Name _____ Date_____

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

	Same as yellow lemon drink	*Better than yellow lemon drink*	*Worse than yellow lemon drink*
My response (show with an X)		X	
My group's response (Show number of each)		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.

Name _____ Date_____

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)

	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)	14	1	1
Treatment Group (Recevied medicine)		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, their 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. **Revisit the issue:** How do the effects of the medicines described in this activity demonstrate interactions between body systems?

_____

_____

_____

_____

_____

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