SCHOOL OF PUBLIC HEALTH
UNIVERSITY OF MINNESOTA

PUBH 6307, SECTION 320

Clinical Epidemiology
Spring 2019

COURSE & CONTACT INFORMATION

Credits: 2 credits
Meeting Day(s), Time, and Place: This course is entirely web-based, delivered via Moodle at http://moodle.umn.edu.

Contact Type	Contact Information	Role	When to Contact
Instructor	Kamakshi Lakshminarayan, MD, PhD, MS kamakshi@umn.edu Phone: 612-624-9492 Fax: 612-624-0315	Primary instructor for this course	Contact your instructor with course-related questions via the Course Q&A/Announcements Forum or the Weekly Q&A lesson-specific forums on the Moodle site. Your instructor check the forums at least once a day and returning emails within 48 hours M-F. You can also contact the instructor directly via email. Please use email for private matters.
Technical Support	Technical support options are available on the SPH website. https://z.umn.edu/sphquickhelp	Troubleshoots technical issues related to the course site or course content.	Technical issues with the course site, media, quizzes or assignments.

Please save this contact information to your computer or print it. That way, you can still contact us in the event that you have difficulty connecting to the Internet or accessing the syllabus.

Communication in Online Courses

Communication is especially important in an online course. The course site announcement forums/discussions and email will be used to communicate with students. You are responsible for reading all course-related emails sent to your University email account and contacting us in a timely manner with any questions you may have. We strongly recommend that you check your U of M email daily.

COURSE DESCRIPTION

Clinical epidemiology is the science of using population methods to answer individual patient questions. This course in clinical epidemiology will cover the design of epidemiological studies and the analysis and interpretation of epidemiological data in order to answer clinical questions. A variety of study designs methods including cohort, case-control, and cross-sectional study designs will be used. In addition to disease and exposure, the course will cover concepts related to prognosis, diagnosis, treatment and prevention. The design and analysis of clinical trials is covered in-depth by other courses (e.g. PubH 7420 and 7415) and hence is not covered here. This course is intended for MS students majoring in clinical research. Others including medical students, students in various MS programs, MPH and PhD programs in the School of Public Health and other interested students are welcome to enroll as long as they meet the course requirements.

If you have already studied advanced methods in epidemiology or biostatistics or completed Epi Methods II (PubH 6342) or more advanced courses, please do not take this 2-credit course since there will be redundant material. Starting Spring of 2020, this course will be split into two 1-credit courses. One of these 1-credit courses will focus on methodological issues and the second will focus on more clinical aspects including prognosis, diagnosis, treatment and prevention. Students who have completed Epi Methods II or equivalent or more advanced courses are strongly advised to wait until Spring 2020 and take just the appropriate 1-credit course.

Acknowledgements
The content of this course was developed by Dr. Kamakshi Lakshminarayan with significant contributions from Dr. Jim Pankow. Guest lecturers include Dr. Deb Hennrikus and Dr. Pam Lutsey.

COURSE PREREQUISITES

- Fundamentals of Epidemiology (PubH 6320; grade of B- or higher), Epidemiological Methods I (PubH 6341; grade B- or higher), or equivalent.
- Biostatistics Literacy (PubH 6414; grade of B- or higher), Biostatistics I (PubH 6450; grade B- or higher), or equivalent.

COURSE GOALS & OBJECTIVES

1. Evaluate quality of scientific literature, assess available evidence, generation of evidence and levels of evidence
2. Apply principles of observational study design, including variants of the case-control design, use of matching, 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. Identify major sources of bias in observational studies and ways to identify their likely direction, magnitude and nature of their threat to causal inference.
5. Understand the concept of prognosis, design of prognostic studies, bias in prognostic studies, and the development of clinical prediction rules.
6. Understand the principles of diagnostic testing and applying them in clinical research and practice, interpretation of multiple tests.

METHODS OF INSTRUCTION AND WORK EXPECTATIONS

Course Workload Expectations
PubH 6307: Clinical Epidemiology is a 2-credit course. The University expects that for each credit, you will spend a minimum of three hours per week attending class or comparable online activity, reading, studying, completing assignments, etc. over the course of a 15-week term. Thus, this course requires approximately 90 hours of effort spread over the course of the term in order to earn an average grade.

Instruction will be through a combination of online lectures, interactive online exercises, and assignments. Students are expected to turn in assignments on time and take exams at scheduled times as well. Exceptions to deadlines will be determined on a case-by-case basis.

The course is NOT offered as an independent study course where you can go at your own pace. Please see the calendar below for a listing of the class schedule and due dates of assignments.

