Measurement in Pharmaceutical Outcomes and Policy Research

PHA 6717

Class Periods: Tuesdays, 9AM-12PM
Location: HPNP 2306 & Zoom
Academic Term: Fall 2022

Instructors:
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Office Hours: By Appointment

Course Description

This course covers measurement of health outcomes as ascertained from real-world data, including patient-reported outcomes and clinical and administrative databases. Additionally, we address strategies for identifying biases arising from misclassification of exposure, outcomes and confounders, as well as approaches to mitigate such biases, including missing data problems and time-related biases in measurement and study design.

Course Pre-Requisites / Co-Requisites

STA 6217 or equivalent

Course Objectives

- Describe the role of measurement in the context of the scientific method.
- Identify key issues in design and validity of patient-reported outcomes measures, including item and response wording, response scaling, item sequencing, and questionnaire administration.
- Identify data ascertainment techniques, weaknesses and strengths for clinical measures that rely on secondary data sources including billing data, registries, and electronic health records.
- Explain methods of determining reliability, validity and acceptability of measures.
- Define and describe examples of measurement error and misclassification bias in both exposure, confounding and outcome measurement.
- Describe approaches to address measurement error and misclassification bias
- Identify measurement error related to time in making causal inferences
- Assess the impact of measure misspecification and missingness on the ability to find unbiased estimates of an association.

Materials and Supply Fees

None

Required Textbooks and Software

- Title: Health measurement scales.
- Author: Streiner DL, Norman GR & J Cairney.
- Publication date: 2015 (5th Edition)
- ISBN number: 978-0199685219

The text above is available from UF Health libraries or may be purchased as a digital eBook or physical book. All other readings and materials are posted on the course Canvas site.

Course Structure and Procedures

Overview: PHA 6717 is a graduate level class that is structured as a "seminar" or discussion class. The success of such a class depends on your keeping up with the assignments and participating actively in class discussions. As a student in the course, you are also expected to read material beyond the required readings. For example, when the assignment is to read and critique a research article(s), you are expected to thoroughly understand the article. If authors state that they based their research on a validated measure, you are expected to read more to determine whether the measure was appropriately validated and can be used for the research question at hand. If authors state that they used a particular analytic method, you will be expected to read about this method to determine whether or not the method was used appropriately and what its advantages or disadvantages may have been.

Resources posted on Canvas for each week will include an overview of learning objectives, related readings and instructions for a written assignment. Each week some students will be chosen to present the core learning content for that week in class. Those students can choose the mode of presentation they prefer and plan on a succinct 15-30 minute summary in class. The content of this summary should follow closely the learning objectives for the week and synthesize relevant content of the readings as it relates to these objectives. For example, in preparing the synthesis it is important to consider that some passages of the readings may not be relevant to the learning content and thus, should be omitted. This implies that it is not acceptable to present a summary of each reading component sequentially, i.e., to summarize each individual paper. Instead, relevant information should be synthesized across papers for presentation.

All students are expected to be prepared to discuss the content that was included in the readings and in their written assignments in class. Students are encouraged to bring supplemental information from additional readings or other materials that can enhance understanding of the topic. In past classes, students have shared a Dropbox folder to allow access to all materials they assembled, and we encourage that. You should be prepared to ask questions that spark discussion, promote critical thinking and even debate, and encourage the application of concepts to specific situations relevant to research in POP.

Weekly written assignments (should not exceed 1-2 pages): Faculty will post several discussion questions each week. Each student must submit his or her answers by noon of the day before class via Canvas. Compliance with this deadline is critical to allow faculty time to read assignments. Answer each of the questions using cohesive paragraphs. Your paragraphs should be textual. Please do not use outlines or sentence fragments for your answers.

Class meetings: Students will be chosen to provide a synthesis of the reading materials related to the weekly topic. The synthesis should be organized according to the learning objectives that were posted for the week, cover the reading materials as well as additional material that the student has found to be useful to enhance discussion of the topic. Following this presentation, the selected student is then expected to lead the class in a discussion.

