Course Description:
The course focuses on the application of epidemiologic study designs and analytic methods used for analysis of data collected from cohort, case-control, and cross-sectional studies and clinical trials. 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 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 interaction effects. It extends the concepts and methods of epidemiology from EPIDB610 and 611.

Course Pre- and Co-requisites:
- Required: EPIB 610 Foundations of Epidemiology, EPIB 650 Biostatistics I, and EPIB 611 Intermediate Epidemiology
- Recommended: None

Course Learning Objectives:
Upon completing this course, the student 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, execution of the study, 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 study designs and approaches to evaluate their likely direction, magnitude, and nature of their threats 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 in epidemiology are addressed in this course:
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.

**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, 3rd edition, Champan & Hall/CRC, 2013
- Moyses Szko 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 a calculator or SAS to do their homework.

**Course Requirements:**
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 the instructor 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 and crucial for success in the course. Excessive lateness or absence from class is disruptive to the class and your learning. **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.

**Major Graded Assignments:**

**Hands-on exercise (35 points)**
Seven sets of hands-on exercises 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 on CAVAS one week before the due dates.

**Group presentation (10 points)**
The group presentation will be given between 1:00 pm -3:45 pm on November 03, 2014 (tentative date). Students will be divided into two or three groups. Each group will critique a research proposal and make a 30-minute power-point presentation. Your instructor will give you a copy of a research proposal in his grant application. After the presentation, students in the other group and your instructor will ask questions for the presenting group (10 minutes). You will be taught how to critique a research proposal in the class. Your instructor will grade the presentations in the unit of team work, that is, everyone in the group will get the same credit point. After grading, your instructor will give you a copy of NIH reviewers’ comments on the grant application so that you are able to learn from experts.

**Final Exam (40 points)**

A final exam will be given between in the final exam week. Formats of the final exam include multiple choices, true or false, short answers, and calculations. It is an open-book exam.

**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 3 pages in Word. Use 11-point Arial as the minimum font size for the text of the protocol. 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 December 8, 2014 (before the class).

**Contents and Grade of final project**

<p>| | |</p>
<table>
<thead>
<tr>
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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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<tr>
<td>3. Selecting an appropriate study design and briefly stating the reasons for the selection</td>
<td>4 Points</td>
</tr>
<tr>
<td>4. Describing and explaining the major variables of interest, i.e., select one for each of the outcome, exposure, and modifiers.</td>
<td>1 points</td>
</tr>
<tr>
<td>5. Listing potential information bias, selection bias, and confounding that may take place in your selected study design. Briefly stating your rationales</td>
<td>5 points</td>
</tr>
</tbody>
</table>
6. Stating approaches that you will use to prevent or eliminate the potential bias listed in 5. 2 points

7. Statistic approaches used to test the hypothesis 1 points

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.

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.

**Course Evaluations**
The University, the School of Public Health, and the Department of Epidemiology and Biostatistics 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. You will be notified when the system ([www.CourseEvalUM.umd.edu](http://www.CourseEvalUM.umd.edu)) is open.

**Grading Procedures:**
Your final grade will be determined by scores of final exam (40%), homework (35%), group presentation (10%), and research project (15%).

**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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<td>94-96</td>
<td>A</td>
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<tr>
<td>90-93</td>
<td>A-</td>
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<tr>
<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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<td>70-73</td>
<td>C-</td>
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<tr>
<td>60-69</td>
<td>D</td>
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<tr>
<td>&lt; 60</td>
<td>F</td>
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</tbody>
</table>

**Course Outline / Course Calendar:**

<table>
<thead>
<tr>
<th>Session</th>
<th>Date (Tentative)</th>
<th>Topic</th>
<th>Assignments (Tentative)</th>
</tr>
</thead>
<tbody>
<tr>
<td># 1</td>
<td>09/08</td>
<td>Lecture 1: Introduction to this course and overview of epidemiologic research</td>
<td></td>
</tr>
</tbody>
</table>
| # 2     | 09/15            | Lecture 2: Study design: Cohort studies  
Lecture 3: Study design: Cross-sectional studies | Homework 1 (Due on 10/06) |
<p>| # 3     | 09/22            | Lecture 4: Study design: Case-control studies |             |</p>
<table>
<thead>
<tr>
<th>#</th>
<th>Day/Date</th>
<th>Topic</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td># 4</td>
<td>09/29</td>
<td>Lecture 4: Study design: Case-control studies</td>
<td></td>
</tr>
<tr>
<td># 5</td>
<td>10/06</td>
<td>Lecture 5: Study design: Experimental studies</td>
<td>Homework 2 (due on 10/13)</td>
</tr>
<tr>
<td># 6</td>
<td>10/13</td>
<td>Lecture 6: Measures of disease occurrence</td>
<td>Homework 3 (due on 10/20)</td>
</tr>
<tr>
<td># 7</td>
<td>10/20</td>
<td>Lecture 7: Measures of association and impact</td>
<td>Homework 4 (due on 10/27)</td>
</tr>
<tr>
<td># 8</td>
<td>10/27</td>
<td>Lecture 8: Bias in epidemiologic studies: Selection bias</td>
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<tr>
<td></td>
<td></td>
<td>Lecture 9: Bias in epidemiologic studies: Information bias</td>
<td></td>
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<tr>
<td># 9</td>
<td>11/03</td>
<td>Group presentations</td>
<td></td>
</tr>
<tr>
<td># 10</td>
<td>11/10</td>
<td>Lecture 10: Bias in epidemiologic studies: Confounding</td>
<td>Homework 5 (Due on 11/24)</td>
</tr>
<tr>
<td># 11</td>
<td>11/17</td>
<td>Lecture 10: Bias in epidemiologic studies: Confounding</td>
<td></td>
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<tr>
<td># 12</td>
<td>11/24</td>
<td>Lecture 10: Bias in epidemiologic studies: Confounding</td>
<td></td>
</tr>
<tr>
<td># 13</td>
<td>12/01</td>
<td>Lecture 11: Interaction effect</td>
<td>Homework 6 (due on 12/08)</td>
</tr>
<tr>
<td># 14</td>
<td>12/08</td>
<td>Lecture 12: Use logistic regression to assess interaction effects and control for confounding</td>
<td>Homework 7 (due on the final exam day)</td>
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<tr>
<td># 15</td>
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</table>

