Brown University School of Public Health
PHP 2440 Introduction to Pharmacoepidemiology
Spring 2024 Syllabus

Instructors

- **Kaley Hayes, PharmD, PhD** – Assistant Professor, Department of Health Services, Policy, and Practice (she/her/hers)
  Dr. Hayes is a pharmacoepidemiologist whose research aims to measure the comparative benefits and harms of medications for older adults and provide guidance for researchers on best practices in pharmacoepidemiology. She specializes in medication exposures in healthcare administrative databases and causal inference methods.

- **Andrew Zullo, PharmD, PhD** – Associate Professor, Departments of Epidemiology and Health Services, Policy, and Practice (he/him/his)
  Dr. Zullo is a pharmacoepidemiologist focused on optimizing medication and vaccine use for the outcomes of greatest importance to older adults, such as physical and cognitive function. He specializes in studying medication use in institutional post-acute care and long-term care and causal inference methods.

Emails (preferred contact)

- kaley_hayes@brown.edu
- andrew_zullo@brown.edu

Class Time & Location

- Thursdays 2:30-5:00 PM
- Room: SPH Conference Room 259, 121 S Main Street

Office Hours

- Dr. Hayes: Thursdays 1:00 – 2:30 PM, SPH Room 632 (Zoom available by request): Please reserve a time through this Google Calendar appointment page (you can book multiple slots if you think you will need more time to discuss!)
    - Full URL for office hours booking page: https://calendar.app.google/H7omchSV5it8uCLWA
- Dr. Zullo: By request. Please email Dr. Zullo in advance with his project manager, Ms. Jen Croteau (jen_croteau@brown.edu), copied.

Prerequisites and Audience

(PHP 2507, PHP 2508, PHP 2510 or PHP 2511) and (PHP 2120 or PHP 2150) or consent of the instructor. Please note that these prerequisites are intended to ensure that all students have a basic understanding of introductory biostatistics and epidemiology methods so that they can derive maximum benefit from the course. This course is open to a diverse audience, including master's degree students, PhD students, practicing clinicians, and advanced undergraduates with permission of the course instructor. This course is the first in the two-course Pharmacoepidemiology sequence and should ideally be taken before the PHP 2490 Methods in Pharmacoepidemiology course in the fall semester.

Course Description

Pharmacoepidemiology applies the principles of epidemiology and health services research to the study of the therapeutic benefits and adverse effects of medications, vaccines, or medical devices in large populations under "real world" conditions. The course will focus on substantive topics in pharmacoepidemiology, including study design considerations, common data sources for pharmacoepidemiologic studies, inference from spontaneous case reports, drug utilization review, and medication adherence. This course will provide students with the foundational knowledge needed for jobs in regulatory agencies, like the U.S. Food and Drug Administration, health care consulting, and the pharmaceutical and biotech industries.

Course Learning Outcomes

Upon completion of this course, students should be able to:

- Define pharmacoepidemology, including basic principles and terminology
- Describe the drug and medical device approval processes and life cycles in the US
- Explain how principles of clinical pharmacology and epidemiology can be applied to pharmacoepidemiologic study design and measures
- Describe pharmacovigilance and its application worldwide through passive and active surveillance
- List the potential data sources for pharmacoepidemiologic research and their relative advantages and disadvantages
- Compare and contrast common study designs used in pharmacoepidemiology
- Explain the major roles pharmacoepidemiology plays in academic research; the healthcare and biotech industries; and the regulatory sector
- Articulate methods of measuring drug exposure and outcomes of drug therapy

Course-related work and time expectations

Over 14 weeks, students will spend 2.5 hours in class/lecture sessions (35 hours); required readings are expected to take 3 hours per week (42 hours), on average. Homework and studying for tests/quizzes will take 8 hours per week (112 hours), on average. The total time of course involvement is expected to be 189 hours. However, this time will vary from learner to learner based on individual learning needs. If you find yourself regularly requiring significantly more time to complete these components, please contact the course instructors as soon as possible for assistance with time management and recommended learning strategies. Additional resources, including individualized academic coaching, are available via Academic Support Services.

