RUTGERS
School of Public Health

9/2/2022

Course Title: Analysis of Real-World Pharmacoepidemiological Data

Course Number: EPID0678

Course Pre- and Co-requisite(s): EPID0656; EPID0672; BIST0535

Course Location: School of Public Health, Piscataway, Room 234

Course Date & Time: Monday 3-5pm

Course Instructor: Greta Bushnell, PhD, MSPH

Assistant Professor of Epidemiology
Rutgers School of Public Health
Center for Pharmacoepidemiology and Treatment Science
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Office Hours: By Appointment

Course Assistant: None

Course Website: *canvas.rutgers.edu*

Required Course Text: None required

Course Description: This course is intended for students interested in applying pharmacoepidemiology theory to real-world data. Broadly, the course will cover: 1) Research with and structure of healthcare databases, 2) Creating a study cohort and defining study variables for pharmacoepidemiological research in healthcare data, and 3) Descriptive and comparative pharmacoepidemiological analysis in longitudinal healthcare data. The majority of the course will be spent in a lab format with students applying the course topics to a longitudinal administrative claims dataset.

Selected Concentration Competencies Addressed: Competencies addressed for the MS in Epidemiology with a concentration in Pharmacoepidemiology:

- Appropriately analyze and interpret pharmacoepidemiologic data, including large national or international level datasets
- Develop and test a specific hypothesis using an appropriate pharmacoepidemiologic study design and analysis plan
- Synthesize epidemiologic literature on pharmacoepidemiology topics in order to generate conclusions and recommendations
- Select and implement pharmacoepidemiologic techniques to quantitatively assess patterns and changes in disease and treatment of disease
- Determine appropriate use and implement data systems in pharmacoepidemiologic research and/or practice

- Implement complex quality control methods during pharmacoepidemiologic data analysis

Please visit the Concentration webpages on the School of Public Health's website at sph.rutgers.edu for additional competencies addressed by this course for other degrees and concentrations.

Course Objectives: By the completion of this course, students will be able to:

- Understand the strengths and limitations of real-world data used in pharmacoepidemiological research
- Understand pharmacoepidemiological study design considerations and the steps involved in creating a research cohort
- Build a study cohort in longitudinal claims data using SAS
- Analyze data from a large administration claims dataset
- Interpret findings from an analysis completed in a large healthcare dataset
- Develop a research question and design an appropriate pharmacoepidemiological study to address the research question using administrative claims data

Course Requirements and Grading: *In this section, Instructor should include*

Required projects, assignments, and activities:

	Grade value	Notes
Weekly assignments	30%	Each week there will be an assignment related to the student's individual project. Assignments will run in-parallel with the topics covered that week in lecture and lab.
In-class lab activities	30%	In the weekly lab section of class, students apply the topic of the week to the dataset. Completion of this activity may be checked through SAS code, data output, table completion, or other means as appropriate. Group work will be encouraged for certain weeks.
Project peer-review	15%	Partway through the semester, students will formally review another student's study protocol. Students will be graded on their feedback.
Final project and presentation	15%	The final project (study protocol) is an accumulation of the weekly assignments. The final project should incorporate feedback received through the weekly assignments and peer-reviews. Projects will be presented at semester's end.
Class Participation	10%	Class participation grades will be assigned based on weekly attendance and contribution to the group discussion.
Total	*100%*	

Course assessments linked to course competencies:

Competency	Course Objectives(s)	Lessons (Week # in course schedule)	Assessment(s)
Appropriately analyze and interpret pharmacoepidemiologic data, including large national or international level datasets.	D, E	10-15	Participation in and completion of in-class lab activities; Individual assignments (analysis plan in study protocol)
Develop and test a specific hypothesis using an appropriate pharmacoepidemiologic study design and analysis plan	A, B, C, D, F	1-15	Individual assignments (study protocol development); Final project/presentation
Synthesize epidemiologic literature on pharmacoepidemiology topics in order to generate conclusions and recommendations	E, F	4-9	Individual assignments (study design decisions in study protocol); Final project
Select and implement pharmacoepidemiologic techniques to quantitatively assess patterns and changes in disease and treatment of disease	B, D, F	10	In-class lab (week 10); Individual assignment (descriptive analysis plan)
Determine appropriate use and implement data systems in pharmacoepidemiologic research and/or practice	A, B	1, 2, 3	Individual assignment (dataset selection); In-class lab (weeks 1-3)
Implement complex quality control methods during pharmacoepidemiologic data analysis	D	11, 12	Individual assignment (sensitivity analyses)

Grading Policy:

94 – 100	A
90 – <94	A-
87 – <90	B+
84 – <87	B
80 – <84	B-
77 – <80	C+
70 – <77	C
<70	F

Course Schedule:

Block	Week	Weekly Topic	Weekly Online30 and reading	In-class lecture topic (≈45 minutes)	In-class lab activity (≈75 minutes)	Post-class assignment
Research with and structure of healthcare data	**1** 9/12	Healthcare databases	Online30: Review syllabus; Honor Code Reading: Guidelines for good pharmacoepidemiology practice	**Course Overview**: Course structure **Review of pharmacoepi datasets**: Data types (EHR, claims, registries); Strengths and limitations; Research questions addressed in these data	Set-up SAS; Access course dataset Examine structure and components of enrollment dataset Submit: See Lab slide	**#1**, Select a drug safety or effectiveness research question that can be addressed within US insurance claims data; this will be the basis of the study proposal you will develop during the course. **Or select one of the provided examples from lecture slide**
	2 9/19	Prescription claims	Online30: ISPE lecture on RWE databases Optional reading: Pharmaco-epidemiology textbook chapter on various PE datasets	**Prescription claims**: Structure and contents of prescription claims (ex. days supply, strength) Defining/identifying dispensed prescriptions in claims (NDC and ATC codes)	Explore structure of prescription claims; Select NDC codes for a medication of interest; Practice pulling sample of prescriptions for that medication Submit: See Lab slide	**#2**, Individual study proposal: Identify drug class of interest and identify the specific ATC codes / generic names to define drug exposure Draft paragraph with these details, references where needed
	3 9/26	Medical and procedure claims	Online30: ISPE lecture on validation Reading: TBD	**Medical claims**: Structure and contents of inpatient and outpatient service records **Guest lecture: Mary Beth Ritchey, PETS part-time faculty. Validity of diagnoses in claims**.	Explore structure of medical claims from inpatient and outpatient settings; Practice pulling records for a specific diagnostic code Submit: See Lab slide	**#3**, Individual study proposal: Select a diagnosis relevant to your research question and define with ICD-10-CM codes Draft paragraph with these details, references where needed
Creating a study cohort	**4** 10/3	New user cohort	Online30: ICPE course, Cohort Studies Optional, 5min Confounding by indication YouTube video Reading: Lund et al., The active comparator, new user study design in pharmaco-epidemiology: historical foundations and contemporary application; *PDS* 2016	**New user design and active comparator**: Historical context, implementation	Identify cohort of new users; Add active comparator cohort Submit: See Lab slide	**#4**, Individual study proposal: a) Identify active comparator appropriate for your research question, b) set parameters for new use cohort (i.e., washout period length) Draft paragraph with these details, references where needed
	5		Online30: TBD			

	10/10	Inclusion, exclusion criteria	Reading: Sendor & Sturmer, Core concepts in pharmacoepidemiology: Confounding by indication and the role of active comparators; PDS 2021	**Inclusion/exclusion criteria**: Discuss common cohort inclusion criteria: treatment indication, insurance enrollment, contraindications, other criteria **Guest lecture: Chintan Dave, PETS faculty.**	Practice adding variables (ex. diagnosis for treatment indication) to new user cohort that will be used in part of inclusion or exclusion criteria Submit: See Lab slide	**#5**, Individual study proposal: Create list of inclusion / exclusion criteria along with reasoning for each criterion Draft paragraph with these details, references where needed
	6 10/17	Within subject study designs	Online30: Prepare in-class assignments #1-5 into 1 cohesive document to prepare for peer review Reading: TBD	**Guest lecture: Farzin Khosrow-Khavar, PETS faculty.** Within subject study designs. Pharmacoepidemiology study schematics Peer review assignment discussion	Continue coding inclusion / exclusion criteria Submit: See Lab slide	**#6**: Peer review #1 (Due 10/23)
Adding baseline and follow-up details	**7** 10/24	Baseline covariates	Online30: TBD Reading: TBD	**Identifying and defining covariates**: Considerations in selecting and defining baseline covariates (timing, confounders of interest, definitions) **>> PETS faculty guest lecture.**	Add a confounder to the new user cohort; Decide on definition; Evaluate prevalence Submit: See Lab slide	**#7**, Individual study proposal: Identify covariates to measure during baseline (diagnoses, medications, demographics), provide brief reasoning, specify confounders Draft paragraph, references where needed
	8 10/31 (virtual)	Treatment duration, Drug utilization	Online30: TBD Reading: TBD	**Follow-up treatment**. Treatment duration, adherence	Add follow-up treatment information; Evaluate treatment duration Submit: See Lab slide	**#8**, Individual study proposal: Detail treatment details to be collected; draw study schematic Draft paragraph, references where needed
	9 11/7	Outcome	Online30: ICPE video on outcome validation Reading: TBD	**Safety, effectiveness outcome**: Considerations in selecting and defining study outcome (timing, definition, in/out-patient, etc.); Outcome misclassification **Guest lecture: Monica D'Arcy, PETS faculty.**	Add outcome to new user cohort; Evaluate outcome counts Submit: See Lab slide	**#9**, Individual study proposal: Define study outcome; Pull evidence on outcome validation from literature Draft paragraph with these details, references where needed
Descriptive and	**10** 11/14	Descriptive analysis	Online30: ICPE 2021 podium presentation video: Impact of	**Descriptive analyses in healthcare claims**: Prescribing trends, describing new users, dose	Explore descriptive topic within the new user cohort	**#10,** Individual study proposal: Develop descriptive analytic plan, could include: treatment

