FACULTY OF MEDICINE

STUDY PROGRAM 0912.1 MEDICINE

NICOLAE TESTEMIȚANU CHAIR OF SOCIAL MEDICINE AND MANAGEMENT

APPROVED
at the meeting of the Commission for Quality Assurance and Evaluation of the Curriculum in Medicine
Minutes No. 1 of 16.09.21
Chairman, PhDH, associate professor
Suman Serghei _____

APPROVED
at the Council meeting of the Faculty Medicine no. 1 _____
Minutes No. 1 of 21.09.21
Dean of Faculty, PhDH, associate professor
Plăcintă Gheorghe _____

APPROVED
at the meeting of *Nicolae Testemițanu* Chair of Social Medicine and Management
Minutes No. 2 of 14.09.2021
Head of Chair, PhDH, associate professor
Raevschi Elena _____

SYLLABUS

DISCIPLINE **EVIDENCE-BASED MEDICINE: CRITICAL ASSESSMENT OF MEDICAL ARTICLES**

Integrated studies

Type of course: **Optional discipline**

Curriculum developed by the team of authors:

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I. INTRODUCTION

- Evidence-Based Medicine (*EBM*) is an important transformation of the studying and research way of practical activity in medicine. The evidence-based approach to patient care is a captivating experience of the intellectually guiding medical practice throughout life. EBM creates a basic guideline for understanding when and how to use new diagnostic and treatment methods, how to find the answer to the clinical questions that arise daily in the process of examining patients.

The evidence-based approach excludes the need to rely on doctrines and traditions, and allows for critical and objective evaluation of the traditional and alternative therapeutic modalities. EBM places the patient at the medical activity centre by emphasizing the important results for patients: the symptoms of the disease, morbidity, mortality, the quality of life and the price.

The evidence-based approach for a researcher creates a solid basis for evaluating new evidence in the scientific literature, critically assessing existing practical methods, and rationally using clinical data obtained from patients. The introduction of the evidence-based approach in the study and research process contributes to the improvement of the daily medicine practice. This allows you to:

- use latest medical literature;
- actively communicate with counsellors;
- use more efficiently information sources;
- use rationally the data obtained from the assemblage of the anamnesis, the performance of the physical examination and the diagnostic tests;
- avoid the typical difficulties in taking clinical decisions.

- **Mission (aim) of the curriculum in professional training**: Gaining the knowledge and developing students' skills in the Evidence-Based Medicine field to could effectively research through scientific literature, correctly formulating questions about the clinical case, assessing the relevance and validity of the research.
- Language (s) of the course: Romanian, English, Russian, French
- Beneficiaries: students of the Vth year, faculty of Medicine I and Medicine II, specialty Medicine

II. MANAGEMENT OF THE DISCIPLINE

Code of discipline		**U.09.A.081.1**	
Name of the discipline		**Evidence-Based Medicine: critical assessment of medical articles**	
Person(s) in charge of the discipline		**Spinei L., Ferdohleb A., Globa N.**	
Year	**V**	Semester/Semesters	**IX**
Total number of hours, including:			**30**
Lectures	**10**	Practical/laboratory hours	**10**
Seminars	-	Self-training	**10**

Form of assessment	E	Number of credits	1

III. TRAINING AIMS WITHIN THE DISCIPLINE

At the end of the discipline study the student will be able to:

✓ ***at the level of knowledge and understanding:***

- to define EBM, internal evidence and external evidence.
- to understand the concepts of "relevance" and "validity" of research results.
- familiarization with different types of scientific articles.
- knowledge of the review types: narrative, systematic and meta-analysis.
- knowledge of indicators for a deep understanding of the research results.
- to describe the parts of an article.
- to enlist the most important scientific sources.