Each time a student's leads a discussion during class, performance will be graded on a scale of 0-5. Grading of performance in class meetings is based on the following criteria:

- Class presentation is well organized and provides an accurate and concise overview of the assigned topic
- The presentation uses examples or other additional material to emphasize or exemplify learning objectives
- Questions to the group reflect insightful understanding of the assigned readings

- Leader effectively encourages and leads discussion throughout the discussion period
- Leader summarizes key points raised during the discussion

Selection of a measurement instrument (group assignment, 2-3 students per group): During the course of the semester, you will be asked to conduct a review regarding measurement of commonly used outcomes. Because commonly used measures have a large volume of literature testing their reliability and validity, you will work in groups. You will summarize your findings in a presentation in class and a term paper that is due 1 week before the scheduled presentation.

The outcome that has been selected for this year is "active suicidal ideation." Suicidal ideation is defined by the DSM-5 as thoughts about self-harm, and the state of 'active' suicidal ideation describes a person who is engaging in deliberate planning of techniques and/or gathering tools to commit suicide. The observed increases in attempted and completed suicides in the United States in the last two years is hypothesized to have several drivers. Two hypothesized drivers that receive significant attention are: 1) effects from COVID-19 (including physical/mental health effects of COVID as well as general social unrest and economic instability), and 2) reduced access to opioid pharmacotherapies for chronic pain management. Imagine that you are planning a study to examine change in active suicidal ideation over time and to identify causes. Specifically, you are interested in evaluating one of two effects: whether the pandemic or whether efforts to restrict access to prescription opioids have caused an increased risk in suicidal ideation. You are therefore requested to select and/or propose a **measure to assess active suicidal ideation**. We are not interested in your study design, but rather your choice of a measure that is reliable, valid, and stable across time. We are also not interested in measures of suicide attempts or suicide mortality. You are expected to present at least 3 different approaches in how the construct has been measured. Present a published validation (if available) and discuss the strengths and weaknesses of each selected approach. Then, develop the "ideal" measure for your study.

Course outline

The table below provides an overview of all class sessions along with planned topics, learning objectives and readings. Some class session dates may change due to travel or department events. Assignments will be posted online in separate documents for each week. Please note that the listed readings may not be final. For each week, we will post a word document in Canvas that outlines the learning objectives, readings and assignments. Please refer to this document for all preparatory work. Materials will be available one week before the actual meeting time.

Date	Topic	Learning objectives	Readings
W1 9/6	Introduction to class		Kimberlin CL, Winterstein AG. Am J Health Syst Pharm. 2008; 65:2276-84
	Causal inference and scientific method	1. Describe key considerations in making causal inferences in science 2. Provide a brief overview of the evolution of theory of science and the scientific method	Rothman JK. Epidemiology: An Introduction. Oxford University Press. 2nd edition. Chapter 3: What is causation? Optional: Rothman KJ, Gallacher JEJ, Hatch EE. Why representativeness should be avoided. Int J Epidem 2013;42:1012-1014 - Commentaries and rebuttal following the article above: Int J Epidem 2013;42:1014-1028
	Constructs of health in clinical assessment	1. Explain the relationship of clinical outcomes to measurement constructs 2. Name some approaches to categorization of outcomes	Optional: Starfield B. Measurement of Outcome – Proposed Scheme. The Milbank Quarterly, Vol. 83, No. 4, 2005 (pp. 1–11)
	Measurement Matters	1. Explain why issues with measurement may lead to erroneous conclusions	Measurement case study, reading #1: Bergin & Keller. December 21, 2021. "Uncounted: Inaccurate death certificates across the country hide the true toll of COVID-19." Measurement case study, reading #2: Aschwanden. October 20, 2021. "Debunking the false claim that COVID death counts are inflated." Readings are available for download from the course site.
W2 9/9	Classical test theory (Goodin)	1. Define the process of measurement in science 2. Define key features of classical test theory	Streiner DL, Norman GR, Cairney J. Health measurement scales. 5th edition. 2015. Oxford University Press, Ontario, Canada. Chapter 1 & 2.
	Reliability and reliability coefficients (Goodin)	1. Define reliability per classical test theory 2. Explain the meaning of ICCs and the distinction between consistency versus absolute agreement 3. Compare and contrast the meaning, advantages, and disadvantages of various reliability coefficients 4. Describe the relationship between reliability coefficients and sample size	Streiner DL, Norman GR, Cairney J. Health measurement scales. 5th edition. 2015. Chapter 5 from "homogeneity of items". Streiner DL, Norman GR, Cairney J. Health measurement scales. 5th edition. 2015. Chapter 8 until section "reliability generalization." Optional: Trevethan R. Intraclass correlation coefficients: clearing the air, extending some cautions, and making some requests. Health Services and Outcomes Research Methodology. 2017 Jun 1;17(2):127-43. Krell RW, Hozain A, Kao LS, Dimick JB. Reliability of Risk-Adjusted Outcomes for Profiling Hospital Surgical Quality. *JAMA Surg.* 2014;149(5):467–474. doi:10.1001/jamasurg.2013.4249.
	Measure generalizability (Goodin)	1. Describe key considerations in generalizing measure reliability	Streiner DL, Norman GR, Cairney J. Health measurement scales. 5th edition. 2015. Chapter 8 from "reliability generalization". Boonstra AM, et al. Reliability and validity of the visual analogue scale for disability in patients with chronic musculoskeletal pain. International Journal of Rehabilitation Research 2008;31(2):165-169.
W3 9/13	Validity (Goodin)	1. Define validity in the context of classical test theory and theory of science 2. Explain the use of content, criterion, construct, discriminant and convergent validation approaches to assess validity 3. Explain the concept of responsiveness and sensitivity to change	Streiner DL, Norman GR, Cairney J. Health measurement scales. 5th edition. 2015. Chapter 10. Validity. Read up to "Validity and types of indices".

