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Bicycle Helmet Effectiveness in Preventing Injury and Death

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As adapted by

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Lesson Plan

TITLE: Bicycle Helmet Effectiveness in Preventing Injury and Death

SUBJECT AREA: Social studies (particularly economics), school health education, environmental science

OBJECTIVES: At the end of the instructional unit, the student will be able to:

- Define cost-effectiveness and how it is measured
- Review cost-effectiveness analysis examples from the literature
- Calculate and apply cost-effectiveness principles
- Apply economic evaluation concepts

TIME FRAME: Two or three 45-minute lessons (depending on whether Section C is included)

- **PREREQUISITE KNOWLEDGE:** For the teacher, prior familiarity with cost-effectiveness analysis and cost-benefit analysis will be important, as this module moves rather quickly though these complex ideas. For students, Section C requires knowledge of study design, including the case-control study, and of the nature of bias, but could be omitted. If Section C is to be included, consider first teaching the units on study design (by Olsen and Stolley) and on bias (by Olsen and Bayona).
- **MATERIALS NEEDED:** Calculator, overhead projector; Microsoft[®] Excel or other spreadsheet program would be useful.
- **PROCEDURE:** Introduction of the concepts of cost-effectiveness and cost-benefit is an ambitious undertaking for high school, but the example used here is pretty accessible, provided the teacher has the background to enable students' questions to be answered. If Section C is omitted, the first class session can cover Sections A, B and D, and the second class session can cover Sections E and F. If Section C is included, the first class covers A and B; the second, C and D; and the third, E and F.

This module examines the cost-effectiveness of three interventions to increase utilization of bicycle helmets to avert head injuries in individuals 18 years of age and under in Onondaga County, New York. Students are initially presented with data on head injuries, hospitalization and death related to bicycle use. They then appraise a published study on the effectiveness of bicycle helmets in averting head injury. In the second (or third) class session, students work in groups to determine the cost-effectiveness of each intervention by calculating implementation costs and the specific number of head injuries averted associated with intervention. The three interventions are legislative, school and community-based campaigns to increase helmet use. Students are provided with budget estimates and assumptions needed to complete the exercise. Cost-effectiveness analysis, cost-benefit analysis and related concepts are discussed, including provider versus societal perspectives and importance of sensitivity analysis.

ASSESSMENT: Students are asked to describe how they would assess the cost-effectiveness of a policy to require smoke detectors in homes.

LINK TO STANDARDS:

SOCIAL STUDIES

1	Social studies programs should include experiences that provide for the study of the ways human beings view themselves	 Analyzing and explaining the ways groups, societies and cultures address human needs and concerns. 		
	in and over time.	 Predicting how data and experiences may be interpreted by people from diverse cultural perspectives and frames of reference. 		
3	Social studies programs should include experiences that provide for the study of interactions among individuals, groups, and institutions.	 Explaining and applying ideas and modes of inquiry drawn from behavioral science and social theory in the examination of persistent issues and social problems. 		
4	Social studies programs should include experiences that provide for the study of relationships among science, technology, and society.	1) Evaluating various policies that have been proposed as ways of dealing with social changes resulting from new tech- nologies, such as genetically engineered plants and animals.		
5	Social studies programs should include expe- riences that provide for the study of global connections and interdependence.	1) Analyzing the causes, consequences, and possible solutions to persistent, contem- porary and emerging global issues, such as health, security, resource allocation, economic development, and environmen- tal quality.		

SCHOOL HEALTH EDUCATION

	Standards	Performance Indicators
1	Students will comprehend concepts related to health promotion and disease prevention.	Identifying what good health is, recogniz- ing health problems, and ways in which lifestyle, the environment, and public poli- cies can promote health.
2	Students will demonstrate the ability to access valid health information and health- promoting products and services.	Identification of valid health information, products, and services including advertise- ments, health insurance and treatment options, and food labels.
4	Students will analyze the influence of cul- ture, media, technology, and other factors on health.	Describing and analyzing how one's cultural background, messages from the media, technology, and one's friends influence health.
7	Students will demonstrate the ability to advocate for personal, family, and community health.	Identifying community resources, accurately communicating health information and ideas, and working cooperatively to pro- mote health.

SCIENCE

Content Standard A: Science as Inquiry

• Abilities necessary to do scientific inquiry

• Formulate and revise scientific explana- tions and models using logic and evidence.	 Student inquiries should culminate in formulating an explanation or model. 		
	• In the process of answering questions, students should engage in discussions and arguments that result in the revi- sion of their explanations.		
 Recognize and analyze alternative explana- tions and models. 	 Students should be able to use scien- tific criteria to find the preferred explanations. 		

- Understandings about scientific inquiry. Students should understand that:
 - Scientific explanations must adhere to criteria such as: a proposed explanation must be logically consistent; it must abide by the rules of evidence; it must be open to questions and possible modification; and it must be based on historical and current scientific knowledge.
 - Results of scientific inquiry—new knowledge and methods—emerge from different types of investigations and public communication among scientists. In communicating and defending the results of scientific inquiry, arguments must be logical and demonstrate connections between natural phenomena, investigations, and the historical body of scientific knowledge. In addition, the methods and procedures that scientists used to obtain evidence must be clearly reported to enhance opportunities for further investigation.

Content Standard E: Science and Technology

As a result of activities in grades 9-12, all students should develop

- Understandings about science and technology
 - Scientists in different disciplines ask different questions, use different methods of investigation, and accept different types of evidence to support their explanations. Many scientific investigations require the contributions of individuals from different disciplines, including engineering. New disciplines of science, such as geophysics and biochemistry, often emerge at the interface of two older disciplines.
 - Science and technology are pursued for different purposes. Scientific inquiry is driven by the desire to understand the natural world, and technological design is driven by the need to meet human needs and solve human problems. Technology, by its nature, has a more direct effect on society than science because its purpose is to solve human problems, help humans adapt, and fulfill human aspirations. Technological solutions may create new problems. Science, by its nature, answers questions that may or may not directly influence humans. Sometimes scientific advances challenge people's beliefs and practical explanations concerning various aspects of the world.

