

Course Title: Pharmacoepidemiology & Therapeutic Risk Management
Course Number: EPID 0672
Course Pre- and Co-requisite(s): Any basic statistics or biostatistics course
Course Instructor: Yola Moride PhD FISPE, Research Professor of Pharmacoepidemiology, Institute for Health, Health Care Policy and Aging Research. morideyo@ifh.rutgers.edu
Office Hours: By appointment, personal meeting room: [Yola Moride's Zoom room](#)
Course Assistant: None
Course Website: canvas.rutgers.edu
Required Course Text: Strom, Kimmell, Hennessy (eds.), Textbook of Pharmacoepidemiology (3rd edition); Chichester, West Sussex, UK; Hoboken, NJ; Wiley Blackwell, 2021. Full text available from the Rutgers library at: [Link to PE textbook](#)

Additional/Supplemental Readings/Resources: *Weekly list of references provided for each module.*

Course Description: This web-based asynchronous course is designed to introduce students to the basic concepts and methods of pharmacoepidemiology and therapeutic risk management. Pharmacoepidemiology is the study of the use and effects (benefits and risks) of therapies, including medical devices, in the real-world clinical practice setting. Therapeutic risk management is a set of activities that aim to ensure that the benefits of a particular medicinal product exceed the risks by the greatest achievable margin. Lectures will be available online for asynchronous viewing supplemented by weekly activities (discussion forum or assignment). There are two online live sessions scheduled on Wednesday February 15, 3-5PM, and Wednesday April 19, 3-5PM in order to work on case studies, and Q&As.

Selected Concentration Competencies Addressed: Each Concentration identifies competencies for each degree offered. The competencies addressed in this course for the MPH in Epidemiology, or MS in Epidemiology or Pharmacoepidemiology, at the School of Public Health.

Competencies for the MPH in Epidemiology include:

1. Critique epidemiologic literature, assess its strengths and weaknesses, and determine if conclusion(s) are supported
2. Use epidemiologic techniques to quantitatively assess patterns and changes in disease occurrence
3. Formulate a specific hypothesis and determine an appropriate study design and analysis plan
4. Design, implement, and assess ordinary data collection systems for public health research
5. Design and implement basic quality control methods during data entry and analysis
6. Appropriately analyze and interpret epidemiologic data, including large national and state level datasets
7. Communicate and present study findings to professional audiences

Competencies for the MS in Pharmacoepidemiology include:

1. Synthesize epidemiologic literature on pharmacoepidemiology topics in order to generate conclusions and recommendations
2. Select and implement pharmacoepidemiologic techniques to quantitatively assess patterns and changes in disease and treatment of disease
3. Develop and test a specific hypothesis using an appropriate pharmacoepidemiologic study design and analysis plan
4. Determine appropriate use and implement data systems in pharmacoepidemiologic research and/or practice
5. Implement complex quality control methods during pharmacoepidemiologic data analysis
6. Appropriately analyze and interpret pharmacoepidemiologic data, including large national or international level datasets

Competencies for the MS in Epidemiology include:

1. Identify and synthesize scientific literature on clinical and public health topics in order to generate hypotheses, conclusions, and recommendations
2. Select and implement epidemiologic techniques to quantitatively assess patterns and changes in disease occurrence
3. Develop and test a specific hypothesis using an appropriate study design and analysis plan
4. Evaluate strengths and limitations of health data for public health research and/or practice
5. Design and implement data quality control and management methods during data collection and/or analysis
6. Appropriately analyze and interpret epidemiologic data to extend the current knowledge of public health research or practice
7. Discuss study findings and their implications with professional audiences

Please visit the Concentration webpages on the School of Public Health's website at sph.rutgers.edu for more information about the curriculum and competencies for our degrees and concentrations.

