METHODS FOR OBSERVATIONAL STUDIES: PLANNING THE ANALYSIS

COURSE INSTRUCTORS

Boris Sobolev, Nicole Hu, Lisa Kuramoto

PLACE AND TIME

Room 700 of the VGH Research Pavilion, 828 West 10th Avenue, Vancouver BC. November 12, 19, 26, 2026 from 1:30pm to 4:30pm.

COURSE DESCRIPTION

This course offers an introduction to methods for observational studies across health services, health outcomes and public health research. Its goal is to equip multidisciplinary teams with the essential tools needed for planning and analyzing observational data. Key topics include developing an analytical framework, designing dataset creation strategies, and planning data analysis.

TARGET AUDIENCE

The course will benefit those who analyze patient registries, hospital discharge summaries, administrative health databases, cohorts of study participants and other data arising from observational studies. This course is ideal for clinicians, healthcare professionals, hospital administrators, residents, health services researchers, data analysts, and students. Participants should have some experience with quantitative analysis. Basic knowledge of statistics is an advantage.

COURSE OBJECTIVES

Participants will develop competencies and skills in:

1. Presenting study questions within the framework of observational studies.
2. Developing protocols for dataset creation.
3. Planning effective analyses of observational data.

COURSE STRUCTURE

The course is delivered as a series of three half-day modules. Teaching is done through lectures, practical exercises, and discussions. Participants will be provided with a case study at the start of the first module, which will be used throughout the course.

COURSE MATERIALS

Participants will receive lecture notes and tools for planning analyses in observational studies.

Case study readings:

- Sobolev BG, Fradet G, Kuramoto L, Rogula B. An observational study to evaluate 2 target times for elective coronary bypass surgery. Medical Care 2012; 50(7):611–619.
- Sobolev, BG, Fradet G, Kuramoto L, Sobolyeva R, Rogula B, Levy AR. Evaluation of supply-side initiatives to improve access to coronary bypass surgery. BMC Health Services Research 2012; 12:311.

Recommended readings:

- Ghaferi AA, Schwartz TA, Pawlik TM. STROBE reporting guidelines for observational studies. JAMA surgery. 2021 Jun;156(6):577-8.
- Vandenbroucke JP, von Elm E, Altman DG, Gøtzsche PC, Mulrow CD, Pocock SJ,Poole C, Schlesselman JJ, Egger M; STROBE Initiative. *Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration*. Epidemiology. 2007 Nov;18(6):805–35.
- Berger ML, Mamdani M, Atkins D, Johnson ML. Good Research Practices for Comparative Effectiveness Research: Defining, Reporting and Interpreting Nonrandomized Studies of Treatment Effects Using Secondary Data Sources: The ISPOR Good Research Practices for Retrospective Database Analysis Task Force Report–Part I. Value in Health. 2009; 12(8):1044–1052.
- Loder E, Groves T, Macauley D. *Registration of Observational Studies*. BMJ. 2010; 340:c950.
- Thomas L, Peterson ED. The Value of Statistical Analysis Plans in Observational Research. JAMA. 2012; 308(8):773–774

Further readings

- Ravitch, S.M. and Riggan, M. Reason and Rigor: How Conceptual Frameworks Guide Research. Sage, Los Angeles, 2012.
- Lang TA, Secic M. How to report statistics in medicine annotated guidelines for authors, editors, and reviewers. American College of Physicians, 2nd edition. Philadelphia, 2006.

COURSE CONTENT

MODULE I. ANALYTICAL FRAMEWORK

An analytical framework operationalizes the study question by relating underlying theoretical constructs to data elements.

Learning objectives

To develop confidence in:

- describing elements of the analytical framework
- contrasting types of outcome variables
- relating types of outcome variables to summary measures and to measures of effect size
- interpreting measures of effect size

To develop skills in:

- identifying elements of the analytical framework for a specific study question

MODULE II. ANALYTICAL DATASET CREATION PLAN

The plan for creating an analytical dataset serves as a tool to develop the dataset amenable for analysis, to advise data management, and to establish communication among members of the research group.

Learning objectives

To develop confidence in:

- stating the purpose of a dataset creation plan
- describing parts of a dataset creation plan
- relating elements of the analytical framework to parts of a dataset creation plan

To develop skills in:

- developing a dataset creation plan

MODULE III. PLAN OF DATA ANALYSIS

A plan of data analysis brings methodological rigor to observational research by identifying statistical methods and tools and by framing anticipated results according to reporting guidelines, in advance. This facilitates transparency in generating the results.

Learning objectives

To develop confidence in:

- stating the purpose of a plan of analysis
- describing the parts of a plan of analysis
- relating elements of the analytical framework to parts of a plan of analysis
- relating parts of a dataset creation plan and parts of a plan of analysis
- identifying parts of a plan of analysis from a journal article

To develop skills in:

developing a plan of analysis