Communications: We will use the Class Q&A forums in Moodle and the University of Minnesota X500 email to communicate important information to you. Please check for our messages throughout the semester. The instructor is available to meet for office hours by Webex, or by phone or in person. Please email her for an appointment.

We will follow a class calendar with scheduled lessons, discussion posts, other assignments, and quizzes. Our expectations and requirements for this course are no different from those for a graduate level epidemiology course that is taught in-person, so you will need to properly pace yourself as you work through the class content and assignments.

We expect you to take part in the ClinEpi Cafe discussions. Please check the ClinEpi café each week to answer questions posed by the teaching team and respond to another student's post. The instructions will be available under that week's activities. Some weeks may not have a ClinEpi Café discussion and this will be posted. Participation in ClinEpi Café will contribute to your participation grade. See the section on grading for further discussion of ClinEpi Café grading. A separate document on ClinEpi Café guidelines is also posted.

We expect you to take quizzes and exams independently, without help from any other person, unless otherwise specified.

We expect you to be polite, succinct and professional in your e-mail communications and discussion postings, please remember to use the same etiquette that you would use in face-to-face conversations with both fellow students and instructional staff.

Technology
We expect that students will have access to a computer and access to the internet. High speed internet access is recommended. For computer hardware and software specifications, please see http://www.oit.umn.edu/moodle/technical-support. We also expect students in the course to be able to use their computers and software, and their knowledge of the World Wide Web, to fully participate in class discussion and submit labs, assignments and quizzes via Moodle. It is the responsibility of students to determine if they will have

adequate internet access, particularly if they are in remote areas. Poor internet access will not be accepted as an excuse for late assignments. Computer labs are also available throughout campus (for locations and hours see: http://it.umn.edu/computer-labs-locations-and-hours). It is also recommended that you back up your files frequently in case of computer disasters, and that you save your work frequently when completing assignments online (e.g. Quizzes and Exams).

Learning Community
School of Public Health courses ask students to discuss frameworks, theory, policy, and more, often in the context of past and current events and policy debates. Many of our courses also ask students to work in teams or discussion groups. We do not come to our courses with identical backgrounds and experiences and building on what we already know about collaborating, listening, and engaging is critical to successful professional, academic, and scientific engagement with topics.

In this course, students are expected to engage with each other in respectful and thoughtful ways.

In group work, this can mean:

- Setting expectations with your groups about communication and response time during the first week of the semester (or as soon as groups are assigned) and contacting the TA or instructor if scheduling problems cannot be overcome.
- Setting clear deadlines and holding yourself and each other accountable.
- Determining the roles group members need to fulfill to successfully complete the project on time.
- Developing a rapport prior to beginning the project (what prior experience are you bringing to the project, what are your strengths as they apply to the project, what do you like to work on?)

In group discussion, this can mean:

- Respecting the identities and experiences of your classmates.
- Avoid broad statements and generalizations. Group discussions are another form of academic communication and responses to instructor questions in a group discussion are evaluated. Apply the same rigor to crafting discussion posts as you would for a paper.
- Consider your tone and language, especially when communicating in text format, as the lack of other cues can lead to misinterpretation.

Like other work in the course, all student to student communication is covered by the Student Conduct Code (https://z.umn.edu/studentconduct).

COURSE TEXT & READINGS

Required Texts

- The required text book for the course is Epidemiology Beyond the Basics by Szklo and Nieto, 3rd edition. This book is available for student use electronically via the UMN library. A link to this text is provided. The link leads to the book's table of contents and students can navigate to the required readings. No purchase is required.
- The course uses readings from other texts including Designing Clinical Research, Hulley, Cummings et al., 4th edition. Many students may already have this book from other classes. To accommodate those who do not have this text, we have linked to this book electronically via the library.
- All other readings are listed and available via the Moodle course site.

This course uses journal articles, which are available via the University Libraries' E-Reserves and will be linked from the course site. It is good practice to use a citation manager to keep track of your readings. More information about citation managers is available at https://www.lib.umn.edu/pim/citation.