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

- A. Define the scope of pharmacoepidemiology and its role in drug regulation and coverage (reimbursement) decisions
- B. Distinguish between and calculate the various measures of occurrence of events (absolute risk, excess risk, relative risk, incidence rate, etc.), including visualization
- C. Describe and explain the basic pharmacoepidemiologic study designs and data sources, as well as their major strengths and weaknesses
- D. Appreciate and explain modern pharmacoepidemiologic methods of analysis and control of biases
- E. Critically review and interpret the literature related to the studies of drug safety and effectiveness
- F. Recognize the importance of considering sex and gender in the reporting of health research
- G. Understand therapeutic risk management principles and apply pharmacoepidemiologic methods to the evaluation of risk minimization measures
- H. Become familiar with the specificities of pharmacoepidemiology of mental health and medical devices

Course Communication: The instructor will communicate with students primarily through the tools within the Canvas course. If you have a question that you feel may help other students as well, please post your question in the “Class Help: Ask A Question” discussion thread. If you have a personal concern or question you would like to talk about, please email the instructor directly or attend office hours. During the work week, the instructor will aim to respond to personal emails or your posts directed to the instructor within 48 hours. For communications posted/emailed over the weekend, the instructor will try to respond by the end of the business day on Tuesday for most situations. If the instructor is out of town without Internet access, the instructor will post a note in Canvas in Announcements. The goal will be to post grades within seven days of the final due date of the assignment, unless otherwise stated. Midterm grades will be posted within 14 days after the due date.

Fostering Course Community: The instructor will work to foster community through discussion boards, chat sessions, online activities, etc. Students are encouraged to get to know each other and contribute their particular strengths, expertise, and experience to enrich the class. Working with your classmates, explaining concepts to each other, and interacting with your instructor (and course assistant, if assigned) are the most effective ways to understand the course concepts and succeed in this course. By posting questions on Canvas (rather than via email) the entire class has the benefit of learning from the discussions, so please consider posting your question as a first option. There will be 2 live sessions with case studies that students will discuss in Zoom breakout rooms, which will also provide an opportunity to interact with one another.

Canvas Announcements: This course will use Announcements in Canvas to share course information, highlight lessons learned, and send reminders. Be sure you review your notification settings in Canvas so that you receive these Announcements using your preferred contact method. In addition, please be sure to check the Announcements tab at least once each week in the Canvas shell for this course.

Module Schedule: All course deadlines are listed in Eastern Time Zone. Canvas will record all deadlines in this time zone. If you are in a different time zone, plan accordingly. Each week will begin on a Saturday and will end on the Sunday of the following week. In order to complete all of the module assignments, you should plan to spend approximately 9 hours per week on the course material for a total of approximately 145 hours of course-related activities (discussion boards, assignments, papers, readings, etc).

Discussion Board Guidelines and Expectations: Discussion prompts will be posted on Canvas weekly. You will utilize readings, videos and other information to inform and engage in the discussion boards each week. Respect, critical thinking and application of knowledge will guide these discussions. Original posts for Discussions are due by Wednesday midnight and your replies are due Sunday midnight. The instructions and expectations for the Discussion Board, including a rubric, are posted on Canvas.

Course Requirements and Grading:

- The course relies on student self-learning. All session assignments, PDF formatted handouts, web-conference sessions, hyperlinks, readings and other information will be available at the course website or through the Rutgers Library Resources website.

- PDF-based PowerPoint lecture handouts are located on the course lesson page and can assist the student in extracting the most relevant information from the readings. Websites provide more detailed information and examples to clarify discussed material. Through directed study, the student will learn and apply the content materials by completing structured assignments and discussion activities. Each Module will open on Saturday and activities will need to be completed by Sunday midnight the following week (with the exception of Assignments that will be due within 9 days, i.e., the Monday of the following week at noon).

