

A Middle School Experience With
Clinical Trials: The Scientific Method in Action

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OKLAHOMA CITY COMMUNITY COLLEGE

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DVD containing the take home video (English and Spanish subtitles) with teacher lesson plans included. To access the lesson plan word files, go to “my computer”, right click on DVD drive, and select “Explore” and lesson plan files will appear.

Middle School Levels 5-8

National Science Standards

Content Standard A: Science as Inquiry

- Ask questions that can be answered through scientific investigations.
- Design and conduct a scientific investigation
- Use appropriate tools and techniques to gather, analyze, and interpret data
- Develop descriptions, explanations, predictions, and models using evidence
- Recognize and analyze alternative explanations and predictions
- Communicate scientific procedures and explanations
- Value and practice skepticism, questioning, evaluation, and suggesting alternatives in making scientific advances
- Process of displacement of ideas by better explanations.

Content Standard C: Life Science

- Structure and Function; Diseases and their causes
- Reproduction and Heredity; Characteristics of an organism resulting from inheritance and from interactions with the environment
- Diversity and Adaptations of Organisms; Biological diversity and adaptation

Content Standard F: Science in Personal and Social Perspectives

- Personal Health; Importance of regular exercise and physical fitness to maintenance and improvement of health
- Consequences of variations in nutrition
- Consequences of tobacco use
- Substance abuse including alcohol and other drugs
- Understanding sexually transmitted diseases
- Maintaining environmental health
- Natural Hazards; Human activities can induce hazards (toxic waste), natural hazards (radon, dead) that present personal and societal challenges

Content Standard G: History and Nature of Science

- Science as a human endeavor; Kinds of people engaged in science and engineering and ways they work
- Human capacities and qualities required for science
- Nature of Science; normalcy of disagreement in areas of active research
- Importance of evaluating results of scientific inquiry and of open communication among scientists
- Importance of experimentation and observational confirmation in testing and changing ideas in science
- History of science; value of studying the contributions of individuals and of looking at science in history of many peoples

Oklahoma Priority Academic Student Skills Process Skills (Middle school level)

Process Standard 2: Classify – Events are classified based on similarities and differences and interrelationships.

Process Standard 3: Experiment - Experimenting is a method of discovering information. It requires making observations and measurements to test ideas. The student will accomplish these objectives to meet this process standard.

1. Ask questions about the world and design investigations that lead to scientific inquiry.
2. Evaluate the design of a scientific investigation.
3. Identify variables and/or controls in an experimental setup: independent (tested/ experimental) variable and dependent (measured) variable.
4. Identify a testable hypothesis for an experiment.
5. Design and conduct experiments.
6. Recognize potential hazards and practice safety procedures in all science activities.

Process Standard 4: Interpret and Communicate – Interpreting is the process of making inferences, predictions or conclusions from patterns. Communicating is the process of describing, recording and reporting experimental procedures and results to others.

Process Standard 5: Inquiry - Inquiry can be defined as the skills necessary to carry out the process of scientific or systemic thinking. In order for inquiry to occur, students must have the opportunity to ask a question, formulate a procedure, and observe phenomena. The student will accomplish these objectives to meet this process standard.

1. Use systematic observations, make accurate measurements, and identify and control variables.
2. Use technology to gather data.
3. Review data, summarize data, and form logical conclusions.
4. Formulate and evaluate explanations proposed by examining and comparing evidence, pointing out statements that go beyond evidence, and suggesting alternative explanations.

Clinical Trials Lesson Plan – Overview

Rationale: Middle school students are constantly bombarded by media and peer influence. They are experiencing more independence in making personal choices. Their feelings of being indestructible may lead to poor or unhealthy choices. They need to be aware of the relationship between personal actions and the quality of health. Teachers can facilitate middle school students' independence through science experiences that promote responsible choices.

Some middle school students consider events over which they have no control (hurricanes and tornadoes) to be frightening. Those same students may consider some voluntary, risky behavior (smoking, not using a bike helmet) to be no one else's business. This module will help students understand risk/benefit relationships that could assist them in making healthier choices.