Note: Numbers in brackets after learning objectives show linkage between material covered in each session and the numbered program competencies shown on page 1 of this syllabus.

### Required Session Outline

**Session 1**

<table>
<thead>
<tr>
<th>Day/Date</th>
<th>Topic</th>
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</thead>
<tbody>
<tr>
<td></td>
<td><strong>Lecture 1: Introduction to this course and overview of epidemiologic research</strong></td>
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<tr>
<td></td>
<td>1. Introduction to this course</td>
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<tr>
<td></td>
<td>2. Type of populations</td>
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<td></td>
<td>3. Aims of epidemiologic research and practice</td>
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<td></td>
<td>4. Hypothesis and study design</td>
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<td></td>
<td>5. Quantitative procedures in epidemiologic methods</td>
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<td></td>
<td>6. Counterfactual theory in epidemiology</td>
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</tbody>
</table>

Learning Objectives for Session (#1 in “Program Competencies Addressed in this Course” on page 1)

- Overview the course
- Understand types of study populations.
- Improve ability to develop a research hypothesis
- Understand the counterfactual theory to

Required and recommended readings:


**Session 2**

<table>
<thead>
<tr>
<th>Day/Date</th>
<th>Topic</th>
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</thead>
<tbody>
<tr>
<td></td>
<td><strong>Lecture 2: Study design: Cohort studies</strong></td>
</tr>
<tr>
<td></td>
<td>1. Basic observational study designs</td>
</tr>
</tbody>
</table>
Lecture 3: Study design: Cross-sectional studies

- 2. Elements of cohort studies
- 3. Dynamic population
- 4. Strength and limitation

Learning Objectives for Session (#1 and #4)
- Able to design and conduct cohort and cross-sectional studies
- Understand in what conditions that a cohort or cross-sectional study needs to be used.

Required and recommended readings

<table>
<thead>
<tr>
<th>Session 3</th>
<th>Day/Date</th>
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</thead>
<tbody>
<tr>
<td>Topic</td>
<td></td>
</tr>
<tr>
<td>Lecture 4: Study design: Case-control studies</td>
<td></td>
</tr>
<tr>
<td>1. Basic case-control studies</td>
<td></td>
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<tr>
<td>2. Critical assumption in case-control studies</td>
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<tr>
<td>3. Selection of cases</td>
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<tr>
<td>4. Principles of control selection</td>
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<tr>
<td>Base population principle</td>
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<tr>
<td>Deconfounding principle</td>
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<tr>
<td>Comparable accuracy principle.</td>
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</tbody>
</table>

Required and recommended readings

<table>
<thead>
<tr>
<th>Session 4</th>
<th>Day/Date</th>
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<tbody>
<tr>
<td>Topic</td>
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<tr>
<td>Lecture 4: Study design: Case-control studies</td>
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<tr>
<td>5. Population-based case-control studies</td>
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<tr>
<td>6. Case-crossover studies</td>
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<tr>
<td>7. Strength and limitation</td>
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</table>

Learning Objectives for Session (#1 and #4)
- Understand the principle of case-control studies
- Ability to design and conduct case-control studies

<table>
<thead>
<tr>
<th>Session 5</th>
<th>Day/Date</th>
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</thead>
<tbody>
<tr>
<td>Hands-on exercise one</td>
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</tbody>
</table>
### Lecture 5: Study design: Experimental studies

1. Two basic study designs
   - (1) Randomized controlled trials
   - (2) Crossover trials

2. 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

3. Strategies for RCT data analysis
   - (1) Intention-to-treatment (ITT) analysis
   - (2) Treatment-received analysis (TR)

### Learning Objectives for Session (#2 and #3)
- Understand the application of experimental studies
- Design a valid RCT
- Able to analyze data collected in RCTs

### Required and recommended readings

### Hands-on exercise two

### Session 6

<table>
<thead>
<tr>
<th>Topic</th>
<th>Day/Date</th>
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</table>

