

**Credits:** 3  
**Meeting Days:** Tuesdays and Thursdays  
**Meeting Time:** 4:00-5:15 p.m.  
**Meeting Place:** Moos Tower 2-690  
**Instructor:** **Jim Pankow**, Ph.D., M.P.H.  
**Office Address:** Room 452, 1300 S. 2<sup>nd</sup> St. (WBOB)  
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**Office Hours:** Tuesdays, 2:30-3:30pm, 1-338 Moos Tower or by appointment

**Instructor:** **Claudia Muñoz-Zanzi**, D.V.M., M.P.V.M., Ph.D.  
**Office Address:** Room 484, 1300 S. 2<sup>nd</sup> St. (WBOB)  
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Jan 22 through Feb 12: Room 484 WBOB  
Feb 19 through May 7: 1-338 Moos Tower

**Teaching Assistant:** **Ericka Welsh**  
**Office Address:** Room 331B, 1300 S. 2<sup>nd</sup> St. (WBOB)  
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**Teaching Assistant:** **Josh Rounds**  
**E-mail:** roun0030@umn.edu  
**Office Hours:** Tuesdays, 1:30-2:30pm, 1-338 Moos Tower

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## 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 four-course sequence on the theory and practice of epidemiology. This course is designed primarily for masters students 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).

## 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 Methods I (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 2009, you should be enrolled in Biostatistics II this semester (Spring 2009).*

## III. Course Goals and Objectives

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

1. Apply epidemiologic study designs and methods in public health surveillance and evaluation of screening.
2. 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.
3. Apply principles of case-control study design and analysis, including variants of the case-control design, use of matching, and sample size and power calculations.
4. Apply principles of cohort study design and analysis, including survival analysis through Kaplan-Meier and person-time approaches, and sample size and power calculations.
5. Select and develop procedures for subject selection and recruitment, including sampling and methods to enhance participation rates and response.
6. Select and develop appropriate exposure and outcome measurement procedures, including questionnaires, interviews, collection of biological specimens, physical measurements, and quality control and assurance methods.
7. 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 homework 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 tests at the scheduled times as well. Exceptions to deadlines will be determined on a case-by-case basis.

## V. Course Text and Readings

Required Text:

***Epidemiology: Beyond the Basics*** by Moyses Szklo and F. Javier Nieto, 2nd edition (2006), ISBN: 0763729272

*Epidemiology: Beyond the Basics* is specifically designed to expand reader knowledge while avoiding complex statistical formulations. Emphasizing the quantitative issues of epidemiology, this book focuses on study design, measures of association, interaction, research assessment, and other methods and practice.

*Epidemiology: Beyond the Basics* takes readers who have a good understanding of basic epidemiological principles through more rigorous discussions of concepts and methods. It is valuable for both graduate students in public health and public health professionals.

Supplemental Readings:

Chapters are assigned from the following texts and are available in a **coursepack** at the University of Minnesota Bookstore:

*Designing Clinical Research* by Stephen B. Hulley et al.; 3rd edition (2007); ISBN: 9780781782104  
*Handbook of Biosurveillance* by Michael M. Wagner, Andrew W. Moore, and Ron M. Aryel; 1<sup>st</sup> edition (2006); ISBN: 0123693780

*Interpreting Epidemiologic Evidence: Strategies for Study Design and Analysis* by David A. Savitz; 2nd edition (2001); ISBN: 019510840X

*Modern Epidemiology* by Kenneth J. Rothman and Sander Greenland; 2<sup>nd</sup> edition (1998); ISBN: 0316757802

*Modern Epidemiology* by Kenneth J. Rothman, Sander Greenland, and Timothy L. Lash; 3rd edition (2008); ISBN: 0781755646