Textbooks and Materials

- **Required text:** *Pharmacoepidemiology, 6th Edition*, Strom BL, Kimmel SE, Hennessy S (eds.), Wiley-Blackwell, Chichester, England, 2020. Available through Brown University libraries as an online text.
- **Readings/materials:** Posted on Canvas
- **Estimated cost of required learning resources:** No costs are anticipated for required learning resources, which are available through Brown University libraries or will be provided directly by the Course Instructors.

Lectures

Lecture material will be presented in a seminar format with accompanying slides, with opportunities for active learning. The instructors will post the slides the day before lecture so that students can download and review them as necessary, although this is not a requirement.

Marks and Grading

- **Homework assignments (40%).** The class has two homework assignments worth 20% each. Students will be provided with specific guidelines for the homework, including the learning objectives and assessment criteria, via Canvas.
- **Exams (40%).** There are two cumulative exams in this course that students will take at home via Canvas. These will be open-book and comprised of a combination of multiple choice, fill-in-the-blank, matching, short answer, and long-answer questions.
  - Midterm: 20%: March 14
  - Final: 20%: May 9
- **Class Participation (20%).** Students are expected to actively participate in the course. A general rubric and a list of examples of opportunities for participation are provided below. Students will be given feedback on their participation if it is unsatisfactory (grade based on current performance <80%) or if they specifically request it from one of the instructors. If you send us a picture of a pet or your favorite animal by the second week of class, we will add 1 bonus point to your class participation grade.

Participation Rubric				
Component	**Very good to excellent (4-5)**	**Good (2-3)**	**Fair to poor (0-1)**	**Score**
Preparation	Arrives on time and is fully prepared	Arrives mostly, though not fully, prepared	Arrives with limited preparation or is late	/ 5
Engagement	Actively supports, engages, and listens to peers	Interacts with peers	Limited interaction with peers	/ 5
Initiative	Plays an active role in discussions or actively asks questions in lectures	Participates constructively in discussions or lectures	Follows the discussion groups or the class	/ 5
Quality	Questions or comments reflect analysis, synthesis, and evaluation; level of discussion is consistently better because of the student's presence	Questions or comments are relevant to the topic discussed; level of discussion is occasionally better (never worse) because of the student's presence	Questions or comments are generally vague or too far from the topic discussed; level of discussion is not affected by the student's presence	/ 5
TOTAL				/ 20

Examples of opportunities for class participation:

- Providing evidence of having completed the readings prior to class by referencing them in class
- Asking questions during lecture
- Engaging in class discussions
- Attending office hours
- Participating in the check-in and check-out activities
- Actively working in group settings (during class exercises). Instructors will observe the groups during the class exercises.

Classification of Marks:

Grade	Numerical Scale
A	90-100 points
B	80-89 points
C	70-79 points
NC	<70 points

Attendance and Lateness

We ask that you let us know in advance if there are extenuating circumstances that will affect classroom attendance or punctuality to allow us to try to accommodate you. If you don't contact the instructors in advance or as soon as extenuating circumstances are known, you will receive a 2% deduction for each missed class from your class participation grade (i.e., 0.98 times the grade attained).

Policy for Late Assignments

The purpose of setting deadlines for homework assignments is so that we can grade them and provide feedback to support student learning throughout the semester. Late assignments are only accepted in extenuating circumstances (e.g., severe illness, death in the family) if accompanied by official documentation. This is the same policy for missing exams. If requesting an extension on an assignment for another reason, you must obtain permission from a course instructor at least one week prior to the due date. Approval is not guaranteed. If you do not obtain approval in advance, your assignments will receive a penalty of 10% (i.e., 0.9 times the grade attained) if they are submitted within one week after the due date. Assignments submitted more than a week late will be assigned a grade of zero.

