

BOSTON UNIVERSITY

SCHOOL OF PUBLIC HEALTH

Syllabus

EP711 Section B1
Professor LaMorte

Introduction to Epidemiology



Instructor:

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Location and Time of Course: ??

Course Objectives:

Epidemiology is a methodology that enables public health professionals to identify the determinants of health, disease and injury in human populations and provides a means of assessing the magnitude of public health problems and the success of interventions designed to control them. Epidemiology is universally regarded as a discipline that is essential for understanding and solving public health problems, regardless of one's area of concentration or specialization. The Council on Education for Public Health (CEPH) states that, "A professional degree is one that, based on its learning objectives and types of positions its graduates pursue, prepares students with a broad mastery of the subject matter and methods necessary in a field of practice; it typically requires students to develop the capacity to organize, analyze, interpret and communicate knowledge in an applied manner." Accordingly, The Association of Schools of Public Health (ASPH) has enumerated specific competencies in epidemiology and biostatistics that all MPH graduates are expected to have mastered regardless of their area of concentration.

The **overall goals of this course** are:

- 1) To introduce the basic principles and methods of epidemiology and demonstrate their applicability to public health.
- 2) To provide fundamental skills needed to interpret and critically evaluate literature relevant to public health professionals.
- 3) To provide a structured method for organizing and analyzing raw data and to enable you to interpret and communicate the results to public health professionals and to the general public.

Specific Learning Objectives: Each section of the course reader begins with a list of specific learning objectives that emphasize the mastery of concepts and skills necessary to achieving the goals and enabling you to function as a public health professional. The Learning Objectives for each lecture can be found in the Course Schedule.

Course Structure: Classes generally utilize a lecture format, but lectures are interspersed with active learning exercises consisting of a mixture of in-class problems, exercises, and discussions.

- The instructor's lectures will focus primarily on epidemiologic principles and methods.

- Guest speakers have been carefully selected to present detailed overviews of relevant epidemiologic studies that illustrate epidemiologic principles and methods.
- Learning objectives covered in class will be reinforced through carefully selected assigned readings.
- Learning objectives will be further reinforced through graded homework assignments that you must complete and submit via Blackboard.bu.edu (see below).
- Skills in organization and analysis will also be developed with structured exercises on how to use Excel to organize and analyze raw data. The last section of the reader provides a detailed explanation of the basics of how to use Excel for this purpose. It provides step-by-step structured exercises to teach you how to perform basic analyses using raw data sets. The raw data sets are located on Blackboard.bu.edu in the “Assignments” section. The Excel exercises are not graded.

Questions and Help:

If you have questions or don't understand something, please ask. You may interrupt and ask questions at any time during class. I will generally arrive at class early to answer questions, and I will be happy to stay after class as well. You may also call my direct office phone line at any time, and you may also email questions to me. I check my email frequently, and I will generally answer email questions promptly. You may also arrange to meet with me for additional help. I do not have fixed office hours at the medical campus, because your schedules are so varied. However, feel free to email to set up a meeting for additional help. Again, if you are struggling with something, please ask promptly.

Attendance is required for all classes; you are responsible for all material presented in class.

Course Materials and Blackboard.bu.edu Website:

Since students differ in their preferred learning style. Many are visual learners, but others prefer textbooks or lectures, and some prefer to learn through solving real problems. Probably most of us rely on a combination of learning styles. In recognition of this I have tried to present course materials in several ways that emphasize different learning styles. While the actual classes would best be described as lectures, they incorporate a variety of techniques including visualization of concepts, in-class problems, small and large group discussion, and anonymous testing and feedback with an Audience Response System (electronic “clickers”). I have designed the class to combine clear explanations of key concepts with opportunities for active learning and mastery of skills. I would strongly encourage you to attend classes.

- The **course reader for EP711 Section B1** provides specific learning objectives and detailed information for each topic covered in the course. The reader is available for free on Blackboard in the Course Document section.
- **Recommended Textbook:** I strongly recommend Essentials of Epidemiology in Public Health by Ann Aschengrau and George Seage. The text goes into greater detail than necessary for EP711, but the explanations are readable and clear, and they are consistent with the way things are presented in class. It is also a good general reference for epidemiology, and it makes a good addition to the library of anyone interested in public health. For this course, you should primarily rely on the course reader and the class lectures and PowerPoint slides; use the text as a

reference to fill in the gaps or to clarify. **Note:** The 1st and 2nd editions of this text are identical except for the cover design. If you plan to purchase it, I would suggest looking online at Amazon.com or other vendors who may have used copies which may be cheaper.

