

PubH 6342
Epidemiologic Methods II
Spring 2016

Credits: 3
Meeting Days: Tuesdays and Thursdays
Meeting Time: 4:00-5:15 p.m.
Meeting Place: Jackson Hall 2-137

Instructor: **Jim Pankow**, PhD, MPH
Office Address: Room 452, 1300 S. 2nd St. (WBOB)
Office Phone: 612-624-2883
Fax: 612-624-0315
E-mail: pankow@umn.edu
Office Hours: Tuesdays, 2:30-3:30pm, C-302 Mayo

Instructor: **Claudia Muñoz-Zanzi**, DVM, MPVM, PhD
Office Address: Room 484, 1300 S. 2nd St. (WBOB)
Office Phone: 612-626-2849
Fax: 612-624-0315
E-mail: munozzan@umn.edu
Office Hours: Thursdays, 2:30-3:30pm, C-302 Mayo

Teaching Assistant: **Steven Nguyen**, MPH
E-mail: nguy2295@umn.edu
Office Hours: TBD, SPHere

Teaching Assistant: **Adrita Rahman**, MPH
E-mail: rahma139@umn.edu
Office Hours: TBD

I. Course Description

This intermediate course covers methods and techniques for designing, implementing, analyzing, and interpreting observational epidemiologic studies, including cohort, case-control, and cross-sectional studies. It is the second course in a three course sequence on the theory and practice of epidemiology. This course is designed primarily for MPH students majoring in epidemiology. Students from other programs, particularly those who seek a more in-depth coverage of epidemiologic concepts and methods beyond those provided by an introductory course, are also welcome to enroll. Students primarily interested in the design and analysis of experimental studies are encouraged to take PubH 7420 (Clinical Trials: Design, Implementation, and Analysis) and/or PubH 6363 (Design and Analysis of Group-Randomized Trials in Epidemiology).

Acknowledgments

The content of PubH 6342 has been developed by Jim Pankow and Claudia Muñoz-Zanzi. Dr. Eyal Shahar contributed to the early conceptual development of the course. The instructors also acknowledge former teaching assistants for their contributions to the course.

II. Course Prerequisites

- a. Epidemiologic Methods I (PubH 6341; grade of B- or higher), Fundamentals of Epidemiology (PubH 6320; grade of A- or higher), or equivalent
- b. Biostatistics I (PubH 6450; grade of B- or higher), Biostatistical Literacy (PubH 6414; grade of B- or higher), or equivalent

Special note for students proceeding to Epidemiologic Methods III (PubH 6343): Biostatistics II (PubH 6451) is a prerequisite for Epidemiologic Methods III. If you wish to take Epidemiologic Methods III in Fall 2016, you should be enrolled in Biostatistics II this semester (Spring 2016).

III. Course Goals and Objectives

As a result of this course, students will be able to:

1. Develop procedures for subject selection and recruitment, including sampling and methods to enhance participation rates and response.
2. Apply principles of observational study design, including variants of the case-control design, use of matching, and sample size and power calculations.
3. Select and develop appropriate exposure and outcome measurement procedures, including questionnaires, interviews, collection of biological specimens, physical measurements, and quality control and assurance methods.
4. Apply principles of observational study analysis, including survival analysis through Kaplan-Meier and person-time approaches.
5. Identify major sources of bias (i.e., information, selection, and confounding bias) in observational epidemiologic studies and ways to evaluate their likely direction, magnitude, and nature of their threat to causal inference.
6. Apply strategies to assess joint effects of exposures.
7. Apply epidemiologic study designs and methods in public health surveillance and evaluation of screening.
8. Evaluate epidemiologic methods through critical review of published epidemiologic research.

IV. Methods of Instruction and Work Expectations

Instruction will be through a combination of lectures, discussions, in-class exercises, reviews of published articles, and assignments. Students are expected to come to class having read the assigned readings and notes for the class. Students are expected to turn in assignments on time and take exams at the scheduled times as well. Exceptions to deadlines will be determined on a case-by-case basis.