National Science Objectives: National Middle School Science Standards (see attached)

State Objectives: Oklahoma Priority Academic Student Standards (see attached)

Local Objectives: This unit is appropriate for 7th grade integrated science units titled "Experimental Design" and "Body Systems". Or the unit works well in 9th grade pre-AP or Biology curriculum in conjunction with the film Lorenzo's Oil.

Lesson Plan – Session 1

Engagement: Pretest (10 minutes) (see **Figure 1**, p. 8)

- Survey of Clinical Trials Awareness
- Experimental design questions

Explore Activity Part 1: Individual Reflection (15 minutes)

Adapted from “A Discovery-Based Approach to Understanding Clinical Trials” from the DESTINY Traveling Science Learning Program.

Give each student the page of clinical trial advertisements from Figure 2. (Additional clinical trial options can be found at www.clinicaltrials.gov or the local newspaper)

Lead students in a discussion of the following information found in ads for Clinical Trials:

1. What is the purpose of the trial?
2. What are the requirements for this trial?
3. If you meet the requirements for the trial, would you consider participating?
4. What questions would you want to ask the researchers about the trial?
5. Would you be interested in the *results* of any of these trials?

Explore Activity Part 2: Group Share (10 minutes)

Students will be divided into four groups and assigned one of the Clinical Trials from the ad page. Each group will list their responses to the questions for the assigned Clinical Trial.

Explore Activity: Part 3: (20 min)

Using the four groups from Part 2, assign one of the word lists to each group. (see **Figure 3**, p. 10) Students will use the internet to define each of the assigned terms using their own words. Each student will maintain their own word list The following website glossary: www.clinicaltrials.gov is very helpful.

Assignment: (Post Session 1) Take the DVD (accompanying this lesson plan) home to be viewed by students with an adult who will fill out and return the survey questions. (see Figure 5, p.12).

Lesson Plan Session 2

Assignment Discussion: (10 min) Students return with DVDs and surveys. Classroom discussion on the video and their interest in clinical trials led by the teacher.

Explore Activity Part 1: (10 min) Students reconvene in their groups (based on the Clinical Trial they received in Session 1) and come to a consensus definition of their assigned terms.

Explain Activity Part 2: (30 min) Students will form new groups composed of students representing each of the former groups (to bring together the different vocabulary lists) . Each student will be given a crossword puzzle (see Figure 4, p. 10,11) with all 23 terms. The group members must work together to complete the puzzle. Groups will receive points as they

accurately complete their puzzles. The first group to finish receives more points than the last group, with ALL groups receiving extra points.

Lesson Plan Session 3

Extend/Assessment: Small Group Assignments: (entire class period)

Group assignments may be based on crossword puzzle groups or otherwise assigned by the teacher. They will be given (or allowed to choose) one of the following assignments for preparation as a classroom presentation.

- Select a clinical trial and design a visual comparison (poster/chart) to a science research project. [original handout and students will use their notebooks or texts] (*higher order thinking skills required*)
- Clinical trials historical timeline. (<http://www.roche.com/pages/facets/18/histclinte.htm>) (*higher order thinking skills required*)
- Discuss the risks/benefits and safeguards for participants and provide examples. (clinicaltrials.gov) (eg. Panel discussion format for presentation)
- Discuss or illustrate the different types of clinical trials. (clinicaltrials.gov)
- Do a statistical analysis of the adult attitude surveys returned from session 1.

Posttest

- Give the survey and experimental design questions to students (**see Figure 1**).

Teaching Notes

Additional alternative assessment choices include:

- A brochure to recruit people for clinical trials
- TV commercial advertising clinical trials available
- News article about products resulting from former clinical trials
- Short essay on “Clinical Trials: Pros and Cons”
- Role playing of a clinical trial including a researcher, scientist/doctor, parent, and student who is participating in a current trial

(Figure 1) Student Pretest and Posttest

Rank your responses by using: 1 strongly disagree, 2 disagree, 3 agree, or 4 strongly agree

| Question | Ranking: | Before | After |
|--|----------|--------|-------|
| I have heard of clinical trials. | | | |
| There may be benefits as well as risks for people who participate in clinical trials. | | | |
| Clinical trials take place in many locations including Oklahoma City. | | | |
| <i>Participation in clinical trials is always voluntary.</i> | | | |
| Studies done in a clinical trial are subject to rules and regulations. | | | |
| I admire people who volunteer for clinical trials. | | | |
| I would consider participating in a clinical trial if it was about an issue important to me. | | | |

Gender (circle one): M F

A researcher is conducting a clinical trial to compare the effectiveness of a sports drink vs. water on decreasing dehydration during exercise. In this scenario, identify the:

- a) Independent variable

- b) Dependent variable

- c) Control group

- d) In an experiment or clinical trial, how could the data used?
(What value does data have?)