COURSE OUTLINE/WEEKLY SCHEDULE

This course has specific deadlines. All coursework must be submitted via the course site before the date and time specified on the site. **Note: assignments are due by 11:55pm CST unless indicated otherwise.**

Week	Topic	Readings	Activities/Assignments
Week 1 **Jan 22 - 27**	**Course Orientation, Levels of Evidence, Identifying the Study Population** **Lectures** • Introduction to the course, Course Overview (Lakshminarayan) • Levels of Evidence: Setting the Context (Lakshminarayan) • Identifying the Study Population (Pankow)	**Text** • **Hulley et al. Designing Clinical Research (4th Ed.),** Chapter 2: Conceiving the research question and developing the study plan. **Articles** *Introduction and Levels of Evidence* • Howick, et al. The 2011 Oxford CEBM Evidence Levels of Evidence (Introductory Document). Oxford Centre for Evidence-Based Medicine. • Howick, et al. Explanation of the 2011 • Oxford Centre for Evidence-Based Medicine (OCEBM) Levels of Evidence (Background Document). Oxford Centre for Evidence-Based Medicine. • OCEBM Levels of Evidence Working Group. "The Oxford Levels of Evidence 2". Oxford Centre for Evidence-Based Medicine. • Brozek et al. GRADE Working Group. Grading quality of evidence and strength of recommendations in clinical practice guidelines. Part 1 of 3. An overview of the GRADE approach and grading quality of evidence about interventions. Allergy. 2009 May;64(5):669-77. • Brozek et al. GRADE Working Group. Grading quality of evidence and strength of recommendations in clinical practice guidelines: Part 2 of 3. The GRADE approach to grading quality of evidence about diagnostic tests and strategies. Allergy. 2009 Aug;64(8):1109-16. • Brozek et al. GRADE Working Group. Grading quality of evidence and strength of recommendations in clinical practice guidelines part 3 of 3. The GRADE approach to developing recommendations. Allergy. 2011 May;66(5):588-95. • Guidelines for the Primary Prevention of Stroke *Identifying Study Population* • Ness NB. Tools for innovative thinking in epidemiology. Am J Epidemiol 2012; 175: 733-738. • Paneth N. Restoring science to the National Children's Study. JAMA 2013; 309: 1775-1776. • Rothman KJ, Gallacher JE, Hatch EE. Why representativeness should be avoided. Int J Epidemiol 2013; 42: 1012-1014.	**Assignments** • **ClinEpi Café: Introductions** (due Fri 1/25) • Begin working on **Homework 1 Guideline Analysis**. This assignment has two parts: ○ **Part 1 (guideline)** is due Sat 2/2 ○ **Part 2 (recommendations)** is due Sat 2/9

Week 2 **Jan 28 – Feb 3**	**Study Design, Implementation, Leveraging existing Studies for Manuscript Proposals** **Lectures** • Study Design Part 1 (Pankow) • Study Design Part 2 (Pankow) • Designing a Large Cohort Study: MESA (Lutsey) • How to use Large NIH funded Cohort Studies to Create New Manuscripts: Examples from WHI and ARIC (Lakshminarayan)	**Text** • **Szklo and Nieto**, **Epidemiology: Beyond the Basics, 3rd edition** chapter 1.2 (p. 4-14); chapter 1.4.1 and 1.4.2 (p. 19-31); chapter 1.4.4 and 1.4.5 (p. 32-38;) chapter 4.4.2 (p. 135-140) **Articles** • Knol MJ, Vandenbroucke 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. • Pearce N. What does the odds ratio estimate in a case-control study? International Journal of Epidemiology 1993; 22: 1189-1192. • Maclure M and Mittleman MA. Should we use a case-crossover design? Annu Rev Public Health 2000; 21: 193-221. *Designing a Large Cohort Study* • Olson JL, Bild DE, Kronmal RA, Burke GL. Legacy of MESA. Glob Heart. 2016 Sep;11(3):269-274. *NIH-Funded Cohort Studies* • The Women's Health Initiative website • Cowan LT, Alonso A, Pankow JS, Folsom AR, Rosamond WD, Gottesman RF, Lakshminarayan K. Hospitalized Infection as a Trigger for Acute Ischemic Stroke: The Atherosclerosis Risk in Communities Study. Stroke. 2016 Jun;47(6):1612-7. • WHI P&P Policies • WHI Manuscript proposal template • ARIC Manuscript proposal template • Shufelt et al. Hormone therapy dose, formulation, route of delivery, and risk of cardiovascular events in women: findings from the Women's Health Initiative Observational Study. Menopause. 2014 Mar;21(3):260-6.	• **Assignments** ○ **ClinEpi Café 1: Levels of Evidence** (initial post due Fri 2/1, response due Mon 2/4) ○ **Homework 1 Guideline Analysis Part 1** (due Sat 2/2) ○ Begin working on **Homework 1 Guideline Analysis Part 2 of 2** (due Sat 2/9)
Week 3 **Feb 4 - 10**	**Sample Size and Power** **Lecture** • Sample Size and Power Calculations (Pankow)	**Text** • **Hulley, Designing Clinical Research,** chapters 5-6	**Assignments** • **ClinEpi Café 2: Sample Size** (due Mon 2/11, no response due) • **Homework 1 Guideline Analysis Part 2** (due Sat 2/9) • Begin working on **Homework 2 Manuscript Proposal**. This assignment has three parts: ○ **Homework 2 Manuscript Proposal Part 1** (due Sat 2/16) ○ **Homework 2 Manuscript Proposal Part 2** (due Sat 3/30) ○ **Homework 2 Manuscript Proposal Part 3** (due Fri 5/10)

