IRB Activity

Case	Does a Human Subjects Violation occur? Explain	Ethical principle violated?	Recommended changes(s) to study
Case 1: Winning by Losing: A Weight Loss Plan for Overweight Children			
Case 2: College Course			
Case 3: Sun Screen or Sun Scream			
Case 4: Under the Knife			

Smoking True/False Quiz

1____Tobacco kills more people in the US than car accidents, fire, homicide, suicide, AIDS, alcohol, cocaine, and heroin combined.
2____ About 50% of smokers get started when they are teens.
3____ Tobacco companies are careful to design ads that do not make smoking appealing to young people.
4____ Most people who smoke regularly do so because they are addicted to nicotine.
5____ So long as you don't inhale, smoking won't hurt you.
6____ Chewing tobacco is a safe substitute for smoking cigarettes because it isn't harmful to your health.
7____ The main cause of smoking related deaths is lung cancer.
8____ People who have smoked for 15 or more years should not bother to quit, because there will be no improvement to their health.
9 ____ Women are less likely to stop smoking than men.
10____ People have a right to smoke because they're only hurting themselves.
11____Most teens who smoke have a parent who smokes.
12____With modern treatments for helping people to quit smoking, almost all smokers who try to quit are successful.

Answer these questions as you read and share the smoker profiles.

1. What patterns do you see across the profiles? Did people start smoking around the same age? When? Note any other patterns.

2. What factors influence people to…
a. begin smoking?

b. continue smoking after they have started?

Mark the factors that are environmental with an E and those that are physiological with a P.

3. Why do smokers have difficulty quitting?

Does Smoking Cause Lung Cancer? Evidence?

Epidemiology: Study of distribution and causes of disease as well as prevention and control.

Study	Pros	Cons
#1		
#2		
#3		
#4		

Student Sheet B1-4. Epidemiological Study Designs

Classify each of the following studies appropriately by filling in the table below.

Study A. Mr. Limon notices that each day a number of students fall asleep in his history class. He thinks students are falling asleep because they don't get enough sleep at night. He asks students who fall asleep in class and those who don't whether or not they slept for 7 hours or more the night before and compares these two figures.

Study B. One of the students Mr. Limon catches sleeping, Jake, insists that students fall asleep in class because they're bored. Jake divides the students in Mr. Limon's history class into two groups: those who find the class boring and those who enjoy it. He asks students to keep a record for the next month of whether they fall asleep in class. Then he compares total "falling asleep days" of students who are bored by history class to those who aren't.

Study	Prospective or Retrospective?	Cohort study or Case control study?	Outcome	Exposure
A				
B				

Study _____ is a case control study. For this study, fill out the study design form below.

Case Control Study Design

Research Question:

Outcome:

Exposure:

Study Population:

Study Size:

Cases:

Controls:

ODDS RATIO COMPARISON

COMPARE ODDS OF CASES TO ODDS OF CONTROLS

ODDS OF CASE (CANCER) BEING A SMOKER
ODDS OF CONTROL (NO CANCER) BEING A SMOKER

IF = 1 THEN SMOKING IS NOT ASSOCIATED WITH DEVELOPING CANCER, NO ASSOCIATION BETWEEN THE OUTCOME & EXPOSURE

IF THE ODDS RATIO IS X THEN CASES ARE X TIMES MORE LIKELY TO HAVE BEEN EXPOSED THAN CONTROLS

IF THE ODDS RATIO IS 6, THEN CASES ARE 6 TIMES MORE LIKELY TO HAVE BEEN EXPOSED THAN CONTROLS, THERE IS A STRONG ASSOCIATION BETWEEN OUTCOME & EXPOSURE. AN ODDS RATIO OF 2 OR GREATER IS NECESSARY TO DEMONSTRATE AN ASSOCIATION.

