



## Syllabus

### EPID 765: Methods and Issues in Pharmacoepidemiology

Spring 2023

3 Credits

#### Course Description:

Application of the epidemiologic knowledge, methodology, and reasoning to the study of the effects (beneficial and adverse) and uses of drugs in human populations.

Pharmacoepidemiology is a public health discipline that mainly relies on non-experimental (epidemiologic) methods to assess intended and unintended drug effects to support decision-makers in the absence of specific evidence from experimental studies (randomized controlled trials). This course is for clinicians, pharmacists, epidemiologists and scientists from related fields in academia, industry and regulatory agencies. It will provide an introduction and overview of pharmacoepidemiologic topics, methods, databases, and review examples of current research. The course will look at specific aspects and potential pitfalls of epidemiologic study designs when applied to the study of drug effects and provide an overview of ways to limit the potential for bias.

**Prerequisites:** [EPID 600 and BIOS 600] or equivalents

#### Instructors:

##### Til Stürmer, MD, PhD

Nancy A. Dreyer Distinguished Professor and Chair

Department of Epidemiology

2101-B McGavran-Greenberg Hall

Phone: 919-966-7433

Email: [sturmer@unc.edu](mailto:sturmer@unc.edu)

##### Juan M. Hincapie-Castillo, PharmD, PhD

Assistant Professor

Department of Epidemiology

2101-F McGavran-Greenberg Hall

Phone: 919-966-7421

Email: [jhincapie-castillo@unc.edu](mailto:jhincapie-castillo@unc.edu)

For appointments: <https://outlook.office365.com/owa/calendar/JuanHincapieCastillo@admin.live.unc.edu/bookings/>

**Office Hours:** Available by appointment.

**Course Website:** On Canvas, use your ONYEN and password.

Link: <https://uncch.instructure.com/courses/18733>

**Class Days, Times, Location:** Tues/Thur, 2:00-3:15pm, Marsico Hall - Rm 4004.

### Zoom link:

The class is in-person. The following Zoom link is provided only for special circumstances

<https://unc.zoom.us/j/91811362717?pwd=SFMvQWtHb09pUVZvT0FrcTIIRm9VZz09>

### Course Format:

Journal club discussion, lectures, case studies, invited speakers. The course is organized as a sequence of relevant topics. Most lessons will start usually with a 30-minute discussion of the topic followed by a 45 minute lecture. Discussions are either student-led (journal club) or led by the instructors. Preparation and active participation in the discussion is expected from all. Grasp of challenges and concepts is encouraged over knowledge about solutions. Readings are from a draft PE textbook by the lead instructor, from the Textbook of Pharmacoepidemiology (see below), and from the literature.

### Expectations:

- All students are expected to read required materials (all provided on Canvas) before class and to participate actively in class discussions. Suggested readings are intended for future reference.
- All students will lead a journal club discussion. We will ask for volunteers but may need to assign students.
- All students are expected to write a term paper on a pharmaco-epidemiologic topic (see below). Groups for projects will be assigned by instructors.

### Journal Club presentation:

During the last 20 minutes of class. The student will provide a summary of the paper (3 minutes, not more than 5) and then lead the discussion. The discussion should cover important aspects of methods, results, and conclusions. Do not try to cover everything, but rather focus on specific aspects of these. Are the conclusions supported by the data presented? Would you change clinical practice (treat a relative differently) based on the data presented? A document with the guidelines for journal club presentations is posted on the Canvas site.

### Term paper:

Students will be divided into assigned groups to work throughout the semester on a research protocol pertaining to a drug effectiveness and/or safety question. The course coordinators will provide feedback on deliverables at multiple time points throughout the semester to guide students in the process of developing the grant-style proposal. Topics for the effectiveness and/or safety study have to be approved by the course coordinators and must respond to **2018-2022 Drug Safety Communications from the FDA** (posted periodically based on potential signals or reported safety issues). A document with instructions and expectations for the term paper is posted on the Canvas site.

### Readings:

- **Main reference textbook available from UNC Library**
  - *Strom, B. L., Kimmel, S. E., & Hennessy, S. Pharmacoepidemiology. 6<sup>th</sup> Edition. United Kingdom, Wiley, 2019.*
- All required readings for each lesson are posted on each Canvas module.
- Additional supplemental readings and relevant textbooks are posted on the Canvas site.

### Recommended parallel course:

Because pharmacoepidemiology relies heavily on the use of large healthcare databases, participants are encouraged to also take EPID 766 "Epidemiologic Research with Healthcare Databases" taught in spring 2023 (Lead-Instructors: Drs. Jennifer Lund and Alan Kinlaw).

## Course Schedule

The instructors reserve the right to make changes to the syllabus, including topics, readings, assignments, and due dates. Any changes will be announced as early as possible. For session-by-session course schedule details, please see the Canvas site.