- This table lists assignments that must be done and grade value

Assessments	Due	Grade value
SPH Honor Code Acknowledgement	Sunday Jan.22, 11:59PM	1
Week 1 Discussion- <i>Your Introduction</i>	Sunday Jan.22, 11:59PM	1
Week 2 Assignment - <i>Calculate and interpret measures of risk</i>	Monday Jan.30, noon	5
Week 3 Assignment- <i>Elements of a cohort study</i>	Monday Feb.6, noon	5
Week 4 Discussion- <i>Describe your data source</i>	Sunday Feb.12, 11:59PM	5
Week 5 Zoom Live Session	Wednesday Feb.15, 3-5PM	4
Week 6 Assignment- <i>Identify confounding and methods of control</i>	Monday Feb.27, noon	5
Week 7 Discussion- <i>Improvement of inclusivity in PE research</i>	Sunday March 5, 23:59	5
Week 8 Midterm Exam	Friday March 10, 11:59PM	20
Week 9 Assignment- <i>Critique assigned study in mental health PE</i>	Monday March 27, noon	5
Week 10 Discussion- <i>Appropriateness of control group</i>	Sunday Apr.2, 11:59PM	5
Week 11 Assignment- <i>Identify the different types of biases in assigned study</i>	Monday Apr.10, noon	5
Week 12 Assignment- <i>Propose appropriate REMS strategy</i>	Monday Apr. 17, noon	5
Week 13 Zoom Live Session	Wednesday Apr.19, 3-5PM	4
Week 14 Discussion- <i>Situational problem in drug utilization research</i>	Sunday Apr.30, 11:59PM	5
Week 15 Final Exam	Friday May 5, 11:59PM	20

Students are expected to participate in all graded activities. A complete description of each graded activity will be provided in the relevant weekly modules.

The student will be notified of any changes to this syllabus. Any changes to the schedule will be posted in the course calendar.

Written Assignments: Six (6) written assignments are spaced out throughout the semester. The assignments expand on important aspects of topics covered in the course and will need to be completed individually by each student (there are no group assignments). Each will require research, interpretation, consideration, and opinion from the student. Demonstration of good command of written English will be important for success in these assignments. Each assignment will be worth a maximum of **5 points**.

Each session will open on Saturday noon (12:00PM); the assignment is due Monday noon (12:00PM) of the following week (i.e., 9 days later). Late submissions will receive a zero, unless excused by the instructor. All assignments should be submitted through the Canvas platform for that week's lecture topic. They will be returned with individual feedback within 7 days after the deadline.

	Excellent (5 pts)	Competent (4 pts)	Needs improvement (3 pts)
Knowledge	Narrative demonstrates a depth of understanding by using accurate and relevant details. Supporting evidence for student's viewpoint is presented. Work demonstrates that the student has gone beyond what was presented in class.	Narrative demonstrates understanding by using relevant details with minimal inaccuracies. Some evidence is presented that supports student's viewpoint. Work does not go beyond what has been present in class.	Narrative is filled with several inaccuracies. No support is given for student's viewpoint. Does not go beyond what has been presented in class.
Mechanics	Narrative is clear and concise. Uses proper grammar and sentence structure. No misspellings.	Few or no errors but sentence structure could be improved.	Several errors in spelling, punctuation, and/or sentence structure.

Total possible points per assignment = **5 points** Adapted from Stevens, D. D. & Levi, A. J. (2005). *Introduction to Rubrics*. Sterling, VA:

Discussion Activities:

There will be five (5) separate discussion topics throughout the semester. Students are expected to participate in all discussions and will be graded on their level of contribution. Four discussions will be worth **5 points** and one will be worth **1 point**. The discussion forum for each topic will run from Saturday to Sunday midnight the following week they are assigned (exceptionally they may run longer if necessary-please make sure to verify the end date of each discussion). In order to allow for interactions between participants, you will be expected to provide a response to each of the discussion topic/question(s) for each unit of class. In order to obtain full credit for weekly participation, you will need to post your initial responses to the question(s) or topic(s) by Wednesday midnight. Then you will be asked to post a reply to any of your colleagues' questions by the following Sunday midnight. Quality of thought and writing, rather than simple number of contributions, will be considered important in evaluating each student's participation. Simply agreeing or disagreeing with your colleagues, without providing an in-depth justification will not be acceptable. The first Discussion involves introducing yourself to the class, and hence will be worth 1 point.

Student participation in the online discussions will be graded by the instructor using the following criteria
1. Student has posted at least two times during the Unit.
2. The information contributed is correct and supported by references.
3. Statements and ideas build on the comments by others.
4. The information contributed is relevant to the discussion.
5. Postings are submitted on time.

Each criterion is worth one point therefore each discussion is worth a total of **5 points**.