- **Online readings:** For most classes there is an online reading assignment from the Epidemiologic Research and Information Center (ERIC) at the University of North Carolina. These are relatively short, well-written explanatory articles that dovetail very well with the structure of this course. You should read the articles, but you can skip the problems at the end of the ERIC articles. (there are errors in some of the problems).
- **Assigned Journal Articles:** Some classes also have assigned journal articles. The primary purpose of the journal articles is to provide insights about the details of how epidemiologic studies are conducted. Therefore, you should pay particular attention to the abstract, the introduction, and the methods sections of these articles. You should also take note of the presentation of results that are relevant to course learning objectives (e.g., interpretation of odds ratios, relative risks, confidence intervals, p-values, etc.). You are not expected to memorize any of the results presented. The links to these assigned readings can be found in the Assignments section of Blackboard.bu.edu for Section B1 of EP711.
- **Blackboard.bu.edu:** All students are required to obtain a Boston University e-mail account and password in order to be able to access the Blackboard web site. The website will enable students to check announcements, get links to all assigned readings, view lecture slides, and take online quizzes.

Printing PowerPoint Slides: You are certainly not expected to print the PowerPoint slides. However, if you choose to do so, there is a specific method that will ensure optimal readability. Open the PowerPoint file that you want to print. From the toolbar at the top click on “File”, “Print”. When the Print window opens, indicate that you want to print “handouts”, and choose 4 or 6 per page. Make sure that you select **“Pure Black and White”** in the lower left corner of the dialog box, otherwise the slides will be unreadable.

Graded Homework Assignments (“Quizzes”):

Homework is intended to reinforce concepts, to identify misconceptions, and to provide practice questions that are very similar to what will be found in the exams, although you will be expected to show your calculations on exams, and exams will also include open-ended questions (e.g. List four advantages of cohort studies).

You are expected to work through the homework assignments on your own. If you are having difficulty with a homework question, you may ask the instructor for help on the related topic, but not the answers to specific homework problems. You are expected to complete and submit the homework assignments on time; your average score on the homework will count for 15% of your semester grade.

Note: Homework assignments must be completed before class on the day the assignment is due, which is generally the week after that topic is covered in class. In other words, the homework or “quiz” on Measures of Association must be complete during the week after the lecture on that topic.

Previews of the online quiz/homework problems are posted on Blackboard.bu.edu in the Assignments section. You may download the problem sets and work on them at your leisure using class slides, or the reader, or textbooks. When you have completed the exercise, you must submit your answers online via Blackboard.bu.edu. Once you have submitted your answers to a quiz, it will be automatically graded and you will receive immediate feedback on the correct answers. **NOTE:** Do not open the quizzes online until you have finished all the problems in a homework set and you are ready to submit all your answers for that homework set. *You will have only one opportunity to submit each quiz*, but the previews of the quizzes will allow plenty of time to work through each set before you submit the answers online (assuming you don't wait until the last day).

Reviewing past quizzes and feedback:

After your quizzes have been submitted and graded, you can still review them to see what you got wrong and what the feedback was. To review, go to Blackboard.bu.edu to the "Tools" section, and click on "Check Your Grade". You should see a table that summarizes all of your quizzes and test grades. (Ignore the total score; this is meaningless.) To review a quiz click on the score for that quiz, and you should be able to see how you answered, what the correct answer was, and what the feedback was (if any).

Exams and Semester Grades:

Semester grades will be based on the following:

- Graded homework [open book online "quizzes"] (15% of grade)
- A take-home exam [open book] (15% of grade)
- An in-class midterm [closed book] (35%)
- An in-class final [closed book] (35%)

The take-home exam will be "open book", meaning that you may use your notes, the reader, online articles, etc. However, you must complete the take-home exam on your own without help from anyone else.

The midterm exam and the final exam will be "closed book," i.e. you may not use any books or notes. You may use a non-programmable calculator during the exams if you wish.

The final exam will be cumulative (i.e., it may include questions from any part of the course). However, the final exam will focus mainly on material covered after the midterm exam.

Course Grades will be based on the following levels of performance and achievement:

A: A grade of "A" in this course identifies consistently outstanding work that distinguishes the student among MPH candidates. The student's work consistently demonstrates clear, accurate, detailed, and comprehensive understanding of relevant definitions and concepts and consistent ability to apply these concepts and definitions to a wide array of new problems. This level of work also requires a consistent ability to organize and analyze raw data sets, to conduct appropriate analysis, and to interpret and communicate results clearly and appropriately.

B: The student's work demonstrates an adequate understanding of relevant definitions and concepts and an adequate ability consistent ability to apply these concepts and definitions

to a new problems. This level of work also requires an adequate ability to organize and analyze raw data sets, to conduct appropriate analysis, and to interpret and communicate results clearly and appropriately.