Content Standard F: Science in Personal and Social Perspectives

- Personal and community health
 - Hazards and the potential for accidents exist. Regardless of the environment, the possibility of injury, illness, disability, or death may be present. Humans have a variety of mechanisms—sensory, motor, emotional, social, and technological—that can reduce and modify hazards.
 - The severity of disease symptoms is dependent on many factors, such as human resistance and the virulence of the disease-producing organism. Many diseases can be prevented,

controlled, or cured. Some diseases, such as cancer, result from specific body dysfunctions and cannot be transmitted.

- Personal choice concerning fitness and health involves multiple factors. Personal goals, peer and social pressures, ethnic and religious beliefs, and understanding of biological consequences can all influence decisions about health practices.
- Natural and human-induced hazard
 - Natural and human-induced hazards present the need for humans to assess potential danger and risk. Many changes in the environment designed by humans bring benefits to society, as well as cause risks. Students should understand the costs and trade-offs of various hazards—ranging from those with minor risk to a few people to major catastrophes with major risk to many people. The scale of events and the accuracy with which scientists and engineers can (and cannot) predict events are important considerations.

Bibliography

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Study Design: In *Prevention Effectiveness: A Guide to Decision Analysis and Economic Evaluation*. Haddix AC, Teutsch SM, Shaffer PA, Dunet DO, eds. New York: Oxford University Press; 1996.

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Lesson: Bicycle Helmet Effectiveness in Preventing Injury and Death (Student Version)

Section A: Cost-Effectiveness

Cost-effectiveness plays a critical role in determining the best course of action in many areas of public policy. In cost-effectiveness analysis, alternative policies are compared by calculating for each the ratio of the cost of a policy to its impact on some outcome of interest (its "effectiveness"). The policy with the lowest ratio is said to be the most cost effective. Thus, if one wished to increase the average fuel efficiency of automobiles in the country, one might estimate the effectiveness and cost of the alternative policies of (1) raising the tax on gasoline 10 cents per gallon, (2) levying a \$2,000 tax on new gas-guzzling vehicles or (3) banning vehicles more than 15 years old. Calculating the ratio of cost to effectiveness would allow an "apples-to-apples" comparison of the cost in dollars for every mile-per-gallon increase in average fuel efficiency for each of the possible policy changes. Basically, cost-effectiveness analysis is a tool to identify the policy that is the most efficient way to achieve a certain worthy goal.

One must distinguish cost-effectiveness analysis from cost-benefit analysis. In cost-benefit analysis, one compares the cost of a policy to its benefits. In cost-benefit analysis, both costs and benefits are measured in the same units (generally, dollars or other monetary units). If a policy generates more dollars' worth of benefits than it costs, it is considered cost beneficial; if the costs outweigh the benefits, it is not cost beneficial. Basically, cost-benefit analysis is a way to identify those policies that more than pay for themselves.

For both cost-effectiveness and cost-benefit analysis, one must be clear about whose costs are counted. Purchasers of a new gas-guzzling car may find a \$2,000 tax very expensive and so judge such a tax not cost effective, whereas the federal government, because it receives the tax, might find it very cost effective.

Questions

1. Define cost-effectiveness.

2. How is cost-effectiveness calculated and, for matters related to health, what outcome measures might commonly be used?

Section B: Analysis of Available Data— Effectiveness of Bicycle Helmets in Preventing Morbidity and Mortality

As a consultant to the local legislature, you are asked to determine the best means of reducing morbidity and mortality associated with bicycle riding in your county in New York. To provide advice regarding this issue, you need to be able to interpret the available data. Local data on morbidity are not available because of the lack of uniform reporting of such injuries. In regard to mortality data, the number of fatalities associated with bicycle use in a community of this size is too small to be useful for analysis. Fortunately, the New York State Department of Health (NYSDOH) is able to provide you with the information in the following table.

Age (in years)	Males: Number (rate)*	1996 Population	Females: Number (rate)*	1996 Population	Total: Number (rate)*	1996 Population
0-4	0 (0)	671,564	0 (0)	643,473	0 (0)	1,315,037
5–9	4 (0.58)	686,178	0 (0)	652,821	4 (0.30)	1,338,999
10-14	4 (0.63)	630,136	0 (0)	600,153	4 (0.33)	1,230,289
15–19	6 (1.01)	596,126	1 (0.18)	570,697	7 (0.60)	1,166,823
20–24	4 (0.65)	611,686	0 (0)	602,435	4 (0.33)	1,214,121
25–44	17 (0.57)	2,973,953	2 (0.07)	3,009,727	19 (0.32)	5,983,680
45-64	9 (0.49)	1,823,532	0 (0)	2,022,921	9 (0.23)	3,846,453
65+	2 (0.21)	943,640	1 (0.07)	1,467,358	3 (0.12)	2,410,998
Total	46 (0.51)	8,936,815	4 (0.04)	9,569,585	50 (0.27)	18,506,998

Table 1. Deaths Due to Bicycle Injuries by Age and Sex

*Rate: Number/1996 estimated population × 100,000.

Source: New York State Department of Health, Bureau of Injury Prevention and Biometrics.

Questions

1. Comment on the differences in bicycle injury mortality by age and sex as well as on the interaction between age and sex.

2. What are possible explanations for these differences?

3. How would this information help you formulate prevention strategies for your community?

The NYSDOH is also able to provide you with graphs (see attached Figures 1–4) on overall bicycle-related morbidity (injury) and mortality rates, as well as information specific to traumatic brain injury or death due to bicycle use for the period 1991–1996.

4. What are your hypotheses with respect to the trends in rates for death, hospitalization and traumatic brain injuries associated with bicycle use during these years?

5. What are some of the limitations of the data that have been presented?











Figure 3:DEATHS DUE TO BICYCLE-RELATED TRAUMATIC BRAIN INJURIES Rate per 100,000 by Age Group New York State Residents, 1991–1996



Figure 4: HOSPITALIZATIONS DUE TO BICYCLE-RELATED TRAUMATIC BRAIN INJURIES Rate per 100,000 by Age Group New York State Residents, 1991–1996

Section C: Effectiveness of Bicycle Helmet Use—An Appraisal of Scientific Evidence

In addition to demographic information provided, you need more knowledge about the effectiveness of bicycle helmets before you present your official recommendations to the local health advisory board. Review the abstract of "A Case–Control Study of the Effectiveness of Bicycle Safety Helmets," as published in the *New England Journal of Medicine* in May 1989:

A case-control study of the effectiveness of bicycle safety helmets.

