PubH 6390
Clinical E
Spring 2017

Credits:	**2**
Meeting Days:	online
Instructor:	**Kamakshi Lakshminarayan MD PhD MS**
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I.   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.

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.

II.   Course Prerequisites

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

III. Course Goals and Objectives

1. Apply epidemiological study designs and methods to answer questions of clinical relevance.
2. Evaluate quality of scientific literature, assess available evidence, generation of evidence and levels of evidence
3. Apply principles of observational study design, including variants of the case-control design, use of matching, sample size and power calculations.
4. Select and develop appropriate exposure and outcome measurement procedures, including questionnaires, interviews, collection of biological specimens, physical measurements, and quality control and assurance methods.
5. Identify major sources of bias in observational studies and ways to identify their likely direction, magnitude and nature of their threat to causal inference.
6. Understand the concept of prognosis, design of prognostic studies, bias in prognostic studies, and the development of clinical prediction rules.
7. Understand the principles of diagnostic testing and applying them in clinical research and practice, interpretation of multiple tests.

IV. Methods of Instruction and Work Expectations

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 (a tool within 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 Café, a round table discussion.** Please check the ClinEpi café) each week to answer questions posed by the teaching team and respond to another student's post. The instructions each week 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.

- **We expect you to take quizzes and exams independently**, without help from any other person, unless otherwise specified. You may be required to take the final exam in the presence of an online proctor. Details will follow.

- **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).

- **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.

V. Course Text and Readings

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 and a link is available to this book. 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 available on the class website as well.

VI. Course Outline/Weekly Schedule

Week	Topic, Lectures, Readings	Assignments
WEEK 1 Jan 17-21	**Course Orientation, Levels of Evidence, Identifying the Study Population** • **Module 1.** Introduction to the course, Course Overview (Lakshminarayan) • **Module 2.** Levels of Evidence: Setting the Context (Lakshminarayan) • **Module 3.** Identifying the Study Population (Pankow) **Module 2 Readings** • Jeremy Howick, Iain Chalmers, Paul Glasziou, Trish Greenhalgh, Carl Heneghan, Alessandro Liberati, Ivan Moschetti, Bob Phillips, and Hazel Thornton "The 2011 Oxford CEBM Evidence Levels of Evidence (Introductory Document)". Oxford Centre for Evidence-Based Medicine. *http://www.cebm.net/index.aspx?o=5653 http://www.cebm.net/wp-content/uploads/2014/06/CEBM-Levels-of-Evidence-Introduction-2.1.pdf* • Jeremy Howick, Iain Chalmers, Paul Glasziou, Trish Greenhalgh, Carl Heneghan, Alessandro Liberati, Ivan Moschetti, Bob Phillips, and Hazel Thornton. "Explanation of the 2011 Oxford Centre for Evidence-Based Medicine (OCEBM) Levels of Evidence (Background Document)". Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653 *http://www.cebm.net/wp-content/uploads/2014/06/CEBM-Levels-of-Evidence-Background-Document-2.1.pdf* • OCEBM Levels of Evidence Working Group*. "The Oxford Levels of Evidence 2". Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653 *http://www.cebm.net/wp-content/uploads/2014/06/CEBM-Levels-of-Evidence-2.1.pdf* • Brozek JL, Akl EA, Alonso-Coello P, Lang D, Jaeschke R, Williams JW, Phillips B, Lelgemann M, Lethaby A, Bousquet J, Guyatt GH, Schünemann HJ; 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. doi: 10.1111/j.1398-9995.2009.01973.x. Review. • Brozek JL, Akl EA, Jaeschke R, Lang DM, Bossuyt P, Glasziou P, Helfand M, Ueffing E, Alonso-Coello P, Meerpohl J, Phillips B, Horvath AR, Bousquet J, Guyatt GH, Schünemann HJ; GRADE Working Group. Grading quality of evidence and strength of recommendations in clinical practice guidelines: Part 2 of 3. The	• Complete the ClinEpi Café: Introductions (due 1/23) • Begin working on Homework 1 Guideline Analysis. This assignment has two parts: o Part 1 (guideline) is due 1/28 o Part 2 (recommendations) is due 2/4