Communication about course materials

We ask you to post questions about the course assignments and materials in the “Q&A Discussion Forum” near the top of the Moodle course site. The instructors and teaching assistant will monitor the discussion

forum to answer questions, but active discussion between students is encouraged as well. Please post any questions you have in the discussion forum, as opposed to emailing questions to the instructors and teaching assistant directly, so that everyone in the class can benefit from the discussion.

V. Course Text and Readings

The course does not have a required text. Readings are provided through links on the course website.

VI. Course Outline / Weekly Schedule

The schedule for the semester is organized according to the foundational steps* for designing and implementing an epidemiologic study:

1. Identifying the research question and the population of interest
2. Taking a sample of the population
3. Conceptualizing and creating measures of exposures and health indicators
4. Estimating measures of association between exposures and health indicators
5. Evaluating whether the observed association is causal
6. Assessing the evidence for causes working together

*Keyes KM and Galea S. *Am J Epidemiol* 2014; 180: 661-668.

Near the end of the course we will also address several topics important for epidemiologists working in public health practice (e.g., screening; public health surveillance).

Class	Date	Instructor(s)	Topic
1	1/19	Pankow	Introduction to the course; review of major concepts from Epi Methods I
2	1/21	Pankow	Identifying the study question and sampling from a population of interest Readings: Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. <i>Designing Clinical Research</i> (4 th ed), Chapter 2: Conceiving the research question and developing the study plan. Ness NB. Tools for innovative thinking in epidemiology. <i>Am J Epidemiol</i> 2012; 175: 733-738. Paneth N. Restoring science to the National Children’s Study. <i>JAMA</i> 2013; 309: 1775-1776. Rothman KJ, Gallacher JE, Hatch EE. Why representativeness should be avoided. <i>Int J Epidemiol</i> 2013; 42: 1012-1014.
3	1/26	Pankow	Cross-sectional studies: design options Reading: Szklo and Nieto, chapter 1.2 (p. 4-14); chapter 4.4.2 (p. 135-140) In-Class Participation Exercise

4	1/28	Pankow	Case-control and cohort studies: design options I Readings: Szklo and Nieto, chapter 1.4.1 and 1.4.2 (p. 19-30) Knol MJ, Vandenbroucke JP, Scott P, Egger M. What do case-control studies estimate? Survey of methods and assumptions in published case-control research. <i>American Journal of Epidemiology</i> 2008; 168: 1073-1081. Pearce N. What does the odds ratio estimate in a case-control study? <i>International Journal of Epidemiology</i> 1993; 22: 1189-1192. Due: Homework Assignment #1 – Study Question and Sampling (completed in Moodle)
5	2/2	Pankow	Case-control and cohort studies: design options II Readings: Szklo and Nieto, chapter 1.4.4 and 1.4.5 (p. 32-38) Maclure M and Mittleman MA. Should we use a case-crossover design? <i>Annu Rev Public Health</i> 2000; 21: 193-221.
6	2/4	All	Review of published paper and discussion Reading: TBD Note: Some students may meet elsewhere and not in the regular classroom
7	2/9	Pankow	Sample size estimation Reading: Hulley, <i>Designing Clinical Research</i> , chapters 5-6 In-Class Participation Exercise Due: Homework Assignment #2 – Case-control designs
8	2/11	All	Study design project; introduction and begin working in groups Note: Some students will meet elsewhere and not in the regular classroom
9	2/16	Muñoz-Zanzi	Principles of exposure measurement In-Class Participation Exercise
10	2/18	Pankow	Designing questionnaires and data collection instruments Reading: Fowler F. Designing questions to be good measures. In: <i>Survey Research Methods</i> . Thousand Oaks, CA: SAGE Publications, 2002, pp. 76-95. In-Class Participation Exercise Due: Group preliminary report (study design project)