✓ ***at the application level:***

- the development of skills of using the terms without difficulty: EBM (*Evidence-Based Medicine*), POEM (*Patient Oriented Evidence that Matters*), DOE (*Disease Oriented Evidence*).
- to accurately use the information about the health status of the population.
- to select the best scientific evidence.
- the ability to develop a systematic review.
- the calculation of indicators to determine the validity of therapeutic and diagnostic research.
- the usage of a meta-analysis results for clinical decision taking.
- the bachelor's thesis preparation as a secondary study - systematic analysis.

✓ ***at the integration level:***

- to identify the unique contribution of EBM in the study of population health.
- to appreciate the importance of using EBM for a researcher.
- to understand the evidence spectrum (internal and external).
- to use the correct methods to assess the relevance of a research.
- to use the correct methods to assess the validity of the treatment and diagnostic methods.
- to appreciate correctly the results presented in the scientific articles.
- to organize the scientific research using the theoretical knowledge and practical skills, obtained during the course.
- to prepare an article for publication.
- to apply the knowledge obtained in the preparation stage of the bachelor's thesis.

IV. PROVISIONAL TERMS AND CONDITIONS

1. Language requirements;
2. Basics of the school level mathematics;
3. Basic biostatistics and research methodology;
4. Basic computer skills (MS Office EXCEL);
5. Ability to work in a team.

V. THEMES AND ESTIMATE ALLOCATION OF HOURS

Lectures, practical hours/ laboratory hours/seminars and self-training

No.	THEME	Number of hours		
		Lectures	Practical hours	Self-training
1.	Evidence-based medicine: the essence, importance, advantages and disadvantages. The steps of evidence-based medicine.	2	2	
2.	General characteristic of primary biomedical research: descriptive, observational, experimental and diagnostic.	2	2	2
3.	Secondary studies. Quantitative and qualitative syntheses. Application of the Evidence-Based Medicine principles in clinical decision taking.	2	2	2
4.	Critical evaluation of medical scientific articles and abstracts.	2	2	2
5.	Writing medical scientific texts: articles, abstracts, theses.	2	2	4
Total		**10**	**10**	**10**

VI. PRACTICAL SKILLS AQUIRED AT THE END OF THE DISCIPLINE

Mandatory essential practical skills are:

- to use current medical literature;
- to actively use communication with consultants;
- to make better use of information sources;
- to make better use of the data / information obtained in collecting the anamnesis, in performing the physical examination, and in the diagnostic tests;
- to avoid typical difficulties in making the clinical decision.

VII. REFERENCE OBJECTIVES OF CONTENT UNITS

Objectives	Content units
Theme (chapter) 1. Evidence-based medicine: the essence, importance, advantages and disadvantages. The steps of evidence-based medicine.	
•*To define* EBM; •*To know* how to apply the six steps of EBM; •*To demonstrate the* levels of evidence-seeking; •*To apply the* knowledge to determine the relevance and validity of experimental study results; •*To integrate* the comparative analysis of different types of scientific studies.	1. Definition of EBM. EBM goals. Six steps of EBM. Research stages. 2. Research problem: forms; the purpose and objectives of a research. 3. The advantages of practicing EBM for the doctor and the patient. Limitations of EBM. 4. Evaluation of the quality of an article in the treatment plan (relevance, validity, significance of the results: RR, RP, CI-95%, RAR, NNT). 5. Evaluation of the quality of an article in the diagnostic plan (relevance, validity, significance of the results: (Se, Sp, VPP, VPN, RP +, RP-).

