| *PEER One Health Curriculum* | |
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| **Leader Guide** | **Prescription Drug Ads: Clinical Trials Case Study** |

**Summary:**

This module uses the concept of clinical trials to teach the scientific method. Through the One Health in Action case study, students will have the opportunity to apply the steps of the scientific method to investigate the claims of prescription drug advertisements.

**Keywords:** clinical trial, conclusion, controlled variable, data, dependent variable, experiment, hypothesis, independent variable, scientific method, scientific question, variable

**Subject TEKS:**

- Scientific Processes All Sciences
- (2) Scientific investigation and reasoning. The student uses scientific practices during laboratory and field investigations.
    - (B) design and implement experimental investigations by making observations, asking well defined questions, formulating testable hypotheses, and using appropriate equipment and technology;
    - (C) collect and record data using the International System of Units (SI) and qualitative means such as labeled drawings, writing, and graphic organizers;
    - (D) construct tables and graphs, using repeated trials and means, to organize data and identify patterns; and
    - (E) analyze data to formulate reasonable explanations, communicate valid conclusions supported by the data, and predict trends.
    - (3) Scientific investigation and reasoning. The student uses critical thinking, scientific reasoning, and problem solving to make informed decisions and knows the contributions of relevant scientists.
        - (A) analyze, evaluate, and critique scientific explanations by using empirical evidence, logical reasoning, and experimental and observational testing, so as to encourage critical thinking by the student;
        - (D) relate the impact of research on scientific thought and society, including the history of science and contributions of scientists as related to the content.

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**NGSS Science and Engineering Practices:**

- Ask questions that can be investigated within the scope of the classroom, outdoor environment, and museums and other public facilities with available resources and, when appropriate, frame a hypothesis based on observations and scientific principles.
- Plan an investigation individually and collaboratively, and in the design: identify independent and dependent variables and controls, what tools are needed to do the gathering, how measurements will be recorded, and how many data are needed to support a claim.
- Conduct an investigation and evaluate the experimental design to produce data to serve as the basis for evidence that can meet the goals of the investigation.
- Collect data to produce data to serve as the basis for evidence to answer scientific questions or test design solutions under a range of conditions.

**Grade Level:** $6^{th}$ - $9^{th}$

**Learning Objectives:**

1. Describe the steps in the scientific method.
2. Ask a scientific question that defines a problem.
3. Develop a hypothesis that shows cause and effect, correlation, or comparison.
4. Identify independent, dependent, and controlled variables.
5. Design an experiment that correctly uses variables.
6. Describe a clinical trial.
7. Compare clinical trials to the scientific method.

**Time Required:** Two to three, 45-minute class periods.

**Materials:**

- Devices with internet access
- 6-8 magazine advertisements for pharmaceuticals; laminated so that they may be used in all classes.
- Art supplies
- Video cameras or smart phones for filming

**Background and Concepts for Teachers:**

The Scientific Method

The scientific method is a logical problem-solving approach used by scientists. The goal of this method is to discover cause and effect relationships by asking questions, carefully gathering and examining the evidence, and seeing if all the available

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information can be combined into a logical answer. Scientists generally include the following components in the scientific method:

- Define a question
- Gather information and resources (observe)
- Form a hypothesis
- Test the hypothesis by performing an experiment and collecting data in a reproducible manner
- Analyze the data
- Interpret the data and draw conclusions
- Publish results
- Retest (frequently done by other scientists)

While often described as a linear series of steps, the scientific method is an iterative process that may involve backing up and repeating steps based on new information.

A scientific question may be based on a specific observation, as in "Why is the sky blue?" or an open-ended inquiry, as in "How can I design a drug to cure this particular disease?" Good questions should involve finding and evaluating evidence from previous experiments, personal scientific observations or assertions, as well as the work of other scientists.

A hypothesis is a prediction based on prior knowledge that may explain a phenomenon. It should be a clear and simple statement that can be tested. A hypothesis can be written in three ways.

- Cause and effect or if…then statements: "**If** women with knee osteoarthritis take glucosamine and chondroitin supplements during a weight loss and fitness program **then** their symptoms of pain will lessen."
- Correlation: "**Taking glucosamine and chondroitin supplements** during a weight loss and fitness program **will lessen symptoms of pain** in women with knee osteoarthritis."
- Comparison: "**Women** with knee osteoarthritis **who take glucosamine and chondroitin supplements** during a weight loss and fitness program will have less symptoms of pain **than women who don't**."

Scientists test hypotheses by conducting experiments. The purpose of an experiment is to determine whether observations of the real world agree with or conflict with the predictions made in a hypothesis. A **controlled experiment** is a scientific test done under controlled conditions, meaning that just one (or a few) factors are changed at a time, while all others are kept constant. Variables are the factors that change in an experiment and include the independent variable (the component of the experiment changed by the scientist), the dependent variable(s) (which might change in response to the independent variable) and the controlled variables (all other factors which are kept constant and used for comparison).

Results are obtained from data analysis and describe what the experiment produced. Results will also help determine the next actions scientists should take. If the experimental evidence rejects the hypothesis, a new hypothesis is required. Once a hypothesis is strongly supported by evidence, a new question can be asked to provide further insight on the same topic.

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A conclusion is a summary of the experiment. The conclusion should state the hypothesis and whether the results of the experiment supported the hypothesis. The conclusion may also discuss further experiments or tests that could be done to support findings from the current experiment.

Clinical Trials

Clinical trials are research studies performed in people or animals that are aimed at evaluating a medical, surgical, or behavioral intervention. They are the primary way that researchers find out if a new treatment, like a new drug, diet or medical device is safe and effective.