Synchronous (live) Web Sessions:

There will be two live sessions by Zoom, each worth **4 points**, Wednesday February 15, 3-5PM, and Wednesday April 19, 3-5PM. Live sessions aim at reviewing the material prior to the mid-term and final exam. There will be directed activities either in small groups or plenary.

Student participation in the online live sessions will be graded by the instructor using the following criteria:	
1.	Attendance: Attended the session or received approval for a necessary absence
2.	Preparedness: Student has completed the preparatory work prior to attending the session (preparatory work may involve for example, drafting at least 1 question to ask the group)
3.	Quality: Student is providing informative and constructive comments
4.	Listening: Student is attentive when others present ideas, materials, as indicated by comments that reflect & build on others' remarks.

Each criterion is worth one point therefore each discussion is worth a total of **4 points**.

Mid-term and Final Exams:

There will be one mid-term exam and one final exam. Exams will be online, timed (maximum of 3 hours to complete the exam) and single entry. It will not be possible to exit and come back to the exam later. They will consist mainly of applications of concepts seen in class. Exams will include short-answer questions, some multiple-choice questions, and perhaps essay question. The points for each question will vary and will be specified next to the question. For short-answer and essay questions, students will be expected to apply the concepts and justify their answers using the criteria and assumptions presented in class. Mock exams will be posted to assist in the preparation of each exam.

	Excellent	Competent	Needs improvement
Knowledge	Narrative demonstrates a depth of understanding by using accurate and relevant details. Student is able to apply the concepts seen in class and can selectively make valid choices with accurate justifications.	Narrative demonstrates understanding by using relevant details with minimal inaccuracies. Some evidence is presented that supports student's viewpoint. Answer lacks accurate justification.	Narrative is filled with several inaccuracies. There is no justification provided.
Structure	Narrative is clear and concise, and shows continuity of thought process.	Narrative is not concise enough; it seems that student did not quite know which principles applied to the question and hence, repeated what was seen in class without discrimination.	Narrative unclear or out of topic.

Grading policy (%)*:

This table contains the numerical and letter grades

Number Value	Letter Value
94-100	A
90-94	A-
87-<90	B+
84-<87	B
80-<84	B-
77-<80	C+
70-<77	C
<70	F

*Grades will not be rounded.

Assignment Standards

Lateness. Assignments turned in after the official collection period are considered late. Unless the instructor and student come to an arrangement at least one week before due date, there is a 1 point penalty per day if a written work is turned in late (for example, if an assignment is turned in 2 days late, there is a 2-point penalty). It will not be possible to submit an assignment after the grades have been released. Assignments are posted to Canvas by the due date. If you need to turn in something after the date due, please discuss it with the instructor to avoid point penalty. Students who fail to participate in a weekly Discussion will receive zero point, unless agreed with the instructor at least 1 week before due date.

Grammar/Spelling. If more than eight (8) gross punctuation, grammar or spelling errors occur in the written assignments, they will be returned with no grade. These can be resubmitted within one week with a five (5) point penalty or the student can accept a failing grade.


Citations. Preferred citation style for references in written assignments will be American Psychological Association (APA). Please use this APA citation style for electronic references.

Margins and Page Limits Requirements. Refer to each assignment instructions for margins and page limit requirements. A deduction of 10% will occur if assignment over the maximum page limit. Instructions will be available on Canvas.

Extra Credit (if offered). Extra credit opportunities will be posted.

Course Schedule:

Lesson/ Date	School of Public Health Topics	Instructor
<p>1 Jan.17-22</p>	<p>Role of PE in Drug Development and Decision-Making- How to interpret real-world data</p> <p>Required Viewing/Listening:</p> <ul style="list-style-type: none"> • Course logistics & Grading schemes • Role of Pharmacoepidemiology in Drug Development and Decision-Making • How to interpret real-world evidence (strengths and limitations) <p>Required Reading:</p> <ul style="list-style-type: none"> • Raphael et al. Real- world evidence and regulatory drug approval. Nature Review 2020; 17: 271. • Wu et al. Use of real-world evidence in regulatory decisions for rare diseases in the United States—Current status and future directions. Pharmacoepidemiol Drug Saf. 2020;29:1213–1218. • Baumfeld André et al. Trial designs using real-world data: The changing landscape of the regulatory approval process. Pharmacoepidemiol Drug Saf.2020;29:1201–1212. • Roberts and Ferguson. Real-World Evidence: Bridging Gaps in Evidence to Guide Payer Decisions. PharmacoEconomics - Open (2021) 5:3–11 <p>Week One Discussion (1): Post your introduction (who you are, your background and program you are registered in) Due Jan.22 midnight</p>	<p>Y. Moride</p>
<p>2 Jan.21-29</p>	<p>Measures of Risk and Occurrence of Disease/Outcome</p> <p>Required Viewing/Listening:</p> <ul style="list-style-type: none"> • Measures of Risk (PPT and Podcast) <p>Required Reading:</p> <ul style="list-style-type: none"> • Quartey G. Wang J. Kim J. A review of risk measures in pharmacoepidemiology with tips for statisticians in the pharmaceutical industry. Pharm Stat. 2011;10(6):548-553 • Weissgerber, T. L. et al. Reveal, don't conceal: transforming data visualization to improve transparency. Circulation, 2019;140(18), 1506-1518 • Midway, S. R. (2020). Principles of effective data visualization. Patterns, 2020 1(9) <p>Week Two Assignment (1) : Calculations, interpretations, and visualization of measures of risk and incidence rate. Due Jan.30 noon</p>	<p>Y. Moride</p>
<p>3 Jan.28- Feb.5</p>	<p>Cross-Sectional and Cohort Studies</p> <p>Required Viewing/Listening:</p> <ul style="list-style-type: none"> • Cross-sectional studies (PPT and Podcast) • Cohort Studies (PPT and Podcast) <p>Required Reading:</p> <ul style="list-style-type: none"> • Kate Ann Levin. Study design III: Cross-sectional studies. Evidence-Based Dentistry volume 7, pages24–25 (2006) • Euser AM, Zoccali C, Jagger KJ, et al. Cohort studies: Prospective versus Retrospective. Nephron Clin Pract 2009; 113 : c214-c217. 	<p>Y. Moride</p>

	<ul style="list-style-type: none"> Zuo et al. Antihypertensive treatment decrease stroke occurrence: a prospective cohort study. <i>Journal of Hypertension</i> 2021, 39:1652–1661. Gopalakrishnan et al. Association of Fluoroquinolones With the Risk of Aortic Aneurysm or Aortic Dissection. <i>JAMA Intern Med</i> 2020 Dec 1;180(12):1596-1605. <p>Week Three Assignment (2): Read the assigned article and discuss the elements that make this a cohort study (please use template/checklist in Assignment activity). Due Feb.6 noon</p>	
<p>4 Feb.4-12</p>	<p>Data Sources in Pharmacoepidemiology</p> <p>Required Viewing/Listening:</p> <ul style="list-style-type: none"> Data sources in pharmacoepidemiologic research Practical example/viewing of an administrative claims database and an EMR <p>Required Reading:</p> <ul style="list-style-type: none"> Hall GC. Sauer B. Bourke A. Brown JS. Reynolds MS. Guidelines for good database selection and use in pharmacoepidemiology research <i>Pharmacoepidemiology and Drug Safety</i>. 2011. DOI:10.1002/2229 Bourke A et al. Incorporating patient generated health data into pharmacoepidemiological research. <i>Pharmacoepidemiol Drug Saf</i>. 2020;29:1540–1549. <p>Week Four Discussion (2): Provide a description, data collection structure, population covered, and an example of a pharmacoepidemiologic study conducted with your assigned database. Due Feb.12 midnight</p>	<p>Y. Moride</p>
<p>5 Feb.11-19</p>	<p>Epidemiology of Medical Devices (incl.registries)</p> <p>Required Viewing/Listening:</p> <ul style="list-style-type: none"> Medical Devices (PPT and Podcast) <p>Required Reading:</p> <ul style="list-style-type: none"> Jalbert JJ, Ritchey ME, Mi X, et al. Methodological considerations in observational comparative effectiveness research in implantable medical devices: an epidemiological perspective. <i>Am J Epidemiol</i>. 2014; 180(9):949-58. Jalbert 2014 AJE - Implanted devices.pdf  Textbook of Pharmacoepidemiology, Chapter 22: Special Applications of Pharmacoepidemiology – sections relevant to implantable medical devices <p>*** Zoom Live Session *** (graded attendance) Wednesday Feb.15 – 3-5PM EST https://rutgers.zoom.us/j/7355773183?pwd=QkI5NDdxY2xWYj8yMmtRVEVkJUJFJTU09</p>	<p>M.B. Ritchey</p> <p>Y. Moride</p>