Week 4 **Feb 11- 17**	**Designing Data Collection Instruments** **Lectures** • Designing data collection instruments: Best practices (Hennrikus) • Part 1: Intro and Improving Response Rates • Part 2: Designing Surveys • Part 3: Selecting/Writing Survey Questions • Part 4: Response Categories • Part 5: Putting the Survey Together	**Articles** • Fowler, FJ. (2014). Evaluating Survey Questions and Instruments. In Survey research methods. Thousand Oaks, CA: Sage Publications, pp. 99-109. • Dillman DA, Smyth JD, Christian LM. (2014) Reducing People's reluctance to respond to surveys. In Internet, phone, mail, and mixed-mode surveys: The Tailored design method (4th Edition). Hoboken, NJ: John Wiley & Sons, pp. 19-55. • Dillman DA, Smyth JD, Christian LM. (2014) The fundamentals of writing questions. In Internet, phone, mail, and mixed-mode surveys: The Tailored design method (4th Edition). Hoboken, NJ: John Wiley & Sons, pp. 94-126.	**Assignments** • **Homework 2 Manuscript Proposal Part 1 of 3** (due Sat 2/16) • Begin working on **Part 2 of the Manuscript Propos**al (due Sat 3/30) • Begin working on **ClinEpi Café 3: Ancillary Studies from Existing Cohort Studies** (initial post due Fri 2/22 by 12:00pm CST, response due Mon 3/4)
Week 5 **Feb 18 - 24**	**Cohort Study Analysis** **Lectures** • Cohort Study Analysis Part 1 (Lakshminarayan) • Cohort Study Analysis Part 2	**Text** • **Szklo & Nieto: Epidemiology: Beyond the Basics, 3rd edition** 2.1 to 2.2.2 (pp. 47-70); 3.1 to 3.2 (pp. 79-90) *Optional Readings for Veterinary Medicine Students* • Guy et al. (2015). The Golden Retriever Lifetime Study: Establishing an Observational Cohort Study with Translational Relevance for Human Health. Phil. Trans R. Soc. B, The Royal Society Publishing, 370. • Asher et al. (2017). Application of Survival Analysis and Multistate Modeling to Understand Animal Behavior: Examples from Guide Dogs. Frontiers in Veterinary Medicine.	**Assignment** • **ClinEpi Café 3: Ancillary Studies from Existing Cohort Studies** (initial post due Fri 2/22 by 12:00 CST, response due Mon 3/4)
Week 6 **Feb 25 – Mar 3**	**Case-control and Cross-sectional Study Analysis** **Lecture** • Case-control and Cross-sectional Study Analysis (Pankow)	**Text** • **Szklo & Nieto: Epidemiology: Beyond the Basics, 3rd Ed.,** 3.4.1 (p 90-101) *Optional Readings for Veterinary Medicine Students* • Cabal, A. et al. (2016). Prevalence of Escherichia coli Virulence Genes in Patients with Diarrhea and a Subpopulation of Health Volunteers in Madrid, Spain. Frontiers in Microbiology. • Mermin, J. et al. (2004). Reptiles, Amphibians, and Human Salmonella Infection: A Population-Based, Case-Control Study. CID. 2004:38.	**Assignments** • Post a **response** to **ClinEpi Café 3: Ancillary Studies from Existing Cohort Studies** (due Mon 3/4) • Complete the **Mid-semester Feedback Survey** (optional) • Begin working on **Homework 3 Cohort and Case Control Study Exercises** (due Sat 3/16)

