EPIB 612 Epidemiologic Study Design

Semester: Spring, 2013
Classroom and Time: Rm 0305, Fridays, 1:00 – 3:45pm
Office Hour: 4:00-5:00pm or by appointment
Instructor: Hongjie Liu, PhD, MS
Office: 2234A, SPH Bldg
Phone: 301-405-3102
Email: hliu1210@umd.edu
ELMS site: http://elms.umd.edu/

Course Pre- and Co-requisites:
Required: EPIB 610 Foundations of Epidemiology, EPIB 650 Biostatistics I, and EPIB 611 Intermediate Epidemiology

Required Texts and Other Readings:
Required:
- No required books, but class notes and readings from various epidemiology journals will be distributed in class

Recommended:
- Woodward M. Epidemiology: Study Design and Data Analysis, 2nd edition, Champan & Hall/CRC, 2005
- Moyses Szklo M and Nieto J. Epidemiology: Beyond the basic, 3rd edition, Jones & Bartlett Learning, 2012
- Rothman KJ and Greenland S. Modern Epidemiology, 3rd edition, Lippincott Williams & Wilkins, Philadelphia, PA, 2008

Additional Materials Required:
Students will use calculator or SAS to do their homework.

Course Description:
The course focuses on the application of epidemiologic study designs and analytic methods used for analysis of cohort, case-control, cross-sectional, and clinical trials research. Its overall objective is to allow students to develop a solid understanding of the theoretical basis and practical tools of epidemiologic study designs. Features of epidemiologic designs, biases, and analytic reasoning are emphasized throughout the class. The course provides analytic approaches for selection of an appropriate study design to address a specific research question, identification of bias, control of confounding, and assessment of effect modification. It extends the concepts and methods of epidemiology from EPIDB610 and 611.
Course Goal
The goal of this course is to provide principles and techniques that are commonly used in epidemiologic research. After the course, students will be confident in the design of epidemiologic studies, analysis of epidemiologic data, and report of findings.

Course Learning Objectives:
By the end of this course, students will be able to:

1. In-depth understand the theoretic issues in each type of epidemiologic study designs and its strengths and weaknesses.
2. Define a research question, select an appropriate epidemiologic study design to address the question, map out and implement an analytic plan, and interpret findings.
3. Identify and control major sources of bias (i.e., information, selection, and confounding bias) in each type of epidemiologic studies and approaches to evaluate their likely direction, magnitude, and nature of their threat to causal inference.
4. Demonstrate the ability to independently plan epidemiologic studies and data analysis with emphases on effect estimation, controlling for confounding, and assessment of interaction.
5. Demonstrate understanding of epidemiologic methods through critical review of published epidemiologic research.

Program Competencies Addressed in this Course:
The following competencies for the MPH degree in epidemiology are addressed in this course. This course also meets the requirements for training in epidemiologic principles for other MPH degrees at the University of Maryland College Park School of Public Health:

1. Design, analyze, and evaluate an epidemiologic study.
2. Design interventions to reduce prevalence of major public health problems.
3. Describe and apply statistical approaches to address threats to validity in epidemiologic studies.
4. Critique different study designs.
5. Critically appraise epidemiologic literature.

Course Organization
The class sessions will be lectures and discussions to review main concepts of epidemiology in depth, followed by exercises. Lectures will not necessarily cover all materials included in the reading assignments. Students are expected to complete the assigned readings prior to the class. Students are asked to actively participate in in-class discussions and exercises.

The instructor welcomes meetings with students outside of class to discuss questions, as well as to gain more insight about the material presented in class. Students may e-mail or ask during class for an appointment. Please be reminded, however, that the class will be taught during class time only. Material will not be presented again on a one-on-one basis at other times. Therefore, attendance at every class is expected. Excessive lateness or absence from class is disruptive to the class and your learning. It can not help you in the grading process. Students who miss class are responsible for obtaining notes and hand-outs from other students. The instructor will not meet with student to retrieve copies of hand-outs from past lectures except in pre-arranged circumstances.
Course Requirements and evaluation:

**Mid-term Exam (30 points)**
The mid-term exam will be given between 1:00-3:45 pm on March 29\(^{th}\), 2013 (after the spring break). Formats of the mid-term exam include multiple choices, true or false, calculations, and short answers. It is an open-book exam. You are required to work independently on the mid-term in class.

**Final Exam (25 points)**
A final exam will be given between 1:00-3:45 on May 17\(^{th}\), 2013. Formats of the final exam include multiple choices, true or false, short answers, and calculations. It is an open-book exam.

**Homework (30 points)**
Six sets of homework will be assigned. Each set of homework is worth 5 points. You are encouraged to form study groups and discuss homework with your peers. Homework assignments will be posted in Blackboard one week before the due dates.