Lesson	Date	Day	Content	Instructor	Journal Club
1	1/10	Tue	What is pharmacoepidemiology?	TS	No
2	1/12	Thu	Sources of data for pharmacoepidemiology	JHC	No
3	1/17	Tue	Principles of clinical pharmacology	JHC	Yes-1
4	1/19	Thu	Drug, outcome, and comorbidity data	TS	Yes-2
5	1/24	Tue	Drug utilization research	JHC	Yes-3
6	1/26	Thu	Methodologic challenges in PE (Confounding by indication and selection bias)	TS	Yes-4
7	1/31	Tue	Study design solutions (New user design and active comparators)	TS	Yes-5
8	2/2	Thu	Risk periods (First treatment carried forward, as treated, induction, carry-over, lag periods)	TS	Yes-6
9	2/7	Tue	Propensity scores	TS	Yes-7
10	2/9	Thu	Disease risk scores	TS	Yes-8
	<b>2/14</b>	<b>Tue</b>	<b>Well-being Day</b>		
11	2/16	Thu	Non-uniform treatment effects	TS	Yes-9
12	2/21	Tue	Instrumental variables	TS	Yes-10
13	2/23	Thu	Validation studies, external control for confounding <b>Term Paper Proposal Due</b>	TS	Yes-11
14	2/28	Tue	Crystal ball PE, immortal time bias, immeasurable time bias	TS	Yes-12
15	3/2	Thu	Target trial emulation and time varying confounding	Jenny Lund	Yes-13
16	3/7	Tue	Patients treated contrary to prediction	TS	Yes-14
17	3/9	Thu	Methodologic issues with medication adherence	JHC	Yes-15
	<b>3/14</b>	<b>Tue</b>	<b>Spring Break</b>		
	<b>3/16</b>	<b>Thu</b>	<b>Spring Break</b>		
18	3/21	Tue	Quantitative bias analysis	Michele Jonsson-Funk	Yes-16
19	3/23	Thu	<b>Paper presentation I</b>	TS / JHC	No
20	3/28	Tue	<b>Paper presentation II</b>	TS / JHC	No
21	3/30	Thu	Risk Management – Oncology RWE	*Annie McNeill	No
22	4/4	Tue	Self-controlled study designs	*Jesper Hallas	No
	<b>4/6</b>	<b>Thu</b>	<b>Well-being Day</b>		
23	4/11	Tue	The role of mediation analysis within a trial	*Bob Glynn	No
24	4/13	Thu	Medications in pregnancy	Mollie Wood	Yes-17
25	4/18	Tue	Medical devices	*Mary Beth Ritchey	No
26	4/20	Thu	Equity issues in PE	*Macarius Donneyong	No
27	4/25	Tue	Psychopharmacoepidemiology	*Greta Bushnell	No
28	4/27	Thu	Single arm studies with external comparator	*Christina Mack	No

\*Guest speaker schedule is subject to changes

## Course Assignments and Assessments

This course will include the following graded assignments that contribute to your final grade in the course.

Graded Assignments	Points/Percentages of Final Course Grade
1. Class participation	30
2. Presentation and discussion of journal article	30
3. Term paper	40
TOTAL	100

## Course Grading Scale(s)

Final course grades will be determined using the following [UNC Graduate School grading scale](#). The relative weight of each course component is shown in the Graded Assignments section.

- **H**—High Pass (93-100): Clear excellence
- **P**—Pass (80-92): Entirely satisfactory graduate work
- **L**—Low Pass (70-79): Inadequate graduate work
- **F**—Fail (0-69)

## Expectations, Policies, and Resources

### Accessibility at UNC Chapel Hill

The University of North Carolina at Chapel Hill facilitates the implementation of reasonable accommodations, including resources and services, for students with disabilities, chronic medical conditions, a temporary disability or pregnancy complications resulting in barriers to fully accessing University courses, programs and activities. Accommodations are determined through the Office of Accessibility Resources and Service (ARS) for individuals with documented qualifying disabilities in accordance with applicable state and federal laws. See the [ARS Website](#) for contact information or email [ars@unc.edu](mailto:ars@unc.edu).

### Attendance/ Participation

Your attendance and active participation are an integral part of your learning experience in this course. If you are unavoidably absent, please notify the course instructor. No right or privilege exists that permits a student to be absent from any class meetings, except for these University Approved Absences:

1. Authorized University activities
2. Disability/religious observance/pregnancy, as required by law and approved by [Accessibility Resources and Service](#) and/or the [Equal Opportunity and Compliance Office](#).
3. Significant health condition and/or personal/family emergency as approved by the [Office of the Dean of Students](#), [Gender Violence Service Coordinators](#), and/or the [Equal Opportunity and Compliance Office](#).

### Community Standards in Our Course and Mask Use.

UNC-Chapel Hill is committed to the well-being of our community – not just physically, but emotionally. The indoor mask requirement was lifted for most of campus on March 7, 2022. If you feel more comfortable wearing a mask, you are free to do so. There are many reasons why a person may decide to continue to wear a mask, and we respect that choice. For additional information, see [Carolina Together](#).