Week 7 **Mar 4 - 10**	**Confounding** **Lecture** • Confounding: Using Causal Models to Identify Confounders (Pankow)	**Text** • **Szklo & Nieto: Epidemiology: Beyond the Basics, 3rd Ed.,** Chapter 5 (p. 153-180); chapter 7.1 to 7.3.4 (p. 229-248 **Article** • Burgess S et al. Mendelian randomization: where are we now and where are we going? Int J Epidemiol 2015; 44: 379-388.	**Assignments** • Continue working on **Homework 3 Cohort and Case Control Study Exercises** (due Sat 3/16) • Continue working on **Homework 2 Manuscript Proposa**l (Part 2 is due Sat 3/30, Part 3 is due Fri 5/10)
Week 8 **Mar 11 - 17**	**Midterm Exam**		**Assignments** • **Midterm Exam:** This is a take-home exam. It will be available on the Moodle site Thurs 3/14 8:00am and must be submitted by Sat 3/16 no later than 11:55pm. • **Homework 3 Cohort and Case Control Study Exercises** (due Sat 3/16)
SPRING BREAK Mar 18 - 24			
Week 9 **Mar 25 - 31**	**Strategies to Address Bias** **Lecture** • Strategies to Address Selection and Information Bias (Pankow)	**Text** • **Szklo & Nieto: Epidemiology: Beyond the Basics, 3rd edition,** chapter 4.1 to 4.3 (p. 110-134) **Articles** • Olson SH et al. Reporting participation in case-control studies. Epidemiology 2002; 13: 123-126. • 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.	**Assignment** • **Homework 2 Manuscript Proposal Part 2 of 3** (due Sat 3/30)
Week 10 **Apr 1- 7**	**Strategies to Address Effect Modification** **Lecture** • Effect Modification: Strategies to Address Effect Modification (Pankow)	**Text** • **Szklo & Nieto: Epidemiology: Beyond the Basics, 3rd edition,** chapter 6 (p. 185-222) **Articles** • 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. Epidemiology 2009; 20: 161-166 • Knol MJ, et al. The (mis)use of overlap of confidence intervals to assess effect modification. Eur J Epidemiol 2011; 26: 253-254. **Optional Readings** • Thompson WD. Effect modification and limits of biological inference from epidemiologic data. J Clin Epidemiol 1991; 44: 221-232. • Goodman S. A dirty dozen: twelve P-value misconceptions. Seminars in Hematology 2008; 45: 135-140. • Stang A, Poole C, Kuss O. The ongoing tyranny of statistical significance testing in biomedical research. Eur J Epidemiol 2010; 225-230**.**	**Assignment** • Begin working on **Homework 4 Confounding, Bias, Effect Modification Exercises** (due Sat 4/20)

Week 11 **Apr 8 - 14**	**Epidemiology of Diagnostic Testing** **Lectures** • Epidemiology of Diagnostic Tests: Part 1 (Lakshminarayan) • Epidemiology of Diagnostic Tests: Part 2	**Text** • **Hulley, Designing Clinical Research,** Chapter 12 **Articles/Chapters** • Fletcher, Fletcher & Fletcher: Clinical Epidemiology: Chapter 8 • Anthony J. Viera, MD; Joanne M. Garrett, PhD; Understanding Interobserver Agreement: The Kappa Statistic (Fam Med 2005;37(5):360-3.) • Seong Ho Park, MD, Jin Mo Goo, MD, and Chan-Hee Jo, PhD, Receiver Operating Characteristic (ROC) Curve: Practical Review for Radiologists.	**Assignment** • Continue working on **Homework 4 Confounding, Bias, Effect Modification Exercises** (due Sat 4/20)
Week 12 **Apr 15 - 21**	**Screening Tests and Exercises in Diagnosis and Screening** **Lectures** • Epidemiology of Screening (Lakshminarayan) • Practice Exercises on the Epidemiology of Diagnostic Testing and Screening (Lakshminarayan)	**Text** • **Szklo & Nieto: Epidemiology: Beyond the Basics, 3rd Ed.,** Chapter 4.4.3 (139-146) **Articles/Chapters** • Fletcher, Fletcher & Fletcher: Clinical Epidemiology: Chapter 10, pp. 159-172 • Pepe MS et al. Limitations of the odds ratio in assessing performance of a diagnostic, prognostic and screening marker. Am J Epidemiology 2004; 159: 882-890 • Harris R Overview of screening: where we are and where we may be headed. Epidemiol Rev. 2011; 33:1-6. • Aberle DR, Berg CD, Black WC, Church TR, Fagerstrom RM, Galen B, Gareen IF, Gatsonis C, Goldin J, Gohagan JK, Hillman B, Jaffe C, Kramer BS, Lynch D, Marcus PM, Schnall M, Sullivan DC, Sullivan D, Zylak CJ. The National Lung Screening Trial: overview and study design. National Lung Screening Trial Research Team, Radiology. 2011 Jan;258(1):243-53.	**Assignment** • **Homework 4 Confounding, Bias, Effect Modification Exercises** (due Sat 4/20)