**Project (15 points):**
Students will be required to develop a research protocol in which one type of epidemiologic study designs is selected to investigate a research question. You are required to submit a short-form protocol. The proposal should be no more than 5 pages in Word. Use 11-point Arial as the minimum font size for the text of the application. Single-spaced text is acceptable, and space between paragraphs is recommended. The margins of your text should be at least 0.5 inch all around. You are required to work independently on the project. The deadline for the submission of it is May 17\(^{th}\), 2013 (before the final).

**Contents and Grade of final project**

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<table>
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<tbody>
<tr>
<td>1. Defining a research question with concise explanations</td>
<td>1 points</td>
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<tr>
<td>2. Clearly stating an testable hypothesis</td>
<td>1 points</td>
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<td>3. Selecting an appropriate study design and stating the reasons for the selection</td>
<td>4 Points</td>
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<td>4. Describing and explaining selected variables of interest, e.g., outcome, exposure, potential confounders, and modifiers</td>
<td>1 points</td>
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<tr>
<td>5. Listing potential information bias, selection bias, and confounding that may take place in your selected study design. Briefly stating your</td>
<td>5 points</td>
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rationales

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<tr>
<td>6. Stating approaches that you will use to prevent or eliminate the potential bias listed in 5.</td>
<td>2 points</td>
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<tr>
<td>7. Statistic approaches used to test the hypothesis</td>
<td>1 points</td>
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**Readings:**
After completion of each topic, students are required to critically read one publication that is relevant to the topic. Although reading is not graded, learning the main knowledge and approach used in the published work will help students to deeply understand class materials.

**Grading Procedures:**
Your final grade will be determined by scores of mid-term exam, final exam, homework, and research project.

**Grading**
Below is a ‘general guideline’ for grading.

<table>
<thead>
<tr>
<th>Score Range</th>
<th>Grade</th>
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<tbody>
<tr>
<td>97-100</td>
<td>A+</td>
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<tr>
<td>94-96</td>
<td>A</td>
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<td>90-93</td>
<td>A-</td>
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<td>87-89</td>
<td>B+</td>
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<tr>
<td>84-86</td>
<td>B</td>
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<tr>
<td>80-83</td>
<td>B-</td>
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<tr>
<td>77-79</td>
<td>C+</td>
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<tr>
<td>74-76</td>
<td>C</td>
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<tr>
<td>70-73</td>
<td>C-</td>
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<tr>
<td>60-69</td>
<td>D</td>
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<td>&lt; 60</td>
<td>F</td>
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**Tips for being successful in this course**

(1) **Read course materials prior to class**
This course has a heavy learning load. You should plan to spend a minimum of 5 hours per week outside of class completing class readings and assignments. You are required to preview the course presentations slides that will be posted at least three days before the next class meeting. You are expected to carefully and critically read all material prior to class. Carefully reflecting upon the material
will not only help you understand the material and make valuable contributions to the discussion, but will also help you to incorporate new ideas, perspectives, and techniques into your own research. In short, an exciting and lively class discussion depends in large part on everybody carefully and critically reading the course material.

(2) Come to see your instructor as often as possible

Your instructor will review your homework, exams, and other assignments to see what questions you missed and to explore how you might be able to improve on your study habits. If you feel you do not understand lectures or have questions about some topics, you need see your instructor as frequently as possible. Do not accumulate questions to the end of the course.

(3) Be active in learning

You are advised to make notes, rewrite notes, and share notes with your peers. If you have questions or miss some points in class, feel free to raise your hand and ask questions. You shall form a study group that meet weekly and discuss lecture topics and homework with your peers.

Canvas:

The syllabus and readings from journals, and other course materials will be posted on the ELMS website for EPIB612: [http://elms.umd.edu/](http://elms.umd.edu/). Presentation slides are posted under the folder of Files. Please remember to check it on a regular basis.

Course Policies:

**Email – The Official University Correspondence:**

Verify your email address by going to www.my.umd.edu.

All enrolled students are provided access to the University’s email system and an email account. All official University email communication will be sent to this email address (or an alternate address if provided by the student). Email has been adopted as the primary means for sending official communications to students, so email must be checked on a regular basis. Academic advisors, faculty, and campus administrative offices use email to communicate important and time-sensitive notices.

Students are responsible for keeping their email address up to date or for redirecting or forwarding email to another address. Failure to check email, errors in forwarding email, and returned email (from “full mailbox” or “unknown user” errors for example), will not excuse a student from missing University announcement, messages, deadlines, etc. Email addresses can be quickly and easily updated at www.my.umd.edu or in-person at the Student Service Counter on the first floor of the Mitchell Building.
For technical support for University email: www.helpdesk.umd.edu or call 301-405-1400.