C: The student's work demonstrates an uneven, incomplete, or shaky understanding of relevant definitions and concepts and inconsistent ability to apply these concepts and definitions to an array of new problems. Students in this level may also be inconsistent in their ability to organize and analyze raw data sets, to conduct appropriate analysis, and to interpret and communicate results clearly and appropriately.

D: The student's work demonstrates an inadequate understanding of relevant definitions and concepts and extremely limited ability to apply these concepts and definitions to new problems. Students in this level may also be very limited in their ability to organize and analyze raw data sets, to conduct appropriate analysis, and to interpret and communicate results clearly and appropriately.

Past experience in teaching this course suggests that these **definitions generally correspond** to the following overall average scores for the semester. Note that final semester scores will be rounded off to the nearest whole integer. Also note that grades of "A" or "A-" are generally earned by less than half of the class.

| | |
|----|-----------|
| A | 94.0-100 |
| A- | 90.0-93.9 |
| B+ | 88.0-89.9 |
| B | 80.0-88.9 |
| C | 70.0-79.9 |
| D | 60-69 |
| F | <60 |

BUSPH Policy on Academic Honesty

Academic misconduct is any intentional act or omission by a student which misrepresents his or her academic achievements, or attempts to misrepresent these achievements. While not an exhaustive list, the following acts constitute academic misconduct:

- Cheating on examinations. The use or attempted use of any unauthorized books, notes or other materials in order to enhance the student's performance in the examination, copying or attempting to copy from another student's examination, permitting another student to copy from an examination or otherwise assisting another student during an examination, or any other violation of the examination's stated or commonly understood ground rules.
- Plagiarism. Any representation of the work of another person as one's own constitutes plagiarism. This includes copying or substantially restating the work of another person in any written or oral work without citing the source, or collaborating with another person in an academic endeavor without acknowledging that person's contribution.
- Submitting the same work in more than one course without the consent of all the instructors.

- Misrepresentation or falsification of data
- Allowing another student to represent your work as his or her own.
- Violating the rules of an examination or assignment

Charges of academic misconduct will be brought to the attention of the Associate Dean for Education, who will review all such cases and decide upon the appropriate action. A student who is found guilty of academic misconduct may be subject to disciplinary action, up to and including dismissal from the School.

The full academic misconduct policy is available at: www.bu.edu/bulletins/sph/item09.html

BUSPH Policy on Timely Completion of Course Requirements

All students are required to take examinations on the day they are scheduled and to hand in assignments no later than the due date. Syllabi should indicate examination dates and project (which includes papers) due dates, and penalties associated with late submissions of assignments. If a student cannot take an exam or submit a paper or project on time, the student must request an alternate date in writing from the faculty member. The request for extensions should only be approved if the student has encountered a serious problem that arose unexpectedly and that will make it impossible or extremely burdensome for the student to take the exam or fulfill the assignment requirements as scheduled. In such a circumstance faculty may grant a request for an alternate exam or due date. Substitute examinations should ordinarily be scheduled as soon as possible after the scheduled exam date. Students should be warned that if they request a delay in taking a final exam or in completing a final assignment they may receive a grade of "incomplete."

It is the student's obligation to request an extension prior to the time of the exam or date an assignment is due. Only in circumstances when it would be impossible or extraordinarily burdensome for a student to make the request prior to the scheduled date may the faculty member consider a request for an extension of time after the date of the exam or assignment due date.

- Faculty may require a student to provide documentation of the circumstances the student submits as the reason for granting an alternative exam or due date, such as a note from a physician.
- A student's failure to adhere to this policy may result in a failing grade being granted for the exam or paper.
- Disputes between faculty and students arising out of this policy will be decided by the Associate Dean for Academic Affairs.

BUSPH Policy on Minimum Grades and Grade Changes

All MPH degree candidates must achieve a minimum grade of a B- in each core course. An MPH student who receives a grade lower than B- in EP711 may retake the course once to improve the grade. Re-taking of EP711 should be done the next time the course is offered. EP711 is usually offered during the Fall and Spring semesters. Students who wish to retake a class must contact the Registrar's Office at least two months before the start of class.

- A grade of less than B- in a core course will be treated as an Incomplete (I) grade for purposes of the incomplete policy (see the student handbook for the "incomplete policy").
- A student who fails to achieve a minimum grade of B- after retaking a core course a second time must petition the Associate Dean for Academic Affairs for permission to take the core course a third time. In the petition the student must address the reasons for the previous lack of success and state the reasons why a third attempt is likely to be successful. After consultation with the relevant faculty member and department chair, the Associate Dean will make a decision to approve or reject the petition. If the petition is rejected, the student will be dismissed from the School of Public Health.