Week 13 **Apr 22 - 28**	**Prognostic Studies** **Lecture** ○ Epidemiology of Disease Prognosis (Lakshminarayan)	**Articles/Chapters** • Fletcher, Fletcher & Fletcher: Clinical Epidemiology: The Essentials, Chapter 7 • Canto JG, Kiefe CI, Rogers WJ, Peterson ED, Frederick PD, French WJ, Gibson CM, Pollack CV Jr, Ornato JP, Zalenski RJ, Penney J, Tiefenbrunn AJ, Greenland P; NRMI Investigators. Number of coronary heart disease risk factors and mortality in patients with first myocardial infarction. JAMA. 2011 Nov 16;306(19):2120-7. • Lakshminarayan K, Schissel C, Anderson DC, Vazquez G, Jacobs DR Jr, Ezzeddine M, Luepker RV, Virnig BA. Five-year rehospitalization outcomes in a cohort of patients with acute ischemic stroke: Medicare linkage study. Stroke. 2011 Jun;42(6):1556-62. doi: 1 **References for CHADS2VASC** • Atrial Fibrillation Investigators: Risk factors for stroke and efficacy of antithrombotic therapy in atrial fibrillation. Analysis of pooled data from five randomized controlled trials. Arch Intern Med. 1994 Jul 11;154(13):1449-57. • Hart RG, Pearce LA, McBride R, Rothbart RM, Asinger RW. Factors associated with ischemic stroke during aspirin therapy in atrial fibrillation: analysis of 2012 participants in the SPAF I-III clinical trials. The Stroke Prevention in Atrial Fibrillation (S • Gage BF, Waterman AD, Shannon W, Boechler M, Rich MW, Radford MJ. Validation of clinical classification schemes for predicting stroke: results from the National Registry of Atrial Fibrillation. JAMA. 2001 Jun 13;285(22):2864-70. • Original/Primary Reference: Lip GY, Nieuwlaat R, Pisters R, Lane DA, Crijns HJ. Refining clinical risk stratification for predicting stroke and thromboembolism in atrial fibrillation using a novel risk factor-based approach: the euro heart survey on atri • Validation: Friberg L, Rosenqvist M, Lip GY. Evaluation of risk stratification schemes for ischaemic stroke and bleeding in 182 678 patients with atrial fibrillation: the Swedish Atrial Fibrillation cohort study. Eur Heart J. 2012 Jun;33(12):1500-10. • Okumura K, Inoue H, Atarashi H, Yamashita T, Tomita H, Origasa H; J-RHYTHM Registry Investigators.Validation of CHA2DS2-VASc and HAS-BLED scores in Japanese patients with nonvalvular atrial fibrillation: an analysis of the J-RHYTHM Registry.	**Assignments** • **ClinEpi Café 4: Prognosis** (initial post due Sat 4/27, response due Sat 5/11 - *note that you have 2 weeks to complete this discussion*) • Continue working on **Homework 2 Part 3** (due Fri 5/10)

Week 14 **Apr 29 – May 5**	**Using Medicare Data** **Lecture** • Research Using Existing Data: Focus on Medicare Claims Data (Lakshminarayan) **Using Electronic Health Record Data** **Lecture** • Using Data from Electronic Health Records for Research (Lakshminarayan)	**Articles** *Using Medicare Data* • Mell MW, Pettinger M, Proulx-Burns L, Heckbert SR, Allison MA, Criqui MH, Hlatky MA, Burwen DR; WHI PVD Writing Workgroup. Evaluation of Medicare claims data to ascertain peripheral vascular events in the Women's Health Initiative. J Vasc Surg. 2014 Jul;60(1):98-105. • Lakshminarayan K, Larson JC, Virnig B, Fuller C, Allen NB, Limacher M, Winkelmayer WC, Safford MM, Burwen DR. Comparison of Medicare claims versus physician adjudication for identifying stroke outcomes in the Women's Health Initiative. Stroke. 2014 Mar;45(3):815-21. • Hlatky MA, et al.. Use of Medicare data to identify coronary heart disease outcomes in the Women's Health Initiative.Circ Cardiovasc Qual Outcomes. 2014 Jan;7(1):157-62. **Articles** *Using Electronic Health Record Data* • Casey JA, Schwartz BS, Stewart WF, Adler NE. (2016). Using Electronic Health Records for Population Health Research: A Review of Methods and Applications. Annu Rev Public Health.;37:61-81. • Oh W, Kim E, Castro MR, Caraballo PJ, Kumar V, Steinbach MS, Simon GJ. (2016). Type 2 Diabetes Mellitus Trajectories and Associated Risks. Big Data. 2016 Mar 1;4(1):25-30 • Desai, J. R., Wu, P., Nichols, G. A., Lieu, T. A., & O'Connor, P. J. (2012). Diabetes and Asthma Case Identification, Validation, and Representativeness When Using Electronic Health Data to Construct Registries for Comparative Effectiveness and Epidemi • Haneuse S, Bogart A, Jazic, Westbrook EO, Boudreau D, Theis MK, Simon GE, Arterburn D. (2016). Learning About Missing Data Mechanisms in Electronic Health Records-based Research: A Survey-based Approach. Epidemiology. 2016 Jan;27(1):82-90. • Manuel, Douglas G; Laura C Rosella; and Therese A Stukel. (2010). Importance of Accurately Identifying Disease in Studies Using Electronic Health Records. BMJ 341. BMJ 2010;341:c4226 • Nichols GA, Desai J, Elston Lafata J, Lawrence JM, O'Connor PJ, Pathak RD, et al. Construction of a Multisite DataLink Using Electronic Health Records for the Identification, Surveillance, Prevention, and Management of Diabetes Mellitus: The SUPREME-DM • Nichols, et al., (2014). Trends in Diabetes Incidence Among 7 Millin Insured Adults, 2006-2011, the SUPREME-DM Project. American Journal of Epidemiology, 181(1), 32-39.	**Assignments** • **ClinEpi Café 5: Medicare Data** (post due Fri 5/10) • **Homework 2 Manuscript Proposal Part 3 of 3** (due Fri 5/10)
Week 15 **May 6 - 12**	• **Final Exam**		• **Final Exam -** this is a take-home exam. It will be available on the Moodle site Saturday 5/11 at 8:00am and must be submitted by Monday 5/13 no later than 11:55pm.