		in measure validation	McHorney CA et al. The MOS-36-Item Short-Form Health Survey: II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Medical Care* 1993; 31:247-263.
	Criterion validation (Goodin)	1. Define validation approaches for clinical measures of disease 2. Define and rank the relevance of sensitivity, specificity and positive predictive value for different clinical and research scenarios 3. Explain ROC curves	Wiley LK, et al. ICD-9 tobacco use codes are effective identifiers of smoking status. Journal of the American Medical Informatics Association: JAMIA. 2013;20(4):652-658. doi:10.1136/amiajnl-2012-001557. Chen G et al. Validating ICD9 coding algorithms for diabetes mellitus from administrative data. Diab Res Clin Pract 2010;89:189-195. Martin, Greg, et al. "The Severity of Dependence Scale (SDS) in an adolescent population of cannabis users: reliability, validity and diagnostic cut-off." Drug and Alcohol Dependence83.1 (2006): 90-93.
		1.	

W4 9/20	Patient-reported outcomes (Goodin)	1. Define the construct of patient-reported outcomes and discuss their relevance in the assessment of drugs and healthcare service 2. Describe how patient-reported outcomes measurement is implemented	McKenna SP. Measuring patient-reported outcomes: moving beyond misplaced common sense to hard science. BMC Medicine 2011; 9(1), 86.
	PRO item selection (Goodin)	1. Describe ways to identify items for PROs 2. Define key features of content validity of a PRO and how it is assessed 3. List key considerations for item selection in PRO development	Streiner DL, Norman GR, Cairney J. Health measurement scales. 5th edition. 2015. Chapter 3 and 5 until section "homogeneity of the items" Rothman M, Burke L, Erickson P et al. Use of existing patient-reported outcome (PRO) instruments and their modification: Value in Health 2009; 12(8): 1075-83.
	PRO response scales (Goodin)	1. Compare advantages of continuous versus categorical PRO response scales 2. Describe examples of direct PRO estimation methods and discuss advantages and disadvantages 3. Name examples of comparative PRO scaling methods	Streiner DL, Norman GR, Cairney J. Health measurement scales. 5th edition. 2015. Oxford University Press, Ontario, Canada. Chapter 4 "Scaling responses" and Chapter 6 "Biases in responding"
	PRO in HSR and PharmEpi (Goodin)	1. Explain how and why PRO is used for different purposes in HSR and PharmEpi	Elliot MN, et al. *Patterns of Unit and* Item Nonresponse in the CAHPS Hospital Survey. Health Services Research 2005;40(6): 2096-2119. England LJ, et al. Misclassification of maternal smoking status and its effects on an epidemiologic study of pregnancy outcomes. Nicotine & Tobacco Research 2007;9(10), 1005-1013.