	GRADE approach to grading quality of evidence about diagnostic tests and strategies. Allergy. 2009 Aug;64(8):1109-16. doi: 10.1111/j.1398-9995.2009.02083.x. Review. • Brozek JL, Akl EA, Compalati E, Kreis J, Terracciano L, Fiocchi A, Ueffing E, Andrews J, Alonso-Coello P, Meerpohl JJ, Lang DM, Jaeschke R, Williams JW Jr, Phillips B, Lethaby A, Bossuyt P, Glasziou P, Helfand M, Watine J, Afilalo M, Welch V, Montedori A, Abraha I, Horvath AR, Bousquet J, Guyatt GH, Schünemann HJ; 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. doi: 10.1111/j.1398-9995.2010.02530.x. Review. • Guidelines for the Primary Prevention of Stroke *http://stroke.ahajournals.org/content/45/12/3754.full.pdf+html* **Module 3 Readings** • Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. *Designing Clinical Research* (4th ed), Chapter 2: Conceiving the research question and developing the study plan. • 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.	
WEEK 2 Jan 22-28	**Study Design, Implementation, Leveraging existing Studies for Manuscript Proposals** • **Module 4a.** Study Design Part 1 (Pankow) • **Module 4b.** Study Design Part 2 (Pankow) • **Module 5**. Cohort Study Implementation: Practical Issues (Lutsey) • **Module 6:** How to use large NIH funded cohort studies to create new manuscripts: Examples from WHI and ARIC (Lakshminarayan) **Module 4 Readings** • Szklo and Nieto, chapter 1.2 (p. 4-14); chapter 4.4.2 (p. 135-140) • Szklo and Nieto, chapter 1.4.1 and 1.4.2 (p. 19-31) • 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. • 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? *Annu Rev Public Health 2000*; 21: 193-221. **Module 5 Readings** • Legacy of MESA. • Olson JL, Bild DE, Kronmal RA, Burke GL. Glob Heart. 2016 Sep;11(3):269-274. doi: 10.1016/j.gheart.2016.08.004. Review. • Handouts – 2 Mesa handouts from Pam Lutsey available on the Moodle site. **Module 6 Readings** • The Women's Health Initiative*: https://www.whi.org https://www2.cscc.unc.edu/aric/desc* • Cowan LT, Alonso A, Pankow JS, Folsom AR, Rosamond WD,	• Submit Homework 1 Guideline Analysis Part 1 (due 1/28) • Begin working on Homework 1 Guideline Analysis Part 2 of 2 (due 2/4)

	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. doi: 10.1161/STROKEAHA.116.012890. Epub 2016 May 10. • WHI P&P Policies: https://www.whi.org/researchers/Documents%20%20Write%20a%20Paper/PP%20policy.pdf • WHI Manuscript proposal template. Electronic copy available on the Moodle site. Also available at: *https://www.whi.org/researchers/SitePages/Write%20a%20Paper.aspx* • ARIC Manuscript proposal template: Electronic copy available – given to e-learning for placing on website. Also available at this website https://www2.cscc.unc.edu/aric/pubs-policies-and-forms-pg • Hormone therapy dose, formulation, route of delivery, and risk of cardiovascular events in women: findings from the Women's Health Initiative Observational Study. • Shufelt CL, Merz CN, Prentice RL, Pettinger MB, Rossouw JE, Aroda VR, Kaunitz AM, Lakshminarayan K, Martin LW, Phillips LS, Manson JE., Menopause. 2014 Mar;21(3):260-6. doi: 10.1097/GME.0b013e31829a64f9.	