**VI. Class Schedule**

**Class Date Instructor(s) Topic**

**Part 1: Causal inference, confounding, and effect modification**

1	1/20	Pankow	<p><u>Introduction to the course; review of major concepts from Epi Methods I</u></p> <p>Readings: Szklo and Nieto, chapter 3.1-3.2 (p. 77-88)</p>
2	1/22	Pankow	<p><u>Causal inference in epidemiology</u></p> <p>Reading: Szklo and Nieto, chapter 5 (p. 151-182)</p>
3	1/27	Pankow	<p><u>Effect modification</u></p> <p>Reading: Szklo and Nieto, chapter 6 (p. 183-223)</p>
4	1/29	Pankow	<p><u>Effect modification</u></p> <p>Reading: 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 (see link on website).</p> <p><b>In-class writing assignment today based on article by Knol et al.</b></p>
5	2/3	Pankow	<p><u>Confounding adjustment</u></p> <p>Readings: Szklo and Nieto, chapter 7.1-7.2 (p. 227-232), chapter 7.3.3 (p. 239-245), and chapter 7.5-7.6 (p. 282-286)</p> <p>Note: students planning to take the full epidemiology methods sequence may wish to skim Szklo and Nieto, p. 246-282 for a “preview” of Epidemiologic Methods III</p>

**Part 2: Design and implementation of cross-sectional studies**

6	2/5	Pankow	<p><u>Cross-sectional designs</u></p> <p>Readings: Szklo and Nieto, chapter 1.2 (p. 4-14), chapter 1.4.3 (p. 31-32); chapter 2.3 (p. 71-73); chapter 3.3 (p. 89); chapter 4.4.2 (p. 134-139)</p> <p><b>Due today: Evaluating effect modification (Homework #1)</b></p>
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- 7      2/10   Pankow      Cross-sectional designs
- Readings: Lang IA, Galloway TS, Scarlett A, Henley WE, Depledge M, Wallace RB, Melzer D. Association of urinary bisphenol A concentration with medical disorders and laboratory abnormalities in adults. *JAMA* 2008;300:1303-1310. (see link on website)
- von Elm E, et al., The Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Prev Med* 2007; 45: 247-251. (see link on website)
- Pocock SJ, Collier TJ, Dandreo KJ, de Stavola BL, Goldman MB, Kalish LA, Kasten LE, McCormack VA. Issues in the reporting of epidemiological studies: a survey of recent practice. *British Medical Journal* 2004; 329: 883. (see link on website)
- Szklo and Nieto, chapter 9 (p. 353-374)

**In-class writing assignment today based on article by Lang et al.**

**Part 3: Validity and precision of measurements in epidemiologic studies**

- 8      2/12   Leiendecker-Foster      Exposure measurement - biospecimen collection and laboratory practices
- Due today: Confounding adjustment (Homework #2)**
- 9      2/17   Muñoz-Zanzi      Quality control and quality assurance: evaluating reliability and validity
- Reading: Szklo and Nieto, chapter 8 (p. 297-349)

**Part 4: Principles of screening**

- 10     2/19   Muñoz-Zanzi      Screening
- Readings: Rothman and Greenland, *Modern Epidemiology*, (2<sup>nd</sup> ed), chapter 25 (coursepack)
- Peeling RW, Smith PG, Bossuyt PMM. Evaluating diagnostics: a guide for diagnostic evaluations. *Nat Rev Microbiol* 2006; 4 (9 Suppl) S2-S6 (see link on website)
- 11     2/24   Muñoz-Zanzi      Screening
- Readings: Szklo and Nieto, chapter 4.4.3 (p. 139-146)
- Gray JAM. New concepts in screening. *British Journal of General Practice* 2004; 54: 292-298. (coursepack)

**Part 5: Design and implementation of cohort studies**

- 12     2/26   Pankow      Bias analysis in cohort studies
- Readings: Szklo and Nieto, chapter 4.1-4.4.1 (p. 109-134) and chapter 10.3 (p. 392-394)
- Savitz, *Interpreting Epidemiologic Evidence*, chapter 6 (coursepack)
- Cotter RB et al. Contacting participants for follow-up: how much effort is required to retain participants in longitudinal studies? *Eval Program Plann* 2005; 28: 15-21. (see link on website)
- 13     3/3     Pankow      Sample size / power calculations for cohort studies
- Reading: Hulley, *Designing Clinical Research*, chapters 5-6 (coursepack)
- Due today: Screening (Homework #3)**