SPH AND UNIVERSITY POLICIES & RESOURCES

The School of Public Health maintains up-to-date information about resources available to students, as well as formal course policies, on our website at www.sph.umn.edu/student-policies/. Students are expected to read and understand all policy information available at this link and are encouraged to make use of the resources available.

The University of Minnesota has official policies, including but not limited to the following:

- Grade definitions
- Scholastic dishonesty
- Makeup work for legitimate absences
- Student conduct code
- Sexual harassment, sexual assault, stalking and relationship violence
- Equity, diversity, equal employment opportunity, and affirmative action
- Disability services
- Academic freedom and responsibility

Resources available for students include:

- Confidential mental health services
- Disability accommodations
- Housing and financial instability resources
- Technology help
- Academic support

EVALUATION & GRADING

Assignments

ClinEpi Café Discussions (total 20 points)

- ClinEpi Café is an online discussion forum and participation is part of your grade. There is a total of 20 points for the ClinicEpi café discussions (see chart below). Each late post will lead to the deduction of 0.5 points from the 20 points. However, once a post is closed you will not be able to post on the topic and hence will not be able to earn the points for that discussion topic. *Forums will be closed 1 week (7 days) after the final due date.*

Homework 1 (total 10 points)

- **Part 1 (2 points).** Find a substantial guideline in your field/area of interest and send me a link in a word document. The guideline should address both treatments and diagnostic testing and should have recommendations spanning various levels of evidence.
- **Part 2 (8 points).** In the guideline you submitted in Part 1, identify a total of 5 recommendations. Three of these 5 should be in treatment or prevention and 2 in diagnosis. For each of these 5 recommendations, state the level of evidence underlying that recommendation and the study designs which provided the evidence. In the lecture titled, Levels of Evidence, I showed this type of analysis for the AHA Stroke Prevention Guidelines. Create a word document showing your answer. (**Note:** In part 2, you will parse your guideline for levels of evidence and study design underlying 3 recommendations in treatment / prevention and 2 recommendations in diagnosis. You are requested to pick no more than 2 level 1 recommendations in total. So you will have to use other levels of evidence.)

Homework 2 (total 30 points)

- **Part 1 (2 points).** Identify a large federally funded data source relevant to your field similar to the studies discussed in Week 2 on Cohort Study Implementation. You can use one of the listed cohorts. Identify the manuscript development template that is usually available on the study website. Upload this for the instructor's review by end of week 4. The instructor will have to approve your choice to move forward.
- **Part 2 (8 points).** Develop a manuscript proposal (the idea has to be novel) based on the template identified on Part 1. The instructor will provide feedback within 2 weeks of the due date. Feedback will be in person or via skype or google chats as preferred.
- **Part 3 (20 points).** Submit final manuscript proposal.

Homework 3 (20 points)

- Exercises on cohort and case control study analysis. Due end of week 9.

Homework 4 (20 points)

- Problems on confounding, bias and effect modification.

Midterm & Final Exams

- Midterms (50 points) and Final (50 points) are take-home, open book exams.