17	3/22	Muñoz-Zanzi	<p>Review of published paper and discussion</p> <p>Reading: TBD</p> <p>In-Class Participation Exercise</p> <p>Due: Preliminary individual report (study design project)</p>
18	3/24	Pankow	<p>Using causal models to identify confounders</p> <p>Reading: Szklo and Nieto, chapter 5 (p. 153-180)</p>
19	3/29	All	<p>Study design project: instructor feedback</p> <p>Note: Some students will meet elsewhere and not in the regular classroom</p> <p>Due: Online Midterm Quiz</p>
20	3/31	Pankow	<p>Strategies to address confounding</p> <p>Reading: Szklo and Nieto, chapter 7.1 to 7.3.4 (p. 229-248)</p>
21	4/5	Pankow	<p>Mendelian randomization: a new tool to address the threat of confounding</p> <p>Reading: Burgess S et al. Mendelian randomization: where are we now and where are we going? <i>Int J Epidemiol</i> 2015; 44: 379-388.</p>
22	4/7	Muñoz-Zanzi	<p>Methods in infectious disease epidemiology</p> <p>Due: Homework Assignment #5 – Confounding adjustment</p>
23	4/12	Pankow	<p>Strategies to address selection and information bias</p> <p>Reading: Szklo and Nieto, chapter 4.1 to 4.3 (p. 110-134)</p> <p>Olson SH et al. Reporting participation in case-control studies. <i>Epidemiology</i> 2002; 13: 123-126.</p> <p>Cotter RB et al. Contacting participants for follow-up: how much effort is required to retain participants in longitudinal studies? <i>Eval Program Plann</i> 2005; 28: 15-21.</p>

24	4/14	Pankow	Strategies to assess effect modification Readings: Szklo and Nieto, chapter 6 (p. 185-222) Knol MJ, Egger M, Scott P, Geerlings MI, Vandenbroucke JP. When one depends on the other: reporting of interaction in case-control and cohort studies. <i>Epidemiology</i> 2009; 20: 161-166 Knol MJ, et al. The (mis)use of overlap of confidence intervals to assess effect modification. <i>Eur J Epidemiol</i> 2011; 26: 253-254. Optional: Thompson WD. Effect modification and limits of biological inference from epidemiologic data. <i>J Clin Epidemiol</i> 1991; 44: 221-232. Goodman S. A dirty dozen: twelve P-value misconceptions. <i>Seminars in Hematology</i> 2008; 45: 135-140. Stang A, Poole C, Kuss O. The ongoing tyranny of statistical significance testing in biomedical research. <i>Eur J Epidemiol</i> 2010; 225-230.
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**Due: Homework Assignment #6 – Infectious Disease Modeling
In-Class Participation Exercise**

25	4/19	Muñoz-Zanzi	Study design project: broader issues for consideration Note: Some students will meet elsewhere and not in the regular classroom
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26	4/21	All	Study design project: synthesis and final discussion Note: Some students will meet elsewhere and not in the regular classroom Due: Final study design project report
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27	4/26	Muñoz-Zanzi	Screening Readings: Szklo and Nieto, chapter 4.4.3 (p. 140-147) Harris R. Overview of screening: where we are and where we may be headed. <i>Epidemiologic Reviews</i> 2011; 33: 1-6.
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In-Class Participation Exercise

28	4/28	Muñoz-Zanzi	Public health surveillance: study design, biases, data analysis Reading: Pia MacDonald. <i>Methods in Field Epidemiology</i> . Chapter 3 (p. 23-54) In-Class Participation Exercise Due: Homework Assignment #7 - Bias analysis and Effect Modification Also due by Monday, 5/2 at 9am: participation exercise (question for expert panel on public health surveillance)
29	5/3	All	Public health surveillance: expert panel discussion
30	5/5	All	Review session
	5/10		Final Exam (4:00-6:00pm)

VII. Evaluation and Grading

Students will be evaluated through a combination of class participation, homework assignments, midterm quiz, study design project, and final exam. Both A/F and S/N grading options are available. MPH students majoring in epidemiology are required to take the A/F option and achieve a grade of B- or higher to advance in the program.

Class participation - 10%

Class participation will be based on participation in ten ungraded exercises: nine exercises will be completed in class and be worth 1% each (1/26, 2/9, 2/16, 2/18, 3/22, 4/14, 4/21, 4/26, 4/28); in addition, one exercise (question for the expert panel on public health surveillance) will be submitted via the course Moodle site by 5/2. Class participation exercises are noted in the class schedule. Make-ups for class participation will be granted if the student sends an e-mail notification to one of the instructors before the class in which the class participation point is offered in order to indicate an anticipated absence.