W5 9/27	Measuring mortality (Goodin)	1. Describe the coding conventions for cause of death 2. Identify limitations of cause of death data	Introduction into measurement of death: http://www.deathreference.com/Bl-Ce/Causes-of-Death.html Anderson RN et al. Comparability of Cause of Death between ICD–9 and ICD–10: Preliminary Estimates. NVSS 2001;49(2) Kiang et al. Every Body Counts: Measuring Mortality From the COVID-10 Pandemic. Annals of Internal Medicine. 2020;173(12):1004-1007.
	Measuring Social Determinants	1. Define examples of Social Determinants of Health (SDoH), including Race, Ethnicity, socioeconomic status, and "place" (geography) 2. Analyze strengths and limitations of typical measurement	Lett E, Asabor E, et al. Conceptualizing, contextualizing, and operationalizing race in quantitative health services research. *Annals of Family Medicine.* 2022;20. Magnan S. Social determinants of health '101' for healthcare: five plus five. *National Academy of Medicine Perspectives.* 2017:Oct 9.

	of Health (SDoH)	approaches for capturing SDoH from claims and EHR 3. Describe approaches for incorporating SDoH measures	Nead KT, et al. Cautions when using race and ethnicity in administrative claims datasets. *JAMA Health Forum.* 2022;3(7):e221812.
	Surrogate endpoints	1. Describe key requirements for a surrogate endpoint to serve as valid proxy for the measurement of a drug effect 2. Describe key challenges in establishing epidemiologic evidence for the link between a surrogate and hard clinical endpoint.	Fleming TR. Surrogate endpoints and FDA/s accelerated approval process. Health Affairs 2005;24:67-78. Riddle MC et al. Epidemiologic relationship between A1c and all-cause mortality during a median 3.4-year follow-up glycemic treatment in the ACCORD trial. Diabetes Care 2010;33:983-90

W6 10/4	EHR & claims data (Smith)	1. Summarize key issues with the use of EHR data in drug safety and effectiveness research. 2. List approaches to evaluate the quality of EHR data 3. Compare and contrast the validity of outcomes definitions using EHR versus claims data	Caveats for the Use of Operational Electronic Health Record Data in Comparative Effectiveness Research. Medical Care. 2013;51: S30-S37 Data Quality Assessment for Comparative Effectiveness Research in Distributed Data Networks. Medical Care. 2013;51: S22-S29 Terris et al. Health State Information Derived from Secondary Databases was affected by Multiple Sources of Bias. J Clin Epidemiol. 2007 July; 60(7): 734–741.

W7 10/11	Misclassification of outcomes (Winterstein)	1. Describe common ways how outcomes can be misclassified by inappropriate or invalid data ascertainment methods 2. Explain the concepts of differential and non-differential misclassification 3. Describe how misclassification of outcomes affects the estimate of associations between exposure and outcomes	Hartzema AG and Schneeweiss S. Addressing misclassification in pharmacoepidemiologic studies. (Chapter 13) in: Hartzema et al (ed) Pharmacoepidemiology and Therapeutic Risk Management, Harvey Whitney Books, Cincinnati, OH 2008 Setoguchi S et al. Agreement of diagnosis and its date for hematologic malignancies and solid tumors between Medicare claims and cancer registry data. Cancer Causes Control 2007;18:561-569
	Composite endpoints (Winterstein)	1. Describe the advantages and disadvantages in utilizing composite endpoints 2. List the key requirements for the composition of multiple endpoints in safety or efficacy assessments	Montori VM et al. Validity of composite end points in clinical trials. BMJ 2005;330:594-f Ignacio Ferreira-González et al. Problems with use of composite end points in randomised controlled trials cardiovascular trials: systematic review of trials BMJ 2007;334;786 Tomlinson et al. Composite End Points in Randomized Trials: There Is No Free Lunch. JAMA.2010; 303: 267-268
	Addressing outcomes misclassification (Winterstein)	1. Describe approaches to address outcomes misclassification	Funk MJ et al. Misclassification in administrative claims data: quantifying the impact on treatment effect estimates. Curr Epidemiol Rep 2014;1:175-195 Magder LS, Hughes JP. Logistic regression when the outcome is measured with uncertainty. Am J Epi 1997;146:195-203

