SEMESTER AT SEA COURSE SYLLABUS

Voyage: Spring 2013
Discipline: Public Health
Course Title: SEMS 2500-104 Fundamentals of Epidemiology
Lower Division
Faculty Name: Mary Ropka Ph.D., RN, FAAN Professor of Public Health Sciences

Class Meeting Time: A Day 0800 - 0915

Pre-requisites: None. Of note -- a background in statistics is not required, but doing the work of the course frequently involves doing arithmetic calculations with a calculator.

[NOTES
The course objectives are adopted from "Recommendations for Undergraduate Public Health Education", form the Association of American Colleges & Universities and Association for Prevention Teaching and Research. http://www.ccas.net/files/public/Publications/Undergrad_Public_Health_Recommendations.pdf (Accessed 10/09/12)

The required textbook is designed to fulfill the four essential learning outcomes of Liberal Education and America's Promise (LEAP) – a campaign of the Association of American Colleges and Universities**. It follows the basic curriculum framework recommended by the 2006 Consensus Conference on Undergraduate Public Health Education** that **recommended all undergraduates have access to a curriculum such as this as part of their general education.** It is part of the Essential Public Health book series.]

COURSE DESCRIPTION

This course provides a general introduction to epidemiology methods and topics related to health care and public health. The course focuses on the distribution and determinants of health-related states or conditions in specified populations at local through global levels, and on the application of epidemiology to control health problems. The course covers the methods of epidemiologic research and introduces epidemiologic research for key topics of health and disease in the U.S. and globally. Specific attention will be paid to health problems in the areas being visiting by SAS. The course will equip the student to read and understand basic health and medical literature that uses epidemiologic methods. Epidemiology embodies many useful critical thinking skills, which are the hallmark of the scientific method and embody modes of thinking that benefit well-educated citizens even if they do not intend to become public health professionals.

COURSE OBJECTIVES

On successful completion of this course, the student should be able to:

1. Describe the *history, philosophy, and uses of epidemiology*, including its contribution to the evolution of the scientific method. (Chapter 1)
2. Explain how *ethical principles* affect epidemiologic research. (Chapter 1)
3. Identify *sources of epidemiologic data* and explain related *measures of morbidity and mortality*. (Chapters 2 and 3)
4. Define *descriptive epidemiology* and describe the application of descriptive epidemiology to the health of populations. (Chapter 4)
5. Explain how to use evidence of an *association* to make a judgment about whether an association is causal. (Chapter 5)
6. Define *analytic epidemiology* and differentiate among the types of analytic research designs. (Chapter 6)
7. Explain *evidence-based public health* and discuss its applications, including to public policy in the U.S. and selected areas visited by SAS. (Chapter 7)
8. Describe the concepts of measurement of *test performance* and be able to apply the concepts of testing and screening in different settings. (Chapter 7)
9. Apply epidemiology to *infectious diseases* and *outbreak investigations*. (Chapter 8)

10. Describe applications of epidemiology *to social and behavioral phenomena*, such as tobacco use, alcohol consumption, and obesity, and *special topics*, such as unintentional injury. (Chapters 9 &10)
11. For *each course topic*: In a few sentences, identify for the class *major issues relevant to that topic in the SAS Voyage Country you have "adopted"* for the course (USA, Japan, China, Vietnam, Singapore, Myanmar, India, Mauritius, South Africa, Ghana, Morocco, Spain).

REQUIRED TEXTBOOKS

AUTHOR: Robert H Friis
TITLE: Epidemiology 101
PUBLISHER: Jones and Bartlett Learning
ISBN #: 978-0-7637-5443-3
DATE/EDITION: 2010/1st

TOPICAL OUTLINE OF COURSE

[Between Ensenada &Hilo]
Day 1:

- Introduction to course and course requirements/evaluation
- Review of course textbook and accessing other resources (including YES website resources)
- Introduction to course-related Field Lab
- Discussion after viewing YES video: "Is Epidemiology in Your Future?" Young Epidemiology Scholars (YES) Program, Robert Wood Johnson Foundation http://www.rwjf.org/pr/product.jsp?id=26931&cid=xsh_rwjf_em