**Class Schedule, Homework Assignments, and Learning Objectives for
EP711 (Section B1) – Introduction to Epidemiology –
Fall 2010**

1) Class 9/7/10 - Introduction; Descriptive Epidemiology

Assignment prior to next class on 9/14/10:

- **Read**
 - For fun, take a look at <http://ocp.hul.harvard.edu/contagion>
This is a webpage entitled “Contagion: Historical Views of Diseases and Epidemics.”
- **Submit** Discussion #1 (See Assignments on Blackboard)
 - Course Reader: Section on Descriptive Epidemiology
 - Course Reader: Overview of Analytic Study Designs
 - Aschengrau & Seage: Chapter 1, Chapter 5, & Chapter 6
 - **Look at:** the abstract by Gottlieb et al. on Pneumocystis Pneumonia from MMWR 1981 posted in the Assigned Reading folder in Blackboard.bu.edu Assignments). Just get a feel for this important piece of ‘descriptive epidemiology’. You do not have to memorize this, and you will not be tested on it.
- **OPTIONAL RESOURCES:**
 - ERIC #1 – Introduction: http://eric.unc.edu/notebooks/issue1/eric_notebook_1.pdf
 - ERIC #7 – Cross Sectional Studies: http://eric.unc.edu/notebooks/issue7/eric_notebook_7.pdf
 - ERIC #12 – Ecologic Studies: http://eric.unc.edu/notebooks/issue12/eric_notebook_12.pdf

Learning Objectives for this Lecture:

- After successfully completing this unit, the student will be able to:
 - Explain the role of descriptive studies for identifying problems and establishing hypotheses.
 - Explain how hypotheses are formulated based on differences, similarities, and concomitant variation.
 - Explain how the characteristics of *person*, *place*, & *time* are used to formulate hypotheses in acute disease outbreaks and in studies of chronic diseases.
 - Identify case reports and case series and explain their uses and their limitations.
 - Describe the design features of an ecologic study and discuss their strengths and weaknesses.
 - Explain the concept of ecologic fallacy both in general and in the context of a study.
 - Identify the strengths and limitations of an ecologic study.
 - Describe the design features of a cross-sectional study and describe their uses, strengths, and limitations.

2) Class 9/14/10 – Overview of Analytic Studies (LaMorte);

Assignment prior to next class on 9/21/10:

- **Exercises:**
 - Complete and submit the online **quiz: Q1 - Study Designs.**
- **Read:**
 - Course Reader: Section on Measures of Disease Frequency
 - Aschengrau & Seage: Chapter 2
- **OPTIONAL RESOURCES:**
 - ERIC #2 – Incidence and Prevalence:
http://eric.unc.edu/notebooks/issue2/eric_notebook_2.pdf
 - ERIC #4 – Incidence Measures in Cohort Studies:
http://eric.unc.edu/notebooks/issue4/eric_notebook_4.pdf
 - ERIC #9 – Calculating Person-time:
http://eric.unc.edu/notebooks/issue9/eric_notebook_9.pdf

Learning Objectives for this Lecture:

- After successful completion of this section, the student will be able to:
 - Identify the following types of analytical studies: case-control, retrospective and prospective cohort studies, and clinical trials.
 - Distinguish analytical studies from descriptive studies, such as case reports, case series, correlational studies, and cross sectional studies.
 - Describe the distinguishing features of cohort studies, case-control studies, and clinical trials.
 - Discuss the differences in strategy between cohort studies and case-control studies.
 - Explain the advantages and disadvantage of cohort studies, case-control studies, and clinical trials & the factors that are considered when determining which to do.

3) Class 9/21/10 - Measures of Disease Frequency: Counts, Prevalence, & Incidence

Assignment prior to next class on 9/28/10:

- **Exercises:** Complete and submit online quiz: Q2 - Measures of Disease Frequency.
- **Read Ahead:**
 - Course Reader: Section on Measures of Association
 - Aschengrau & Seage: Chapter 3: pp. 59-63 & 67-69; Chapter 9: pp. pp 247-249
- **OPTIONAL RESOURCES:**
 - ERIC #17 – Common Epidemiologic Measures (Association):
http://eric.unc.edu/notebooks/issue17/eric_notebook_17.pdf

Learning Objectives for this Lecture:

- After successfully completing this section, the student will be able to:
 - Define what is meant by the term 'population' in both descriptive epidemiology and analytic epidemiology.
 - Explain the difference between fixed versus dynamic populations.
 - Explain the differences among the parameters: ratio, proportion, & rate.