### Counseling and Psychological Services at UNC Chapel Hill

CAPS is strongly committed to addressing the mental health needs of a diverse student body through timely access to consultation and connection to clinically appropriate services, whether for short or long-term needs. Go to the [CAPS website](#), call them at 919-966-3658, or visit their facilities on the third floor of the Campus Health Services building for a walk-in evaluation to learn more.

## Honor Code

You are not permitted to upload any content from this course to the web in any form, including but not limited to Chegg, Course Hero, Coursera, Google Drive, etc. If you post my course content, you may be violating my intellectual property rights. If you post your own work from this course, you are allowing sites to profit from your intellectual property. In utilizing web sources to upload or download course content, you risk violating the University's Honor Code.

If you have any questions about your rights and responsibilities, consult the [Office of Student Conduct](#) or review the following resources: [Honor System](#); [Honor System module](#); [UNC Library's plagiarism tutorial](#); [UNC Writing Center's handout on plagiarism](#).

## Inclusive Excellence

We are committed to expanding diversity and inclusiveness across the School — among faculty, staff, students, on advisory groups, and in our curricula, leadership, policies and practices. We measure diversity and inclusion not only in numbers, but also by the extent to which students, alumni, faculty, and staff members perceive the School's environment as welcoming, valuing all individuals, and supporting their development. For more information about how we are practicing inclusive excellence at the Gillings School, visit the following webpages: [Inclusive Excellence](#), [Inclusive Excellence Action Plan](#), [Minority Health Conference](#), and [National Health Equity Research Webcast](#).

Additional campus resources include: the [LGBTQ Center](#); [Non-Discrimination Policies at UNC Chapel Hill](#); [Ombuds](#); and [Prohibited Discrimination, Harassment, and Related Misconduct at UNC Chapel Hill](#).

In this class, we practice the Gillings School's commitment to inclusion, diversity, anti-racism and equity in the following ways.

- Develop classroom participation approaches that acknowledge the diversity of ways of contributing in the classroom and foster participation and engagement of *all* students.
- Encourage and solicit feedback from students to continually improve inclusive practices.
- Treat all members of the Gillings community (students, faculty, and staff) as human persons of equal worth who deserve dignity and respect, even in moments of conflict and disagreement.
- Contribute to creating a welcoming and inclusive classroom environment, where all are able to learn and grow from one another.
- Acknowledge and respect the diversity of experiences that others bring to the classroom and the ways in which this richness enhances everyone's learning
- Strive to maintain a spirit of curiosity and generosity, particularly in the face of new and/or seemingly contradictory information and perspectives Encourage and solicit feedback from students to continually improve inclusive practices.

## Land Acknowledgement

Please read The Gillings School's [Land Acknowledgement](#).

## Student Feedback and Equity Concerns

The Gillings School has in place a [mechanism for students to provide feedback](#), including specifically equity concerns and bias-related issues. You can use this form to describe feedback, both positive and negative, about anything including issues related to your experience as a student at Gillings, administrative processes, and classroom activities. This form will also allow you to specifically describe incidents in which racial or other equity-related bias, or microaggressions, occurred. You may submit this form anonymously. However, for us to follow up and provide the necessary support, we encourage you to include your contact information. For further information, please visit the [Student Feedback and Equity Concerns FAQ](#).

Please note that this form does not take the place of any University process or policy. If you would like to report an incident under the University's policy on [Prohibited Discrimination, Harassment, and Related Misconduct including Sexual and Gender Based Harassment, Sexual Violence, Interpersonal Violence, and Stalking](#), please visit [Safe At UNC](#) or the [Equal Opportunity and Compliance Office](#) (EOC) for additional information, including resources, contact, and reporting options.

## Technical Support

The best way to help prevent technical issues from causing problems for assignments and quizzes is to submit them at least 24-36 hours before the due date and time. Your instructor cannot resolve technical issues, but it's important to notify them if you are experiencing issues. If you have problems submitting an assignment or taking a quiz in Sakai, immediately do the following:

1. Contact the UNC Information Technology Services (ITS) department with the time you attempted to do your course action and what the course action was.
2. Email your instructor with the information you sent to ITS and what time you sent the information.

The ITS department provides technical support 24-hours per day, seven days per week. If you need computer help, please contact the ITS Help Desk by phone at +1-919-962-HELP (4357), or by [online help request](#), or by [UNC Live Chat](#).

## Title IX at UNC Chapel Hill

Any student who is impacted by discrimination, harassment, interpersonal (relationship) violence, sexual violence, sexual exploitations, or stalking is encouraged to seek resources on campus or in the community. Please contact the Director of Title IX Compliance / Title IX Coordinator ([Adrienne Allison](#)), [Report and Response Coordinators in the Equal Opportunity and Compliance Office](#), Counseling and Psychological Services (confidential), or the [Gender Violence Services Coordinators](#) (confidential) to discuss your specific needs. Additional resources are available at the ["Safe at UNC" website](#).