i>Worse than yellow lemon drink</i>
<i>My response (show with an X)</i>		X	
<i>My group’s response (Show number of each)</i>		2	2

3. Each group of students was given a pink drink cup and a yellow drink cup. Look at the class data, shown on the next page, of the results.

Results of a Clinical Trial

Cup number	Same as yellow lemon drink	Better than yellow lemon drink	Worse than yellow lemon drink
1	4	0	0
2	0	2	2
3	3	1	0
4	0	3	1
5	4	0	0
6	0	1	3
7	3	0	1
8	0	1	3
Total	14	8	10

4. Based on these results, does the “medicine” appear to have worked?

5. There were actually two different kinds of pink lemon drink. All of the lemon drinks were originally the same; however, some of the class tasted a pink lemon drink that was identical to the yellow lemon drink except for a flavorless ingredient—red food coloring. Others tasted a sample of the pink lemon drink that also had additional sugar (the “medicine”).

Only the groups receiving the pink lemon drink with additional sugar actually tested the “medicine.” They were in the “treatment” group. Why was it important to have a group that did not receive the medicine?

6. The group that did not receive the *medicine* received a *placebo*. A *placebo* simulates a medicine but doesn’t have the active ingredient in it, so it can be used for the control group.

7. On the next page, look at the sample class results shown. Copy these class results onto Student Sheet 13.1, “Analysis of Clinical Trial,” which is attached to this packet.

Name _____

Date _____

Response to Treatment vs. Placebo (our class)

	<i>Same as yellow lemon drink (Headache the same)</i>	<i>Better than yellow lemon drink (Headache better)</i>	<i>Worse than yellow lemon drink (Headache better, but side effects)</i>
<i>Control Group (Received placebo)</i>	14	1	1
<i>Treatment Group (Received medicine)</i>		7	9

8. Using Student Sheet 13.1, create a bar graph of the class's data.

9. Answer the following: Assume that the side effects of a headache medicine are mild, such as a slight stomachache. Do you think this medicine should or should not be sold to people suffering from a headache? Are there any trade-offs involved in your decision? If so, why did you make the decision you did?

Analysis:

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

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

Name _____

Date _____

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

4. 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?

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.

Name _____

Date _____

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

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)		