Reading Assignment:

- Fraser, DW. (1987). Epidemiology as a liberal art. NEJM, 316(6), 309-314.
- Review http://www.aacu.org/public_health/index.cfm The Educated Citizen and Public Health webpage from the Association of American Colleges and Universities (Accessed 10/09/12)
- Review http://www.un.org/millenniumgoals/ United Nations Millennium Development Goals **to get a global perspective** (Accessed 10/09/12)
- Review http://www.who.int/en/ World Health Organization **to get a global perspective** (Accessed 10/09/12)

Assignment Due Today:
None

Day 2:

- History, Philosophy, and Uses of Epidemiology (Chapter 1)
- View Ted Talk, "Steven Johnson Tours the Ghost Map" and **discuss in class** http://www.ted.com/talks/lang/en/steven_johnson_tours_the_ghost_map.html (Accessed 10/09/12)
- Ethics and Philosophy of Epidemiology

Reading Assignment:

- Friis – Chapter 1
- Resnik, DB. What is Ethics in Research & Why Is It Important? NIEHS/NIH Website. Accessed April 16, 2012. http://www.niehs.nih.gov/research/resources/bioethics/whatis/ (Accessed 10/09/12)

Assignment Due Today:
Answer Study Questions at end of chapter and **bring to class prepared to discuss**. **Submit answers in writing** prior to start of class.

[Between Hilo &Yokohama/Kobe]

Day 3:

- Epidemiologic Measurements Used to Describe Disease Occurrence (Chapter 2)

Reading Assignment:
Friis – Chapter 2

Assignment Due Today:
Answer Study Questions at end of chapter and **bring to class prepared to discuss**. **Submit answers in writing** prior to start of class.

Day 4:

- **Quiz #1: Chapters 1 & 2**
- Data and Additional measures of Disease Occurrence (Chapter 3)

Reading Assignment:
Friis – Chapter 3

Assignment Due Today:
Study for Quiz #1
Answer Study Questions at end of chapter and **bring to class prepared to discuss**. **Submit answers in writing** prior to start of class.

Day 5:

- Descriptive Epidemiology: Patterns of Disease Occurrence – Person, Place, Time (Chapter 4)
- View Ted Talk, "Hans Rosling Show the Best Stats You've Ever Seen" and **discuss in class** http://www.ted.com/talks/hans_rosling_shows_the_best_stats_you_ve_ever_seen.html (Accessed 10/09/12)

Reading Assignment:
Friis – Chapter 4

Assignment Due Today:
Answer Study Questions at end of chapter and **bring to class prepared to discuss**. **Submit answers in writing** prior to start of class.

Day 6:

- **Quiz #2: Chapters 3 & 4**
- Association and Causality (Chapter 5)

Reading Assignment:
Friis – Chapter 5

Assignment Due Today:
Study for Quiz #2
Answer Study Questions at end of chapter and **bring to class prepared to discuss**. **Submit answers in writing** prior to start of class.

[Between Yokohama/Kobe & Shanghais/Hong Kong]

Day 7:

- Analytic Epidemiology: Types of Study Designs – **Part 1** (Chapter 6)

Reading Assignment:
Friis – Chapter 6

Assignment Due Today:
None

[Between Shanghai/Hong Kong & HCMC]
Day 8:
- Analytic Epidemiology: Types of Study Designs – **Part 2** (Chapter 6)

Reading Assignment:
Friis –Chapter 6

Assignment Due Today:
Answer Study Questions at end of chapter and **bring to class prepared to discuss**. **Submit answers in writing** prior to start of class.

Day 9: [A9 before HCMH; B9 after HCMC]
- **Quiz #3: Chapters 5 & 6**
- Catch-up

Reading Assignment:
None

Assignment Due Today:
Study for Quiz #3

[Between HCMC & Singapore/Rangoon]
Day 10: [A10 before Singapore; B10 after Singapore]
- Epidemiology and the Policy Arena (Chapter 7)

Reading Assignment:
Friis – Chapter 7

Assignment Due Today:
Answer Study Questions at end of chapter and **bring to class prepared to discuss**. **Submit answers in writing** prior to start of class.