<p>6 Feb.18-26</p>	<p>Bias and Interactions- Part 1: Confounding Required Viewing/Listening:</p> <ul style="list-style-type: none"> Bias and Interaction-Part 1 (PPT and Podcast) <p>Required Reading</p> <ul style="list-style-type: none"> Sendor and Sturmer. Core concepts in pharmacoepidemiology: Confounding by indication and the role of active comparators. <i>Pharmacoepidemiol Drug Saf.</i> 2022;31:261–269. ENCePP Guide on Methodological Standards in Pharmacoepidemiology, rev.10, 2022 https://www.encepp.eu/standards_and_guidances/methodologicalGuide.shtml <p>Week Seven Assignment (3): Read the assigned article and discuss the presence of confounding and method of control (please use template/checklist in Assignment activity). Due Monday Feb.27, noon.</p>	<p>Y. Moride</p>
<p>7 Feb.25 – March 5</p>	<p>Integration of sex and gender in health research and use of reporting guidelines</p> <p>Required Viewing/Listening:</p> <ul style="list-style-type: none"> Sex and gender in health research (PPT and Podcast) <p>Required Reading:</p> <ul style="list-style-type: none"> Gogovor et al. Sex and gender considerations in reporting guidelines for health research: a systematic review. <i>Biol Sex Differ.</i> 2021 Nov 20;12(1):62. DOI: 10.1186/s13293-021-00404-0 <p>Week Seven Discussion (3): Propose 1 item that could improve inclusivity in pharmacoepidemiology research. Due March 5 midnight</p>	<p>A.Gogovor</p>
<p>8 March 4- 10*</p>	<p>Mid-Term Exam consisting of the following:</p> <ul style="list-style-type: none"> timed multiple-choice questions timed short-answer questions and essay question (3 hours maximum- single entry only, to be completed by March 10, 11:59PM) <p>* Exam will be available on Saturday March 4 to allow for a full week to complete prior to spring recess</p>	<p>Y. Moride</p>
<p>March 11-19</p>	<p>Spring recess</p>	
<p>9 March 20-26</p>	<p>Application: Pharmacoepidemiologic studies in Mental Health</p>	<p>T. Gerhard</p>