W8 10/18	Drug exposure measurement (Winterstein)	1. Describe methods of exposure measurement from secondary data sources 2. Explain how dose and duration can be summarized to quantify exposure and discuss strengths and weaknesses of various approaches	Wettermark B et al. Drug Utilization Research. In: Hartzema et al (ed) Pharmacoepidemiology and Therapeutic Risk Management, Harvey Whitney Books, Cincinnati, OH 2008, pages 159-174 Raebel et al. Standardizing Terminology and Definitions of Medication Adherence and Persistence in Research Employing Electronic Databases. Medical Care 2013;51:S11-21 Van Staa TP et al. oral corticosteroids and fracture risk: relationship to daily and cumulative doses. Rheumatology 2000;39:1383-1389
	Exposure mis-classification (Winterstein)	1. Describe common sources of exposure misclassification in drug studies 2. Estimate the impact of exposure misclassification on association estimates	Hartzema AG and Schneeweiss S. Addressing misclassification in pharmacoepidemiologic studies. (Chapter 13) in: Hartzema et al (ed) Pharmacoepidemiology and Therapeutic Risk Management, Harvey Whitney Books, Cincinnati, OH 2008.

		3. Describe approaches to address exposure misclassification in studies on drug effects	Funk MJ et al. Misclassification in administrative claims data: quantifying the impact on treatment effect estimates. Curr Epidemiol Rep 2014;1:175-195 Bodnar et al. The Impact of Exposure Misclassification on Associations Between Prepregnancy BMI and Adverse Pregnancy Outcomes. Obesity 2010

W9 10/25	Time in measuring exposure (Winterstein)	1. Describe ways and provide examples how associations between drugs and outcome can vary over time 2. Describe the set-up of time-varying exposure and how drug exposure windows can be varied to determine the duration and intensity of drug effects, including addressing depletion of susceptibles. 3. Describe how measures of exposure duration or intensity can be incorporated into the time-varying exposure definitions.	Rothman KJ and Greenland S. Cohort Studies. In: Rothman KJ, Greenland S, Lash TL. Modern Epidemiology. 3rd Edition. 2008, Philadelphia, PA Stricker BHCh and Stijnen T. Analysis of individual drug use as a time-varying determinant of exposure in prospective population-based cohort studies. Eur J Epidemiol 2010;24:245-251 Suissa S et al. First-time use of newer oral contraceptives and the risk of venous thromboembolism. Contraception 1997;56:141-146 Ray WA. Evaluating medication effects outside of clinical trials: new-user designs. Am J Epidemiol 2003;158:915-920 This is a cool way to estimate risk windows – just review briefly to get an idea about the approach: Drug exposure risk windows and unexposed comparator groups for cohort studies in Pharmacoepidemiology. PDS 1998;7:275-280
	Time-related biases	1. Describe time-related biases including time window bias and immeasurable time bias. 2. Describe approaches in design and analysis that address time-varying effects	Suissa S et al. Time-window bias in case control studies: statins and lung cancer. Epidemiology 2011;22:228-231 http://www.ncbi.nlm.nih.gov/pubmed/21228697 Suissa S. Immeasurable time bias in observational studies of drug effects on mortality. Am J Epidemiol 2008;168:329-35 Suissa S et al. Metformin and the risk of cancer. Diabetes Care 2012;35:2665-2673
	Immortal time bias	3. Describe immortal time bias and discuss design and analytical solutions.	Suissa S. Immortal time bias in observational studies of drug effects. PDS 2007;16(3):241-249 Suissa S. Immortal time bias in pharmacoepidemiology. Am J Epidemiol 2008;167 (4): 492-499. Zhou Z et al. Survival Bias Associated with Time-to-Treatment Initiation in Drug Effectiveness Evaluation: A Comparison of Methods. Am J Epidemiol 2005;162 (10): 1016-1023

W10 11/1	Identify types of missingness (Goodin)	1. Describe types of missingness in epidemiological research 2. Identify different types of missingness 3. Select appropriate approaches to address missingness	Neil J. Perkins, Stephen R. Cole, Ofer Harel, Eric J. Tchetgen Tchetgen, BaoLuo Sun, Emily M. Mitchell, and Enrique F. Schisterman Principled Approaches to Missing Data in Epidemiologic Studies. Am J Epidemiol 2017; 187 (3). Janssen et al. Missing covariate data in medical research: To impute is better than to ignore. J Clin Epidem. 2010;63:721-727
	Unstructured Data (Rouhizadeh)	1. Describe measurement considerations for social media data 2. Identify strengths and limitations of measurement strategies for unstructured EHR data	Selected readings