(Figure 2)

Sample clinical trials

Think You Might Have Dental Cavities?

RESEARCH PARTICIPANTS NEEDED

UCC Center for Inflammatory Disorders
-and-
UCC Center for Oral and Systemic Diseases

Male and female subjects with cavities are needed for a clinical research study. This study will assess the effect of gum chewing on dental health. Eligible subjects will receive certain treatments at reduced fees or no charge.

For information please call or e-mail the UCC School of Dentistry Health Center.

Lung Study

Do you live with somebody who smokes?

The Center of Environmental Medicine at UNC is looking for individuals for a research study. This study involves 3 visits and a total of 4 hours of your time.

You will be reimbursed for completion of the study.
If you participate, you will have a breathing test and learn more about your lungs.
Participants will be given information about how to quit smoking.

Study of Sports Drinks vs. Water for Athletes

Agua-Sub Bottling Co. is looking for males and females 6-15 years of age who spend 8 hours or more per week participating in sports.

The sports drink company will be testing students hydration levels while exercising. Participants must be able to endure an hour of prolonged exercise after drinking 12 oz of fluid. Participants will receive samples of Agua-Sub

Video Games and Violence

Do you spend a lot of time playing video games?

Nintendo Corporation is willing to reward participants for completing video game play in the study over a period of ten months. Participants will receive \$200 worth of free games.

(Figure 3)

List A * Phases of clinical trials

- adverse reaction
- approved drugs
- baseline
- bias
- clinical trial

List B

- cohort
- control
- control group
- controlled trials
- drug interaction
- exclusion criteria/inclusion criteria