Academic Integrity

For graduate students, please see the Academic Code, Graduate Student edition. In summary, the Academic Code states: "Academic achievement is evaluated on the basis of work that a student produces independently. A student who obtains credit for work, words, or ideas which are not the products of his or her own effort is dishonest. Such dishonesty undermines the integrity of academic standards of the University. Infringement of the Academic Code entails penalties ranging from reprimand to suspension, dismissal or expulsion from the University. Brown students are expected to tell the truth. Misrepresentation of facts, significant omissions or falsifications in any connection with the academic process (including Change of Course permits, the academic transcript, or applications for training or employment) are violations of the Code. This policy also applies to alumni, insofar as it relates to Brown transcripts and other records of work at Brown. Misunderstanding the Code will not be accepted as an excuse for dishonest work. If a student has questions on any aspect of the Academic Code as it relates in a particular course or as it may be interpreted in practice, he or she should consult the instructor in the course or one of the deans of the Graduate School so as to avoid the serious charge of academic dishonesty." *Academic Code*, p.4)

Technology

This course will use Canvas as its sole technological platform. We are committed to ensuring access to online course resources by students. If you have any concerns or questions about access or the privacy of any of these platforms, please reach out to us. The IT Service Center (**https://it.brown.edu/get-help**) provides many IT Services including remote assistance, phones, tickets, and chat. Please also see the Online and Hybrid Learning Student Guide.

Chat GPT and AI-generated text

If Chat GPT (or any AI-generated text) is used for any assessment, you must cite it appropriately, including citing all sources used. We highly recommend that such software should be primarily used to assist with grammar rather than idea-generation, as critical thinking is essential to the study of pharmacoepidemiology. In general, given the current state of generative AI technologies and the complexity of pharmacoepidemiology, text generated by AI is unlikely to be sufficiently correct to be of value. We therefore advise against generative AI technologies for idea generation.

Title IX Information

If you choose to tell one of the instructors about an incident of gender-based violence, including sexual assault, dating violence, and stalking, or harassment that you experienced as a student, we are required to direct the information to the Title IX Coordinator Amanda Walsh. If you ask that we keep the details of the incident private, we will make sure to include that in the notice we send to the Title IX Office. If you would rather speak to a confidential resource, the following services are available to you on campus:

Sexual Assault Hotline	401-863-6000
SHARE Advocate	401-863-2794, alana_sacks@brown.edu
CAPS	401-863-3476, brown.edu/caps
Chaplain's Office	401-863-2344, brown.edu/chaplains

Accessibility and Accommodations Statement

Brown University is committed to full inclusion of all students. Please inform one of the instructors early in the term if you may require accommodations or modification of any of course procedures. You may speak with the instructors after class, during office hours, or by appointment. If you need accommodations for online or in-class learning, please reach out to **Student Accessibility Services (SAS)** for their assistance (**seas@brown.edu,** 401-863-9588). Graduate students may contact one of the deans in the Graduate School by emailing **graduate_school@brown.edu.**

Campus resources

Student Support Services Deans can be a helpful resource to discuss personal, family or health-related concerns, as well as a potential academic and personal plan. They are available for same-day consult and/or scheduled appointment. A list of other campus resources, including community-focused centers and programs, can be found here. Graduate student resources, including academic resources, can be found here.

Diversity & Inclusion

The Departments of Health Services Policy and Practice (HSPP) and Epidemiology enthusiastically endorse the Diversity Statement of the Brown University School of Public Health, which reads:

The School of Public Health is committed to fostering a diverse and inclusive working and learning community of faculty, staff, and students. We embrace diversity along its many dimensions—including race, ethnicity, sex, religion, socio-economic background, sexual orientation, gender identity, physical ability, and other aspects of identity. We encourage debate and open discussion to promote respect, understanding, and innovation. Meeting the public health challenges of our increasingly globalized and connected world requires that we value all of our members and encourage all voices to be heard. As the School of Public Health pursues its mission of educating future public leaders, producing relevant research and scholarship, and achieving measurable impact in the communities we serve, we recognize that our success derives from the dedication of every member of our community to the principles of diversity and inclusion.