comparative analysis			Disparities and Stigma on Drug Access and Utilization Reading: TBD	augmentations, event counts and rates **>> PETS faculty guest lecture.**	(ex. treatment length, examine new users by age) Submit: See Lab slide	duration, description of new users, description of prescriptions (dose, days supply) Draft paragraph, references where needed
	11 11/21 (virtual)	Analytic decisions	Online30: ICPE 2021 podium presentation video with comparative analysis Reading: TBD	**Analytic decisions:** Discuss comparative safety/effectiveness analytic decisions: ITT vs. as-treated, effect measure, unadjusted and adjusted outcome measures	Add any variables necessary for analysis (prep for PS next week); Review material from prior weeks Submit: See Lab slide	**#11**, Individual study proposal: Develop analytic plan for evaluation of comparative analysis Draft paragraph, references where needed
	12 11/28	Propensity scores (1)	Online30: Podcast, Causal Inference: quantitative bias analysis Reading: Brookhart et al., Propensity Score Methods for Confounding Control in Nonexperimental Research; *Circ Cardiovasc Qual Outcomes*, 2013	**Propensity scores**: Introduction; Estimation (variable selection); Implementation	Select variables for PS model; Run logistic regression; Examine PS distribution Submit: See Lab slide	**#12**, Individual study proposal: Continue drafting analytic plan, incorporate propensity score analysis
	13 12/5	Propensity scores (2) / Time to event analysis	Online30: Listen to podcast on Scientific communication Optional reading: High-dimensional PS article	**Propensity scores**: Implementation continued (trimming); PS adjusted Cox regression analysis **Guest lecture: Hillary Samples, PETS faculty.**	Apply PS matching / weighting; Create table with standardized differences; Run Cox regression Submit: See Lab slide	**#13**: Peer Review #2 (Due 12/12)
	14 12/12	Additional advanced methodologies	Online30: Compose short twitter thread to summarize proposal Reading: TBD	**Spotlight on additional methods**: **Guest lecture: TBD**	Dependent on presenter Submit: See Lab slide	**#14**, Individual study proposal: Finalize proposal; Prepare final presentation
Final presentations	**15** 12/19	Presentations	Online30: Complete course evaluation	Individual presentations on project proposal; Course wrap-up	--	--

Student Well-Being: The School of Public Health recognizes that students may experience stressors or challenges that can impact both their academic experience and their personal well-being. If the source of your stressors or challenges is academic, students are encouraged to discuss these challenges and circumstances with their instructor, if they feel they may need additional support or temporary accommodations at the beginning or during this course. The course instructor may consider making reasonable temporary adjustments depending on the student's situation. For personal concerns or if additional support is needed, students may reach out to the Office of Student Affairs (studentaffairs@sph.rutgers.edu) or any of the appropriate referral resources listed on the SPH Student Connect Canvas page.

Overview of School Policies: Academic and non-academic policies and procedures, such Auditing a Course, Retaking Courses, Grade Grievance and others that cover registration, courses and grading, academic standing and progress, student rights and responsibilities, graduation and more may be found under Policies on the School of Public Health website. Below are select specific policies; however, students are responsible for keeping informed about academic and non-academic policies and procedures beyond those noted on this syllabus.

Learning Management System: Canvas will be used extensively throughout the semester for course syllabus, assignments, announcements, communication and/or other course-related activities. It is the student's responsibility to familiarize themselves with Canvas and check it regularly. If you have difficulties accessing Canvas, please inform the instructor and Canvas Support (help@canvas.rutgers.edu). Canvas is accessible at canvas.rutgers.edu.