- 14 3/5 Pankow Insights from comparisons of randomized trials and observational cohort studies  
 Reading: Prentice RL et al. Combined analysis of Women's Health Initiative observational and clinical trial data on postmenopausal hormone treatment and cardiovascular disease. *Am J Epidemiol* 2006; 163: 589-599. (see link on website)  
**In-class writing assignment today based on article by Prentice et al.**
- 15 3/10 Muñoz-Zanzi Longitudinal data analysis in cohort studies  
 Reading: Szklo and Nieto, chapter 2.1-2.2 (p. 47-71)  
**Due today: Sample size / power calculations (Homework #4)**
- 16 3/12 Muñoz-Zanzi Longitudinal data analysis in cohort studies
- Part 6: Design and implementation of case-control studies**
- 17 3/24 Pankow Variants of the case-control design  
 Readings: Szklo and Nieto, chapter 1.4.2-1.4.5 (p. 23-39) and chapter 3.4 (p. 89-100)  
 Knol MJ, Vandembroucke JP, Scott P, Egger M. What do case-control studies estimate? Survey of methods and assumptions in published case-control research. *American Journal of Epidemiology* 2008; 168: 1073-1081. (see link on website)  
**Due today: Survival analysis (Homework #5)**
- 18 3/26 Pankow Matching in case-control studies / review
- 19 3/31 Pankow **Midterm Exam**
- 20 4/2 All Introduction to study design project; meet as groups
- 21 4/7 Pankow Bias analysis in case-control studies  
 Readings: Olson SH et al. Reporting participation in case-control studies. *Epidemiology* 2002; 13: 123-126. (see link on website)  
 Sandler DP. On revealing what we'd rather hide: the problem of describing study participation. *Epidemiology* 2002; 13: 117. (see link on website)
- 22 4/9 Pankow Bias analysis in case-control studies  
**Due today: Preliminary outline of study design project**
- 23 4/14 All Open time to work on study design projects
- 24 4/16 Pankow Sample size / power calculations for case-control studies  
 Reading: Hulley, *Designing Clinical Research*, chapters 5-6 (coursepack)  
**Due today: Bias analysis (Homework #6)**
- 25 4/21 Pankow Designing questionnaires and data collection instruments  
 Reading: Fowler F. Designing questions to be good measures. In: *Survey Research Methods*. Thousand Oaks, CA: SAGE Publications, 2002, pp. 76-95. (coursepack)

### **Part 7: Public health surveillance**

26	4/23	Muñoz-Zanzi	<u>Public health surveillance</u> Readings: Rothman and Greenland, <i>Modern Epidemiology</i> (3 <sup>rd</sup> ed), Chapter 22 (coursepack) Wagner, Moore and Aryel. <i>Handbook of Biosurveillance</i> , chapter 4, (coursepack) <b>Due today: Report on a public health surveillance system (Homework #7)</b>
27	4/28	Muñoz-Zanzi	<u>Public health surveillance</u> <b>Due today: Submit question for expert panel on public health surveillance</b>
28	4/30	Expert Panel	<u>Public health surveillance</u>

### **Part 8: Synthesis**

29	5/5	All	<u>Study design project discussion</u> <b>Due today: Study design project report</b>
30	5/7	All	<u>Study design project discussion</u>

## **VII. Evaluation and Grading**

Students will be evaluated through a combination of class participation, homework assignments, a midterm exam, and a final study design project. Both A/F and S/N grading options are available. Masters and doctoral 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 include participation in three ungraded in-class writing assignments (2% each), submission of a question for the expert panel on public health surveillance (2%), and study design project discussion (2%).

### **Homework assignments – 30%**

There will be seven take-home 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. Assignments are due at the beginning of class (4:00pm) on the date indicated in the class schedule. Late assignments will lose 1% per business day (Saturdays and Sundays excluded). Late assignments may be submitted by e-mail to one of the instructors.