W11 11/8	DAGs (Albogami)	1. Describe principles of causal diagrams 2. Explain confounding using DAGs	Hernán MA, Hernández-Díaz S, Robins, JM. A Structural Approach to Selection Bias. Epidemiology 2004;15(5):615-625. doi: 10.1097/01.ede.0000135174.63482.43 Hernan M et al. Causal Knowledge as a Prerequisite for Confounding Evaluation: An Application to Birth Defects Epidemiology. AJE 2002;155(2):176-184 https://academic.oup.com/aje/article/155/2/176/108106

	Selecting and measuring confounders (Winterstein)	1. Delineate a strategy to establish a comprehensive set of confounders that should be considered for adjustment in causal inference studies. 2. Discuss strategies to select confounders for inclusion in multivariate adjustment.	Klein-Geltink JE et al. Readers should systematically assess methods used to identify, measure and analyze confounding in observational cohort studies. JCE 2007;60(8):766.e1-11 Sauer BC et al. A Review of Covariate Selection for Nonexperimental Comparative Effectiveness Research. Pharmacoepidemiol Drug Saf. 2013 Nov;22(11):1139-45. Schisterman EF et al. Overadjustment Bias and Unnecessary Adjustment in Epidemiologic Studies. Epidemiology. 2009 Jul; 20(4): 488–495.

W12 11/15	Misclassified confounders (Winterstein)	1. Describe types and examples of confounder misclassification 2. Describe the parameters that define the direction and strength of impact of misclassified or unmeasured confounders on associations 3. Describe how the impact of residual confounding can be estimated	Hartzema AG and Schneeweiss S. Addressing misclassification in pharmacoepidemiologic studies. (Chapter 13) in: Hartzema et al (ed) Pharmacoepidemiology and Therapeutic Risk Management, Harvey Whitney Books, Cincinnati, OH 2008 Oliveira et al. self-reporting weight and height: misclassification effect on the risk estimates for acute myocardial infarction. Europ J Publ Health 2009 Knol et al. Unpredictable bias when using the missing indicator method or complete case analysis for missing confounder values: an empirical example. J Clin Epi 2010;63:728-736 Gamble et al. Quantifying the Impact of Drug Exposure Misclassification due to Restrictive Drug Coverage in Administrative Databases: A Simulation Cohort Study. Funk MJ et al. Misclassification in administrative claims data: quantifying the impact on treatment effect estimates. Curr Epidemiol Rep 2014;1:175-195
	Time-varying confounding	1. Distinguish the concept of time-varying confounding and time-modified confounding and explain how they matter in causal inferences on exposure effects. 2. Explain the particular problems that arise with time-varying or time-modified confounding where the confounder is affected by prior treatment. 3. Describe in concept why marginal structure models can create unbiased estimates of treatment effects.	Xie D et al. Statistical methods for modeling time-updated exposures in cohort studies of chronic kidney disease. Clin J Am Soc Nephr 2017;12:1892-1899. Platt RW et al. Time-modified confounding. AJE 2009;170:687-694

W13 11/22	Propensity scores (Winterstein)	1. Describe basic principles and assumptions in using exposure propensity scores to adjust for confounding 2. Summarize advantages and disadvantages in using a propensity score for confounder adjustment	Webster-Clark, M, Stürmer, T, Wang, T, et al. Using propensity scores to estimate effects of treatment initiation decisions: State of the science. Statistics in Medicine. 2021; 40: 1718– 1735. Glynn, R.J., Schneeweiss, S. and Stürmer, T. (2006), Indications for Propensity Scores and Review of their Use in Pharmacoepidemiology. Basic & Clinical Pharmacology & Toxicology, 98: 253-259. Westreich, D., Cole, S.R., Funk, M.J., Brookhart, M.A. and Stürmer, T. (2011), The role of the c-statistic in variable selection for propensity score models. Pharmacoepidem. Drug Safe., 20: 317-320. Brookhart MA, Wyss R, Layton JB, Stürmer T. Propensity Score Methods for Confounding Control in Nonexperimental Research. Circulation Cardiovascular Quality and Outcomes. 2013;6:604–611.
	Addressing misclassified confounders with external data	1. Describe how to address residual confounding with external information 2. Explain the steps and assumptions in use of propensity score calibration	Schneeweiss S et al. Adjusting for Unmeasured Confounders in Pharmacoepidemiologic Claims Data Using External Information. Epidemiology 2005;16: 17–24 Stuermer T et al. Adjusting Effect Estimates for Unmeasured Confounding with Validation Data using Propensity Score Calibration. AJE 2005;162:279-289

	Instrumental variables	1. Define what an instrumental variable is in causal inference. 2. Describe the general application of instrumental variables to address residual confounding	Brookhart et al. Evaluating Short-Term Drug Effects Using a Physician-Specific Prescribing Preference as an Instrumental Variable. Epidemiology 2006;17: 268–275) Schneeweiss S et al. Aprotinin during coronary artery bypass grafting and risk of death. N Engl J Med 2008;358:771-83.