### Lecture 6: 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
   - (1) General Cumulative incidence (Risk)
   - (2) Life-table method of cumulative incidence (risk) estimation
   - (3) Kaplan-Meier (KM) method of CI estimation
   - (4) Assumptions
5. Incidence based on person-time units at risk
6. Comparison between measures of incidence
7. Measures of prevalence
8. Relationship between prevalence and incidence

### Learning Objectives for Session (#3, #4, #5)
- Able to select most appropriate measures
- Able to estimate risk, rate, and prevalence in different study designs
Hands-on exercise three

<table>
<thead>
<tr>
<th>Session 7</th>
<th>Day/Date</th>
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</thead>
<tbody>
<tr>
<td>Topic</td>
<td></td>
</tr>
<tr>
<td><strong>Lecture 7: Measures of association and impact</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Cohort studies:</strong></td>
<td></td>
</tr>
<tr>
<td>Risk ratio (RR), odds ratio of disease (DOR), and Incidence ratio (IDR)</td>
<td></td>
</tr>
<tr>
<td><strong>Cross-sectional, case-control, and ecologic studies:</strong></td>
<td></td>
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<tr>
<td>(1) Prevalence ratio (PR) and prevalence odds ratio (POR)</td>
<td></td>
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<tr>
<td>(2) Disease OR and Exposure OR</td>
<td></td>
</tr>
<tr>
<td>(3) OR as an estimate of RR in case-control studies</td>
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<tr>
<td>(4) Calculation of OR when there are more than 2 exposure categories</td>
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<tr>
<td>(6) RR in ecologic studies</td>
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</tbody>
</table>

Learning Objectives for Session (#3, #4, and #5)
- Understand the measure of association and impact
- Enable to use best measure in different study designs.

Required and recommended readings

Hands-on exercise four

<table>
<thead>
<tr>
<th>Session 8</th>
<th>Day/Date</th>
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</thead>
<tbody>
<tr>
<td>Topic</td>
<td></td>
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<tr>
<td><strong>Lecture 8: Bias in epidemiologic studies: Selection bias</strong></td>
<td></td>
</tr>
<tr>
<td>1. Selection bias</td>
<td></td>
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<tr>
<td>2. Type of selection bias</td>
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<tr>
<td>3. Self-selection bias</td>
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<td>4. Selective loss to follow-up</td>
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<td>5. Selective survival bias</td>
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<td>6. Berkson's bias</td>
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<td>7. Detection bias</td>
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<td>8. Temporal ambiguity bias</td>
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<tr>
<td>9. Dealing with selection bias</td>
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</tr>
</tbody>
</table>

**Lecture 9: 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

Learning Objectives for Session (#4, #5)
- Identify different bias in epidemiologic studies
- Control for bias at different stages in a study

Required and recommended readings

Assignments – explanation and due date

Session 9
Day/Date
Topic
Group presentations

Learning Objectives for Session (#1 and #5)
- Evaluate a study design in a grant application
- Critically appraise a study
- Improve the quality of a study

Session 10/11/12
Day/Date
Topic
Lecture 10: Bias in epidemiologic studies: Confounding
1. Review of Concept of counterfactual conditions
2. Property of confounders
3. Directed Acyclic Graphics (DAGs) in causal inference
   Concept and terminology
   Assumption in using DAGs
   Graphical representation of confounding
   Minimal sufficient adjustment models
4. Adjusting for confounding: Stratification Methods
5. How to identify a confounder?
   The prior knowledge strategy (knowledge-driven approach)
   The “change-in-estimate” (CIE) strategy (data-driven approach)
6. Caveats in use conventional roles for confounding
7. Methods to controlling for confounding
   At the stage of design and execution
   At the stage of data analysis

Learning Objectives for Session (#1 and #3)
- Understanding confounding issues in epidemiologic studies
- Identify confounders at the stage of study design, execution, data collection and data analysis
- Able to control for confounding

Required and recommended readings

Hands-on exercise five

Session 13

Topic
Lecture 11: 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

Learning Objectives for Session (#1 and #3)
- Understand interaction effect
- Differentiate confounding and interaction
- Estimate interaction effect
- Interpret findings

Required and recommended readings

Assignments – explanation and due date

Session 14

Topic
Lecture 12: Use logistic regression to assess interaction effects and control for confounding
   1. Review RR, OR and logistic regression model
   2. Reasons for using logistic regression control for confounding
   3. Multiple logistic regression model
   4. Assumptions in logistic regression model
   5. Modeling strategy guidelines
      (1) Variable selection
      (2) Interaction assessment
      (3) Confounding assessment
6. A common mistake: use of bivariable analysis to screen candidates in multiple logistic regression
7. Use "Tests of regression", "R2" and "test of fit" with caution
8. Ordinal logistic regression: the Proportional odds model
9. Conditional logistic regression

Learning Objectives for Session (#3)
- Apply epidemiologic principles in data analysis
- Understand logistic regression
- Ability to use it to control for confounding
- Ability to use it to estimate interaction effects

Required and recommended readings

Hands-on exercise seven

Critical university policies:

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.