Day 11:
- Infectious Disease and Outbreak Investigations – **Part 1** (Chapter 8)

Reading Assignment:
- Friis – Chapter 8
- Review http://www.aseanplus3-eid.info/index.php Information Centre on Emerging Infectious Diseases in the ASEAN Plus Three Countries (Accessed 10/09/12)

Assignment Due Today:
None

[Between Rangoon & Cochin]

Day 12:

- Infectious Disease and Outbreak Investigations – **Part 2** (Chapter 8)

Reading Assignment:
Friis -- Chapter 8

Assignment Due Today:
Answer Study Questions at end of chapter and **bring to class prepared to discuss**. **Submit answers in writing** prior to start of class.

Day 13: [A13 before Cochin; B13 after Cochin]

- Work through "Outbreak at WaterEdge" CD (individually or in pairs/groups TBD based on # students enrolled) [20 CDs received from Univ of Minnesota School of Public Health]

Reading Assignment:
Review Fries Chapter 8 again

Assignment Due Today:
Turn in first class participation form

[Between Cochin & Port Louis]

Day 14:

- **Quiz #4: Chapters 7 & 8**
- Social and Behavioral Epidemiology (Chapter 9)

Reading Assignment:
Friis – Chapter 9

Assignment Due Today:
Study for Quiz #4
Answer Study Questions at end of chapter and **bring to class prepared to discuss**. **Submit answers in writing** prior to start of class.

Day 15:

- Evaluation of Diagnostic and Screening Tests; Population Screening
- **Part 1: Initial Class** Should the Population Be Screened for HIV? -- Young Epidemiology Scholars (YES) Program MODULE

Reading Assignment:

- Gordis, L. (2009). Chapter 5 Assessing the validity and reliability of diagnostic and screening tests. In L. Gordis, Epidemiology (4th ed). Saunders Elsevier.
- Review the entire Module Information.

Assignment Due Today:
None

[Between Port Louis & Cape Town]

Day 16:

- **Part 2: Group Work on Case Studies** Should the Population Be Screened for HIV? -- Young

Epidemiology Scholars (YES) Program MODULE

Reading Assignment:
None

Assignment Due Today:
None

Day 17:

- **Part 3: Group Report** on their case studies and what they have learned about the issues related to screening

Reading Assignment:
None

Assignment Due Today:
Group Report on your case studies and what you have learned about the issues related to screening

Day 18: [A18 before Cape Town; B18 after Cape Town]

- **Part 1: Initial Class Discussion** Testing Ephedra: Using Epidemiologic Studies to Teach the Scientific Method -- Young Epidemiology Scholars (YES) Program MODULE

Reading Assignment:

- Review Friis – Chapter 6
- Review the entire Module Information.

Assignment Due Today:
Review Module Information -- **Part 1: Initial Class Discussion** and come to class prepared to discuss.

[Between Cape Town & Tema]
Day 19:

- **Part 2: Individual Presentation** Testing Ephedra: Using Epidemiologic Studies to Teach the Scientific Method -- Young Epidemiology Scholars (YES) Program MODULE

Reading Assignment:
Review Module Information -- **Part 2: Individual Presentations** in Module Information document.

Assignment Due Today:
PART 2 INDIVUDAL PRESENTATIONS – 5 MINUTES maximum EACH

- Prepare written answers to **Part 2: Questions 1-6** in Testing the Effectiveness of Ephedra: How Do We Know It Works? (Student Version). You will turn this in.
- Come to class prepared to give a very brief (no more than 5 minutes) presentation of your answers.

Day 20:

- **Part 3: Wrap-up Discussion and Questions** Testing Ephedra: Using Epidemiologic Studies to Teach the Scientific Method -- Young Epidemiology Scholars (YES) Program MODULE

Reading Assignment:
Review Module Information – **Part 3: Wrap-up Discussion Questions**

Assignment Due Today:

Come to class prepared to discuss **PART 3 WRAP-UP DISCUSSION QUESTIONS.**

Between Tema & Casablanca]

Day 21:

- **Part 1: Introduce Module and Organize Groups for Debate**: Epidemiology and Public Health Policy: Using the Smoking Ban in New York City Bars As a Case Study -- Young Epidemiology Scholars (YES) Program MODULE

Reading Assignment:

- Review the entire Module Information.