Thompson RS, Rivara FP, Thompson DC.

Center for Health Studies, Group Health Cooperative of Puget Sound, Seattle, WA 98121.

Bicycling accidents cause many serious injuries and, in the United States, about 1300 deaths per year, mainly from head injuries. Safety helmets are widely recommended for cyclists, but convincing evidence of their effectiveness is lacking. Over one year we conducted a case-control study in which the case patients were 235 persons with head injuries received while bicycling, who sought emergency care at one of five hospitals. One control group consisted of 433 persons who received emergency care at the same hospitals for bicycling injuries not involving the head. A second control group consisted of 558 members of a large health maintenance organization who had had bicycling accidents during the previous year. Seven percent of the case patients were wearing helmets at the time of their head injuries, as compared with 24 percent of the emergency room controls and 23 percent of the second control group. Of the 99 cyclists with serious brain injury only 4 percent wore helmets. In regression analyses to control for age, sex, income, education, cycling experience, and the severity of the accident, we found that riders with helmets had an 85 percent reduction in their risk of head injury (odds ratio, 0.15; 95 percent confidence interval, 0.07 to 0.29) and an 88 percent reduction in their risk of brain injury (odds ratio, 0.12; 95 percent confidence interval, 0.04 to 0.40). We conclude that bicycle safety helmets are highly effective in preventing head injury. Helmets are particularly important for children, since they suffer the majority of serious head injuries from bicycling accidents.

Questions

1. Why did the authors choose to do a case-control study to determine cost-effectiveness of helmet use? Could they have done a randomized controlled trial? A prospective cohort study? What are the major limitations of these study designs to address this issue?

2. Identify biases associated with case-control studies, including selection of cases and controls.

3. Comment on the comparability between cases and controls.

4. What information provided by this study regarding effectiveness of bicycle helmets is generalizable?

Section D: Assessing Bicycle Helmet Use Locally

1. Discuss how you would develop and implement a study to determine use of bicycle helmets by age, gender and location in your county. Discuss sampling and measurement issues.

2. What are some of the factors that would influence the effectiveness of bicycle helmets in preventing injuries and death at a population level?

Section E: Development of Preventive Programs Utilizing a Cost-Effectiveness Approach

You now have epidemiologic information about bicycle-related injuries and deaths, and there is scientific evidence that bicycle helmets are 85% effective in reducing bicycle-related head injury. You determine that there are three feasible options for preventive programs aimed at increasing helmet use in your county. The options are as follows:

LEGISLATIVE OPTION: This option involves efforts to educate the public about the passage of a new law that requires helmet use for all individuals 18 years old or younger. It also requires enforcement of this new law.

- Target population (all residents ≤ 18 years old): 125,000
- Program costs to be considered:
 - Limited public education (publicity/media) to increase awareness of helmet law
 - Enforcement of law
- Provision of helmets: No helmets are provided under this option. Target population is expected to purchase helmets.
- **COMMUNITY OPTION:** The local health department is responsible for a comprehensive program to educate the entire community about the risks of bicycle injuries and the benefits of helmet use. The health department will also provide helmets at cost to indigent children.
 - Target population (all county residents): 450,000
 - Program costs to be considered:
 - Health education (publicity/media) about bicycle injuries and helmet use
 - Distribution of helmets at cost to all indigent children
 - Provision of helmets: County provides helmets at cost for indigent children. On the basis of the most recent census data, 20% of all children less than 18 years old are indigent $(125,000 \times 20\% = 25,000)$.
 - The health department will buy helmets for 25,000 children at \$10 per helmet.
 - The health department will sell helmets to parents/guardians of 20,000 children at \$10 per helmet (assuming that not all helmets will be sold).
- **SCHOOL OPTION:** The school board and the health department are responsible for educating school-aged children about the risks of bicycle injuries and the benefits of

helmet use. The health department will also provide helmets at cost to indigent children.

- Target population (all school-aged children): 84,000
- Program costs to be considered:
 - Classroom education about helmet use is aimed at school-aged children. Educational efforts will also be made to parents of the target population.
 - Distribution of helmets at cost to all indigent children.
- Provision of helmets: County provides helmets for indigent children at cost. On the basis of the most recent census data, 20% of all school-aged children less than 18 years old are indigent ($84,000 \times 20\% = 16,800$).
 - The health department will buy helmets for 16,800 children at \$10 per helmet.
 - The health department will sell helmets to the parents/guardians of 13,500 children at \$10 per helmet.

Calculating Cost-Effectiveness

As a class, you are asked to determine which option is the most cost effective. For each of the options, you need to use the following formula:

Cost-effectiveness = $\frac{\text{cost of option}}{\text{number of head injuries averted}}$

Both the numerator and the denominator need to be calculated. To find the total cost of your option, you will need to use your own judgment to determine how much will be spent on personnel costs and how much will be used on the education campaign. For personnel costs, depending on the option, the cost of health educators, of the staff responsible for organizing and distributing helmets, and of officers for enforcement of the law will need to be considered. Guidelines for the estimated costs are provided in the following table.