HOW TO CALCULATE ODDS RATIOS:
THE ODDS COMPARES THE LIKELIHOOD OF SOMETHING OCCURRING TO THE LIKELIHOOD OF SOMETHING NOT OCCURRING

OF TIMES AN EVENT OCCURS
OF TIMES THAT THE EVENT DOES NOT OCCUR

EXAMPLE: If you flip a coin, what are the odds you'll get heads?
2 possible outcomes: heads & tails, one possible outcome is heads, one is not heads (tails)
1 (flip of heads)
1 (flip of tails) the odds are 1:1 that you will flip heads

You have a sack of 10 tootsie rolls, 20 jolly ranchers & 10 gumballs. What are the odds that you will draw a tootsie roll out of the bag?

10 possible outcomes are tootsie; 30 possible outcomes are not tootsie

Odds are 1:3 the you will choose a tootsie

Student Sheet B1-5. The 2 X 2 Table **Name:** _____

Mr. Limon notices that each day a number of students fall asleep in his World History class. He thinks students are falling asleep because they don't get enough sleep at night. He decides to do a case control study to test his idea. He will ask students who fall asleep in class and those who don't whether or not they slept 7 hours or more the night before and then compare these two figures.

The next day Mr. Limon passes out anonymous questionnaires to his 4 World history classes and collects the following data. Out of 120 students, 28 reported falling sleep in class yesterday. Of these students, 20 had slept less than 7 hours the night before. Among students who ahd stayed awake, 39 had slept less than 7 hours.

1. What is Mr. Limon's research hypothesis?

2. Why do you think Mr. Limon did not require students to put their names on the questionnaires?

3. Why did Mr. Limon give the questionnaire to all 4 of his World History classes instead of just Jake's class?

4. Who are the cases and who are the controls? Label the Cases and Controls Columns below.

5. What is the exposure (the factor you think may have caused the outcome)? Label the "Exposed" and "Not Exposed" rows.

6. Fill in the shaded boxes in the 2 X 2 table with the appropriate numbers.

	Cases	**Controls**
Exposed		
Not Exposed		
Total		

7. What are the odds of having slept less than 7 hours the night before for cases? Show your work.

8. What are the odds of having slept less than 7 hours the night before for controls? Show your work.

9. The odds ratio is a comparison between two ratios. What is the odds ratio for this case control study? Show your work.

10. Do these results support Mr. Limon's hypothesis? Give evidence from your calculations to support your answer.

Criteria for causality
Does-response relationship. An increased does of the exposure is associated with a greater risk for having the outcome. (For example, sleeping 2 hours a night is associated with a greater likelihood of falling asleep then sleeping 6 hours a night.)
Temporal sequence. The exposure must occur before the outcome. (Sometimes in case control studies, this can be difficult to verify.)
Consistent with other studies. The result should be mostly consistent with what is already known in the field. (If it is not, there is always the possibility that you have discovered something new and unexpected, but there is also the possibility that your study design or assumptions were in the same way flawed.
Biological plausibility. The result should make biological sense. (For example, it makes sense that too little sleep would cause on to fall asleep the next day.)
Lack of confounder or significant bias. Can the association be explained by another factor? Is there a factor or bias that explains the association? (Read student sheet 5.6: Sources of Error in Case Control Studies.

11. For Mr. Limon's case control study, do you believe that the exposure (low sleep) is likely to have caused the outcome (falling asleep in class)? Justify your answer using the criteria for causality.

STUDENT SHEET 5.6, Continued

Test Your Knowledge
Which of the following, made-up studies is an example of each type of error?

Type of error	Study number
a. Random error	
b. Selection bias	
c. Information bias	
d. Confounding	

Study 1: Sam hypothesized that smokers are more likely to have believed they could not become addicted to cigarettes during their experimental smoking phase. Therefore, Sam performed an odds ratio calculation from the smoking behavior database for Question 20: During your experimental smoking phase, did you believe that you could become addicted to cigarettes? Sam found that smokers were 1.23 times more likely to not believe they could become addicted compared to non-smokers. However, the 95% confidence interval (0.76 to 1.98) contains the number one, which means that there is not an association between believing you could become addicted to cigarettes and becoming a regular smoker.