Assignment Due Today:

- Review the documents below before class. **Note especially: Points to Consider When Looking at Documents in the Module Information – Factors Influencing the Policy and Effects of This Policy.**

New York City Smoke-Free Air Act of 2002 brochure. March 2003. [pdf]

City of New York Letter to Business Owners and Employers about the Smoke-Free Air Act of 2002. March 25, 2003. [pdf]

City of New York Department of Health and Mental Hygiene Press release. Employment Up in City Bars and Restaurants since Implementation of the Smoke-Free Air Act. July 23, 2003. http://www.nyc.gov/html/doh/html/press_archive03/pr081-0723.shtml (Accessed 10/09/12)

New York City Department of Health and Mental Hygiene. Fact Sheet 4: Smoke-Free Workplace Laws Don't Hurt Businesses. [pdf]

Centers for Disease Control (CDC). Secondhand Smoke Facts http://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/general_facts/index.htm (Accessed 10/09/12)

Day 22:

- **Part 2: Group Working Sessions to Prepare for Debate:** Epidemiology and Public Health Policy: Using the Smoking Ban in New York City Bars As a Case Study -- Young Epidemiology Scholars (YES) Program MODULE**.**

Reading Assignment:

Review the entire Module Information. **Note especially Steps of the debate format**.

Assignment Due Today:

None

[Between Casablanca & Barcelona]

Day 23: [A23 before Casablanca; B23 after Casablanca]

- **Part 3: Debate:** Epidemiology and Public Health Policy: Using the Smoking Ban in New York City Bars As a Case Study -- Young Epidemiology Scholars (YES) Program MODULE
- Summary and Wrap-up

Reading Assignment:

None

Assignment Due Today:
DEBATE: Epidemiology and Public Health Policy: Using the Smoking Ban in New York City Bars As a Case Study -- Young Epidemiology Scholars (YES) Program MODULE. **Note especially Steps of the debate format.**
Turn in second/last class participation form

FIELD WORK

FIELD LAB (*At least 20 percent of the contact hours for each course, to be led by the instructor.*)

***Participation is mandatory.**
***20% of your course grade is based on the field assignments drawn from the lab and other in-port experiences.**

Field Lab:
- Title: Emerging Infectious Diseases in the Asia Pacific
- Port – Singapore
- Date – Thursday 2/21/12 (Day 2 in Port)
- Destination(s) – Forthcoming
- Number of Projected Participants (maximum class size is 35) – Depends on course enrollment
- Duration (hours) of lab – 8 hours max
- Attendance is mandatory

Academic Objectives:
1. Describe the broad applicability of epidemiologic methods to understanding emerging infectious diseases.
2. Apply epidemiology to the identification of emerging infectious diseases and outbreak investigations.
3. Identify behavioral and social phenomena in a real world setting and explain their relevance to epidemiology of emerging infectious diseases.

Field Lab Description:

Forthcoming

METHODS OF EVALUATION / GRADING RUBRIC

TEACHING METHODS:
The course will be delivered primarily in a lecture/discussion format with application-related experiences and small group work. Students will also work in small groups to complete selected assignments or projects. Class attendance and participation is expected.
Readiness concept: The responsibility to learn is fundamentally that of the student. In order to succeed in learning, students must actively engage in the process. For this reason, you are expected to come to class prepared. Being prepared means that you will read the assignments, give the assignments thoughtful consideration, and you will be able to advocate for your point of view.