Program Component	Cost
Helmets	\$10 cost; \$25 retail
Health education staff	\$40,000/employee/year
Helmet program staff	\$30,000/employee/year
Public information campaign	
Develop one television spot	\$10,000
Pay for one television spot	\$2,000
Public service television spot	Free— \$250
Develop and pay for one radio spot	\$350
Brochures	\$2,500 for 10,000 brochures
Enforcement	\$50,000 per year

Table 2. Cost Estimates for Budget Calculation

Questions

1. What is the total cost of your option?

2. How would you estimate the number of head injuries prevented by one of these preventive programs?

To simplify calculations, certain assumptions about helmet use must be made. Some of these assumptions may be optimistic. For this exercise, it is assumed that all people in the target population are potential bicyclists. Data from the health department indicate that baseline helmet use is approximately 20%. It is assumed that helmet use will increase to approximately 50% after each of the interventions. The national injury rate for bicycle use is 50/100,000. Finally, the efficacy rate of helmet use, based on current literature, is assumed to be 85%. Taking these assumptions into account, we should apply the following formula:

Number of head injuries averted = $0.30 \times \text{target population} \times 50/100,000 \times 0.85$

3. On the basis of information provided, how many head injuries were averted with each option?

4. What is the cost per head injury averted?

5. Which is the most cost-effective option?

Section F: Economic Evaluation

When the cost-effectiveness of a program is interpreted, the perspective from which the analysis was performed must be taken into account. In other words, was the analysis done from a broad perspective in which all costs and benefits to the population are considered, or was it done from a narrow perspective in which only costs or benefits to a certain subgroup were addressed? In general, a societal perspective is the broadest perspective. In contrast, an analysis done from the point of view of a hospital or an insurance company provides a much more narrow perspective.

Questions

1. From what perspective did you conduct your analysis in Section E? Consider the perspective of each option when answering this question. (For example, does a health department have a different point of view than does the legislature or society as a whole?) How would your results change if you were to conduct your analysis from a societal perspective?

Thus far in this unit, cost-effectiveness has been used to determine the cost per head injury averted. Different techniques are available to conduct an economic analysis, one of which is cost-benefit analysis.

2. What is the difference between cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA)?

3. What are the strengths and weaknesses of each analysis?

4. What questions are best answered by each method?

Finally, because an economic analysis is based on certain sets of assumptions about variables, it should include a sensitivity analysis in which the assumptions are challenged to see how much they affect the outcome of the analysis. Examples of variables for which sensitivity analysis is helpful include success rate of the intervention, valuation of costs of the intervention, or valuation of the benefits. An example of sensitivity analysis is available in the following recommended reading: Gaspoz JM, Coxson PG, Williams LW, Kuntz KM, Hunink MM, Goldman L. Cost effectiveness of aspirin, clopidogrel, or both for the secondary prevention of coronary heart disease. *New England Journal of Medicine*. 2002:346(23):1800–1806.

5. In your analysis of the cost-effectiveness of bicycle helmets, what were the most important variables?

6. How would changes in these variables affect the outcome of the analysis?

7. Taking perspective, type of economic analysis, and sensitivity analysis into account, which preventive approach do you now think is the most cost-effective means to decrease death and injury due to bicycle-related accidents in your county?

Lesson: Bicycle Helmet Effectiveness in Preventing Injury and Death (Teacher's Annotated Version)

Section A: Cost-Effectiveness

Cost-effectiveness plays a critical role in determining the best course of action in many areas of public policy. In cost-effectiveness analysis, alternative policies are compared by calculating for each the ratio of the cost of a policy to its impact on some outcome of interest (its "effectiveness"). The policy with the lowest ratio is said to be the most cost effective. Thus, if one wished to increase the average fuel efficiency of automobiles in the country, one might estimate the effectiveness and cost of the alternative policies of (1) raising the tax on gasoline 10 cents per gallon, (2) levying a \$2,000 tax on new gas-guzzling vehicles or (3) banning vehicles more than 15 years old. Calculating the ratio of cost to effectiveness would allow an "apples-to-apples" comparison of the cost in dollars for every mile-per-gallon increase in average fuel efficiency for each of the possible policy changes. Basically, cost-effectiveness analysis is a tool to identify the policy that is the most efficient way to achieve a certain worthy goal.

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For both cost-effectiveness and cost-benefit analysis, one must be clear about whose costs are counted. Purchasers of a new gas-guzzling car may find a \$2,000 tax very expensive and so judge such a tax not cost effective, whereas the federal government, because it receives the tax, might find it very cost effective.

Questions

1. Define cost-effectiveness.

Cost-effectiveness is a measure of the efficiency of an intervention. It is the cost of an intervention per unit improvement in an outcome of interest caused by that intervention, as viewed from the perspective of a party interested in that intervention. Given that resources are almost always limited, tools are needed to assist decisionmakers in determining how they can best utilize the limited resources they have to achieve a particular outcome. Cost-effectiveness can be used to assist such decisionmaking by measuring costs incurred by an intervention as it relates to an identified measurable outcome. When two interventions are being compared (cost-effectiveness analysis), the same outcome measure must be used.

You can use an example to illustrate cost-effectiveness. An excellent example is Gaspoz JM, Coxson PG, Williams LW, Kuntz KM, Hunink MM, Goldman L. Cost effectiveness of aspirin, clopidogrel, or both for the secondary prevention of coronary heart disease. *New England Journal of Medicine*. 2002;346(23):1800–1806. This article compares aspirin with clopidogrel (Plavix) in the prevention of coronary heart disease.

2. How is cost-effectiveness calculated, and, for matters related to health, what outcome measures might commonly be used?

To calculate cost-effectiveness, one determines the cost of an intervention and divides that by the change in the outcome resulting from the intervention:

Cost-effectiveness = <u>cost of intervention</u> <u>outcome measure (usually a gain in health)</u>

In health care fields, the cost may include direct medical costs (such as drug therapy, hospital stay, surgery), direct nonmedical costs (such as child care for ill parents, transportation costs, etc) or indirect costs (such as lost wages, disability, pain). The identified outcome measures may include number of deaths, diseases or disabilities *averted* or the number of life years gained. Later in this exercise, you will calculate the cost of an intervention and divide by the number of head injuries averted.

Section B: Analysis of Available Data— Effectiveness of Bicycle Helmets in Preventing Morbidity and Mortality

As a consultant to the local legislature, you are asked to determine the best means of reducing morbidity and mortality associated with bicycle riding in your county in New York. To provide advice regarding this issue, you need to be able to interpret the available data. Local data on morbidity are not available because of the lack of uniform reporting of such injuries. In regard to mortality data, the number of fatalities associated with bicycle use in a community of this size is too small to be useful for analysis. Fortunately, the New York State Department of Health (NYSDOH) is able to provide you with the information in the following table.