WEEK 3
Jan 29-Feb 4
	Sample Size and Power
	
	• **Module 7.** Sample Size and Power Calculations (Pankow)
	
	Module 7 Readings
	• Hulley, *Designing Clinical Research*, chapters 5-6
		• Submit Homework 1 Guideline Analysis Part 2 (due 2/4)
		• Begin working on Homework 2 Manuscript Proposal. This assignment has three parts:
		  ○ Homework 2 Manuscript Proposal Part 1 (due 2/11)
		  ○ Homework 2 Manuscript Proposal Part 2 (due 3/25)
		  ○ Homework 2 Manuscript Proposal Part 3 (due 5/5)

WEEK 4 Feb 5 – 11	**Designing Data Collection Instruments** • **Module 8.** Designing data collection instruments: Best practices (Hennrikus) **Module 8 Readings:** • 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.	• Submit Homework 2 Manuscript Proposal Part 1 of 3 (due 2/11) • Begin working on Part 2 of the Manuscript Proposal (due 3/25) • Begin working on ClinEpi Café 3: Ancillary Studies from Existing Cohort Studies (initial post due 2/17 by 12:00 CST, response due 2/27)
WEEK 5	**Cohort Study Analysis**	• Post an initial response

Feb 12-18	• **Module 9.** Cohort study analysis: Longitudinal data (Lakshminarayan) **Module 9 Readings** • Szklo & Nieto: 2.1 to 2.2.2 (p47-70); 3.1 to 3.2: 79-90	to ClinEpi Café 3: Ancillary Studies from Existing Cohort Studies (initial post due 2/17 by 12:00 CST, response due 2/27)
WEEK 6 Feb 19-25	**Case-control and cross-sectional study analysis** • **Module 10.** Case-control and Cross-sectional Study Analysis (Pankow) **Module 10 Readings** • Szklo & Nieto: 3.4.1 (p 90-101)	• Begin working on Homework 3 Cohort and Case Control Study Exercises (due 3/11) • Post response to ClinEpi Café 3: Ancillary Studies from Existing Cohort Studies (due 2/27)
WEEK 7 Feb 26-Mar 4	**Confounding** • **Module 11.** Using Causal Diagrams to Identify Confounders (Pankow) **Module 11 Readings** • Szklo and Nieto, chapter 5 (p. 153-180); • Szklo and Nieto, chapter 7.1 to 7.3.4 (p. 229-248) • Burgess S et al. Mendelian randomization: where are we now and where are we going? *Int J Epidemiol* 2015; 44: 379-388.	• Continue working on Homework 3 Cohort and Case Control Study Exercises (due 3/11) • Continue working on Homework 2 Manuscript Proposal (Part 2 is due 3/25, Part 3 is due 5/5)
WEEK 8 Mar 9-11	**Midterm Exam**	• Midterm Exam • Submit Homework 3 Cohort and Case Control Study Exercises (due 3/11)
Mar 13-17	Spring Break	
WEEK 9 Mar 19-25	**Strategies to Address Bias** **Module 12.** Bias: Strategies to Address Selection and Information Bias (Pankow) **Module 12 Readings** • Szklo and Nieto, chapter 4.1 to 4.3 (p. 110-134) • 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.	• Submit Homework 2 Manuscript Proposal Part 2 of 3 (due 3/25)
WEEK 10 Mar 26-Apr 1	**Strategies to Address Effect Modification** **Module 13.** Effect Modification: Strategies to Address Effect Modification (Pankow) **Module 13 Readings** • Szklo and Nieto, chapter 6 (p. 185-222)	• Begin working on Homework 4 Confounding, Bias, Effect Modification Exercises (due 4/15)