Study 2: In a study of chronic back pain, cases were 2.5 times more likely than controls to recall having over-exerted themselves lifting heavy objects in the past 10 years.

Study 3: A recent study suggested that people who are overweight are less likely to attend college than people who are in the "normal" weight range. However, when the data were stratified for family income (high, average, and low), there was no observable association between being overweight and not attending college.

Study 4: Several participants mentioned that they learned about the study and the $30 gift card at the homeless shelter they frequented. This group was almost entirely smokers, and they tended to be older compared to control participants. On the other hand, several study subjects expressed delight that they could contribute to a study that involved high school students in doing research on why people smoke. In general, this population tended to be younger and was much more likely to be non-smokers. Based on these facts, what bias could occur in question 83: How well off is your current family/household?

Student Sheet B1-7. Car Passenger Case Control Study **Name:** _____

The contribution of passengers to car accidents—a case control study (2007)

Whether cell phones contribute to car accidents is an important safety issue and has implications for public policy and law, as well as phone design. To answer this question, the contribution of passengers to accidents resulting in non-fatal injuries was assessed and then compared to the contribution of cell phone use by drivers. The data from the passenger part of the study are presented below. The presence and number of passengers in cars involved in injury-causing accidents and cars not involved in accidents were compared. The study was performed in Perth, Western Australia, in 2003-2004, and included drivers aged 17 and older. Controls were matched to cases by location (recruited from nearby service stations), time of day, day of the week, and road and driving conditions.

	Cases (drivers in car accidents)	**Controls** (drivers not in car accidents)
2 or more passengers	23	39
1 passenger	50	151
0 passengers	201	906
Total	274	1096

1. Fill out the Case Control Study Design form below for the car passenger study

Case Control Study Design

Research Question:

Outcome:

Exposure:

Study Population:

Study Size:

Cases:

Controls:

Student Sheet B1-7, Car Passenger Case Control Study *(continued)*

3. What are the odds that a case was carrying 1 or more passengers?

4. What are the odds that a control was carrying 1 or more passengers?

5. Considering cars carrying 1 or more passengers, what is the odds ratio? Show your work.

6. Considering only a subset of the exposed is called **stratification.** If you stratify your analysis by considering only cars carrying 2 or more passengers, what is the odds ratio? (Compare cars with 0 passengers to cars with 2 or more.) Show your work.

8. What do the two odds ratios you calculated tell you about passengers and car accidents? Give evidence from your calculations to support your answer.

9. What laws or public policies can you think of that may have been influenced by studies like this one?

10. Write a conclusion using the criteria for causality.

Original Reference

McEvoy, S. P., Stevenson, M. R., & Woodward, M. (2007). The contribution of passengers versus mobile phone use to motor vehicle crashes resulting in hospital attendance by the driver. Accident Analysis and Prevention 39, 1170-1176.

Questions

1. Fill in the Case Control Study Design template for our StarNet research study.

Case Control Study Design
Research Question:
Outcome:
Exposures:
Study Population:
Study Size:
Cases:
Controls:

2. Look at your descriptions of the case and control subjects, and answer the following questions.
   a) In what ways will the cases and the controls be similar?

   b) Why is it important for these two groups to be similar in many ways?

   c) In what way(s) are the two groups different?

   d) Consider the difference(s) between case and control subjects. How does this difference enable us to ask our research question?

3. The role of an institutional review board (IRB) is to ensure that human subjects in research studies are protected from unnecessary risks. What potential risks does our study pose for research subjects? How can we design the study to minimize these risks?

