HUMANITAS MEDICAL SCHOOL

Course: Biostatistics

Year: 3rd

Period: 2nd semester

Credits: 4

Objectives

Biostatistics is essential to ensure that findings and practices in public health and medicine are supported by reliable evidence. Epidemiology, on the other hand, is the study of the distribution and determinants of health and disease in human populations, and the application of methods to improve disease outcomes. Both sciences form the cornerstone of health research and evidence-based public health policy and practice.

This course introduces the basic principles and methods of biostatistics and epidemiology, with an emphasis on critical thinking, analytical skills, and application to clinical practice and research. Epidemiological and statistical concepts are taught in parallel to promote integration of knowledge across both disciplines.

The course will cover three domains:

(i) biostatistics: basic concepts; types of data; frequency distributions; methods of summarizing data; central tendency and dispersion; concepts of probability; basic concepts of statistical inference; hypothesis testing; statistical errors; elementary parametric & non-parametric methods in medical research; statistical analysis using real data and statistical software with emphasis in concepts and interpretation;

(ii) epidemiology: basic principles; measures of disease occurrence; measures of association; epidemiological study designs; cohort studies; case-control studies; cross-sectional studies; ecological studies; experimental study designs; randomized controlled trials; criteria of causality; biases (systematic errors); confounding; synthesis and evaluation of the evidence by means of systematic reviews and meta-analyses; and methodological approaches for the development of clinical practice guidelines;

(iii) research methodology: basic concepts; practical steps to develop a clinical research protocol; what elements to address in a clinical trial protocol; how to write a research paper for publication in a medical journal; how to submit an article for publication; practical tips for publishing; ethics in research; and research misconduct.

On completion of this course, the student should be able to describe the basic epidemiological concepts, interpret and critically evaluate literature that is relevant to public health professionals, select and apply appropriate statistical methods for managing common types of health data, interpret and communicate the results to health professionals and to the general public.

Prerequisites

There are no prerequisites for this course.

Contents

Lesson 1. Introduction to epidemiology: historical evolution.

Learning goals: To identify the historical figures and events that played a role in the evolution of epidemiology and public health; define epidemiology and explain its goals; and list the key features and uses of descriptive and analytical epidemiology.

Lesson 2. Introduction to biostatistics: summarizing data.

Learning goals: To distinguish the different types of data; explain how to construct a frequency distribution; calculate and interpret the measures of central location: mode, median, and arithmetic mean; demonstrate how to apply the most appropriate measure of central location for a frequency distribution; and apply and interpret four measures of spread: range, interquartile range, standard deviation, and confidence interval (for mean).

Lesson 3. Measures of disease occurrence + Workshop 1.

Learning goals: To learn how to calculate and interpret the measures of disease occurrence: proportion, ratio and rate, prevalence and incidence proportion, incidence rate, and attack rate. A brief workshop (exercises and discussion) will help the students apply the lesson content.

Lesson 4. Measures of association + Workshop 2.

Learning goals: To learn how to calculate and interpret the measures of association: risk ratio, rate ratio, and odds ratio. A brief workshop (exercises and discussion) will help the students apply the lesson content.

Lesson 5. Experimental study designs: clinical trials.

Learning goals: To discuss the key concepts of trials: fundamentals of trial design, strengths and limitations.

Lesson 6. Special trial issues in data analysis.

Learning goals: To further discuss concepts in clinical trials: intention-to-treat and per-protocol analysis, multiple testing, missing data, interim monitoring and stopping rules.

Lesson 7. Observational study designs: cohort studies and case-control studies.

Learning goals: First, to discuss the features of a cohort study; distinguish between prospective, retrospective, and ambidirectional cohort studies; and explain the main strengths and weaknesses of the cohort study design. Second, to define and explain the features of a case-control study; identify the types of questions that can be addressed by case-control studies; learn how to estimate and interpret odds ratios from case-control studies; and discuss their strengths and limitations.

Lesson 8. Workshop 3.

Learning goals: This workshop (consisting of several exercises and discussion) aims to help the students apply the content of the previous lessons.

Lesson 9. Basics of statistical analysis.