In HSPP, we believe that health care is an inherent right for all people and that health must be maximized and protected through theoretically grounded, evidence-based policies. First, we encourage prospective students, fellows and faculty from diverse backgrounds to consider opportunities to become part of or collaborate with our Department. Varied experiences are vital for exploring and understanding intended and unintended consequences of policies and interventions. Second, we have a proven record of research identifying disparities in access to high quality health care, particularly in the context of long-term care for vulnerable, older adults, but also across low-income populations, racial and ethnic minorities, people with disabilities and chronic illnesses, and Veterans. We continually examine how policies are embedded within social contexts and impact those who have limited capacity or opportunity to be heard in the national debate. Third, as our curriculum emphasizes state-of-the-art methodological approaches to testing and implementing best practices and policies across health care settings, we teach from the perspective of fairness recognizing that not all have access to best practices. Identifying these disparities is essential to calling out or challenging barriers and developing appropriate solutions that improve care for all.

Students are encouraged to share with their classmates their pronouns. If you are unsure of a student's pronoun preference, please either use their first name or they/theirs until you have had the opportunity to discuss with them or they acknowledge their preference publicly. Dr. Hayes uses the following pronouns: she, her, hers. Dr. Zullo uses the following pronouns: he, him, his.

Land Acknowledgment Statement

Brown University is located in Providence, Rhode Island, on lands that are within the ancestral homelands of the Narragansett Indian Tribe. We acknowledge that beginning with colonization and continuing for centuries the Narragansett Indian Tribe have been dispossessed of most of their ancestral lands in Rhode Island by the actions of individuals and institutions. We acknowledge our responsibility to understand and respond to those actions. The Narragansett Indian Tribe, whose ancestors stewarded these lands with great care, continues as a sovereign nation today. We commit to working together to honor our past and build our future with truth.

Letters of Recommendation

Upon completion of this course, you may wish to request a letter of recommendation from us. We strive to provide the strongest letters of recommendation possible in support of your professional pursuits. A strong letter of recommendation will include text about your academic abilities along with specific supporting examples. We may therefore decline to provide you with a letter if we cannot comment on more than just the numerical grades you received in the course. We will not write letters of recommendation that are only adequate or unexceptional. Regularly participating during lecture is one of the best ways that we can get to know you and your abilities. If you would like a letter of recommendation from us in the future, please keep in mind the importance of active class participation. In addition, please ensure that you request a letter of recommendation at least three weeks in advance of the submission deadline so that we have appropriate time to write a strong letter or, alternatively, so that you have appropriate time to identify an alternative recommender should we be unable to provide a strong letter of recommendation. Please note that we only write letters of recommendation at the time of or within two years of successful completion of the course. We do not write letters of recommendation while you are enrolled in the course because sufficient time has not elapsed for us to accrue the specific examples of your academic abilities to write you a strong letter of recommendation.

MPH Thesis Supervision

We are delighted to supervise MPH thesis projects and want to provide students with the most enriching thesis experience possible. Due to a limited number of slots available for us to serve as

supervisors, we have implemented an application process. For those interested in working with Dr. Hayes or Dr. Zullo for their MPH thesis, please complete the following google form. For those interested in working with Dr. Hayes, please complete the form by February 15th, 2024 then reach out to Dr. Hayes (please CC Ms. Tiffany Reynoso [tiffany_reynoso@brown.edu]) to schedule a time to meet. Students will be notified of a decision by March 1st. For those interested in working with Dr. Zullo, please complete the form by April 1st and send an email indicating your interest to Dr. Zullo's project manager, Ms. Jen Croteau (jen_croteau@brown.edu).

Course Schedule and Content

Week & Date	Topics & Activities	Required Readings (to be completed prior to each class session)
1: January 25	• Introductions, walkthrough of syllabus • History and applications of pharmacoepidemiology • The life cycle of a drug	*Pharmacoepidemiology:* • **Preface** (xix-xxii) • **Chapter 1**: What is Pharmacoepidemiology?
2: February 1	• Pharmacology in pharmacoepidemiology • Pharmacovigilance & case reports	*Pharmacoepidemiology:* • **Chapter 2**: Basic Principles of Clinical Pharmacology Relevant to Pharmacoepidemiologic Studies • **Chapter 10**: Postmarketing Spontaneous Pharmacovigilance Reporting Systems
3: February 8	• Data sources in pharmacoepidemiology • Electronic health record databases	*Pharmacoepidemiology:* • **Chapter 11**: Overview of Electronic Databases in Pharmacoepidemiology • **Chapter 13***:* Electronic Health Record Databases Paper: • Wang SV, Schneeweiss S. A Framework for Visualizing Study Designs and Data Observability in Electronic Health Record Data. Clin Epidemiol. 2022;14:601-608. doi: 10.2147/CLEP.S358583. PMID: 35520277.
4: February 15	• Encounter/Administrative Databases	*Pharmacoepidemiology:* • **Chapter 12:** Encounter Databases