	Points
DISCUSSIONS	**20**
ClinEpi Café: Introductions	1
ClinEpi Café 1: Levels of Evidence	5
ClinEpi Café 2: Sample Size	1
ClinEpi Café 3: Ancillary Studies from Existing Cohort Studies	6
ClinEpi Café 4: Prognosis	5
ClinEpi Café 5: Medicare Data	2
HOMEWORK	**80**
Homework 1: Guideline Analysis **Part 1**	2
Homework 1: Guideline Analysis **Part 2**	8
Homework 2: Manuscript Proposal **Part 1**	2
Homework 2: Manuscript Proposal **Part 2**	8
Homework 2: Manuscript Proposal **Part 3**	20
Homework 3: Cohort and Case Control Study Exercises	20
Homework 4: Confounding, Bias, Effect Modification Exercises	20
EXAMS	**100**
Midterm Take-home Exam	50
Final Take-home Exam	50
TOTAL	**200**

Grading Scale
The University uses plus and minus grading on a 4.000 cumulative grade point scale in accordance with the following, and you can expect the grade lines to be drawn as follows:

% In Class	Grade	GPA
93 - 100%	A	4.000
90 - 92%	A-	3.667
87 - 89%	B+	3.333
83 - 86%	B	3.000
80 - 82%	B-	2.667
77 - 79%	C+	2.333
73 - 76%	C	2.000
70 - 72%	C-	1.667
67 - 69%	D+	1.333
63 - 66%	D	1.000
< 62%	F	

- A = achievement that is outstanding relative to the level necessary to meet course requirements.
- B = achievement that is significantly above the level necessary to meet course requirements.
- C = achievement that meets the course requirements in every respect.
- D = achievement that is worthy of credit even though it fails to meet fully the course requirements.
- F = failure because work was either (1) completed but at a level of achievement that is not worthy of credit or (2) was not completed and there was no agreement between the instructor and the student that the student would be awarded an I (Incomplete).
- S = achievement that is satisfactory, which is equivalent to a C- or better
- N = achievement that is not satisfactory and signifies that the work was either 1) completed but at a level that is not worthy of credit, or 2) not completed and there was no agreement between the instructor and student that the student would receive an I (Incomplete).

Evaluation/Grading Policy	**Evaluation/Grading Policy Description**
Scholastic Dishonesty, Plagiarism, Cheating, etc.	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 (As defined in the Student Conduct Code). For additional information, please see https://z.umn.edu/dishonesty The Office for Student Conduct and Academic Integrity has compiled a useful list of Frequently Asked Questions pertaining to scholastic dishonesty: https://z.umn.edu/integrity. If you have additional questions, please clarify with your instructor. 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. Indiana University offers a clear description of plagiarism and an online quiz to check your understanding (http://z.umn.edu/iuplagiarism).
Late Assignments	Each late post for ClinEpi Café discussions will lead to the deduction of 0.5 points from the 20 points. Late homework assignments will be penalized 10% of their total points for each business day (Saturday and Sunday excluded). So a HW carrying 30 points will lose 3 points for each overdue date counting only business days.
Attendance Requirements	N/A

Makeup Work for Legitimate Reasons	If you experience an extraordinary event that prevents you from completing coursework on time and you would like to make arrangements to make up your work, contact your instructor within 24 hours of the missed deadline if an event could not have been anticipated and at least 48 hours prior if it is anticipated. Per University policy, legitimate reasons for making up work may include: • illness • serious accident or personal injury • hospitalization • death or serious illness within the family • bereavement • religious observances • subpoenas • jury duty • military service • participation in intercollegiate athletic events Because this course is entirely online and all materials are available to students from the first day of the term, we expect students to plan accordingly if travels or access to internet will cause them to miss a deadline. Note that our deadlines are generally set for 11:55 p.m. CST, so traveling to a different time zone will require additional planning. Further, circumstances that qualify for making up missed work will be handled by the instructor on a case-by-case basis; they will always be considered but not always granted. For complete information, view the U of M's policy on Makeup Work for Legitimate Absences (http://z.umn.edu/sphmakeupwork).
Extra Credit	
Saving & Submitting Coursework	**Documents that students submit are considered final;** students may not submit more than one version or draft of each assignment.

Technical Issues with Course Materials	You are expected to submit all coursework on time and it is your responsibility to ensure that your work is submitted properly before the deadline.
	
	If you experience technical difficulties while navigating through the course site or attempting to submit coursework:
	
	• Go to Quick Help: http://z.umn.edu/sphquickhelp.
	• Connect with the appropriate person or office within 30 minutes of the problem's occurrence.
	  ○ Provide as much information as possible, so the tech team can best help you as soon as possible.
	  ○ You can expect a response within 1-2 business days to help resolve the problem.