CRITICAL EYE ON RESEARCH IN EPIDEMIOLOGY

By the end of this activity, you will be able to illustrate the purposes, designs, weaknesses, and relevance of a randomized drug trial and of a cross-sectional study.

In this module, you will learn to analyze a research article on an epidemiological topic. It is understood that you may have minimal background in some of the medical terminology and statistical methods described in the paper. However, comprehending these components fully is not critical to evaluating the experimental study design. After reading the article, you should attempt to answer the questions posed for this research. Once you have answered these questions to the best of your ability, you can read commentary provided by your instructor so that you can see how critical analysis is applied to a research article.

In the graded portion of this activity, you will apply this same strategy to another article, answering questions with a critical eye on the research. The instructions below will help you complete this activity.

Step 1  Read the article, Lane et al., Tanezumab for the Treatment of Pain from Osteoarthritis of the Knee. New England Journal of Medicine, 2010; 363; 16. You will find a link for this article in the assignment area.

In reading the article, relate its contents to the faculty notes and readings, paying particular attention to the components of the experimental study design. As you read, think about the investigator’s choices in:

- developing the study hypothesis
- selecting the treatment and comparison groups, and
- how they conducted randomization and blinding of treatment status

Also, consider alternatives to their choices that may have improved the study or perhaps made it even more prone to bias.

Questions to Consider: Think about the design of this randomized controlled trial. What was its purpose? What were the treatment and control assignments, and are they sufficient to answer the study hypothesis? Studies such as this are frequently used to directly inform clinical practice. How might a trial such as this one provide useful information for clinicians treating a patient with osteoarthritis? Perhaps most important, are both the efficacy of the drug and the risk of side effects sufficient to recommend it to patients?

Step 2  After completing Step 1, answer the following questions to the best of your ability. You may want to record your answers in a Word document. Note: Step 2 will not be graded – it is for your practice and understanding:

a. What were the study’s rationale/hypothesis and objectives?

b. Was there any way that the blinding of treatment status could have be compromised (in other words, the investigator somehow figures out treatment status)? If so, what might have been its potential impact?

c. Do you see any problems with the way the outcome of interest was measured? If so, suggest some alternatives.

d. Are there any possible concerns about patient compliance with their assigned treatment? What impact might non-compliance have on study findings?

e. Why do you think there was an entire paragraph dedicated to disclosure of who conducted, oversaw, and analyzed the study’s findings? What implications does this information have on the study?

f. To what population(s) do you think this study’s findings may or may not be generalizable, and why?

g. This trial may have some relevance to clinical practice, but there were adverse events associated
with some of the treatment levels. Based on the frequency and type of adverse events described in the article, what advice might you want to provide physicians regarding the use of Tanezumab for osteoarthritis pain?

**Step 3** Read the commentary I have provided and compare your answers to my analysis. At this point, you may want to review the article to reinforce some of the points I have made in my critical examination of the research article. You will find a link to my commentary in the assignment area.

**Step 4** Now it is your turn to try analyzing epidemiological research! Proceed to read the article, “Mussolino et al., Jogging and Bone Mineral Density in Men: Results From NHANES III, American Journal of Public Health, 2001; 1056-1059.” You will find a link for this article in the assignment area.

As you read the article, I would like you to relate the contents of the article to the faculty notes and readings, paying particular attention to the components of the cross-sectional study design. Think about the strengths and limitations of the cross-sectional study design. What are the problems that arise from using data collected for another purpose? Based on what you understand about the study design, what are the limitations of the investigator’s conclusions?

Consider how useful the cross-sectional study design is when resources are limited and a tentative public health hypothesis needs to be evaluated. How does the availability of the NHANES database make conducting this type of study feasible? There are also some disadvantages to the cross-sectional approach. Could this same study have been conducted using an experimental design? Use the example response for the research article by Lane et al. to guide you as you develop your answers.

**Step 5** After reading the article, answer the following questions by recording your answers in a Word document. As this is a different type of research study, the questions are slightly different from the ones you answered in the previous practice session. **Note:** your answers for this second study will be graded. Submit your Word document in the dropbox for this activity. Remember to answer these questions in your own words. Do not copy entire phrases from the article without attribution.

a. What were the study’s rationale/hypothesis and objectives?

b. Was the use of an existing data source potentially problematic? What are the strengths and weaknesses?

c. What were the inclusion/exclusion criteria for the study analyses?

d. What was the outcome of interest? How was it measured, with respect to the timing of the exposure (jogging)? Can you think of any advantages/disadvantages of the way either the exposure or outcome was measured?

e. To what population(s) do you think this study’s findings may or may not be generalizable, and why?

f. Are there any hypotheses that can be generated from the major findings?

g. Could this same study have been conducted using an experimental design? Why or why not?

**Step 6** Once you have answered the questions in Step 5 and created a Word document, submit it to the dropbox for this activity.