COURSE REQUIREMENTS AND EVALUATION:

1. Readings done prior to class and written answers to questions at end of Friis chapters submitted prior to the start of class. **[5%]**
2. Class Attendance and Participation **[10 %]**
3. Should the Population Be Screened for HIV? -- Young Epidemiology Scholars (YES) Program MODULE **[15%]**
4. Epidemiology and Public Health Policy: Using the Smoking Ban in New York City Bars As a Case Study -- Young Epidemiology Scholars (YES) Program MODULE Debate **[15%]**

5. Testing Ephedra: Using Epidemiologic Studies to Teach the Scientific Method -- Young Epidemiology Scholars (YES) Program MODULE [**15%]**
6. Quizzes (4) [**20% -- 5% each]**
7. Field Lab [**20%]**

GRADING SCALE for COURSE

A+= 97-100	**B+ =**87-89	**C+=** (77-79)	**F** = below 70 failing
A= 94-96	**B=** 84-86	**C**=74-76	
A- = 90-93	**B-** =80-83	**C- =**70-73	

LATE WORK POLICY:

If you are unable to meet one or more of the deadlines in this course, please contact me to negotiate a different due date. I usually grant reasonable requests made ***well before*** the due date (48 hours or more). Unless an extension is granted, I will not accept late work.

FUNDAMENTALS OF EPIDEMIOLOGY: CRITERIA FOR EVALUATING CLASS PARTICIPATION

10% of Grade

Student:_____ Date:

This self-evaluation will be used to assess your overall class participation at **mid-term**, and at the **end of the course**. Any additional information that you would like me to consider in determining your grade should be included in the Comment section below.

Directions: Rate each item: Always (5) -- Rarely (1) by recording number in the right hand column.

1. Attends class and responds to study questions and class discussion.	
2. Prepares for class – Reading and preparation assignments done prior to class..	
3. Actively and thoughtfully contributes to discussions -- Substantively responds to classmates' comments.	
4. Utilizes active listening skills to foster discussion.	
5. Incorporates content from readings into class discussions.	
6. Respects the contributions and opinions of others.	
7. Raises appropriate issues and questions to facilitate discussion.	
Comments:	

Should the Population Be Screened for HIV? -- Young Epidemiology Scholars (YES) Program MODULE Information

15% of Grade

OBJECTIVES:
At the end of this module, the students will be able to:

- Define screening in the context of public health.
- List and explain the criteria used to determine whether a screening program would be helpful for given health events.
- Recognize the many concerns and competing interests that must be addressed when considering the implementation of new screening programs or the continuation of existing ones.

MATERIALS NEEDED:
• **For Case Study 2**: Bureau of Citizenship and Immigration Services. U.S. Department of Justice Web site. HIV Infections: Inadmissibility and Waiver Policies Fact Sheet resource page. July 10, 1998. Available at: http://uscis.gov/graphics/publicaffairs/factsheets/hivfs.htm
. Accessed December 17, 2003.

• **For Case Study 3**: UNAIDS Epidemic Update Available at: http://www.unaids.org/en/. **Click on TAB Data & analysis. Look over what you find there**. (Accessed 10/09/12)

PROCEDURE:
This module provides activities that teach about the criteria for population screening for disease, using the human immunodeficiency virus (HIV) as an example.

Part 1: Initial Class will review the introductory material and use it as the background for a lecture on evolution of diagnostic tests; population screening.

Part 2: Group Case Studies Students divide into four groups and work on a **case study**.

Part 3: Group Report on their case studies and what they have learned about the issues related to screening.

Epidemiology and Public Health Policy: Using the Smoking Ban in New York City Bars as a Case Study -- Young Epidemiology Scholars (YES) Program MODULE Information

15% of Grade

OBJECTIVES:

- Help students understand how public health policy is developed.
- Help students understand that public health policy should be based on valid statistics and sound scientific research; however, political, economic, social, and cultural factors also play an important role in shaping these policies.
- Teach students to analyze a policy to determine if it is actually effective in improving and promoting the health of the population.
- Help students develop skills to learn how to argue for or against a policy.

FORMAT:

This module is **set up** as a debate, with students divided between those *for the issue* and *those against it*. The **goal** of the debate format is to have students learn from each other and see another person's perspective, while still helping them to analyze an issue with a more objective view.

Students will be divided into equal Groups depending on the class size. Each Group will be divided into two Teams, for which one will be assigned to be in favor of the policy and one not in favor.