Age (in years)	Males: Number (rate)*	1996 Population	Females: Number (rate)*	1996 Population	Total: Number (rate)*	1996 Population
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Table 1. Deaths Due to Bicycle Injuries by Age and Sex

*Rate: Number/1996 estimated population × 100,000.

Source: New York State Department of Health, Bureau of Injury Prevention and Biometrics.

Questions

1. Comment on the differences in bicycle injury mortality by age and sex as well as on the interaction between age and sex.

Note: Students may need to be reminded to look at rates, not frequency, to best answer this question.

The overall mortality from bicycle injury is nearly 13 times higher in males than females. The highest mortality in both groups is in the 15- to 19-year age group (though the number of deaths in females is too low to draw a firm conclusion about the role of age). For males, mortality is lowest in the \geq 65- and <5-year age groups.

According to the Centers for Disease Control and Prevention (http://www.cdc.gov/ncipc/bike/problem.htm), nationally the rate of injury is highest for children aged 5–15 years of age, and the rate of death is highest for children aged 10–14 years of age. Head injuries account for almost two-thirds of the bicycle-related deaths. Males are 2.4 times more likely to be killed per bicycle trip than females.

2. What are possible explanations for these differences?

Patterns of behavior most likely explain these differences. Males and adolescents may ride bicycles more frequently, ride them in a more dangerous manner or in more dangerous places, or be less likely to use helmets. Alternatively, drivers may be more careful around female bicyclists. One would like assurance that the system for identifying cases of bicycle trauma is equally efficient for all groups.

3. How would this information help you formulate prevention strategies for your community? Male bicyclists in several age ranges are at highest risk. However, all age and gender groups have some risk. Discuss advantages of the strategy of focusing on groups at risk or the strategy of offering a universal approach to the entire population.

The NYSDOH is also able to provide you with graphs (see attached Figures 1–4) on overall bicyclerelated morbidity (injury) and mortality rates, as well as information specific to traumatic brain injury or death due to bicycle use for the period 1991–1996.

4. What are your hypotheses with respect to the trends in rates for death, hospitalization and traumatic brain injuries associated with bicycle use during these years?

Hospitalizations of 14+-year-olds for bicycle injuries generally and for traumatic brain injuries specifically have been nearly constant, whereas the corresponding rates for 0- to 13-year-olds have dropped considerably. This may be the result of bicycle helmet use among preadolescents or decreases in their use of bicycles for travel to school.

Effective June 1994, New York State enacted a law for persons 14 years old and younger. The regulatory agency is the New York State Department of Public Health and attaches a

fine of \$50.00 for noncompliance (the \$50.00 fine is waived if the violator provides proof of purchase of a helmet within an allotted time frame). In 2001, Onondaga County enacted legislation for persons 18 and under. The downward trend seen in hospitalizations and deaths prior to implementation of the law may be explained by publicity and passage of the law that occurred prior to the actual implementation.

The ratio of deaths to injuries has decreased in all groups, suggesting more effective medical care for trauma.

5. What are some of the limitations of the data that have been presented?

No correction is made for distance traveled on bicycles or for changes in the age distribution of the New York State population. No differentiation is made between bicyclists who were and who were not wearing helmets. Year of death or discharge is recorded rather than year of injury.

This is a good place to talk about limitations in sources of data, specifically death certificates. For example, you can ask students where this information came from and, once they identify death certificates, ask whether death certificates are reliable sources of information.

In addition a limitation is that outpatient and emergency department data are not included because of lack of systematic data collection.











Figure 3:DEATHS DUE TO BICYCLE-RELATED TRAUMATIC BRAIN INJURIES Rate per 100,000 by Age Group New York State Residents, 1991–1996





Source: New York State Department of Health

Section C: Effectiveness of Bicycle Helmet Use— An Appraisal of Scientific Evidence

In addition to demographic information provided, you need more knowledge about the effectiveness of bicycle helmets before you present your official recommendations to the local health advisory board. Review the abstract of "A Case–Control Study of the Effectiveness of Bicycle Safety Helmets," as published in the *New England Journal of Medicine* in May 1989:

A case-control study of the effectiveness of bicycle safety helmets.

Thompson RS, Rivara FP, Thompson DC.

Center for Health Studies, Group Health Cooperative of Puget Sound, Seattle, WA 98121.

Bicycling accidents cause many serious injuries and, in the United States, about 1,300 deaths per year, mainly from head injuries. Safety helmets are widely recommended for cyclists, but convincing evidence of their effectiveness is lacking. Over one year we conducted a case-control study in which the case patients were 235 persons with head injuries received while bicycling, who sought emergency care at one of five hospitals. One control group consisted of 433 persons who received emergency care at the same hospitals for bicycling injuries not involving the head. A second control group consisted of 558 members of a large health maintenance organization who had had bicycling accidents during the previous year. Seven percent of the case patients were wearing helmets at the time of their head injuries, as compared with 24 percent of the emergency room controls and 23 percent of the second control group. Of the 99 cyclists with serious brain injury only 4 percent wore helmets. In regression analyses to control for age, sex, income, education, cycling experience, and the severity of the accident, we found that riders with helmets had an 85 percent reduction in their risk of head injury (odds ratio, 0.15; 95 percent confidence interval, 0.07 to 0.29) and an 88 percent reduction in their risk of brain injury (odds ratio, 0.12; 95 percent confidence interval, 0.04 to 0.40). We conclude that bicycle safety helmets are highly effective in preventing head injury. Helmets are particularly important for children, since they suffer the majority of serious head injuries from bicycling accidents.

Questions

1. Why did the authors choose to do a case-control study to determine cost-effectiveness of helmet use? Could they have done a randomized controlled trial? A prospective cohort study? What are the major limitations of these study designs to address this issue?

A case-control study is an efficient way to study a rare event, as it requires collecting information from relatively few people and does not require the long follow-up of a prospective cohort study. One must, however, use caution in interpreting case-control studies because of the possibility that the case and control groups are not strictly comparable.

A randomized controlled trial of helmet usage would probably not be ethical, given the presumption that helmets are protective—and certainly would be far more expensive than a case–control study. It is also difficult to track participants to see if they cross over to the intervention, in this case, helmet usage. Finally, a cohort study is influenced by self-selection bias in that helmet users versus nonusers may have different characteristics influencing their risk of injury.