Homework Assignments – 30%

There will be seven homework assignments. Students will submit six of these for evaluation; each contributes 5% toward the final grade. If a student chooses to complete all seven assignments, the highest six scores will be counted toward the final grade. All assignments are due at the beginning of class (4:00pm) on the date indicated in the class schedule. Unless otherwise directed, please upload your assignment to the Moodle site. Late assignments will lose 1% (i.e., 1 point out of 5) per business day (Saturdays and Sundays excluded).

1. Study question and sampling (due 1/28)
2. Case-control designs (due 2/9)
3. Diagnostic tests (due 3/1)
4. Analysis of longitudinal data (due 3/10)
5. Confounding adjustment (due 4/7)
6. Infectious disease modeling (due 4/14)
7. Bias analysis and effect modification (due 4/28)

Midterm Quiz – 5%

There will be a short open-notes midterm quiz completed online (due 3/29)

Study design project – 30%

Students will initially work together in groups of 3-4 to develop a tentative research hypothesis and study design to investigate an infectious or chronic disease outcome due 2/18 (5% of grade). Students will be able to choose which of the two available outcomes they wish to study, but membership in groups will be assigned by the instructors. After the initial group submission, each student will then work individually to submit a preliminary report due 3/22 (5% of grade) and final report due 4/21 (worth 20% of grade) describing their research plan.

Final exam – 25%

There will be a final comprehensive exam during finals week (5/10).

Final grades will be assigned as follows:

100.0 - 92.5	A	Represents achievement that is outstanding relative to the level necessary to meet course requirements
90.0 - 92.4	A-	
87.5 - 89.9	B+	Represents achievement that is significantly above the level necessary to meet course requirements
82.5 - 87.4	B	
80.0 - 82.4	B-	
77.5 - 79.9	C+	
72.5 - 77.4	C	Represents achievement that meets the course requirements in every respect
70.0 - 72.4	C-	
67.5 - 69.9	D+	
62.5 - 67.4	D	Represents achievement that is worthy of credit though it fails to meet fully the course requirements
60.0 - 62.4	D-	
< 60	F	Represents failure and signifies that the work was completed but not a level of achievement worthy of credit.
	S	Represents achievement that is satisfactory, which is equivalent to a C- or better
	N	Represents no credit and signifies that the work was not completed at a satisfactory level of achievement and carries no grade points.

For additional information, please refer to:

<http://policy.umn.edu/Policies/Education/Education/GRADINGTRANSCRIPTS.html>.

Course Evaluation

The SPH will collect student course evaluations electronically using a software system called CoursEval: www.sph.umn.edu/courseeval. The system will send email notifications to students when they can access and complete their course evaluations. Students who complete their course evaluations promptly will be able to access their final grades just as soon as the faculty member renders the grade in SPHGrades: www.sph.umn.edu/grades. All students will have access to their final grades through OneStop two weeks after the last day of the semester regardless of whether they completed their course evaluation or not. Student feedback on course content and faculty teaching skills are an important means for improving our work. Please take the time to complete a course evaluation for each of the courses for which you are registered.

Incomplete Contracts

A grade of incomplete "I" shall be assigned at the discretion of the instructor when, due to extraordinary circumstances (e.g., documented illness or hospitalization, death in family, etc.), the student was prevented from completing the work of the course on time. The assignment of an "I" requires that a contract be initiated and completed by the student before the last official day of class, and signed by both the student and instructor. If an incomplete is deemed appropriate by the instructor, the student in consultation with the instructor, will specify the time and manner in which the student will complete course requirements. Extension for completion of the work will not exceed one year (or earlier if designated by the student's college). For more information and to initiate an incomplete contract, students should go to SPHGrades at: www.sph.umn.edu/grades.

University of Minnesota Uniform Grading and Transcript Policy

A link to the policy can be found at onestop.umn.edu.

VIII. Other Course Information and Policies

Grade Option Change (if applicable):

For full-semester courses, students may change their grade option, if applicable, through the second week of the semester. Grade option change deadlines for other terms (i.e. summer and half-semester courses) can be found at onestop.umn.edu.

