

Discipline MCP5884 
Scientific Method Applied to Clinical Research

Concentration area: 5131

Creation: 10/06/2021

Activation: 10/06/2021

Credits: 2

Workload:

Theory (weekly)	Practice (weekly)	Study (weekly)	Duration	Total
1	2	0	10 weeks	30 hours

Professor:

Moacyr Roberto Cuce Nobre

Objectives:

OBJECTIVE: To present and discuss the fundamentals of the scientific method, with the objective of supporting the student in the development of skills, to highlight, criticize, and synthesize research in the health area, with special focus on those applied to clinical practice.

Rationale:

RATIONALE: The discipline is justified by the assimilation of qualified technical-scientific knowledge, the recognition of the choice of the appropriate method in the face of research questions previously formulated, be it of the observational or experimental type; considering their potential bias, and the possibilities of control and adjustment in the planning, execution and analysis phases. At the end, it is expected that students will be able to know the methodological foundations of clinical research, developing skills to observe, analyze, and interpret their publications, from a critical and questioning posture.

Content:

CONTENT: Clinical epidemiology as an area of knowledge. Clinical practice as a research context. Study designs. What characterizes and differentiates the clinical trial, the cohort, the cross-sectional, and the control case. Common systematic errors in the development of research projects. Internal validity and external validity of the results. Application of basic knowledge of statistics for the interpretation of association measures. Random errors, data reproducibility, and uncertainty. Descriptive measures of frequency and association between study variables. Type, magnitude and precision of outcome measures. Statistical significance, clinical relevance, and causal inference. Controls and adjustments for systematic errors and random errors during project planning, execution, and analysis. Critical evaluation and synthesis of scientific literature. Good practice guidelines based on quality rating, and accuracy of benefits and adverse events from clinical procedures. Ethics in clinical research.

Type of Assessment:

EVALUATION: The final concept attributed to the student results from three evaluations, of equal weight, which include: a) presentation of an article during the seminars; b) critical

evaluation structured by the "GRADE" of the submitted article, to be delivered at the end of the activities; c) structured self-assessment of learning during the course.

Notes/Remarks:

NOTE: Minimum number of students: 20 Maximum number of students: 100

Bibliography:

Altman, D.G. - Practical statistics for medical research. Chapman & Hall, London, 1990.
Bland, M. - An Introduction to Medical Statistics, 4a.ed. — Oxford University Press, 2016.
Feinstein AR. Clinical Epidemiology: Architecture of Clinical Research. Philadelphia: Saunders 1985.
Fletcher RH, Fletcher SW, Fletcher GS. Epidemiologia Clínica: Elementos Essenciais, 5a. ed. Porto Alegre: ArtMed, 2014.
Greenhalgh T — Como Ler Artigos Científicos: Fundamentos da Medicina Baseada em Evidências, 5a.ed. — Porto Alegre: Artmed, 2015.
Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Delineando a Pesquisa Clínica: Uma Abordagem Epidemiológica. 4a. ed. Porto Alegre: Artmed, 2015.
Nita ME, Campino ACC, Secoli SR, Sarti FM, Nobre MRC, Costa AMN, Ono-Nita SK, Carrilho FJ, 1a. ed. — Avaliação de Tecnologias em Saúde: evidência clínica, análise econômica e análise de decisão — Porto Alegre: Artmed; 2010.
Nobre MR, Bernardo WM. Prática Clínica Baseada em Evidência. Rio de Janeiro: Elsevier, 2006.
Rothman KJ, Greenland S, Lash TL. Epidemiologia Moderna. 3a. ed. Porto Alegre: Artmed, 2011.
Sackett DL, Haynes RB, Tugwell P, Guyatt GH. Clinical Epidemiology: A Basic Science for Clinical Medicine. 2a. ed. Boston: Little Brown, 1991.
Straus SE, Glasziou P, Richardson WS, Haynes RB. Evidence-based medicine: how to practice and teach EBM. 5a. ed. Elsevier; 2019.
Sutton AJ, Abrams KR, Jones DR, Sheldon TA, Song F — Methods for Meta-Analysis in Medical Research, 1a.ed. — John Wiley & Sons: 2001.
Obs: atendendo solicitação do parecerista, foram incluídas algumas novas referências, atualizadas outras que tiveram edições mais recentes, e mantidas algumas mais antigas que são consideradas básicas. Estas foram mantidas porque correspondem ao período de implementação da epidemiologia clínica e ao lançamento da proposta conceitual da "Medicina Baseada em Evidência".