Name:_____ Date:_____ Period:_____

Lesson 4. The Smoking Behavior Case Control Study

Smoking Behavior Case Control Study

Research Question: What genetic and environmental factors might lead to someone becoming a regular smoker?
Outcome: Being a regular smoker

Exposures: Various environmental and genetic factors that might be associated with becoming a regular smoker.
The Exposure(s) our group is focusing on are_____

Cases: Regular Smokers

Controls: People who have tried smoking and quit

Study Population

Intended Men and women	*Actual number (in database)* Men: _____ Cases _____ Controls Women: _____ Cases _____ Controls Are men and women evenly balanced between cases and controls? Explain.
25 – 54 Years Old	25 - 29 _____ Cases _____ Controls 30-34 _____ Cases _____ Controls 35-39 _____ Cases _____ Controls 40-44 _____ Cases _____ Controls 45-49 _____ Cases _____ Controls 50-54 _____ Cases _____ Controls Are the age groups evenly balanced between cases and controls? Explain
Diverse Racial Backgrounds	American Indian / Alaskan Native _____ Cases _____ Controls Asian _____ Cases _____ Controls Black/African American _____ Cases _____ Controls Native Hawaiian/ Other Pacific Islander _____ Cases _____ Controls White _____ Cases _____ Controls Are the racial groups evenly balanced between the cases and controls? Explain.

The Smoking Behavior Study was conducted in the urban Puget Sound Region through the University of Washington. Why do you think there might have been problems properly matching cases and controls?

How might the problems matching cases and controls (as far as gender, age, and racial group) affect the results of your investigation? Refer to your specific exposure(s).

Student Sheet C.4. Analyze this!

A research group is comparing two smoking cessation methods. They plan to use a questionnaire to learn about the smoking behavior of their subjects. The results of the study will be confidential, as they plan to publish their data in a scientific journal. The lead scientist asks a graduate student to write questions for the questionnaire. When he sees the first draft, he says to the student, "You can't ask these questions! Either they won't get past the IRB, or they'll frustrate the subjects."

Part 1

Read Questions 1 through 4 and analyze why they are not appropriate questions. Write your responses in column 2 of Table C.2. Then in column 3, name the characteristic of a good questionnaire question that needs to be addressed when revising this question.

1. Why have you failed to quit smoking in the past? Circle all answers that apply.
   - a. I have no will power
   - b When I quit smoking I get headaches
   - c When I'm not smoking I crave cigarettes
   - d When I'm not smoking I get stressed
   - e When I'm not smoking I gain weight
   - f When I'm not smoking I can't concentrate

2. What is your address?
   Street and Apt. number_____
   City_____ State._____ Zip._____

3. Are you a heavy smoker?
   - a Yes
   - b No
   - c Don't know/not sure

4. At what grade level did you first get anti-smoking education at school?
   - a Kindergarten
   - b 1st grade
   - c 2nd grade
   - d 3rd grade
   - e 4th grade
   - f 5th grade
   - g 6th grade
   - h 7th grade
   - i 8th grade
   - j 9th grade
   - k 10th grade
   - l 11th grade
   - m 12th grade
   - n didn't go to school
   - o didn't get anti-smoking education at school
   - p don't know/not sure

Table C.2. Characteristics of good questionnaire questions

Question	Why not appropriate	Characteristic of a good questionnaire question
1		
2		
3		
4		

Part 2 (to be completed after class has discussed Part 1):

Revise [redacted] the four questions, using the class list of characteristics for good questionnaire questions.

Name:_____ Date:_____ Period:_____

Lesson 6a. Hypothesis Testing

Go to: gsoutreach.gs.washington.edu/database2/

Big Research Topic:

Overarching Hypothesis:

Complete this section before entering database

Your 1st database question (give question # and question):

Your specific hypothesis for this question:

Exposed: Responses _____ and description in words:

Not exposed: Responses _____ and description in words:

Why did you define "exposed" and "not-exposed" this way?

Study population (select one): Everyone__ Males__ Females__

Testing your Hypothesis: Go to "Hypothesis Testing" to complete this page.