- Define and calculate prevalence (and be able to distinguish between point prevalence and period prevalence). Be able to explain the use of prevalence in public health.
- Define and distinguish between cumulative incidence and incidence rate, and describe their strengths and limitations.
- Explain the relationship between incidence rate and cumulative incidence.
- Calculate cumulative incidence and incidence rate from raw data and convert it into a form that enables you to compare the incidence in two or more groups.
- Explain what is meant by the term "at risk."
- Explain what is meant by "person-years" of observation and be able to calculate person-years of observation from raw data.
- Explain the interrelationship among prevalence, incidence, and average duration of disease (i.e. $P = IR \times D$). Be able to calculate the average duration of disease, given the prevalence and incidence rate.
- Explain and calculate:
 - crude rates
 - category-specific rates (e.g. gender or race)
 - age-specific rates
 - adjusted rates
- Be able to define and calculate the following special types of frequency measurements:
 - morbidity rate
 - mortality rate
 - case-fatality rate
 - attack rate
 - live birth rate
 - infant mortality rate
- Be able to define the following special types of prevalence:
 - autopsy rate
 - birth defect rate

4) Class 9/28/10 - Measures of Association

Assignment prior to next class on 10/5/10:

- **Exercises:**
 - Complete and submit online quiz: Q3 - Measures of Association.
 - Note that there is an OPTIONAL extra exercise on Measures of Disease Frequency and Measures of Association that you may take for extra practice. This will not be counted in your semester grade, regardless of how well or poorly you do. It is just for extra practice.)
- **Read Ahead:**
 - Course Reader: Section on Evaluating the Role of Chance
 - Aschengrau & Seage: Chapter 12: pp. 307-321 & 330-338
- **OPTIONAL RESOURCES:**

- ERIC #18 – Common Statistical Tests:
http://eric.unc.edu/notebooks/issue18/eric_notebook_18.pdf

Learning Objectives for this Lecture:

- After successfully completing this section, the student will be able to:
 - Construct a 2x2 table for summarizing epidemiologic data.
 - Explain how to compare the incidence of disease in two or more groups.
 - Define, calculate, and interpret:
 - risk ratios and rate ratios
 - risk difference (attributable risk)
 - attributable proportion (attributable risk percent) for exposed subjects.
 - odds ratio
 - Discuss the differences between absolute and relative differences in risk.
 - Demonstrate the uses of these measures of association and be able to interpret them.
 - Explain what is meant by a "reference group" when multiple exposure groups are being compared and be able to compute and interpret measures of association based on a reference group.

5) Class – 10/5/10 Evaluating the Role of Chance; Statistical Testing

Assignment prior to next class on 10/19/10:

- **Exercises:** Complete and submit online quiz: Q4 - The Role of Chance.
- ***** **Complete the Take-home Exam** and bring it to class on 10/26/10.
- **Read Ahead:**
 - Course Reader: Section on Intervention Studies (Randomized Clinical Trials)
 - Aschengrau & Seage: Chapter 7 Experimental Studies) & Chapter 17 (Ethics in Research Involving Human Participants)
 - Read the abstract and the methods section in the paper by Ridker et al. on low dose aspirin to prevent heart disease in women. N Engl J Med 2005;352:1293-304.
<http://content.nejm.org.ezproxy.bu.edu/cgi/reprint/352/13/1293.pdf>).
- **OPTIONAL RESOURCES:**
 - ERIC #10 – Randomized Trials:
http://eric.unc.edu/notebooks/issue10/eric_notebook_10.pdf

Learning Objectives for this Lecture:

- After successful completion of this section, the student will be able to:
 - Explain what is meant by "sampling" and "inference."
 - Explain how sampling and "chance" may effect the results of a study.
 - Explain what is meant by "hypothesis testing."
 - Explain what is meant by "null hypothesis" and "alternative hypothesis." Given a study scenario, be able to provide statements for the null hypothesis and the alternative hypothesis.

- Distinguish between categorical and continuous variables and be able to explain the concept of sampling variability for each.
- Explain the effects of sample size on the precision of an estimate made by sampling.
- Define what a 95% confidence interval is and be able to interpret 95% confidence intervals for proportions, risk ratios, and odds ratios.
- Define and interpret "p-values."
- Explain what is meant by the phrase "statistically significant."
- Use the Excel file "Stat Tools.XLS" to compute p-values and 95% confidence limits.