	• 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: 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.	
WEEK 11 Apr 2-8	**Prognostic Studies** • **Module 14.** Prognosis and Prognostic Study Designs; Clinical Prediction Rules; Examples (Lakshminarayan) **Module 14 Readings** • Lloyd-Jones DM. Cardiovascular risk prediction. Basic concepts, current status, and future directions. Circulation 2010; 121: 1768-1777 • Fletcher, Fletcher & Fletcher: Clinical Epidemiology: The Essentials Chapter 7 **References for CHADS2VASC:** **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 atrial fibrillation. Chest. 2010 Feb;137(2):263-72. doi: 10.1378/chest.09-1584. Epub 2009 Sep 17. PubMed PMID: 19762550. **Validation/Comparison** • CHADS2, CHA2DS2-VASc, and long-term stroke outcome in patients without atrial fibrillation. March 12, 2013 80:1009-1017; published ahead of print February 13, 2013 **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. doi: 10.1093/eurheartj/ehr488. Epub 2012 Jan 13. PubMed PMID: 22246443. • Okumura K, Inoue H, Atarashi H, Yamashita T, Tomita H, Origasa H; J-RHYTHM Registry Investigators.Validation of CHA_2DS_2-VASc and HAS-BLED scores in Japanese patients with nonvalvular atrial fibrillation: an analysis of the J-RHYTHM Registry. Circ J. 2014;78(7):1593-9. Epub 2014 Apr 22. **Outcomes** • Camm AJ, Lip GY, De Caterina R, Savelieva I, Atar D, Hohnloser SH, Hindricks G, Kirchhof P; ESC Committee for Practice Guidelines (CPG). 2012 focused update of the ESC Guidelines for the management of atrial fibrillation: an update of the 2010 ESC Guidelines for the management of atrial fibrillation. Developed with the special contribution of the European Heart Rhythm Association. Eur Heart J. 2012 Nov;33(21):2719-47. doi: 10.1093/eurheartj/ehs253. Epub 2012 Aug 24. Erratum in: Eur Heart J. 2013 Mar;34(10):790. Eur Heart J. 2013 Sep;34(36):2850-1. PubMed PMID: 22922413.	• Begin working on ClinEpi Café 4: Prognosis (initial post due 4/10, response due 4/17) • Note: You have 2 weeks to complete this discussion.

WEEK 12 Apr 9-15	**Epidemiology of Diagnostic Testing** • **Module 15.** Epidemiology of Diagnostic Testing: Part 1 (Lakshminarayan) • **Module 16.** Epidemiology of Diagnostic Testing: Part 2 (Lakshminarayan) **Module 15 and 16 Readings** • Fletcher, Fletcher & Fletcher: Clinical Epidemiology: Chapter 8 • Hulley, Cummings, Browner, Grady, Newman: Designing Clinical Research: Chapter 12 • Understanding Interobserver Agreement: The Kappa Statistic • Anthony J. Viera, MD; Joanne M. Garrett, PhD; (Fam Med 2005;37(5):360-3.) https://www.stfm.org/fmhub/fm2005/May/Anthony360.pdf • Receiver Operating Characteristic (ROC) Curve: Practical Review for Radiologists • Seong Ho Park, MD,[1] Jin Mo Goo, MD,[1] and Chan-Hee Jo, PhD https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2698108/	• Complete ClinEpi Café 4: Prognosis (initial post due 4/10, response due 4/17) • Submit Homework 4 Confounding, Bias, Effect Modification Exercises (due 4/15)
WEEK 13 Apr 16-22	**Screening Tests and Exercises in Diagnosis and Screening** • **Module 17.** Epidemiology of Screening (Lakshminarayan) • **Module 18.** Illustrative Exercises in Diagnosis, Screening and Prevention (Lakshminarayan) **Module 17 Readings** • Szklo & Nieto: 4.4.3 (139-146) • Fletcher, Fletcher & Fletcher: Clinical Epidemiology: p 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. • The National Lung Screening Trial: overview and study design.National Lung Screening Trial Research Team, 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. Radiology. 2011 Jan;258(1):243-53. doi: 10.1148/radiol.10091808. Epub 2010 Nov 2.	• Continue working on Homework 2 Manuscript Proposal Part 3 of 3 (due 5/5)
WEEK 14 Apr 23-29	**Using Medicare Data** **Module 19.** Using Medicare Data (Lakshminarayan) **Module 19 Readings** • 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. doi: 10.1016/j.jvs.2014.01.056. Epub 2014 Mar 11. • 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. doi: 10.1161/STROKEAHA.113.003408. Epub 2014 Feb 13. Erratum in: Stroke. 2014 Apr;45(4):e69. • Hlatky MA, Ray RM, **Burwen** DR, Margolis KL, Johnson KC,	• Finalize Homework 2 Manuscript Proposal Part 3 of 3 (due 5/5) • Complete ClinEpi Café 5 Medicare Data (initial post due 5/1, no response due)