Course Withdrawal:

Students should refer to the Refund and Drop/Add Deadlines for the particular term at onestop.umn.edu for information and deadlines for withdrawing from a course. As a courtesy, students should notify their instructor and, if applicable, advisor of their intent to withdraw.

Students wishing to withdraw from a course after the noted final deadline for a particular term must contact the School of Public Health Office of Admissions and Student Resources at sph-ssc@umn.edu for further information.

Student Conduct Code:

The University seeks an environment that promotes academic achievement and integrity, that is protective of free inquiry, and that serves the educational mission of the University. Similarly, the University seeks a community that is free from violence, threats, and intimidation; that is respectful of the rights, opportunities, and welfare of students, faculty, staff, and guests of the University; and that does not threaten the physical or mental health or safety of members of the University community.

As a student at the University you are expected adhere to Board of Regents Policy: *Student Conduct Code*.

To review the Student Conduct Code, please see:

http://regents.umn.edu/sites/default/files/policies/Student_Conduct_Code.pdf.

Note that the conduct code specifically addresses disruptive classroom conduct, which means "engaging in behavior that substantially or repeatedly interrupts either the instructor's ability to teach or student learning. The classroom extends to any setting where a student is engaged in work toward academic credit or satisfaction of program-based requirements or related activities."

Use of Personal Electronic Devices in the Classroom:

Using personal electronic devices in the classroom setting can hinder instruction and learning, not only for the student using the device but also for other students in the class. To this end, the University establishes the right of each faculty member to determine if and how personal electronic devices are allowed to be used in the classroom. For complete information, please reference:

<http://policy.umn.edu/Policies/Education/Education/STUDENTRESP.html>.

Scholastic Dishonesty:

You are expected to do your own academic work and cite sources as necessary. Failing to do so is scholastic dishonesty. Scholastic dishonesty means plagiarizing; cheating on assignments or examinations; engaging in unauthorized collaboration on academic work; taking, acquiring, or using test materials without faculty permission; submitting false or incomplete records of academic achievement; acting alone or in cooperation with another to falsify records or to obtain dishonestly grades, honors, awards, or professional endorsement; altering, forging, or misusing a University academic record; or fabricating or falsifying data, research procedures, or data analysis. (Student Conduct Code:

http://regents.umn.edu/sites/default/files/policies/Student_Conduct_Code.pdf) If it is determined that a student has cheated, he or she may be given an "F" or an "N" for the course, and may face additional sanctions from the University. For additional information, please see:

<http://policy.umn.edu/Policies/Education/Education/INSTRUCTORRESP.html>.

The Office for Student Conduct and Academic Integrity has compiled a useful list of Frequently Asked Questions pertaining to scholastic dishonesty: <http://www1.umn.edu/oscai/integrity/student/index.html>. If you have additional questions, please clarify with your instructor for the course. Your instructor can respond to your specific questions regarding what would constitute scholastic dishonesty in the context of a particular class-e.g., whether collaboration on assignments is permitted, requirements and methods for citing sources, if electronic aids are permitted or prohibited during an exam.

Makeup Work for Legitimate Absences:

Students will not be penalized for absence during the semester due to unavoidable or legitimate circumstances. Such circumstances include verified illness, participation in intercollegiate athletic events, subpoenas, jury duty, military service, bereavement, and religious observances. Such circumstances do not

include voting in local, state, or national elections. For complete information, please see: <http://policy.umn.edu/Policies/Education/Education/MAKEUPWORK.html>.

Appropriate Student Use of Class Notes and Course Materials:

Taking notes is a means of recording information but more importantly of personally absorbing and integrating the educational experience. However, broadly disseminating class notes beyond the classroom community or accepting compensation for taking and distributing classroom notes undermines instructor interests in their intellectual work product while not substantially furthering instructor and student interests in effective learning. Such actions violate shared norms and standards of the academic community. For additional information, please see: <http://policy.umn.edu/Policies/Education/Education/STUDENTRESP.html>.