Learning goals: To explain the concepts of sample, population, and statistical inference; describe the practical procedures for hypothesis testing; discuss the types of statistical errors; and learn the basic parametric and non-parametric statistical methods used in medical research: one-sample t-test and sign test, two-sample t-test and two-sample Wilcoxon rank-sum (Mann-Whitney) test, paired t-test and matched-pairs Wilcoxon signed-rank test, chi squared test, as well as the correlation and linear regression analyses.

Lesson 10. Bias and confounding, causal inference.

Learning goals: To define bias (systematic error); differentiate between the three types of bias: selection bias, misclassification/information bias, and confounding; identify the common sources of bias, and which types of studies are prone to which types of bias; distinguish between an association and a causal relationship; and describe and apply the Hill's criteria for judgment of causality.

Lesson 11. Screening.

Learning goals: To discuss which types of diseases are appropriate for screening; define, calculate and interpret the sensitivity, specificity, positive predictive value and negative predictive value of a screening test; and explain how the predictive value is influenced by prevalence of disease. A brief workshop (exercises and discussion) will help the students apply the lesson content.

Lesson 12. Evidence synthesis: systematic reviews and meta-analysis.

Learning goals: To discuss the main concepts of systematic reviews and meta-analyses; explain how to interpret their results; and apply to a patient scenario.

Lesson 13. Clinical practice guidelines: GRADE & Oxford systems.

Learning goals: To familiarize with current methodologic approaches for the guidance of clinical practice, discuss the OCEBM (Oxford Centre for Evidence-Based Medicine) Levels of Evidence that can be used by clinicians to find the likely best evidence and answer clinical questions quickly, and the GRADE (Grading of Recommendations Assessment, Development and Evaluation) system for developing clinical practice guidelines.

Lesson 14. Research methodology: development of a study protocol.

Learning goals: To discuss the practical steps to develop a research protocol, and elements to address in a clinical trial protocol.

Lesson 15. How to write, submit and publish a scientific article.

Learning goals: To discuss how to write a research paper for publication in a medical journal, how to submit an article for publication, and some practical tips for publishing.

Lesson 16. Research ethics, research misconduct.

Learning goals: To discuss ethics in research; focus on the moral principles that researchers must follow in clinical research; highlight the importance of ethical publishing; and outline the definitions of misconduct.

Lessons 17–22. Stata Lab sessions.

Learning goals: To work with Stata software, explore the data, and deepen our understanding of biostatistics. This Lab module will include: Introduction to Stata software, presentation of data using graphical methods, statistical analysis using real datasets, hypothesis testing, comparison of means and proportions, chi squared test, correlation and linear regression, non-parametric tests, sample size and power calculations. Emphasis will be given in concepts and interpretation.

Lesson 23. Open discussion on the central concepts of the course: Q/A.

Learning goals: To perform an overview/synthesis of the course; look back over the topics covered and try to weave them together; and identify common themes, and recurring issues. Students can ask any questions at all, from material in the course to any other topic of interest.

Lesson 24. Simulation of the written test: multiple choice questions.

Learning goals: To provide students with experience answering the same types of questions they will find on the real test.

Teaching Methods

During the lectures, the course will introduce the basic principles and methods of biostatistics and epidemiology, with an emphasis on critical thinking, analytical skills, and application to clinical practice and research. Statistical and epidemiological concepts will be taught in parallel to promote integration of knowledge across both disciplines.
During the Lab sessions, we will work with Stata software, explore the data, and deepen our understanding of biostatistics. The students are advised to self-practice after the course using the datasets and materials provided for the Lab sessions.

Assessment

The final exam includes 30 multiple choice questions (plus 1 bonus question) worth 1 point each, and focuses on the topics discussed during the course; thus, understanding deeply the material covered in the lectures, workshops and Lab sessions, is the key to success. A mark of at least 18/30 is needed to pass the examination.

Texts

Textbooks of Biostatistics:
— Altman DG. Practical Statistics for Medical Research. Chapman and Hall/CRC.
— Bland M. An Introduction to Medical Statistics. Oxford University Press.
Textbooks of Epidemiology:
— Rothman KJ, Greenland S, Lash TL. Modern Epidemiology. Lippincott Williams & Wilkins.
— Bonita R, Beaglehole R, Kjellström T. Basic Epidemiology. World Health Organization.