2. Identify biases associated with case-control studies, including selection of cases and controls.

Selection bias and information bias are the major concerns associated with case– control studies. Unless cases and controls come from essentially the same group, differences in exposures of cases and controls may result from the process of selection ("selection bias"), rather than the association with the outcome of interest. Here selection bias can occur if the individuals who sustained head injuries engaged in riskier behaviors regarding bicycle riding than did the controls. Information bias may occur when people who have an illness recall prior exposures more vividly or completely than well people do ("recall bias").

3. Comment on the comparability between cases and controls.

In this study, case-patients were bicyclists who had head injuries for which they received emergency care at one of five hospitals. One control group was people with bicycle injuries not involving the head who were treated at the same hospitals; although one cannot be confident that the accidents in which this group was involved were of the same character and severity as those of the case-patients, at least one can have some confidence that the case and control groups were somewhat similar in bicycle riding, health care access and risk taking. The other control group was health maintenance organization (HMO) enrollees who had a bicycle accident; they, too, were similar to the case-patients in being bicyclists and having an accident, but the seriousness of their accidents may have been much less than that of the case-patients (because they may not have required emergency care) and they may have lived in

different places, been different in their risk taking and lived in different circumstances (given the particular features of the HMO population).

4. What information provided by this study regarding effectiveness of bicycle helmets is generalizable?

The results may not be applicable to areas that are different from Puget Sound in terms of terrain, traffic patterns and bicycle usage. One would need to know more about the bicycle helmets used in the Puget Sound and elsewhere to know whether the results would apply in regions where different helmets may be used. Given that most of the head injuries occurred in children, it may be that the overall estimates of effectiveness of bicycle helmets do not apply reliably to older people.

Section D: Assessing Bicycle Helmet Use Locally

1. Discuss how you would develop and implement a study to determine use of bicycle helmets by age, gender and location in your county. Discuss sampling and measurement issues.

Bicycle helmet use might appropriately be defined as the probability that, given a person is riding a bicycle, she or he will be wearing a helmet. One needs to decide whether one is interested in determining prevalence using the number of people as the denominator or time on bicycles as the denominator.

If one is interested in the former (number of people), one might choose a random sample of households in the county and interview household members (by telephone or door-to-door survey) about bicycling and helmet use; this could also be done by mail. You can discuss advantages, disadvantages and feasibility of this type of study as well as what type of study design it is.

If one is interested in the latter (number of people on a bicycle at a given moment), one might select a random set of observation points in the county and send observers to those points to record bicyclists' practices at various times of the day. Again, you can discuss the advantages, disadvantages and feasibility of this type of surveillance and study design.

Both methods would ensure the collection of information from a mix of socioeconomically different neighborhoods, which would be important for assessing intervention needs.

2. What are some of the factors that would influence the effectiveness of bicycle helmets in preventing injuries and death at a population level?

Helmets must be used and used properly, particularly by those at highest risk of accidents. The helmet design must be adequate for the accidents encountered. Education activities promoting safe cycling practices (less risk taking) might paradoxically lower the observed effectiveness of helmets, by decreasing accident frequency or severity or increase it by promoting bicycle use. (Note that if the baseline rate of injury is lower, the number of cases of injury prevented by a given increase in helmet use will be lower, and the program cost per injury prevented will be higher.)

Section E: Development of Preventive Programs Utilizing a Cost-Effectiveness Approach

You now have epidemiologic information about bicycle-related injuries and deaths, and there is scientific evidence that bicycle helmets are 85% effective in reducing bicycle-related head injury. You determine that there are three feasible options for preventive programs aimed at increasing helmet use in your county. The options are as follows:

LEGISLATIVE OPTION: This option involves efforts to educate the public about the passage of a new law that requires helmet use for all individuals 18 years old or younger. It also requires enforcement of this new law.

- Target population (all residents ≤ 18 years old): 125,000
- Program costs to be considered:
 - Limited public education (publicity/media) to increase awareness of helmet law
 - Enforcement of law
- Provision of helmets: No helmets are provided under this option. Target population is expected to purchase helmets.
- **COMMUNITY OPTION:** The local health department is responsible for a comprehensive program to educate the entire community about the risks of bicycle injuries and the benefits of helmet use. The health department will also provide helmets at cost to indigent children.
 - Target population (all county residents): 450,000
 - Program costs to be considered:
 - Health education (publicity/media) about bicycle injuries and helmet use
 - Distribution of helmets at cost to all indigent children
 - Provision of helmets: County provides helmets at cost for indigent children. On the basis of the most recent census data, 20% of all children less than 18 years old are indigent $(125,000 \times 20\% = 25,000)$.
 - The health department will buy helmets for 25,000 children at \$10 per helmet.
 - The health department will sell helmets to parents/guardians of 20,000 children at \$10 per helmet (assuming that not all helmets will be sold).

- **SCHOOL OPTION:** The school board and the health department are responsible for educating school-aged children about the risks of bicycle injuries and the benefits of helmet use. The health department will also provide helmets at cost to indigent children.
 - Target population (all school-aged children): 84,000
 - Program costs to be considered:
 - Classroom education about helmet use is aimed at school-aged children. Educational efforts will also be made to parents of the target population.
 - Distribution of helmets at cost to all indigent children.
 - Provision of helmets: County provides helmets for indigent children at cost. On the basis of the most recent census data, 20% of all school-aged children less than 18 years old are indigent ($84,000 \times 20\% = 16,800$).
 - The health department will buy helmets for 16,800 children at \$10 per helmet.
 - The health department will sell helmets to the parents/guardians of 13,500 children at \$10 per helmet.

Calculating Cost-effectiveness

This section is taught with students divided into at least three groups, one for each option. The groups are given 10–15 minutes to construct their budget and to calculate the number of head injuries averted. They must budget sufficient resources to realistically accomplish the goals set out by their option, but they cannot bankrupt the county, the health department or the school district. Each option entails different budget costs associated with it.