1. Evaluating effect modification
2. Confounding adjustment
3. Screening
4. Sample size / power calculations
5. Survival analysis
6. Bias analysis
7. Report on a public health surveillance program

### **Midterm exam – 30%**

The midterm will test material covered in the first two-thirds of the course (through class 18).

## Final study design project – 30%

Students will work together in groups of 3-4 to develop a preliminary research hypothesis and study design for a case-control study of either an infectious or chronic disease outcome (5%). Each student will then individually submit a final report describing his or her own research plan (25%). 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.

### 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.

### Make-Up Exam Policy

Students who fail to earn at B- or higher (80% or higher) on the midterm examination are required to take a make-up examination during the university's final examination period in May. This will be a written, comprehensive, take-home examination. Students who earn a score of 80% or higher on the make-up examination will be assigned a score of 80% instead of the lower score earned on the midterm examination. If you are eligible for the make-up examination, one of the instructors will contact you with more information and to make arrangements.

### Course Evaluation

Beginning in fall 2008 the SPH will collect student course evaluations electronically using a software system called CoursEval. 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. All students will have access to their final grades 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 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 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: [www.sph.umn.edu/grades](http://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](http://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](http://onestop.umn.edu).

### **Course Withdrawal**

Students should refer to the Refund and Drop/Add Deadlines for the particular term at [onestop.umn.edu](http://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 Student Services Center at [sph-ssc@umn.edu](mailto:sph-ssc@umn.edu) for further information.

### **Student Conduct, Scholastic Dishonesty and Sexual Harassment Policies**

Students are responsible for knowing the University of Minnesota, Board of Regents' policy on Student Conduct and Sexual Harassment found at [www.umn.edu/regents/polindex.html](http://www.umn.edu/regents/polindex.html).

Students are responsible for maintaining scholastic honesty in their work at all times. Students engaged in scholastic dishonesty will be penalized, and offenses will be reported to the Office of Student Academic Integrity (OSAI, [www.osai.umn.edu](http://www.osai.umn.edu)).

The University's Student Conduct Code defines scholastic dishonesty as "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; or altering, forging, or misusing a University academic record; or fabricating or falsifying of data, research procedures, or data analysis."

Plagiarism is an important element of this policy. It is defined as the presentation of another's writing or ideas as your own. Serious, intentional plagiarism will result in a grade of "F" or "N" for the entire course. For more information on this policy and for a helpful discussion of preventing plagiarism, please consult University policies and procedures regarding academic integrity: <http://writing.umn.edu/tww/plagiarism/>.

Students are urged to be careful that they properly attribute and cite others' work in their own writing. For guidelines for correctly citing sources, go to <http://tutorial.lib.umn.edu/> and click on "Citing Sources".

In addition, original work is expected in this course. It is unacceptable to hand in assignments for this course for which you receive credit in another course unless by prior agreement with the instructor. Building on a line of work begun in another course or leading to a thesis, dissertation, or final project is acceptable.

### **Disability Statement**

It is University policy to provide, on a flexible and individualized basis, reasonable accommodations to students who have a documented disability (e.g., physical, learning, psychiatric, vision, hearing, or systemic) that may affect their ability to participate in course activities or to meet course requirements. Students with disabilities are encouraged to contact Disability Services to have a confidential discussion of their individual needs for accommodations. Disability Services is located in Suite 180 McNamara Alumni Center, 200 Oak Street. Staff can be reached by calling 612/626-1333 (voice or TTY).

### **University of Minnesota Uniform Grading and Transcript Policy**

A link to the policy can be found at [onestop.umn.edu](http://onestop.umn.edu).

### **Out-of-Class Communication and Meetings**

We will use email as the main method for out-of-class communication. You are expected to check your email regularly. Course instructors and TAs will read email from students one time per day. Anticipate that it will take 24 hours (or slightly more) to get an email reply from course instructors or TAs Monday through Friday. No promises are made regarding email replies over the weekend.

Please feel free to talk to us about any issue relating to the course. To meet with the instructors outside of 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 WebVista C and can be accessed by going to <http://myu.umn.edu>. Log on using your UMN internet ID and password.