

EPI/ENVH 573

Methods and Issues in Using Biological Measurements in Epidemiologic Research

Autumn 2022

T-663 Health Sciences Center

Tuesdays and Thursdays, 8:30 – 9:50¹

Instructor: Stephen M. Schwartz, Ph.D. (Professor, Department of Epidemiology)

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Course website: <https://canvas.uw.edu/>

Office Hours: By appointment at the FHCRC or UW

Prerequisites: EPI 511 or EPI 512, or by permission of instructor. Students who are permitted to enroll in the course without the prerequisite coursework are still responsible for competency in the material covered in those courses.

Purpose of Course: Human studies of disease etiology and prognosis often require the measurement of one or more characteristics of biological material. The purpose of this course is to provide students with an introduction to the methods and issues arising in the design, conduct, and analysis of these studies. Specifically, by the end of this course, a student should be able to:

- identify strengths and limitations of using biological measures in human studies of disease etiology, and the characteristics of biomarkers that should be established prior to incorporating them into epidemiologic studies;
- identify the goals of, and strategies in conducting, discovery and characterization studies of biomarkers;
- identify potential sources and impact of biomarker measurement error, in particular the role of differential and nondifferential misclassification of binary and continuous biomarkers;
- identify strengths and limitations of various traditional epidemiologic study designs, and implementation strategies, for the purposes of incorporating biomarker measurements;
- critique scientific reports from human populations that involve biologic measures in the study of disease etiology, prognosis, and early detection.

¹ Except on December 13th, when class will meet from 10:30 am – 12:20 pm

Council on Education for Public Health (CEPH) Competencies:

The UW School of Public Health (SPH) is accredited by the Council on Education for Public Health (CEPH). This course fulfills the “Characterize the measurement properties of biomarkers” CEPH competency for the Department of Epidemiology’s MS – Clinical Translational Research (CTR) track.

Format:

There are 20 sessions. Eighteen sessions will consist of lectures on methodologic issues, applications of methodologic issues to particular diseases, discussion of homework assignments, discussion of research papers, discussion of real or hypothetical case studies, or a combination of these. All readings can be downloaded and printed from the course website. Two sessions are reserved for student presentations of final papers.

Evaluation:

EPI/ENVH 573 is a 3 credit, graded course. The grade will be based on three assignments (contributing 20% each), discussions (10%), and a final paper and presentation (30%). The assignments and paper are described generally below.

Assignments: Assignments will be distributed throughout the quarter (see attached course schedule), and will involve written exposition of ideas, interpretation of data and/or calculations, etc. Some may involve data analyses (including multivariate methods) for which access to a statistical package (e.g., SAS, SPSS, STATA, R) will be necessary. STATA is preferred. We will discuss each assignment in class on the date indicated in the syllabus (unless otherwise changed). Note: A student may communicate with other students about general aspects of an assignment, but in all instances must submit answers that they have composed on their own. Evidence that a student or students have collaborated to submit essentially identical written answers will result in zero points awarded for the part(s) of an assignment for which the evidence exists.

Paper: Each student will write a brief paper summarizing the use of a biomarker (or family of related biomarkers) in studies of human disease. More information on this assignment will be provided in a separate handout. During the final two class sessions, each student will deliver a brief (9-12 minutes depending on the number of students) presentation summarizing their paper.

All assignments and papers must be prepared electronically using MS-Word or compatible software and uploaded to the UW Canvas Learning Management System (<https://canvas.uw.edu/>) by the due date and time.

Points for late assignments in the absence of a reasonable excuse (e.g., illness) will be 10% lower than for assignments submitted on time. Assignments will not be accepted after discussion of the answers in class, or after 8:30 am on the 7th day after the due date regardless of when the discussion occurs.

There is no final examination. However, we will meet during the official UW final examination scheduled time (Tuesday, December 14th, from 10:30 am – 12:20 pm) for the final set of student presentations.

First Peoples Land Acknowledgement

The SPH acknowledges the Coast Salish people of this land that touches the shared waters of all tribes and bands within the Duwamish, Suquamish, Tulalip and Muckleshoot nations and was stolen by Europeans. Each of us should assist these nations with their respective pursuits of justice for what was taken from them.

COVID-Related Expectations

Per [UW policy](#), this class will be conducted in person. Therefore, unless you meet the criteria for an accommodation from Disability Resources for Students (DRS) or a special arrangement approved by the [SPH Office of the Dean](#) that allows you to take the course remotely you may not register for this class if you cannot attend in-person.

- Please contact [UW Disability Resources for Students](#) (DRS) directly if you feel you may be eligible for an accommodation based on your status as an immunocompromised individual or based on other diagnosed physical or mental health conditions that might prevent you from being able to take classes in-person.
- If you are a student enrolled in an SPH program, and you are either living with an individual who is immunocompromised, OR you are unable to obtain a visa to travel to the US, you may be eligible for a “special arrangement” that will allow you to take this course remotely. Requests for special arrangements to take the class remotely should have been submitted to and approved by the Students and Academic Services team in the Office of the Dean before the beginning of the quarter. If you have questions about this type of arrangement, please reach out to [Student and Academic Services](#).

All UW students are expected to follow state, local, and UW COVID-19 policies and recommendations.

Please be extra conscientious about masking during the first few weeks of the quarter, because we will have a lot of members of the community traveling and can reasonably expect to see a surge in COVID cases.

If you feel ill or exhibit possible COVID symptoms, please do not come to class. If you need to temporarily quarantine or isolate per CDC guidance and campus policy, you are responsible for notifying me as soon as possible by email. If you receive a positive COVID-19 test result, you must report to campus Environmental Health & Safety (EH&S) by emailing covidehc@uw.edu or calling 206-616-3344.