You are asked to determine which option is the most cost effective. For each of the options, you need to use the following formula:

Cost-effectiveness = $\frac{\text{cost of option}}{\text{number of head injuries averted}}$

Both the numerator and the denominator need to be calculated. To find the total cost of each option, you will need to use your own judgment to determine how much will be spent on personnel costs and how much will be used on the education campaign. For personnel costs, depending on the option, the cost of health educators, of the staff responsible for organizing and distributing helmets, and of officers for enforcement of the law will need to be considered. Guidelines for the estimated costs are provided in the following table.

Program Component	Cost
Helmets	\$10 cost; \$25 retail
Health education staff	\$40,000/employee/year
Helmet program staff	\$30,000/employee/year
Public information campaign	
Develop one television spot	\$10,000
Pay for one television spot	\$2,000
Public service television spot	Free—\$250
Develop and pay for one radio spot	\$350
Brochures	\$2,500 for 10,000 brochures
Enforcement	\$50,000 per year

Table 2. Cost Estimates for Budget Calculation

Questions

1. What is the total cost of your option?

The following calculations make certain (somewhat arbitrary) assumptions about the content of each program—in addition to those given in the preceding table. Students will likely make different assumptions, which will naturally yield somewhat different answers:

	Legislative Option	Community Option	School Option
Target Population	125,000	450,000	84,000
Program Cost	Enforcement \$50,000 Publicity \$10,000 = \$60,000	Media \$100,000 Health education (1 full-time employee [FTE]—\$40,000)	Publicity \$25,000 Distribution (0.5 FTE – \$15,000) = \$40,000
		Distribution (1 FTE—\$30,000) = \$170,000	
Provide Helmets	None	At cost (\$10) for indigent children and adolescents	At cost (\$10) for indigent schoolchildren
		Assumption: BUY (\$10 × 25,000) SELL (\$10 × 20,000)	Assumption: BUY ($10 \times 16,800$) SELL ($10 \times 13,500$)
Total Cost (Narrow perspective)	Program only = \$60,000	Program (\$170,000) + Helmets purchased by agency but not sold (\$10 x 5,000) = \$220,000	Program (\$40,000) + Helmets purchased by agency but not sold (\$10 × 3,300) = \$73,000

2. How would you estimate the number of head injuries prevented by one of these preventive programs?

The number of injuries prevented will equal the number of injuries expected without a program times the increase in helmet use resulting from the program and times the effectiveness of helmet use in preventing head injury. The following formula can be used to determine the number of head injuries averted:

Number of head injuries averted = (change in helmet use) \times (number of bicyclists in the target population) \times (national bicycle-related head injury rate) \times (effectiveness of helmet use)

To simplify calculations, certain assumptions about helmet use must be made. Some of these assumptions may be optimistic. For this exercise, it is assumed that all people in the target population are potential bicyclists. Data from the health department indicate that baseline helmet use is approximately 20%. It is assumed that helmet use will increase to approximately 50% after each of the interventions. The national injury rate for bicycle use is 50/100,000. Finally, the efficacy rate of helmet use, based on current literature, is assumed to be 85%. Taking these assumptions into account, we should apply the following formula:

Number of head injuries averted = $0.30 \times \text{target population} \times 50/100,000 \times 0.85$

3. On the basis of information provided, how many head injuries were averted with each option?

After each group has completed its work, the whole class reconvenes. Each group presents the answers for its option. The answers should be as follows:

Legislative: 16 Community: 57 School: 11

4. What is the cost per head injury averted?

Teaching note: These figures reflect our assumptions from Section E, Question 1, and will change depending on your students' budget. Under the assumptions used in these notes, the answers would be as follows:

Legislative: \$3,750 Community: \$3,860 School: \$6,635

5. Which is the most cost-effective option?

The legislative program is the most cost-effective option, given the cost assumptions offered here (although different cost assumptions could change the ranking of options). When comparing the three different bicycle helmet programs, the legislative program was selected because it had the lowest cost per unit of health outcome (head injury averted).

Section F: Economic Evaluation

When the cost-effectiveness of a program is interpreted, the perspective from which the analysis was performed must be taken into account. In other words, was the analysis done from a broad perspective in which all costs and benefits to the population are considered, or was it done from a narrow perspective in which only costs or benefits to a certain subgroup were addressed? In general, a societal perspective is the broadest perspective. In contrast, an analysis done from the point of view of a hospital or an insurance company provides a much more narrow perspective.

Questions

1. From what perspective did you conduct your analysis in Section E? Consider the perspective of each option when answering this question. (For example, does a health department have a different point of view than does the legislature or society as a whole?) How would your results change if you were to conduct your analysis from a societal perspective?

The above calculations are from the health and police departments' perspective only and include only the impact of the intervention on their budget on the cost side: the salaries of personnel, advertising and media costs, and cost of helmets. This situation represents the narrow perspective, as described above. To consider costs from the societal or broad perspective, you need to include the price paid for helmets by individual citizens and add this to the equation of total costs incurred. The following table provides an example of the costs from a narrow and societal perspective. Considering costs from a societal perspective, one might also include not only the price paid for helmets by individual citizens but also the health care savings that would be expected from prevention of head injuries.

	Legislative Option	Community Option	School Option
Target Population	125,000	450,000	84,000
Change in # of Helmet Users*	37,500	135,000	25,200
Program Cost	Enforcement \$50,000 Publicity \$10,000 = \$60,000	Media \$100,000 Health education (1 full-time employee [FTE]—\$40,000) Distribution (1 FTE—\$30,000) = \$170,000	Publicity \$25,000 Distribution (0.5 FTE—\$15,000) = \$40,000

(Continued)

	Legislative Option	Community Option	School Option
Provide Helmets	None	At cost (\$10) for indigent children and adolescents	At cost (\$10) for indigent school children
		Assumption: BUY (\$10 × 25,000) SELL (\$10 × 20,000)	Assumption: BUY (\$10 × 16,800) SELL (\$10 × 13,500)
Total Cost (Narrow Perspective)	Program only = \$60,000	Program (\$170,000) + Helmets purchased by agency but not sold (\$10 × 5,000) = \$220,000	Program (\$40,000) + Helmets purchased by agency but not sold (\$10 × 3,300) = \$73,000
Total Cost (Societal Perspective)	Program (\$60,000) + Helmets purchased by parents (\$25 × 37,500) = \$997,500	Program (\$170,000) + Helmets purchased by agency but not sold (\$10 × 5,000) + Helmets purchased by parents (\$25 × 120,000) = \$3,420,000	Program (\$40,000) + Helmets purchased by agency but not sold (\$10 × 3,300) + Helmets purchased by parents (\$25 × 11,700) = \$500,500
Head Injuries Averted	16	57	11
Cost/Head Injury Averted (Narrow)	\$60,000/16 = \$3,750	\$220,000/57 = \$3,860	\$73,000/11 = \$6,636
Cost/Head Injury Averted (Societal)	\$997,500/16 = \$62,344	\$3,420,000/57 = \$60,000	\$500,000/11 = \$45,500

* This number is 30% of target population.