	<p>Required Viewing/Listening:</p> <ul style="list-style-type: none"> Mental Health (PPT and Podcast) <p>Required Reading:</p> <ul style="list-style-type: none"> Stroup TS, Gerhard T, Crystal S, Huang C, Olfson M. Comparative Effectiveness of Clozapine and Standard Antipsychotic Treatment in Adults with Schizophrenia. <i>Am J Psychiatry</i>. 2016;173(2):166-73. Gerhard T, Stroup TS, Correll CU, Setoguchi S, Strom BL, Huang C, Tan Z, Crystal S, Olfson M. Mortality Risk of Antipsychotic Augmentation for Adult Depression. <i>PLOS ONE</i>. 2020; 30;15(9):e0239206. <p>Week Nine Assignment (4): Critique your assigned study on pharmacoepidemiology of mental health (please use template/checklist in Assignment activity). Due March 27, noon</p>	
<p>10 March 25- Apr 2</p>	<p>Case-control Studies</p> <p>Required Viewing/Listening:</p> <ul style="list-style-type: none"> Case-Control Studies (PPT and Podcast) <p>Required Reading:</p> <ul style="list-style-type: none"> Dey T, Mukherjee A, Chakraborty S. A practical overview of case-control studies in clinical practice. <i>Chest</i> 2020; 158: S57-S64. <p>Week Ten Discussion (4): Situational problem. Discuss the appropriateness of the control group in the example (you will not see your colleagues' answers for 30 min. after you post your answer). Due Apr.2 midnight</p>	<p>Y. Moride</p>
<p>11 Apr 1-9</p>	<p>Biases Part 2- Selection and Information Bias</p> <p>Required Viewing/Listening:</p> <ul style="list-style-type: none"> Selection and Information Bias (PPT and Podcast) <p>Required Reading:</p> <ul style="list-style-type: none"> Acton et al. Core concepts in pharmacoepidemiology: Key biases arising in pharmacoepidemiologic studies. <i>Pharmacoepidemiol Drug Saf</i>. 2023;32:9-18. <p>Week Eleven Assignment (5) : Identify and discuss the different types of biases in the assigned article. Describe some possible solutions for bias. Due Apr.10, noon</p>	<p>Y. Moride</p>
<p>12 Apr.8-16</p>	<p>Therapeutic risk management</p> <p>Required Viewing/Listening</p> <ul style="list-style-type: none"> Risk management planning (PPT and Podcast) Post-authorization Safety Studies on Covid-19 vaccines 	<p>Y. Moride S. Frise</p>

	<p>Required Reading:</p> <ul style="list-style-type: none"> - FDA REMS guidance. https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems - EMA core RMP requirements for COVID-19 vaccines https://www.ema.europa.eu/en/documents/other/consideration-core-requirements-rmps-covid-19-vaccines_en.pdf - FDA Development and Licensure of Vaccines to Prevent COVID-19 Section VI https://www.fda.gov/media/139638/download <p>Week Twelve Assignment (6): Propose an appropriate REMS strategy and evaluation for the specified situational problem. Due April 17 noon</p>	
<p>13 Apr.15-23</p>	<p>Industry Perspective on Pharmacoepidemiology</p> <p>Required Viewing/Listening:</p> <ul style="list-style-type: none"> • Industry perspective (PPT and Podcast) <p>Recommended Reading:</p> <ul style="list-style-type: none"> • The Role of Pharmacoepidemiology in Industry, Chapter 7, Pharmacoepidemiology, 5th Edition. In: Pharmacoepidemiology, Ed. Strom B et al., 2012 John Wiley & Sons <p>*** Zoom Live Session *** (graded)Apr.19 – 3-5PM EST https://rutgers.zoom.us/j/7355773183?pwd=QkI5NDdxY2xWYj8yMmtRVEVkJUjFjUT09</p>	<p>S. Lopez-Leon</p> <p>Y. Moride</p>
<p>14 Apr.22-30</p>	<p>Drug Utilization Studies</p> <p>Required Viewing/Listening:</p> <ul style="list-style-type: none"> • Drug utilization studies (PPT and Podcast) <p>Required Reading:</p> <ul style="list-style-type: none"> • Jandoc R et al. Interrupted time series analysis in drug utilization research is increasing: systematic review and recommendations. J. Clin. Epidemiol. 2015; 68: 950-956. • Dusetzina SB et al. Impact of FDA drug risk communications on health care utilization and health behaviour: A systematic review. Med. Care 2012; 50:466-478. <p>Week Fourteen Discussion (5): Situational problem on drug utilization studies (you will not see your colleagues' answers for 30 min. after you post your answer). Due Apr.30 midnight</p>	<p>Y. Moride</p>
<p>15 Apr.29- May 5*</p>	<p>Final exam consisting of the following</p> <ul style="list-style-type: none"> • timed multiple-choice questions • timed short-answer questions and essay question (3 hours maximum- single entry only, to be completed by May 5 11:59PM) <p>* Exam will be available the previous Saturday April 29 to allow for a full week to complete prior to end of term</p>	<p>Y. Moride</p>

Learning Management System: Canvas will be used 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@oit.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.

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](#) or any of the appropriate referral resources listed on the [SPH Student Connect](#) Canvas page.

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](#).

Overview of School Policies: Academic and non-academic policies and procedures, such as 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.

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