Clinical trials advance through four phases to test a treatment, find the appropriate dosage, and look for side effects. If, after the first three phases, researchers find a drug or other intervention to be safe and effective, the FDA approves it for clinical use and continues to monitor its effects.

- A **Phase I trial** tests an experimental treatment on a small group of often healthy participants (ex. 20 to 80) to judge its safety and side effects and to find the correct drug dosage.
- A **Phase II trial** uses more participants (ex.100 to 300). While the emphasis in Phase I is on safety, the emphasis in Phase II is on effectiveness. This phase aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition. These trials also continue to study safety, including short-term side effects. This phase can last several years.
- A **Phase III trial** gathers more information about safety and effectiveness, studying different populations and different dosages, using the drug in combination with other drugs. The number of subjects usually ranges from several hundred to about 3,000 people. If the FDA agrees that the trial results are positive, it will approve the experimental drug or device.
- A **Phase IV trial** for drugs or devices takes place after the FDA approves their use. A device or drug's effectiveness and safety are monitored in large, diverse populations. Sometimes, the side effects of a drug may not become clear until more participants have taken it over a longer period of time.

Research Concepts

Scientists implement several techniques to ensure experimental data is accurate and unbiased. Experimenter bias is the phenomenon by which the outcome of an experiment leans towards a result expected by the experimenter. To prevent such bias, researchers try to ensure that experiments are valid, (they measure what they purport to measure) and reliable (they provide consistent results when administered on different occasions). Further, scientists may employ techniques such as randomization (randomly assigning participants to trial groups), blind trials (researchers and/or participant are ignorant of whether they are receiving treatment), and placebos (a product that looks like the new drug, but it does not contain the active ingredient) in order to obtain accurate data.

**Vocabulary / Definitions:**

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- **Clinical trial -** research studies performed in people (or animals if it is a veterinary study) that are aimed at evaluating a medical, surgical, or behavioral intervention
- **Conclusion** - a statement based solely on measurements and observations made during the experiment.
- **Controlled variable -** factors that the scientist keep constant in an experiment.
- **Data -** the measurements such as time, temperature, mass, etc. and/or observations obtained from an experiment.
- **Dependent variable** - the factor that the scientist measures or observes to see how it responds to changes in the independent variable.
- **Experiment** - a detailed procedure designed to test a hypothesis.
- **Hypothesis -** a possible explanation about why something happens based on knowledge, observations, and background research.
- **Independent variable -** the variable tested or changed by the scientist.
- **Scientific method -** a logical problem-solving approach used by scientists.
- **Scientific question -** a question that may lead to a hypothesis and help us in answering (or figuring out) the reason for some observation.
- **Variable -** the components of an experiment that change.

**Lesson Introduction / Motivation:**

Begin the lesson by illustrating the concept of One Health with this simple colored water activity:
https://drive.google.com/file/d/1GgyzUOp0dros2FL7PMeLrmTkAzG4mJMs/view?usp=sharing

Next, have students begin thinking about how scientists solve problems by showing this short video about John Snow and his investigation of a cholera outbreak.
https://youtu.be/7RZAzRQuRrE

Alternately, teachers could introduce the module by facilitating a group discussion (virtually in a chat room or in person) about the impact of COVID-19 on schools, businesses, communities, and families. Questions to help guide the discussion might include:

- Why did schools and business have to close during the COVID-19 pandemic?
- Why weren't you allowed to congregate with friends or family outside of your immediate family?
- What had to happen in order for schools and businesses to reopen?
- Why didn't doctors or scientists just try using various medications on people to prevent or cure Coronavirus?
- Why did it take so long to develop a vaccine for Coronavirus?

Give students ample time to discuss and record their answers and then share their ideas with the entire class. Use these ideas to introduce the concept of clinical trials and how they utilize the steps of the scientific method. This activity incorporates the


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student-centered classroom philosophy, as students will be developing ideas and theories on their own as the leader facilitates the activity.

**Exploration/Explanation: Day 1 – 2**

Students should next examine the required concepts of the scientific method and clinical trials through the Essential Knowledge "Scientific Method" and "Clinical Trials Explained" sections of the Clinical Trials module from the One Health online curriculum. This can be done as a whole group, small group, partner, or individual activity. Slides, videos, and stopping points are listed below.

Scientific Method Essential Knowledge

- Slides 3 – 8 from "Scientific Method"
- Slide 10: "Hypothesis"
- Slide 11: Knowledge Check (use as whole group activity, or create friendly competition – boys v. girls, etc.)
- Slides 13 – 19: "Experiment" and "Variables"
- Slide 21: Knowledge Check (use as whole group activity, or create friendly competition – boys v. girls, etc.)
- Slides 22 – 25: "Data" and "Conclusion"
- Slide 26: Knowledge Check (use as whole group activity, or create friendly competition – boys v. girls, etc.)

Clinical Trials Essential Knowledge

- Slide 4 – 7: "Clinical Trials Explained"
- Slide 8: Knowledge Check (use as whole group activity, or create friendly competition – boys v. girls, etc.)

**Elaborate: Day 2**

- Introduce the activity with slides/video
    - Essential Knowledge "Clinical Trials Explained" slides 1 – 3
- Clinical Trial Recruitment Ad – students will design a recruitment ad for a clinical trial based upon an existing pharmaceutical advertisement. The linked teacher instruction page provides activity details. https://docs.google.com/document/d/14h5XgB5eUuivwqVt8O-ylWNKX8DQnlSk/edit?usp=drive_link&ouid=109252698449386442667&rtpof=true&sd=true

**Assessment/Evaluation:**

The Clinical Trials module includes a post-test, which can be used for an overall learning assessment. Other opportunities for assessment include student output from the Clinical Trial Recruitment Ad.

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