Odds Ratio: _____ Sample size: _____

95% CI: _____ Does the 95% CI contain the value 1? _____

Interpret the result:

a) Use the odds ratio in a sentence that describes what it means.

b) Is the association between the exposure and becoming a regular smoker significant? How do you know?

c) Do you think this exposure causes people to become a regular smoker? Apply the criteria for causality to support your answer.

Name:_____ Date:_____ Period:_____

Lesson 6a. Hypothesis testing, continued

Complete this section before entering database

Your 2nd database question (give question # and question):

Your specific hypothesis for this question:

Exposed: Responses _____ and description in words:

Not exposed: Responses _____ and description in words:

Why did you define "exposed" and "not-exposed" this way?

Study population (select one): Everyone__ Males__ Females__

Testing your Hypothesis: Go to "Hypothesis Testing" to complete this page.

Odds Ratio: _____ Sample size: _____

95% CI: _____ Does the 95% CI contain the value 1? _____

Interpret the result:

a) Use the odds ratio in a sentence that describes what it means.

b) Is the association between the exposure and becoming a regular smoker significant? How do you know?

c) Do you think this exposure causes people to become a regular smoker? Apply the criteria for causality to support your answer.

Name:_____ Date:_____ Period:_____

Lesson 6a. Hypothesis testing, continued

Complete this section before entering database.

Your 3rd database question (give question # and question):

Your specific hypothesis for this question:

Exposed: Responses _____ and description in words:

Not exposed: Responses _____ and description in words:

Why did you define "exposed" and "not-exposed" this way?

Study population (select one): Everyone__ Males__ Females__

Testing your Hypothesis: Go to "Hypothesis Testing" to complete this page.

Odds Ratio: _____ Sample size: _____

95% CI: _____ Does the 95% CI contain the value 1? _____

Interpret the result:

a) Use the odds ratio in a sentence that describes what it means.

b) Is the association between the exposure and becoming a regular smoker significant? How do you know?

c) Do you think this exposure causes people to become a regular smoker? Apply the criteria for causality to support your answer.

Name:_____ Date:_____ Period:_____

Lesson 6a. Hypothesis testing, continued

Complete this section before entering database.

Your 4th database question (give question # and question):

Your specific hypothesis for this question:

Exposed: Responses _____ and description in words:

Not exposed: Responses _____ and description in words:

Why did you define "exposed" and "not-exposed" this way?

Study population (select one): Everyone__ Males__ Females__

Testing your Hypothesis: Go to "Hypothesis Testing" to complete this page.

Odds Ratio: _____ Sample size: _____

95% CI: _____ Does the 95% CI contain the value 1? _____

Interpret the result:

a) Use the odds ratio in a sentence that describes what it means.