10/12/10 NO EP711 CLASS – FOLLOW A MONDAY SCHEDULE

6) Class 10/19/10 - Intervention Studies (Experimental Studies, Clinical Trials)

Assignment prior to next class on 10/26/10:

- **Exercises:**
 - Complete and submit online quiz: Q6 - Intervention Studies.
- **Read Ahead:**
 - Course Reader: Section on Cohort Studies
 - Aschengrau & Seage: Chapter 8
- **OPTIONAL RESOURCES:**
 - ERIC #3 – Cohort Studies:
http://eric.unc.edu/notebooks/issue3/eric_notebook_3.pdf

Learning Objectives for this Lecture:

- After successfully completing this section of the course, students will be able to:
- **Research Ethics:**
 - List and discuss the Belmont Principles
 - Define what 'human research' is and how to identify it.
 - Define equipoise and discuss its relevance to decisions about whether clinical trials are ethical.
 - Explain what is meant by "informed consent."
 - Describe the composition responsibilities of a Data Safety and Monitoring Board.
- **Intervention Studies:**
 - Explain the distinguishing features of a clinical trial (intervention study).
 - Discuss the two major potential advantages of interventions studies and their limitations.
 - Differentiate between preventive, therapeutic, individual and community RCTs
 - Briefly explain the differences among phase I, II, III, & IV clinical trials.
 - Define randomization in the context of a clinical trial and give examples of appropriate methods of randomization.
 - Explain why randomization is used.

- Explain how to determine whether randomization has been successful.
- Define blinding and explain the purpose of blinding.
- Distinguish between single and double blinding.
- Explain what the placebo effect is.
- Define the term “placebo” and explain why placebos are used.
- Explain when the use of a placebo is not appropriate and discuss alternative strategies.
- Explain why it is important to maintain high rates of follow-up in a prospective cohort study or a clinical trial.
- Explain why compliance is important and the effects of non-compliance.
- Define and distinguish between “intention to treat analysis” and an efficacy analysis.
- Define what a run-in period is and explain its purpose.
- Analyze and interpret raw data or summary data from a clinical trial using Excel and the software provided in the course.

7) Class 10/26/10 - Cohort Studies & the Black Women’s Health Study (Dr. Cozier)

Assignment prior to next class on 11/2/10:

• Exercises:

- Complete and submit online quiz: Q5 - Cohort Studies.
- **Pass/Fail assignment:** Read and complete the exercises in Using Excel (last section of the Course Reader posted in Course Documents) on how to analyze cohort studies. Then **conduct the independent analysis of the Framingham data set to determine whether low HDLC (high density lipoprotein cholesterol [the “good cholesterol”]) is a risk factor for myocardial infarction (heart attack)** [See the Assignments section of Blackboard.bu.edu]. Use the Framingham data set. Follow the detailed instructions posted in the Assignments section of Blackboard.bu.edu. When you are done, **submit your file to your Drop Box** (in Tools on Blackboard.bu.edu) with a file name that consists of “HDL”+Your full name [Do NOT send a ZIP file]. This is a required **Pass/Fail assignment**.

• Read Ahead:

- Course Reader: Section on Bias
- Aschengrau & Seage: Chapter 10

• OPTIONAL RESOURCES:

- ERIC #8 – Selection Bias:
http://eric.unc.edu/notebooks/issue8/eric_notebook_8.pdf
- ERIC #16 – Information Bias:
http://eric.unc.edu/notebooks/issue16/eric_notebook_16.pdf

Learning Objectives for this Lecture:

- After successful completion of this section, the student will be able to:
 - Define what a cohort study is and explain its key features.
 - Define and distinguish among:

- Prospective cohort study
- Retrospective cohort study
- Ambidirectional study
- Explain the advantages and disadvantages of the cohort design in general and the strengths and weaknesses of retrospective and prospective cohort studies.
- Explain the factors that should be considered in selecting subjects for a cohort study.
- Explain what is meant by the term "*control*" group.
- Explain the differences among the following types of control groups:
 - An internal control group
 - A logical control group
 - An external control group
- Explain the potential problems in using an external control group.
- Explain what the "*healthy worker effect*" is.
- Define "*loss to follow-up*" and explain what effects it may have on a study.

8) Class 11/2/10 - Bias

Assignment prior to the next class on 11/9/10:

• Exercises:

- Complete and submit online quiz: Q7 – Bias. **Note:** In order to complete the Quiz on Bias, you will need to read the methods sections from three papers in order to determine whether bias could have affected either of these studies. You do not need to read the entire paper. Read:
 - Excerpts from Perneger et al.: NSAIDS and renal failure (See Reading Assignments folder in Blackboard.bu.edu Assignments).
 - The abstract and the methods section of the paper by Ridker et al. on low dose aspirin to prevent heart disease in women. N Engl J Med 2005;352:1293-304.
<http://content.nejm.org.ezproxy.bu.edu/cgi/reprint/352/13/1293.pdf>
 - Read Manson et al.: A prospective study of walking as compared with vigorous exercise in the prevention of coronary heart disease in women. N. Engl. J. Med. 1999;341:650-8.
<http://content.nejm.org.ezproxy.bu.edu/cgi/reprint/341/9/650.pdf>