Absence Policy:
In accordance with University policy if you are absent for a single (1) lecture due to illness or some form of personal or family emergency, this absence will be considered “excused” and the instructor will accept a note from you attesting to the date of the illness/incident, along with an acknowledgement that the information is true. Whenever feasible, you should try to contact the instructor in advance.

Multiple or prolonged absences, and absences that prevent attendance at a major scheduled grading event (like an exam or test) will require written documentation from an appropriate health care provider/organization.

A link to pull information on the new policy covering absences from class can be found at http://www.president.umd.edu/policies/v100g.html

Late work and Missed Exams / Assignments:
All work is due when assigned. Only hard copies of assignments, reports and papers are accepted except where indicated. E-mail and FAX copies will not be accepted except where indicated. Any work not completed and handed in at the beginning of class on the due date will receive a reduction of one letter grade. Work not handed in by 5pm the following day will receive an additional letter grade reduction. Work will not be accepted beyond this point except in extreme circumstance approved by your instructor.

Religious Observances:
The University System of Maryland policy provides that students should not be penalized because of observances of their religious beliefs; students shall be given an opportunity, whenever feasible, to make up within a reasonable time any academic assignment that is missed due to individual participation in religious observances. It is the student’s responsibility to inform the instructor in advance of any intended absences for religious observance.

Special Accommodations / Disability Support Services:
If you have a documented disability and wish to discuss academic accommodations for test taking or other needs, you will need documentation from Disability Support Service (301-314-7682). If you are ill or encountering personal difficulties, please let the instructor know as soon as possible. You can also contact Learning Assistance Services (301-314-7693) and/or the Counseling Center (301-314-7651) for assistance.

Academic Integrity:
The University’s code of academic integrity is designed to ensure that the principle of academic honesty is upheld. Any of the following acts, when committed by a student, constitutes academic dishonesty:

- **CHEATING**: intentionally using or attempting to use unauthorized materials, information, or study aids in an academic exercise.
- **FABRICATION**: intentional and unauthorized falsification or invention of any information or citation in an academic exercise.
• **FACILITATING ACADEMIC DISHONESTY**: intentionally or knowingly helping or attempting to help another to violate any provision of this code.

• **PLAGIARISM**: intentionally or knowingly representing the words or ideas of another as one's own in any academic exercise.

For more information see: [http://www.shc.umd.edu/code.html](http://www.shc.umd.edu/code.html).

The Honor Pledge is a statement undergraduate and graduate students should be asked to write by hand and sign on examinations, papers, or other academic assignments. The Pledge reads:

*I pledge on my honor that I have not given or received any unauthorized assistance on this assignment/examination.*

The University of Maryland, College Park has a nationally recognized Code of Academic Integrity, administered by the Student Honor Council. This Code sets standards for academic integrity at Maryland for all undergraduate and graduate students. As a student you are responsible for upholding these standards for this course. It is very important for you to be aware of the consequences of cheating, fabrication, facilitation, and plagiarism. For more information on the Code of Academic Integrity or the Student Honor Council, please visit [http://www.shc.umd.edu](http://www.shc.umd.edu).

Inclement Weather / University Closings:
In the event that the University is closed for an emergency or extended period of time, the instructor will communicate to students regarding schedule adjustments, including rescheduling of examinations and assignments due to inclement weather and campus emergencies. Official closures and delays are announced on the campus website ([http://www.umd.edu](http://www.umd.edu)) and snow phone line (301-405-SNOW), as well as local radio and TV stations.

**Course Evaluations**
The University, the School of Public Health, and the Department of XXX are committed to the use of student course evaluations for improving the student experience, course and curriculum delivery, and faculty instruction. Your evaluations help instructors improve their courses; help deans and department chairs decide on merit pay for faculty, renewal of contracts, and support tenure and promotion decisions; and help current and future students decide on classes. The system ([www.CourseEvalUM.umd.edu](http://www.CourseEvalUM.umd.edu)) will open Tuesday, April 24th and close on Friday, May 11th for Spring 2012 courses.