Week & Date	Topics & Activities	Required Readings (to be completed prior to each class session)
5: February 22	• Common research designs in pharmacoepidemiology • Bias and confounding	*Pharmacoepidemiology:* • **Chapter 3**: Basic Principles of Clinical Epidemiology Relevant to Pharmacoepidemiologic Studies Papers: • Hartung DM, Touchette D. Overview of clinical research design. Am J Health Syst Pharm. 2009;66(4):398-408. doi: 10.2146/ajhp080300. PMID: 19202050. • Acton EK, Willis AW, Hennessy S. Core concepts in pharmacoepidemiology: Key biases arising in pharmacoepidemiologic studies. Pharmacoepidemiol Drug Saf. 2023;32(1):9-18. doi: 10.1002/pds.5547. PMID: 36216785.
6: February 29	• ***Assignment 1 due at 2:30 PM EST*** • Measuring drug exposures and adherence	*Pharmacoepidemiology:* • **Chapter 37:** Validity of Drug and Diagnosis Data in Pharmacoepidemiology • **Chapter 38:** Studies of Medication Adherence
7: March 7	• Measuring clinical outcomes in pharmacoepidemiologic studies Guest Speaker: Dr. Daniel Harris, PhD Research Scientist, Brown University	*TBD*
8: March 14	***Midterm Exam***	
9: March 21	• Vaccine pharmacoepidemiology Guest Speakers: Dr. Robertus van Aalst, MSc, PhD Head, Global Evidence Generation for Influenza and COVID Vaccines Sanofi Dr. Kevin McConeghy, Pharm.D., M.S., PhD Clinical Pharmacy Specialist Providence VA Medical Center	*Pharmacoepidemiology:* • **Chapter 20:** Pharmacoepidemiologic Studies of Vaccine Safety *Other readings TBD*

Week & Date	Topics & Activities	Required Readings (to be completed prior to each class session)
10: March 28	***Spring Break – NO CLASS***	
11: April 4	• Medical Device Epidemiology Guest Speaker: Dr. Kade Etter, PhD Director, Value, Analytics & Evidence, Health Economics & Market Access at Johnson & Johnson Medical Devices	*Pharmacoepidemiology:* • **Chapter 21**: Epidemiologic Studies of Medical Devices: Methodologic Considerations for Implantable Devices *Other readings TBD*
12: April 11	• Drug Policy and Utilization Guest Speaker: Dr. Mina Tadrous, PharmD, PhD Assistant Professor, University of Toronto Investigator, Ontario Drug Policy Research Network	*Pharmacoepidemiology:* • **Chapter 18**: Studies of Drug Utilization *Other readings TBD*
13: April 18	• Hot topics in Pharmacoepidemiology • Optional: Regulatory Pharmacoepidemiology • Guest Speaker: ***TBD*** ***Assignment 2 due at 2:30 PM ET***	*Pharmacoepidemiology:* **Chapter 8:** The Role of Pharmacoepidemiology in Regulatory Agencies *Other readings TBD*
14: April 25	• Industry pharmacoepidemiology Guest Speaker: Dr. Nicholas Everage, PhD Head of Epidemiology, Analytics and Data Sciences, Biogen	*Pharmacoepidemiology:* • **Chapter 7**: The Role of Pharmacoepidemiology in Industry *Other readings TBD*
15: May 2	Reading Week –Final Exam Review (Optional Attendance)	
16: May 9	**Final Exam**	