

HT 194 - Clinical Epidemiology: Methods for Clinical Research
Harvard-MIT Division of Health Sciences and Technology
Spring 2019

Teaching Staff

- Instructor: Miguel Hernán (mhernan@hsph.harvard.edu)
Office hours by appointment
- Teaching Assistant: Mats Stensrud (mstensrud@hsph.harvard.edu)
Office hours Wednesdays 8-9 am

Course description

How do we learn what we know in clinical medicine? How do we quantify disease burden, identify risk factors for a health condition, and determine whether an intervention is effective for the treatment or prevention of disease? This course introduces epidemiologic methods for the generation, analysis, and interpretation of data in clinical research.

The course is organized around the three main data tasks in clinical research: description, prediction, and causal inference. Besides the essentials of descriptive and predictive analytics, the course discusses causal inference based on randomized trials, clinical cohorts, and analyses of electronic health records.

Students will learn to formulate well-defined research questions, to discuss the adequacy of research data, to evaluate algorithms for clinical prediction, to critically assess causal inference studies, and to identify and prevent biases in clinical research. Familiarity with regression modeling and intermediate statistics is a pre-requisite.

The course emphasizes critical thinking, including daily assignments based on articles published in major clinical journals and the discussion of weekly case studies. A key goal of the course is training students to comprehend, critique, and communicate research findings from the medical literature.

Course Objectives

After successful completion of the course, you will be able to:

- 1) Recognize, classify, and formulate well-defined questions in clinical research
- 2) Design data collection for descriptive and predictive studies
- 3) Evaluate algorithms for clinical prediction
- 4) Discuss the use of randomized trials for causal inference
- 5) Discuss the use of observational analyses for causal inference
- 6) Outline critical evaluations of the clinical literature

Course schedule

The teaching sessions take place from 1:00pm to 4:00pm in the Medical Education Center (Bldg. E), Room TMEC 250. Sessions are divided into 3 components: case study, discussion, and homework review. Students will work in teams of 5-6 persons when discussing case studies and other group assignments.

Course materials

The course materials will consist of lecture notes, case studies, and articles from the medical literature. In addition, the recommended textbooks are:

- Rothman, *Epidemiology: An Introduction*
- Rothman, Greenland, and Lash. *Modern Epidemiology*, 3rd edition (advanced)
- Hernán, Robins. *Causal Inference*. Freely available at
<https://www.hsph.harvard.edu/miguel-hernan/causal-inference-book/>

Student evaluation and participation

Students will be evaluated on two criteria

- 5 homework assignments (due at the start of sessions 1-5)
- Take-home exam (due at the start of session 6)

Students are encouraged to work in teams when completing the homework outside of the classroom, but they must turn in their own answers. Students must work alone on the exam. Should questions arise, they are encouraged to check with the teaching staff during homework review sessions and office hours.

No-screens policy

Use of electronic devices is banned during HST194 sessions unless otherwise indicated by the teaching staff.

HST194 sessions, which are participatory by design, require sustained intellectual engagement. Such engagement is not possible when students are multitasking. The class as an intellectual community fails when the course contents need to compete for students' attention with, say, a Twitter feed. Students can use their electronic devices during breaks and are free to exit the classroom (in the least disruptive way possible) if they have a need to check their screens. Importantly, there is no mandatory attendance policy for HST194, so students always preserve control over decisions about how to invest their learning time.

This no-screens policy is part of a broader bargain under which the HST194 teaching staff makes a firm commitment to designing interactive, informative, and engaging sessions, and to be constantly open to students' feedback about how to keep improving the course.

COURSE OUTLINE

	Case Study	Theme / Discussion	Due at start
SESSION 1 January 7		<p>The three tasks of clinical research:</p> <ul style="list-style-type: none"> • Description • Prediction • Causal inference 	Homework #1
SESSION 2 January 14	<p><i>Description</i> Economic sanctions and child mortality</p>	<p><i>Why do we use P-values in clinical research?</i></p> <p>Clinical prediction and classification</p>	Homework #2
SESSION 3 January 28	<p><i>Prediction</i> Cardiovascular risk assessment and high blood cholesterol treatment</p>	<p><i>Causal Inference</i></p> <ul style="list-style-type: none"> • Comparative Effectiveness Research Using Randomized Trials 	Homework #3
SESSION 4 February 4	<p><i>Causal Inference</i> Circumcision and risk of HIV infection</p>	<p><i>Causal Inference</i></p> <ul style="list-style-type: none"> • Comparative Effectiveness Research Using Observational Studies (I) 	Homework #4
SESSION 5 February 11	<p><i>Causal Inference</i> COX-2 inhibitors and myocardial infarction Guest instructor: Prof. Sonia Hernandez-Diaz, Pharmacoepidemiology Program, HSPH</p>	<p><i>Causal Inference</i></p> <ul style="list-style-type: none"> • Comparative Effectiveness Research Using Observational Studies (II) 	Homework #5
SESSION 6 February 25	<p><i>Causal Inference</i> Hepatitis B vaccine and multiple sclerosis</p>	Review and wrap-up	Exam