Please check your email daily BEFORE coming to class. If we need to conduct class remotely because the session leader (a guest speaker or I) is complying with UW policies and unable to attend in person, we will send all registered students an email with a Zoom link for remote instruction. Please also keep an eye out for email communications from the University or the SPH that will inform you of any future changes to policies or guidelines.

Academic Integrity

UW students are expected to maintain the highest standards of academic conduct, professional honesty, and personal integrity. The SPH is committed to upholding standards of academic integrity consistent with the academic and professional communities of which it is a part. Plagiarism, cheating, and other misconduct are serious violations of the [UW Student Conduct Code](#). You are expected to know and follow the university's policies on cheating and plagiarism, and the [SPH Academic Integrity Policy](#). Any suspected cases of academic misconduct will be handled according to UW regulations.

I am Committed to Multi-cultural Inclusion

I want all students to be fully included in this course. To that end, I strive to create an environment that reflects community and mutual respect. If you have concerns about this course's classroom climate, please talk to me, your academic advisor, a member of the [Department's Equity, Diversity, and Inclusion Committee](#) or [SPH Diversity Committee](#) and/or your program director. The SPH also has a [formal concern policy](#) if you should choose to pursue that option. SPH academic program-specific contacts for formal concerns can be found [here](#).

Religious Accommodations

I follow [UW's policy for accommodation of student absences or significant hardship due to reasons of faith or conscience, or for organized religious activities](#). *Accommodations must be requested within the first two weeks of the course using the [Religious Accommodations Request Form](#).*

Access and Accommodations

If you would like to request academic accommodations due to a disability, please contact [Disability Resources for Students](#) (DRS), 448 Schmitz, 543-8924 (V/TTD). If you have a letter from DRS indicating you have a disability that requires academic accommodations, please present the letter to me during the first full week of the academic term so that I can discuss the accommodations you might need for the class.

Physical Texts on HSL Course Reserves

- Hamdan M, Righetti PG. Proteomics today: protein assessment and biomarkers using mass spectrometry, 2D electrophoresis, and microarray technology. John Wiley & Sons, Hoboken, 2005.
- Pepe MS. The statistical evaluation of medical tests for classification and prediction. Oxford University Press, Oxford, 2003.
- Strachan T, Read AP. Human Molecular Genetics. 5th Edition. Garland Science, London, 2018.
- Tietz NW. Fundamentals of Clinical Chemistry and Molecular Diagnostics. 8th Edition. WB Saunders Co. Philadelphia, 2020.
- White E, Armstrong BK, Saracci R. Principles of Exposure Measurement in Epidemiology. Collecting, evaluating, and improving measures of disease risk factors. Oxford University Press, New York, 2008. (Note: E-text also available through the Canvas site)

E-Texts on Reserve Through HSL Course Reserves

Khoury MJ, Bedrosian S, Gwinn M, Higgins J, Ioannidis J, Little J. Human Genome Epidemiology. 2nd Edition. Oxford University Press, 2010.

E-Texts on Reserve Through Canvas

Wild C, Vineis P, Garte S. Molecular Epidemiology of Chronic Diseases. John Wiley and Sons Ltd, West Sussex, 2008.

Tonolio P, Boffetta P, Shuker DEG, Rothman N, Hulka B, Pearce N. Application of Biomarkers in Cancer Epidemiology. IARC Scientific Publications. No. 142, Lyon, 1997.

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Class Schedule – Autumn 2022

| <u>Session</u> | <u>Topic</u> | <u>Leader</u> |
|----------------|---|---------------|
| Thur 9/29 | Introduction to Course Introduction to Biomarkers in Epidemiologic Research | Schwartz |
| Tues 10/4 | Article Discussion | Schwartz |
| Thur 10/6 | Validity and Reliability Studies for Biological Markers – Part 1 Begin Assignment #1 | Schwartz |
| Tues 10/11 | Validity and Reliability Studies for Biological Markers – Part 2 Assignment #1 Due and Discussed | Schwartz |
| Thur 10/13 | Biomarker Discovery and Characterization | Schwartz |
| Tues 10/18 | Tissues, Assays, and Laboratory Variation | Schwartz |
| Thur 10/20 | Study Design and Implementation – Part 1 Begin Assignment #2 | Schwartz |
| Tues 10/25** | Statistical Analysis of Biomarker Data Assignment #2 Due Begin Assignment #3 | Kerr |
| Thur 10/27 | Study Design and Implementation – Part 2 | Schwartz |
| Tues 11/1 | Homework #2 Discussion | Schwartz |
| Thur 11/3 | Application: Air Pollution | Simpson |
| Tues 11/8 | Application: Vaginal Microbiome | Balkus |
| Thur 11/10 | No Class (Veterans Day Holiday) | |
| Tues 11/15 | Application: Gut Microbiome Assignment #3 Due | Hullar |
| Thur 11/17 | Application: Cancer | Whiteaker |
| Tues 11/22 | No Class | |
| Thur 11/24 | No Class (Thanksgiving Holiday) | |
| Tues 11/29 | Homework #3 Discussion | Schwartz |
| Thur 12/1 | Application: Nutrition | Neuhausser |
| Tues 12/6 | Application: Human Papillomavirus | Winer |
| Thur 12/8 | Student Presentations | All |
| Tues 12/13* | Student Presentations | All |

* This session will take place from 10:30 am – 12:20 pm. Final papers will be due on 12/16/2022 at 8 am PST.

** This session will be held entirely on Zoom. Please see Canvas for details.