Sexual Harassment:

"Sexual harassment" means unwelcome sexual advances, requests for sexual favors, and/or other verbal or physical conduct of a sexual nature. Such conduct has the purpose or effect of unreasonably interfering with an individual's work or academic performance or creating an intimidating, hostile, or offensive working or academic environment in any University activity or program. Such behavior is not acceptable in the University setting. For additional information, please consult Board of Regents Policy: <http://regents.umn.edu/sites/default/files/policies/SexHarassment.pdf>

Equity, Diversity, Equal Opportunity, and Affirmative Action:

The University will provide equal access to and opportunity in its programs and facilities, without regard to race, color, creed, religion, national origin, gender, age, marital status, disability, public assistance status, veteran status, sexual orientation, gender identity, or gender expression. For more information, please consult Board of Regents Policy: http://regents.umn.edu/sites/default/files/policies/Equity_Diversity_EO_AA.pdf.

Disability Accommodations:

The University of Minnesota is committed to providing equitable access to learning opportunities for all students. The Disability Resource Center Student Services is the campus office that collaborates with students who have disabilities to provide and/or arrange reasonable accommodations. If you have, or think you may have, a disability (e.g., mental health, attentional, learning, chronic health, sensory, or physical), please contact DRC at 612-626-1333 or drc@umn.edu to arrange a confidential discussion regarding equitable access and reasonable accommodations. If you are registered with DS and have a current letter requesting reasonable accommodations, please contact your instructor as early in the semester as possible to discuss how the accommodations will be applied in the course. For more information, please see the DS website, <https://diversity.umn.edu/disability/>.

Mental Health and Stress Management:

As a student you may experience a range of issues that can cause barriers to learning, such as strained relationships, increased anxiety, alcohol/drug problems, feeling down, difficulty concentrating and/or lack of motivation. These mental health concerns or stressful events may lead to diminished academic performance and may reduce your ability to participate in daily activities. University of Minnesota services are available to assist you. You can learn more about the broad range of confidential mental health services available on campus via the Student Mental Health Website: <http://www.mentalhealth.umn.edu>.

The Office of Student Affairs at the University of Minnesota:

The Office for Student Affairs provides services, programs, and facilities that advance student success, inspire students to make life-long positive contributions to society, promote an inclusive environment, and enrich the University of Minnesota community. Units within the Office for Student Affairs include, the Aurora Center for Advocacy & Education, Boynton Health Service, Central Career Initiatives (CCE, CDes, CFANS), Leadership Education and Development – Undergraduate Programs (LEAD-UP), the Office for Fraternity and Sorority Life, the Office for Student Conduct and Academic Integrity, the Office for Student Engagement, the Parent Program, Recreational Sports, Student and Community Relations, the Student Conflict Resolution Center, the Student Parent HELP Center, Student Unions & Activities, University Counseling & Consulting Services, and University Student Legal Service.

For more information, please see the Office of Student Affairs at <http://www.osa.umn.edu/index.html>.

Academic Freedom and Responsibility:

Academic freedom is a cornerstone of the University. Within the scope and content of the course as defined by the instructor, it includes the freedom to discuss relevant matters in the classroom. Along with this freedom comes responsibility. Students are encouraged to develop the capacity for critical judgment and to engage in a sustained and independent search for truth. Students are free to take reasoned exception to the views offered in any course of study and to reserve judgment about matters of opinion, but they are responsible for learning the content of any course of study for which they are enrolled.*

Student Academic Success Services (SASS): <http://www.sass.umn.edu>:

Students who wish to improve their academic performance may find assistance from Student Academic Support Services. While tutoring and advising are not offered, SASS provides resources such as individual consultations, workshops, and self-help materials.

Out-of-Class Meetings

To meet with the instructors outside of class or regularly scheduled office hours, it is best to arrange an appointment. As faculty members who have extensive research and service obligations, we are juggling many responsibilities. At times, we may be able to talk with you in our office at the spur of the moment outside of office hours. Sometimes we cannot, and this can be disappointing if you have made the long trek over to the WBOB building without an appointment.

Course Web Site

The course web site is hosted on Moodle. Log on using your UMN internet ID and password.