• Read Ahead:

- Course Reader: Section on Case-Control Studies
- Aschengrau & Seage: Chapter 9

• OPTIONAL RESOURCES:

- ERIC #5 – Case-Control Studies:
http://eric.unc.edu/notebooks/issue5/eric_notebook_5.pdf

Learning Objectives for this Lecture:

- After successfully completing this section, the student will be able to:

- Define and identify selection bias.
- Discuss bias from loss to follow-up (a special type of selection bias).
- Define and identify observation bias, specifically:
 - Recall bias
 - Random misclassification
 - Non-random misclassification
 - Interviewer bias

9) Class 11/9/10 – Case-Control Studies (Dr. LaMorte & Guest Speaker, Dr. Carol Louik)

Assignment prior to the MIDTERM on 11/16/10:

- **Exercises:**
 - Complete and submit online quiz: Q8 - Case-Control Studies.
 - **Pass/Fail Exercise:** Watch the video on Blackboard on how to use Excel to analyze case-control studies (see also the last section of the Course Reader on Using Excel). Then use the Femoral Bypass Data Set to examine the association between smoking and femoral artery occlusion. Follow the detailed directions posted in the Assignments section of Blackboard.bu.edu. Then **submit your file to your Drop Box** (in Tools on <http://Blackboard.bu.edu>) with a file name that consists of “Bypass”+Your full name [Do NOT send a ZIP file]. This is a required **Pass/Fail assignment**.
- **Review for Midterm Exam**
- **Learning Objectives for this Lecture:**
 - After successful completion of this section, the student will be able to:
 - Explain the key features of case-control studies and how they differ from cohort studies.
 - Explain the strengths and weaknesses of the case-control design compared to cohort studies.
 - Define what is meant by the term ‘source population.’
 - Explain the factors that should be considered in selecting valid control subjects for a case-control study.
 - Explain the importance of specific diagnostic criteria and explicit case definitions.
 - Explain the advantages and disadvantages of using hospital-based cases and controls and population-based cases and controls.
 - Calculate and interpret an odds ratio.
 - Compute and interpret the 95% confidence interval for an odds ratio (using ‘Stat Tools’).

10) 11/16/10 MIDTERM EXAM (in class exam; no notes, books, PDAs or other electronic devices; simple, non-programable calculators are ok)

Assignment prior to next class on 11/23/10:

- **Read Ahead:**
 - Course Reader: Section on Adjusted Rates (Direct Standardization)

- Course Reader: Section on Confounding
- Aschengrau & Seage: Chapter 3: pp. 69-73 (Direct Standardization), Chapter 11 (Confounding)
- OPTIONAL RESOURCES:
 - ERIC #14 – Confounding Part I
http://eric.unc.edu/notebooks/issue14/eric_notebook_14.pdf
 - ERIC #15 – Confounding Part II
http://eric.unc.edu/notebooks/issue15/eric_notebook_15.pdf

11) Class 11/23/10 – Adjusted Rates and Confounding

Assignment prior to next class on 11/30/10:

- **Exercises:**
 - Complete and submit online quiz: Q9 - Adjusted Rates
 - Start working online quiz: Q10 - Confounding.
- **Read Ahead:**
 - Aschengrau & Seage: Chapter 13 (Effect Measure Modification)
 - Course Reader: Section on Regression Analysis.

Learning Objectives for this Lecture:

- After successfully completing this unit, the student will be able to:
- **Adjusted Rates:**
 - Explain what is meant by:
 - Crude rates
 - Age-specific rates
 - Adjusted rates
 - Explain what is meant by "adjustment" (standardization) and why it is done.
 - Calculate an adjusted rate of disease or death using direct standardization and interpret the findings in words.
- **Confounding:**
 - Identify the characteristics of a confounder
 - Identify the 3 ways to control confounding in the design phase of the study, their basic characteristics, and their strengths and limitations
 - Conduct and interpret the results of 2 methods to control confounding in the analysis phase of the study; standardization and Mantel-Haenszel
 - Characterize the directions and magnitude of confounding
 - Describe residual confounding, identify 3 possible sources, and assess its direction
 - Explain what confounding is, including the characteristics of a confounder, and what effects it can have on a study.
 - Discuss control of confounding via each of the following, including the strengths and weaknesses of each:
 - Restriction
 - Matching
 - Stratification
 - Randomization
 - Multivariate analysis

- Explain what is meant by a Mantel-Haenszel relative risk or a Mantel-Haenszel odds ratio;

12) Class 11/30/10 –Effect Measure Modification; Regression Analysis to Control for Confounding

Assignment prior to next class on 12/7/10:

- **Exercises:**
 - Complete online quiz: Q10 - Confounding.
- **Read Ahead:**
 - Course Reader: Section on Screening for Disease
 - Aschengrau & Seage: Chapter 16 (Screening)
- **OPTIONAL RESOURCES:**
 - ERIC #11 – Assessment of Diagnostic and Screening Tests
http://eric.unc.edu/notebooks/issue11/eric_notebook_11.pdf

The next three articles are directly relevant to the controversy that Dr. Mendez will be discussing in the next class. These are short perspective articles that you should read, but you do not have to memorize anything from them.