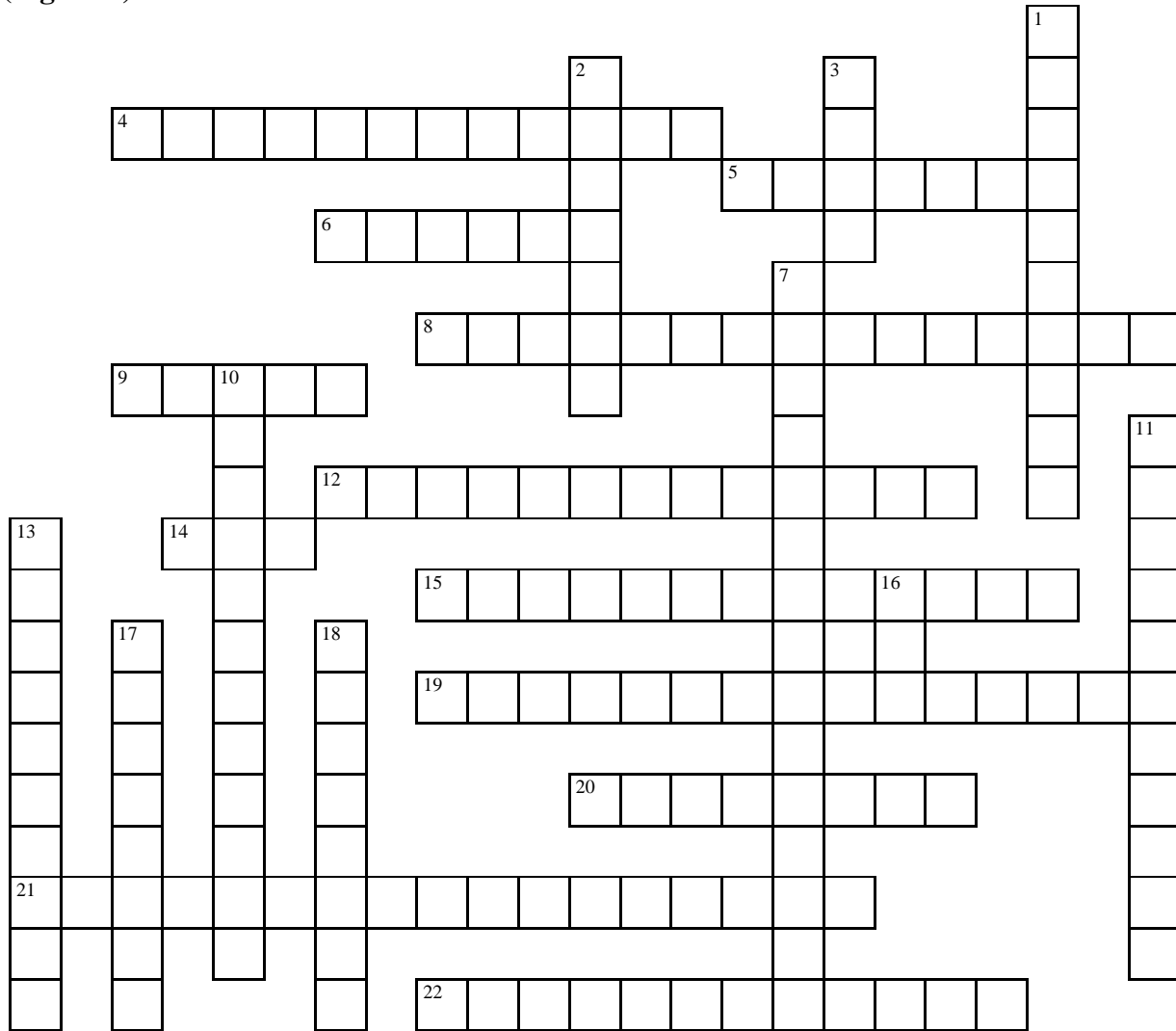
List C

- FDA
- hypothesis
- informed consent
- IRB
- intervention
- orphan drugs

List D

- placebo
- placebo effect
- protocol
- side effect
- toxicity

(Figure 4) Crossword



Use the definitions on the following page. Each team member will complete their own puzzle in collaboration with the other members of the team. Bonus points will be awarded to groups as they correctly complete their team puzzles.

ACROSS

- 4 The group that is not experimented on; this group is just there so that the two groups can be compared
- 5 Inactive pill that has no treatment value
- 6 People with something in common
- 8 Learning everything about a study before deciding to participate
- 9 Each _____ has a different purpose and number within the group
- 12 Research study to determine whether new drugs or treatments are safe
- 14 Committee that determines if an experiment is safe and ethical
- 15 Belief that a treatment works even though the participant was given a placebo
- 19 How two or more drugs react to one another
- 20 Harmful effect of a drug
- 21 Determine whether a person may or may not participate in a study
- 22 Treatment

DOWN

- 1 Prediction about the outcome of the study
- 2 A variable that does not change throughout the study
- 3 A belief that prevents the study from being "fair"
- 7 Unwanted effect of a drug
- 10 Permitted to be sold by the Food and Drug Administration
- 11 Medications used to treat rare diseases
- 13 Undesired effect of a drug
- 16 Ensures the safety and effectiveness of all drugs
- 17 Procedure used during a clinical trial
- 18 Information gathered at the beginning of a study

(Figure 5) PARENT/GUARDIAN SURVEY

Gender (circle one): M F

Age (circle one): 18-24 25-30 31-35 36-40 40-45 46 and up

Rank your responses by using: 1 strongly disagree, 2 disagree, 3 agree, or 4 strongly agree
 BEFORE AFTER

| | | |
|--|--|--|
| I have heard of clinical trials. | | |
| There may be benefits as well as risks for people who participate in clinical trials. | | |
| Clinical trials take place in many locations including Oklahoma City. | | |
| Participants in clinical trials are volunteers. | | |
| Studies done in a clinical trial are subject to rules and regulations. | | |
| I admire people who volunteer for clinical trials. | | |
| I would consider participating in a clinical trial if it was about an issue important to me. | | |

Parent/guardian/adult _____ Initials