****Students should consider the following points <u>when they are looking at documents they are assigned to read</u>.**
****They should also address all of these key points <u>when debating the issue in class</u>.**

<u>Factors Influencing the Policy</u>

- Potential dangers of environmental tobacco smoke (ETS):
    - Dangers to both patrons and employees
    - Mayor pushed it as a policy to support the health and well-being of employees.
- Is ETS truly a serious environmental hazard?
- How will businesses be affected by the policy?
- Will bar employees make less money in tips? Possibly lose their jobs?
- Is it enforceable?
- Personal choice and civil liberties
- Does this policy seem feasible with regard to the character of people in the region?
    - Does it make sense to compare New York with California, which supporters of the policy often use as an example of a place where it has worked?
- Unintended effects:
    - Encourages smokers to quit
    - Improved quality of life in bars
    May result in increased smoke and noise on the sidewalks
    - Reduced societal and health care costs

<u>Effects of This Policy</u>

- Decreased exposure to ETS
- Economic effects:
    - Many argue that the policy will hurt the bar and restaurant industry, but others argue that the policy may encourage those patrons who would normally not go to bars and restaurants because of the smoke to frequent these places more.
- May continue to change the social norm of making public smoking unacceptable
- Decreased costs to society and health care

• Difficulties of enforcing a policy such as this

****Steps of the debate format will be as follows:**

1. The students on each Team are given 5 to 10 minutes to argue their points for or against the policy. When one Team speaks, the other is not allowed to interrupt. They are only allowed to take down notes, which they can use for the next step.
2. Students on each Team are now given 5 to 10 minutes to respond to the arguments made by the opposing Team. Once again, when one team speaks, they are not allowed to interrupt.
3. Students on both Teams are given time to find some valid points made by the opposing Team. The purpose of this step is to find some common ground between the two opposing Teams. This will help the group in the next and final step.
4. Students of both Teams must work to find consensus and develop a public smoking policy that both Teams can live with.

Testing Ephedra: Using Epidemiologic Studies to Teach the Scientific Method -- Young Epidemiology Scholars (YES) Program MODULE Information

15% of Grade

The **goal of this module** is to familiarize students with the design of epidemiologic studies, particularly the randomized clinical trial that is often used in experimental epidemiology.

OBJECTIVES:

- Familiarize students with some examples of epidemiologic studies, mainly the randomized clinical trial (RCT) and, to a lesser extent, the cohort study.
- Use epidemiologic study to help students develop a strong understanding of the scientific method and how scientific experiments are conducted.
- Help students understand why it is important to test the safety and effectiveness of over-the-counter (OTC) and prescription medications.
- Help students understand that dietary supplements and herbal remedies are not heavily regulated and required to be tested for safety and effectiveness.

PART 1: INITIAL CLASS DISCUSSION

- **Review the two sample advertisements for ephedra products just below.**

Sample Advertisements for Ephedra-Containing Products

#1 Nature's SUPER CAP

850 mg Ephedra Extract

Because of Super Cap's high yield of ephedrine, it has many of the benefits of a bronchodilator, opening the airway and dramatically enhancing breathing performance. It is also a preferred product among serious bodybuilders looking to achieve greater endurance and greater strength levels.

8% Ephedra Alkaloids per Capsule, delivering 68 mg of naturally occurring Ephedrine

Supplement Facts

Serving size: One capsule

Amount per serving: *Ephedra sinica* extract (aerial parts)—883 mg
* Daily value not established

Other Ingredients: Calcium sulfate, gelatin, maltodextrin, magnesium stearate, and silica

Directions (adults only): Take one capsule daily as a dietary supplement. **Not for use by minors.**

Warning: Ephedra contains naturally occurring ephedrine. If you are pregnant or nursing, or if you have heart disease, thyroid disease, diabetes, high blood pressure, depression or other psychiatric conditions, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, consult a health care provider before using this product. Do not use if you are using monoamine oxidase inhibitors (MAOI) or for two weeks after stopping an MAOI drug; certain drugs for depression, psychiatric or emotional conditions; drugs for Parkinson's disease; methyldopa; or any product containing ephedrine, pseudoephedrine, or phenylpropanolamine (ingredients found in allergy, asthma, cough/cold, and weight control products). Stop use and call a health care professional

immediately if dizziness, severe headache, rapid and/or irregular heartbeat, chest pain, shortness of breath, nausea, tremor, loss of appetite, sleeplessness, noticeable change of behavior or loss of consciousness occurs. Do not exceed recommended serving.