Thus far in this unit, cost-effectiveness has been used to determine the cost per head injury averted. Different techniques are available to conduct an economic analysis, one of which is cost-benefit analysis.

2. What is the difference between cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA)?

CEA attempts to define the policy that will most efficiently achieve a certain goal; it does so by calculating the cost of each unit of improved outcome, under the various policy options. CBA attempts to determine whether a policy would more than pay for itself; it does so by weighing the dollars spent on the intervention against the dollars saved by the success of the intervention. CEA includes both costs and outcomes. The costs are expressed in monetary terms, and effectiveness is expressed in units of one health outcome, such as head injury averted, head injury hospitalizations averted or head trauma deaths averted. Cost per unit of health outcome is the summary measure used in CEA. CEA is used to compare programs having a common goal and then to decide which program to fund.

CBA expresses all costs and benefits in monetary terms. Benefits must include an improvement in patient outcome with a monetary value placed on it. The computational and conceptual difficulties include deciding the value of a head injury or death averted. The summary measures are

Benefit—cost ratio = benefits in monetary terms divided by cost of terms Net benefits = benefits minus costs.

This provides a decision rule. Benefits exceed costs when the benefit-cost ratio is >1 and has a positive net benefit. This type of analysis can be used to compare several different outcome measures (such as mild, moderate, severe and fatal head injuries.) Medical malpractice lawsuits may employ similar methods.

3. What are the strengths and weaknesses of each analysis?

CEA directly measures the cost of alternative ways to achieve certain measurable outcomes and avoids the artificiality of converting all benefits into financial terms. A limitation of CEA is that it does not take into account the actual dollar amount of cost savings when a health outcome, such as a nonfatal head injury, is averted.

CBA requires benefits to be measured in financial terms, which creates complications. For example, how does one place value on a human life? In addition, how can one adjust for changes in that value over time? Discounting is a technique that reduces the value of future benefits to current values. If costs occur in the future, they also need to be discounted. Based on the concept of time preference, \$1.00 today is worth more than \$1.00 next year. Converting all inputs and effects into a common currency, however, allows for explicit comparisons of costs and benefits.

Both CBA and CEA are particular to local conditions, as costs will vary across time and space, even if the effectiveness of interventions does not.

4. What questions are best answered by each method?

CEA is good for choosing the most efficient—best—way to achieve an identified goal when resources are limited.

CBA is good for identifying initiatives that pay for themselves (when benefits outweigh costs).

Finally, because an economic analysis is based on certain sets of assumptions about variables, it should include a sensitivity analysis in which the assumptions are challenged to see how much they affect the outcome of the analysis. Examples of variables for which sensitivity analysis is helpful include success rate of the intervention, valuation of costs of the intervention or valuation of the benefits. An example of sensitivity analysis is available in the following recommended reading: Gaspoz JM, Coxson PG, Williams LW, Kuntz KM, Hunink MM, Goldman L. Cost effectiveness of aspirin, clopidogrel, or both for the secondary prevention of coronary heart disease. *New England Journal of Medicine*. 2002:346(23):1800–1806.

5. In your analysis of the cost-effectiveness of bicycle helmets, what were the most important variables?

The most important variables were the size of the target population, the change in the prevalence of helmet use achieved by the intervention, the effectiveness of helmets, the base injury rate, the program costs such as the cost of helmets (both for the health department and for citizens) and staff salaries.

6. How would changes in these variables affect the outcome of the analysis?

Conducting a sensitivity analysis involves changing the assumptions (see above variables). Results of economic evaluations are dependent on assumptions used to estimate both costs and benefits. Changes in the valuation of cost and benefits and changes in the choice of outcome measured both affect the result. In this example, you can change the cost of helmets (\$18.00 versus \$40.00), of personnel, and of brochures and advertising to see how that variable affects the cost-effectiveness analysis.

7. Taking perspective, type of economic analysis and sensitivity analysis into account, which preventive approach do you now think is the most cost-effective means to decrease death and injury due to bicycle-related accidents in your county?

The school approach, using a societal perspective, is the most cost-effective means of prevention.

Assessment (Student Version)

The use of smoke detectors in homes is widely recommended as an important way to prevent injuries from fires. Describe how one might assess the cost-effectiveness of a policy to require smoke detectors in homes.

Assessment (Teacher's Annotated Version)

The use of smoke detectors in homes is widely recommended as an important way to prevent injuries from fires. Describe how one might assess the cost-effectiveness of a policy to require smoke detectors in homes.

To assess the cost-effectiveness of smoke detectors, one would need information on the costs of such a program, including (depending on perspective the analysis takes) the costs of the smoke detectors, replacement batteries, time required to install and maintain smoke detectors, educational campaigns to publicize the requirement and enforcement of the requirement, less the revenue that might be generated from fines for violation of the requirement. To assess effectiveness, one would need information on the increase in the prevalence of smoke detectors caused by the adoption of the requirement for smoke detectors in homes and the decrease in incidence and severity of injury resulting from the use of smoke detectors. The assessment of the effect of smoke detectors on injury incidence is complicated by other factors (like poverty and the age of the house) that may confound the association of smoke detector use and home fire injury. For example, see the article that can be accessed by registering at: http://content.nejm.org/cgi/content/abstract/344/25/1911.