- Suzanne Fletcher and Joann Elmore: Mammographic screening for breast cancer. N. Engl. J. Med. 2003;348:1672-80.
<http://content.nejm.org.ezproxy.bu.edu/cgi/reprint/348/17/1672.pdf>
- Partridge AH and Winer EP: On mammography – more agreement than disagreement. **Perspective article in:** N. Engl. J. Med. 2009;361(26):2499-2501.
<http://content.nejm.org.ezproxy.bu.edu/cgi/reprint/361/26/2499.pdf>
- Truog RD: Screening mammography and the "R" word. **Perspective article in:** N. Engl. J. Med. 2009;361(26):2501-2503.
<http://content.nejm.org.ezproxy.bu.edu/cgi/reprint/361/26/2501.pdf>

Given the new recommendations about cervical cancer screening and the controversy around screening for prostate cancer, you may also want to look at these next two articles, but you will not be tested on them.

- Sawaya GF: Cervical-cancer screening – new guidelines and the balance between benefits and harms. **Perspective article in:** N. Engl. J. Med. 2009;361(26):2503-05.
<http://content.nejm.org.ezproxy.bu.edu/cgi/reprint/361/26/2503.pdf>

Lee TH, Kantoff PW, McNaughton-Collins MF. Perspective Roundtable: Screening for Prostate Cancer, New Engl. J. Med. 2009; 360:e18

<http://content.nejm.org.ezproxy.bu.edu/cgi/reprint/360/13/e18.pdf>

Learning Objectives

for this Lecture:

- After successfully completing this unit, the student will be able to:
- **Effect Measure Modification:**
 - Define effect measure modification.
 - Perform a stratified analysis and distinguish between confounding and effect modification.
- **Multiple Variable Regression Analysis:**
 - Interpret the results of an analysis that has used multiple linear regression to control for confounding.

- Interpret the 'adjusted' odds ratios obtained from an analysis that has used multiple *logistic* regression to control for confounding.

13) Class 12/7/10 - Screening for Disease (Dr. LaMorte & Jane Mendez, MD)

Assignment prior to next class on 12/14/10:

- **Exercises:**
 - Complete and submit online quiz: Q11 - Screening.
- **Read Ahead:**
 - Aschengrau & Seage: Chapter 15 (Causation)
- **OPTIONAL RESOURCES:**
 - ERIC #19 – Causality
http://eric.unc.edu/notebooks/issue19/eric_notebook_19.pdf
 - Read the Time magazine article by Wallis, "Does Watching TV Cause Autism?" Time magazine Oct. 10, 2006.
<http://www.time.com/time/health/article/0,8599,1548682,00.html> (Also posted in the Assigned Readings folder in the Assignments section of Blackboard.bu.edu).

Learning Objectives for this Lecture:

- After successfully completing this section, students will be able to:
 - Explain when screening should be done.
 - List the characteristics of a good screening test.
 - Define what is meant by the reliability of a screening test.
 - List the factors that influence the reliability of a test.
 - Define "detectable pre-clinical phase."
 - Define, calculate, and interpret the following:
 - Sensitivity of a screening test
 - Specificity of a screening test
 - Positive predictive value of a screening test
 - Negative predictive value of a screening test
 - Explain how increasing or decreasing the cut-off value for an abnormal test influences sensitivity and specificity.
 - Explain how predictive value is influenced by prevalence of disease.
 - Explain what is meant by:
 - False positive
 - False negative
 - True positive
 - True negative
 - Explain what is meant by lead time bias.
 - Explain what is meant by length time bias.
 - Discuss the hazards of screening.

14) Class 12/14/10 Causal Inference – Making a Judgment of Causality

Assignment prior to FINAL EXAM on 12/21/10:

- **Exercises:**

- NOTE: There is no quiz on causality, but make sure you know Hill's Criteria as discussed in class.
- Review for the in-class final exam

15) FINAL EXAM 12/21/2010 Regular class time - (in class exam; no notes, books, PDAs or other electronic devices; simple, non-programable calculators are ok)