Manufactured under authority of D&E Pharmaceuticals, Inc.

Source: From the D&E Pharmaceuticals, Inc. Web site. Available at: http://d-n-e.com/epsucap85.html
*From the bottle label of the product Ephedra: Nature's Super Caps (24 capsules).

#2Ultimate Energizer, High Potency Ephedra and Caffeine (*Young Again 2002 Web site*)

The Ultimate Energizer has 100 capsules with 257 mg of ephedra and 100 mg of caffeine and a proprietary blend of fat melting herbs. It packs a wallop, and it is not for everyone! Read our cautions and full description. This fat burning supplement is 3 times more potent than Metabolife.

Please note the following cautions about the ULTIMATE ENERGIZER and other products that contain ephedra:

Ephedra, also known as ma huang, is a common ingredient in herbal weight-loss products. It has been shown to be generally safe and effective. It is also used to treat depression, asthma, colds, and other respiratory complaints. Ephedra should not be used by people with anxiety disorders such as panic attacks, or by those with glaucoma, heart disease or high blood pressure. Avoid this herb if you are taking medication for depression. Since it stimulates the central nervous system, avoid caffeine, St. John's Wort, and over-the-counter decongestant medications while taking ephedra.

Source: From the Young Again 2000 Web site, Available at: http://www.youngagain2000.com/marcella75/ulen50100cap.html 2002 Version*

- **Discuss the following questions in class to consider how we can test to see if these products that contain ephedra work.**

1. In setting up an experiment, what principles and guidelines should we follow?
2. Every experiment requires a hypothesis. How would we formulate the hypothesis?
3. What would the experimental variable be in this experiment?
4. What would the independent and dependent variables be?
5. When we select people to be placed in an experimental group, why is it important to select another group of people and place them into a comparison group?
6. Why is it important that members of both the experimental and the comparison groups have certain similar characteristics?
7. What would be some examples of similar characteristics that both groups must have in this experiment?
8. Members of the comparison group would have to take a placebo, whereas members of the experimental group would take the actual drug. However, all participants would not know whether they are in the experimental group or comparison group. This procedure is called blinding or masking. Why must the process of masking occur in an experiment?
9. All participants would be randomly placed in either the experimental group or the comparison group. This procedure is called randomization. How does this procedure keep the experiment valid? Is this internal validty or external validity?
10. How would we collect the data?
11. How can we measure the outcome of our experiment?
12. How would we determine if the data we collect support our hypothesis?

HINT: This experiment that you have just designed is called a randomized controlled trial. It is an experiment that must be conducted by pharmaceutical companies to get approval from the FDA to market a drug.

Important experiments such as these have to follow all the principles of the scientific method, and many of the basic concepts that are part of the scientific method, such as hypothesis testing and experimental variable, must be applied in all experiments and studies.

PART 2 INDIVIDUAL PRESENTATIONS – 5 MINUTES EACH
Testing the Effectiveness of Ephedra: How Do We Know It Works? (Student Version)

Ephedra is one of the many herbal supplements that claimed to help people burn fat, build muscle and increase endurance. As a result, many athletes took it, in the hope it would give them a cutting edge against their competitors. The question is "are these claims really true?" If they are, by how much? If they are not, why are these manufacturers allowed to make these claims?

First, look again at the advertisements that are included. Both were taken from the Internet.

Next, in this activity you will have the opportunity to design your own experimental study to try to determine if these claims are true. You are a research scientist, and you are being paid by an independent consumer rights advocate group to see if this product really does what it claims to do. This type of experiment is called a randomized controlled trial (RCT), commonly known as a "clinical trial". These types of experiments must be done by drug manufacturers in order to get approval from the Food and Drug Administration (FDA). Manufacturers must prove that their product is both safe and effective (effective means that the product does what it claims to do). However, supplements have a loophole to evade these requirements because they are regulated more like a food product than a drug.

1. In every experiment, a scientist must have a hypothesis and a method of testing the hypothesis. To test a hypothesis, a scientist must understand what the experimental variable is. Write a hypothesis and **briefly** describe how to test this hypothesis. In this explanation indicate what your experimental variable is.