	Kucharska-Newton A, Manson JE, Robinson JG, Safford MM, Allison M, Assimes TL, Bavry AA, Berger J, Cooper-DeHoff RM, Heckbert SR, Li W, Liu S, Martin LW, Perez MV, Tindle HA, Winkelmayer WC, Stefanick ML. 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. doi: 10.1161/CIRCOUTCOMES.113.000373.	
WEEK 15 Apr 30- May 5	**Using Electronic Health Record Data** • Using EHR (Electronic **Module 20.** Record) Data: Strengths, Weaknesses, Examples (Lakshminarayan) **Module 20 Readings** • Using Electronic Health Records for Population Health Research: A Review of Methods and Applications. • Casey JA, Schwartz BS, Stewart WF, Adler NE. (2016) • Annu Rev Public Health.;37:61-81. http://www.annualreviews.org/doi/abs/10.1146/annurev-publhealth-032315-021353 • Type 2 Diabetes Mellitus Trajectories and Associated Risks. • Oh W, Kim E, Castro MR, Caraballo PJ, Kumar V, Steinbach MS, Simon GJ. (2016), Big Data. 2016 Mar 1;4(1):25-30. • PMID: 27158565 http://www.ncbi.nlm.nih.gov/pubmed/27158565 • Diabetes and Asthma Case Identification, Validation, and Representativeness When Using Electronic Health Data to Construct Registries for Comparative Effectiveness and Epidemiologic Research. • Desai, J. R., Wu, P., Nichols, G. A., Lieu, T. A., & O'Connor, P. J. (2012), Medical Care, 50: S30-S35. doi: 10.1097/MLR.1090b1013e318259c318011. http://www.ncbi.nlm.nih.gov/pmc/articles/pmid/22692256/ • Learning About Missing Data Mechanisms in Electronic Health Records-based Research: A Survey-based Approach. • Haneuse S, Bogart A, Jazic, Westbrook EO, Boudreau D, Theis MK, Simon GE, Arterburn D. (2016). Epidemiology. 2016 Jan;27(1):82-90. doi: 10.1097/EDE.0000000000000393. http://www.ncbi.nlm.nih.gov/pubmed/26484425 • Importance of Accurately Identifying Disease in Studies Using Electronic Health Records. Manuel, Douglas G; Laura C Rosella; and Thérèse A Stukel. (2010), BMJ 341. BMJ 2010;341:c4226 doi: 10.1136/bmj.c4226 http://www.jstor.org/stable/20766221	• Submit Homework 2 Manuscript Proposal Part 3 of 3 (due 5/5)
May 11-13	**Final Exam**	• Final Exam

HW1. (Total 10 points)

Part 1.

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. 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.

Part 1: 2 points. Part 2: 8 points. (Note: In part 2, students will parse their guideline for levels of evidence and study design underlying 3 recommendations in treatment / prevention and 2 recommendations in diagnosis. Students are requested to pick no more than 2 level 1 recommendations in total. So they will have to use other levels of evidence.)

HW2. (Total 30 points)

Part 1

Identify a large federally funded data source relevant to your field similar to the studies discussed in Module 5. 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. (2 points). The instructor will have to approve your choice to move forward.

Part 2

Develop a manuscript proposal (the idea has to be novel) based on the template identified on Part 1. Submit by end of week 10. Feedback will be provided by week 12. Feedback will be in person or via skype or google chats as preferred. (8 points) Part 3. Submit final manuscript proposal by end of week 15. (20 points).

HW 3 (20 points)

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

HW 4 (20 points)

Problems on confounding, bias and effect modification.

Total HW points = 80

Midterms (60 points) and Final (60 points) will be online, open book exams.