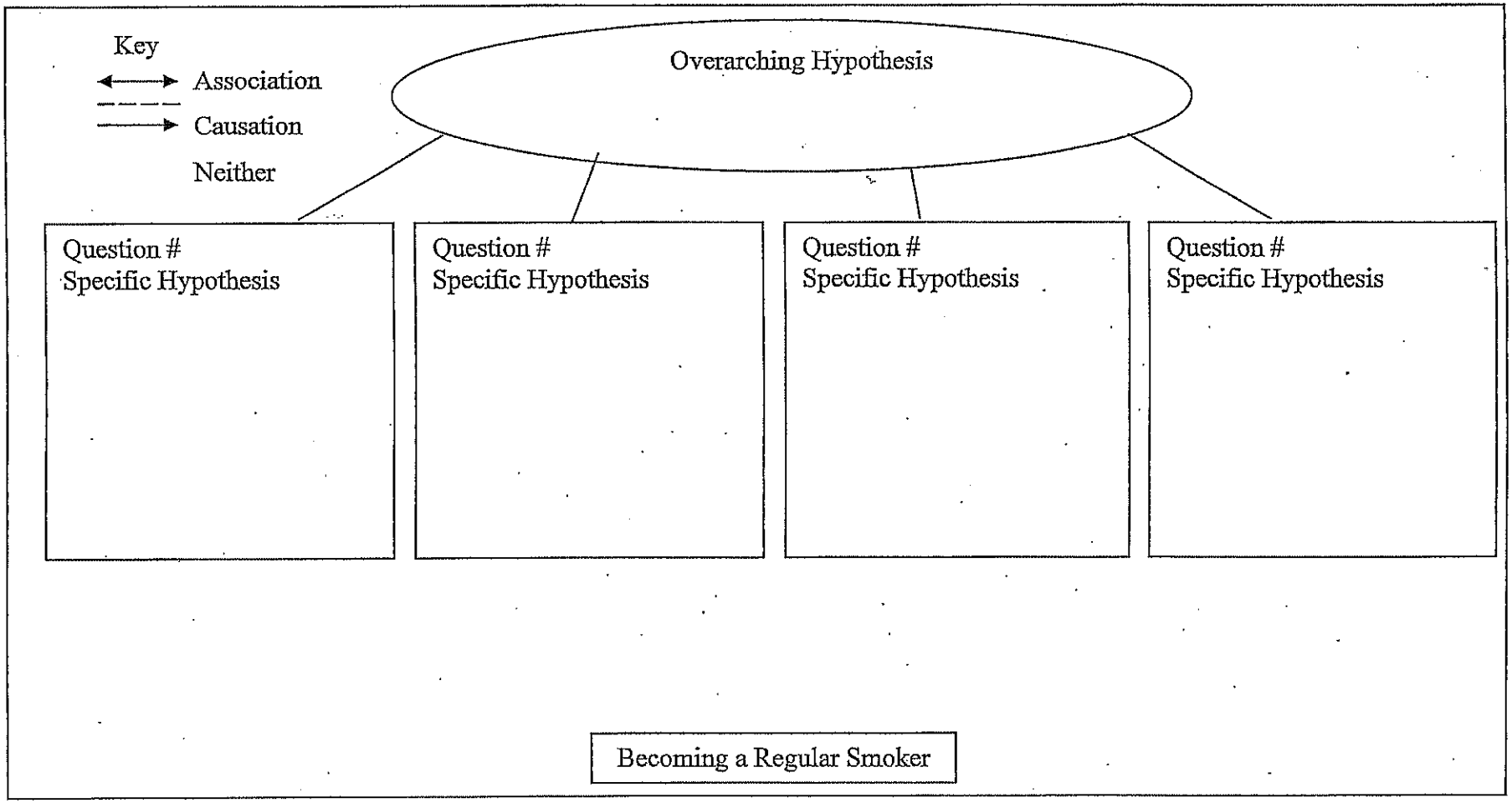
b) Is the association between the exposure and becoming a regular smoker significant? How do you know?

c) Do you think this exposure causes people to become a regular smoker? Apply the criteria for causality to support your answer.

Name:_____ Date:_____ Period:_____

Lesson 6b. Mapping Activity

Directions: Fill in your overarching hypothesis in the oval below; then fill in each square with one of the four database question numbers and specific hypotheses. Using one of the three lines shown in the key, draw the relationship between each Question # and Becoming a Regular Smoker at the bottom of the page.



Name:_____ Date:_____ Period:_____

Lesson 6c. Drawing Conclusions

You will now look at the results for each of your four questions on RPP-7-10 and on the mapping activity to draw conclusions about your overarching hypothesis.

1. What do your results show about your overarching hypothesis?

3. Which pieces of evidence most strongly support your claim?

   a. Discuss one piece of evidence and why it supports your claim.

   b. Discuss a second piece of evidence and why it supports your claim.

3. How strong is the evidence that your overarching hypothesis is supported? Are there other ways to interpret your data?

4. What are the implications of your research for health? For your community?