W14 11/29	Measurement in Prediction (Shao)	1. Describe validation approaches of prediction models 2. Describe key concepts to measure the validity of prediction models 3. Apply best practices of prediction model validation in evaluating published studies on risk score development	Alba AC, Agoritsas T, Walsh M, et al. Discrimination and Calibration of Clinical Prediction Models: Users' Guides to the Medical Literature. JAMA 2017; 318(14): 1377-84. Eddy DM, Hollingworth W, Caro JJ, Tsevat J, McDonald KM, Wong JB. Model transparency and validation: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force–7. Medical Decision Making 2012; 32(5): 733-43.
	Presentation of group assignments		Group paper due at the time of the presentation

12/6	Final Exam

Critical Dates

Group Presentation on Development and Validation of Clinical Measure: **Third Week in April**
Final exam: **December 6th**

Attendance Policy, Class Expectations, and Make-Up Policy

Requests for excused absences MUST be made by email to the course coordinator prior to the scheduled session. Excused absences must be consistent with university policies in the Graduate Catalog and require appropriate documentation. Additional information can be found in Attendance Policies.

Evaluation of Grades

Assignment	***Percentage of Final Grade***
Measure Selection/Validation (group project)	25%
Final Exam (in-house, closed book)	25%
Leading class discussion	25%
Participation in class discussion	15%
Weekly Assignments	10%
	100%

Criteria for grading of participation in class discussion:

15% - consistently active participation with independent contributions that enrich class content
12% - student is consistently well-prepared and participates in class discussion
10% - student is largely well-prepared but participates only when solicited
0% - student is consistently ill-prepared

Interim grades for participation in class discussion will be assigned three times throughout the course: after the end of week 4, week 8 and week 14.

Grading Policy

A	100%	to 95%
A-	< 95%	to 90%
B+	< 90%	to 87%
B	< 87%	to 84%
B-	< 84%	to 80%
C+	< 80%	to 77%
C	< 77%	to 74%
C-	< 74%	to 70%
D+	< 70%	to 67%
D	< 67%	to 64%
D-	< 64%	to 61%
F	< 61%	to 0%

More information on UF grading policy may be found at:
UF Graduate Catalog
Grades and Grading Policies

Students Requiring Accommodations

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the Disability Resource Center. It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester.

Course Evaluation

Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students on the Gator Evals page.

University Honesty Policy

UF students are bound by The Honor Pledge which states, "We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: "On my honor, I have neither given nor received unauthorized aid in doing this assignment." The Honor Code specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Software Use

All faculty, staff, and students of the University are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate. We, the members of the University of Florida community, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

Student Privacy

There are federal laws protecting your privacy with regards to grades earned in courses and on individual assignments. For more information, please see the Notification to Students of FERPA Rights.

Campus Resources

Health and Wellness

U Matter, We Care:
If you or a friend is in distress, please contact umatter@ufl.edu or 352 392-1575 so that a team member can reach out to the student.

Counseling and Wellness Center: counseling.ufl.edu/cwc, and 392-1575; and the University Police Department: 392-1111 or 9-1-1 for emergencies.

Sexual Assault Recovery Services (SARS)
Student Health Care Center, 392-1161.

University Police Department at 392-1111 (or 9-1-1 for emergencies), or police.ufl.edu.

Academic Resources

E-learning technical support, 352-392-4357 (select option 2) or e-mail to Learning-support@ufl.edu.

Career Resource Center, Reitz Union, 392-1601. Career assistance and counseling.

Library Support, Various ways to receive assistance with respect to using the libraries or finding resources.

Teaching Center, Broward Hall, 392-2010 or 392-6420. General study skills and tutoring.

Writing Studio, 302 Tigert Hall, 846-1138. Help brainstorming, formatting, and writing papers.

Student Complaints Campus

On-Line Students Complaints