VII. Evaluation and Grading

Students will be graded through a combination of homework assignments, mid-term quiz, clinical epidemiology paper, and final exam. MS CR students are required to take this course for the A/F grading option to fulfill their curricular requirements and a grade of B- or higher is needed to advance in the program.

There will be 4 homework assignments – scheduled as in the Table above. There will be 1 midterm and 1 Final. Misterms and Finals will be online open book exams.

HW 1 = 10 points

HW 2 = 30 points

HW 3 = 20 points

HW 4 = 20 points

Participation in weekly roundtable discussion = 20 points

Midterm = 50 points

Final = 50 points. Final will cover the entire material taught in the course though the questions will be weighted toward material taught since the mid term

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.

Midterms and Final exams will be available during a 72 hour time window. Students will have 2 hours (120 minutes) to complete each exam. The system will track the start of the exam online and will close the exam after 120 minutes. Please set aside an adequate time window for taking the exam. Expectations are that the student will work by themselves. If you have a genuine reason for being unable to take the exam in that time window, please contact the instructor for alternate arrangements.

The total points above add up to 200.

Grades (A-F) will be assigned on the basis of the following distribution of grades

Highest	Lowest	Letter	
100.00 %	93.00 %	A	Represents achievement that is outstanding relative to the level necessary to meet course requirements
92.99 %	90.00 %	A-	
89.99 %	87.00 %	B+	
86.99 %	83.00 %	B	Represents achievement that is significantly above the level necessary to meet course requirements
82.99 %	80.00 %	B-	
79.99 %	77.00 %	C+	
76.99 %	73.00 %	C	Represents achievement that meets the course requirements in every respect
72.99 %	70.00 %	C-	
69.99 %	67.00 %	D+	
66.99 %	60.00 %	D	Represents achievement that is worthy of credit even though it fails to meet fully the course requirements
59.99 %	0.00 %	F	

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/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 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

Technical Issues and Support

We understand that there can be technical problems or computer "glitches". If you experience a technical problem, DO NOT PANIC. These types of problems can be solved and we can make allowances for such problems. So if you are in the middle of a quiz at 11:55 pm on a Saturday night and the website shuts down and you try to get back in and can't and the deadline for the quiz is at 12:01 am Sunday. DO NOT PANIC. Send an email explaining the problem. Technical issues are electronically documented in the course. We will help you on Monday morning. We will understand that you had a problem, and we can give you a break. Our past experience with this class shows that variety of technical problems can occur during any given semester. Often the teaching team can provide only limited technical support for many of these problems and you may need to contact others for assistance. Listed below are some helpful tips on whom to contact about various technical problems you might encounter during the semester: For content-related problems such as broken links, content or tables not available: post a note in the "Content, Typos, Errors, and Broken Links" discussion forum and/or contact the instructor.

 For Moodle-related technical problems, call the Help Desk (612) 301-4357 (1-HELP on Campus). They respond to questions and concerns Monday-Friday, 8am-5pm. Or, fill out the help request form at: http://it.umn.edu/course-management-system-moodle-related/students. Regularly scheduled maintenance of Moodle would be noted on this website (https://umnprd.service-now.com/sysstatus/), although updates and maintenance for Moodle is infrequent and usually occurs between semesters, so we don't anticipate that this will pose a problem. For technical issues, you may also contact the Distance Education Coordinator, Jim Harpole: harpo002@umn.edu.

For all other computer- and software-related problems contact the Help Line at 612-301-4357, http://www.oit.umn.edu/help-support/

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-oasr@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."

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. Disability Services (DS) 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 DS at 612-626-1333 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: for courses that do not involve students in research

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.*

Reports of concerns about academic freedom are taken seriously, and there are individuals and offices available for help. Contact the instructor, the Department Chair, your adviser, the associate dean of the college, or the Vice Provost for Faculty and Academic Affairs in the Office of the Provost.

* Language adapted from the American Association of University Professors "Joint Statement on Rights and Freedoms of Students".

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