School of Public Health Honor Code: The School of Public Health Honor Code is found in the School Catalog (sph.rutgers.edu/academics/catalog.html). Each student bears a fundamental responsibility for maintaining academic integrity and intellectual honesty in his or her graduate work. For example, all students are expected to observe the generally accepted principles of scholarly work, to submit their own rather than another's work, to refrain from falsifying data, and to refrain from receiving and/or giving aid on examinations or other assigned work requiring independent effort. In submitting written material, the writer takes full responsibility for the work as a whole and implies that, except as properly noted by use of quotation marks, footnotes, etc., both the ideas and the works used are his or her own. In addition to maintaining personal academic integrity, each student is expected to contribute to the academic integrity of the School community by not facilitating inappropriate use of her/his own work by others and by reporting acts of academic dishonesty by others to an appropriate school authority. It should be clearly understood that plagiarism, cheating, or other forms of academic dishonesty will not be tolerated and can lead to sanctions up to and including separation from the Rutgers School of Public Health.

Students with Disabilities: Rutgers University welcomes students with disabilities into all of the University's educational programs. In order to receive consideration for reasonable accommodations, a student must apply for Services by first completing a Registration Form with the Rutgers Office of Disability Services (ODS) at ods.rutgers.edu. The student will also be required to participate in an ODS intake interview and provide documentation. If reasonable accommodations are granted, ODS will provide you with a Letter of Accommodations which should be shared with your instructors as early in your courses as possible.

Commitment to Safe Learning Environment: The Rutgers School of Public Health is committed to helping create a safe learning environment for all students and for the School as a whole. Free expression in an academic community is essential to the mission of providing the highest caliber of education possible. The School encourages civil discourse, reasoned thought, sustained discussion, and constructive engagement. Provocative ideas respectfully presented are an expected result. An enlightened academic community, however, connects freedom with responsibility. The School encourages all students to disclose any situations where you may feel unsafe, discriminated against, or

harassed. Harassment or discrimination of any kind will be not tolerated and violations may lead to disciplinary actions.

Reporting Discrimination or Harassment: If you experience any form of gender or sex-based discrimination or harassment, including sexual assault, sexual harassment, relationship violence, or stalking, know that help and support are available. You may report such incidents to the RBHS Title IX Office or to the School of Public Health's Office of Student Affairs. Rutgers University has staff members trained to support survivors in navigating campus life, accessing health and counseling services, providing academic and housing accommodations, and more. If you experience any other form of discrimination or harassment, including racial, ethnic, religious, political, or academic, please report any such incidents to the School's Office of Student Affairs. The School strongly encourages all students to report any incidents of discrimination or harassment to the School. Please be aware that all Rutgers employees (other than those designated as confidential resources such as advocates, counselors, clergy and healthcare providers as listed in Appendix A to Policy 10.3.12) are required to report information about such discrimination and harassment to the School and potentially the University. For example, if you tell a faculty or staff member about a situation of sexual harassment or sexual violence, or other related misconduct, the faculty or staff member must share that information with the RBHS Title IX Coordinator. If you wish to speak to a confidential employee who does not have this reporting responsibility, you can find a list of resources in Appendix A to University Policy 10.3.12. For more information about your options at Rutgers, please visit Rutgers Violence Prevention and Victim Assistance.

Graduate Student Computer Policy: Students are required to possess a personal laptop, no older than approximately two years, that must meet minimum requirements which may be found online at: sph.rutgers.edu/student-life/computer-support.html

Policy Concerning Use of Recording Devices and Other Electronic Communications Systems: When personally owned communication/recording devices are used by students to record lectures and/or classroom lessons, such use must be authorized by the faculty member or instructor who must give either oral or written permission prior to the start of the semester and identify restrictions, if any, on the use of mobile communications or recording devices.

Policy Concerning Use of Turnitin: Students agree that by taking this course all required papers may be subject to submission for textual similarity review to Turnitin.com (directly or via learning management system, i.e. Canvas) for the detection of plagiarism. All submitted papers will be included as source documents in the Turnitin.com reference database solely for the purpose of detecting plagiarism of such papers. Use of the Turnitin.com service is subject to the Usage Policy posted on the Turnitin.com site. Students who do not agree should contact the course instructor immediately.

Withdrawal/Refund Schedule: Students who stop attending their course(s) without submitting a completed Add/Drop Course form will receive a failing grade. Furthermore, students dropping to zero credits for the semester are considered withdrawn and must submit a completed Leave of Absence form from the School of Public Health's Office of Student Affairs. The School of Public Health refunds tuition only. Administrative and technology fees are non-refundable. You may find the Withdrawal/Refund Schedule on the School of Public Health website at: sph.rutgers.edu/academics/academic-calendar.html

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