**Copyright Notice**: Class lectures and other materials are copyrighted by me, the course instructor. This includes all tangible course materials, including but not limited to written or recorded lecture, PowerPoint presentations, handouts, tests, and other assignments. These materials **may not** be reproduced (e.g. students may not copy and distribute these materials) for anything other than personal use without my explicit written permission.
<table>
<thead>
<tr>
<th>Lecture Topics</th>
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<tbody>
<tr>
<td><strong>Introduction to this course and overview of epidemiologic research</strong></td>
</tr>
<tr>
<td>(1) Introduction to this course</td>
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<tr>
<td>(2) Type of populations</td>
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<td>(3) Aims of epidemiologic research and practice</td>
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<td>(4) Hypothesis and study design</td>
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<td>(5) Quantitative procedures in epidemiologic methods</td>
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<td>(6) Concept of counterfactual theory</td>
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**Reading:**

<table>
<thead>
<tr>
<th>Study design: Ecologic studies</th>
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<tbody>
<tr>
<td>(1) Aggregate measures</td>
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<tr>
<td>(2) Ecologic data analysis</td>
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<td>(3) Ecological fallacy</td>
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<td>(4) Strength and limitation</td>
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**Reading:**

**Homework 1**

<table>
<thead>
<tr>
<th>Study design: Cohort studies</th>
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<tbody>
<tr>
<td>(1) Basic observational study designs</td>
</tr>
<tr>
<td>(2) Elements of cohort studies</td>
</tr>
<tr>
<td>(3) Dynamic population</td>
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<td>(4) Strength and limitation</td>
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**Reading:**

<table>
<thead>
<tr>
<th>Study design: Case-control studies</th>
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<tbody>
<tr>
<td>(1) Basic case-control studies</td>
</tr>
<tr>
<td>(2) Critical assumption in case-control studies</td>
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<tr>
<td>(3) Selection of cases and controls</td>
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<tr>
<td>(4) Population-based case-control studies</td>
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<tr>
<td>(5) Strength and limitation</td>
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**Reading:**

**Homework 2**
### Study design: Cross-sectional studies

1. Elements of cross-sectional studies
2. Examples of National surveys
3. Strength and limitation

**Reading:**


### Study design: Experimental studies

Two basic study designs
1. Randomized controlled trials
2. Crossover trials

General procedures for clinical trials
1. Selection of study subjects
2. Sample size determination
3. Recruitment of subjects
4. Randomization allocation
5. Follow up and data collection
6. Blinding
7. Compliance or adherence
8. Analysis of the results

**Reading:**


### Measures of disease occurrence

1. Outcomes of epidemiologic research
2. Review of epidemiological measures
3. Review of frequency measures
4. Incidence based on individuals at risk
   - General Cumulative incidence (Risk)
   - Life-table method of cumulative incidence (risk) estimation
   - Kaplan-Meier (KM) method of CI estimation
   - Assumptions
5. Incidence based on person-time units at risk Incidence Density (ID)
6. Comparison between measures of incidence
7. Measures of prevalence
8. Relationship between prevalence and incidence

**Reading:**

7. Vu TT, Nguyen CK, Nguyen TL, Le BM, NguyenTrung Le D, Bui TN, Nakamori M,

**Homework 3**

### Measures of association and impact

**Cohort studies:**
- (1) Risk ratio (RR), odds ratio of disease (DOR), and Incidence ratio (IDR)

**Cross-sectional, case-control, and ecologic studies:**
- (1) Prevalence ratio (PR) and prevalence odds ratio (POR)
- (2) Disease OR and Exposure OR
- (3) OR as an estimate of RR in case-control studies
- (4) Calculation of OR when there are more than 2 exposure categories
- (5) RR in ecologic studies

**Reading:**

**Homework 4**

### Bias in epidemiologic studies: Selection bias

- (1) Selection bias
- (2) Type of selection bias
  - Self-selection bias
  - Selective loss to follow-up
  - Selective survival bias
  - Berkson’s bias
  - Detection bias
  - Temporal ambiguity bias
- (2) Dealing with selection bias

**Reading:**

### Bias in epidemiologic studies: Information bias

- (1) Reliability and validity
- (2) Valid studies
(3) Exposure identification bias
   Recall bias
   Interviewer bias
   Approach to prevent recall and interview bias
(4) Outcome identification bias
   Observer bias:
   Respondent bias
   Approach to prevent observer and respondent bias
(5) Consequence of information bias
   Differential misclassification bias
   Non-differential misclassification bias

Reading:

Bias in epidemiologic studies: Confounding
(1) Property of confounders
(2) Adjusting for confounding: Stratification Methods
(3) How to identify a confounder?
   The prior knowledge strategy (knowledge-driven approach)
   The “change-in-estimate” (CIE) strategy (data-driven approach)
(4) Methods to controlling for confounding
   At the stage of design and execution
   At the stage of data analysis

Reading:

Homework 5

Interaction effect
(1) Homogeneity/heterogeneity of effects
(2) Comparison between joint expected and joint observed effects
(3) Assessment of interaction effect in cohort and case-control studies
(4) Interaction and confounding
(5) Reporting of interaction effect

Reading:

Homework 6