2. When testing the experimental variable, a researcher must understand the possible association of one factor with another—in this case the effect of taking ephedra and its effect on the body's metabolism, body weight and available energy. These associations that may be found are labeled as the independent and dependent variables. What is the independent variable in this experiment? What are the dependent variables? Explain the relationship between the independent and dependent variables.

3. Clinical trials are experiments that involve human test subjects. Because of this there are ethical issues that must be dealt with. What are the ethical issues that a researcher must face when conducting an experiment such as this? How can these issues be resolved?

4. Every experiment requires a comparison (control) group and an experimental group, which receives the intervention. What characteristic distinguishes members of the comparison group from those of the control group? What similar characteristics should both the control group and the experimental group members have? Why is it important for the groups to have similar characteristics? What are some characteristics of participants who should be excluded from this study? (Hint: Read the labels of the product.)

5. In a clinical trial, participants are randomly assigned to either the experimental or the comparison group. Another requirement is that the participants do not know which group they are placed in, so the participants do not know what they are taking. This procedure is called **blinding**. In addition to the subjects of the experiment now knowing which group they are in, the researchers may not know who is in each group. This is known as **double blinding**. Why is it important to use double blinding and randomization, when feasible?

6. How would you measure the outcome of you experiment? (Hint: Refer back to Question 2, which asked you about the dependent and independent variable.) How would you determine whether your hypothesis was confirmed? How does research such as this help the public learn more about the products they buy and use?

PART 3 WRAP-UP DISCUSSION QUESTIONS

1. Read the advertisements carefully once again and think of other products that are taken by athletes. Although many herbal remedies and nutritional supplements have been scientifically found to be safe and effective, many products do not have scientific proof that they work and are safe. Why do you think some of these herbal remedies and nutritional supplements seem to get away with making such claims? What do you think should be done to protect consumers from ineffective and unsafe products?

2. Why are issues such as correct dosage of the medication important? Why is it important to have a large number of subjects in both the experimental and the comparison groups?

3. In addition to testing the effectiveness of the product, what else must be tested? (Read the labels again for a hint.) Remember that you are testing this for a consumer rights advocate group. Give a brief summary of how you would test this other factor.

4. When you read an article or watch the news about a new health study confirming how some types of food or nutritional supplement can be beneficial or perhaps detrimental to one's health, what are some questions you should ask yourself about how the study was conducted?

5. Bias can be defined as "any systematic error in the design, conduct or analysis of a study that results in a mistaken estimate of an exposure's effect" on a particular health outcome. (1) Bias can be classified as either selection or information bias. Selection bias occurs when an error is made in the method of selecting test subjects or when errors are made in placing test subjects into either the experimental or the comparison group. *How do randomized controlled clinical trials decrease the potential for selection bias? Are there still possibilities of selection bias occurring in a randomized controlled trial? If so or if not, explain.*

6. **Information bias** occurs when information obtained from the subjects is considered inadequate in some way. This results in incorrect information about exposure or the health outcome being studied, which may lead to misinterpretation of the data collected. A manufacturer, for example, may over report beneficial health outcomes in the intervention group and underreport the same beneficial health outcomes in the comparison group, which may help the manufacturer get approval to market its product. *How do randomized controlled trials limit the occurrence of some potential sources of information bias? How does the practice of blinding and double blinding help decrease the possibilities of information bias in a study? Do these practices eliminate all possibilities of information bias? Explain.*

Reference

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PAGES: 1 - 17

ADDITIONAL RESOURCES
Students will need a calculator to do arithmetic calculations.

HONOR CODE

Semester at Sea students enroll in an academic program administered by the University of Virginia, and thus bind themselves to the University's honor code. The code prohibits all acts of lying, cheating, and stealing. Please consult the Voyager's Handbook for further explanation of what constitutes an honor offense.

Each written assignment for this course must be pledged by the student as follows: "On my honor as a student, I pledge that I have neither given nor received aid on this assignment." The pledge must be signed, or, in the case of an electronic file, signed "[signed]."

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