Objectives	Content units
Theme (chapter) 2. General characteristic of primary biomedical research: descriptive, observational, experimental and diagnostic.	
• *To define* descriptive studies and describe their importance: sample size, design elaboration, advantages and disadvantages; • *To know* the observational studies and to describe their importance: the particularities of the cohort and case-control studies, the design; • *To demonstrate* the calculation of the indicators in Table 2x2, the advantages and disadvantages; • *To apply* the calculation of the indicators in Table 2x2, the advantages and disadvantages; • *To integrate* the importance of preclinical and clinical studies: the particularities of the experimental studies (diagnosis & treatment), design, calculation of indicators in Table 2x2, the advantages and disadvantages.	1. Classification and general presentation of epidemiological studies. Objectives of descriptive studies, methods and sources of data collection, types of comparisons, stages, advantages and disadvantages. 2. The essence of cohort and case-control studies: objectives, direction and sequence, stages, inclusion criteria, difficulties in implementation, flow chart, calculation of indicators for cohort study (relative risk, confidence interval, attributable risk, strength of association) and case-control (odds ratio, confidence interval, attributable risk, strength of association), advantages and disadvantages. 3. Specificity and fields of application of experimental epidemiological studies. RCT (*Randomized Clinical Trial*) stages and phases, preclinical experimental study, ethical rules. *RCT* models, calculation of indicators for *RCT* (RR, CI-95%, NNT, RAR), advantages and disadvantages. 4. Flowchart for diagnostic studies.
Theme (chapter) 3. Secondary studies. Quantitative and qualitative syntheses. Application of the Evidence-Based Medicine principles in clinical decision making.	
• *To define* Review Types; • *To know* the stages of forming Qualitative Systematic Reviews; • *To demonstrate* the stages of forming a meta-analysis (systematic quantitative review);	1. Narrative, systematic reviews. Elaboration / stages of systematic reviews. The advantages of systematic reviews. 2. Navigating electronic sources. 3. Meta-analysis: definition, stages, relevance and validity. 4. Description of Forest-plot.

Objectives	Content units
•*To apply* navigation of different sources; •*To integrate* the benefits of using systematic reviews in clinical decision making.	
Theme (chapter) 4. Critical evaluation of medical scientific articles and abstracts.	
•*To define* the structure of medical scientific articles as primary study and secondary study (review / systematic analysis; •*To know* how to correctly formulate the null or alternative hypothesis for analytical studies; •*To demonstrate and* formulate the purpose and objectives of a SMART research; •*To apply* research protocol; *To integrate* rules for interpreting the results, their representation through text, tables, diagrams;	1. The characteristic of medical scientific articles as a primary study: the peculiarities of formulating the purpose and objectives of research, design elaboration, research methods and methods of primary data accumulation. 2. Characteristics of medical scientific articles as a secondary study: particularities of formulating the purpose and objectives of research, selection of methods for navigating bibliographic sources, elaboration of criteria for their selection. 3. Rules for preparing the final research report (in the PowerPoint): duration of the presentation, structure, ways of presenting the results, rules for compiling a slide).
Theme (chapter) 5. Writing medical scientific texts: articles, abstracts, theses.	
•*To define* describes the types of reviews (articles, abstracts, theses); •*To know* parts of an article; •*To demonstrate* critical evaluation of various scientific publications; •*To apply* prepare an article / medical scientific texts for publication; •*To integrate* – to make a correct list of the studied literature; - to list different ways of presenting statistical data; - to apply correctly the type of table / diagram	1. Analysis of the literature: importance, types. 2. Critical evaluation of the results of scientific research. 3. Summary and introductory part of a report or article. 4. Research methods section. 5. Results and discussions section. 6. Conclusions and preparation of the list of literature studied in research. 7. Presentation of statistical data. 8. Tabular presentation. Types of tables and their characteristic 9. Diagram building technologies. Classification of diagrams and their characteristic. 10. Requirements for oral presentation.

Objectives	Content units
depending on the analysed indicator.	

VIII. PROFESSIONAL (SPECIFIC (SC)) AND TRANSVERSAL (TC) COMPETENCES AND STUDY OUTCOMES

✓ **Professional (specific) (SC) competences**

CP1. - Responsible execution of professional tasks with the application of the values and norms of professional ethics, as well as the provisions of the legislation in force.

CP6. - Carrying out scientific research in the field of health and other branches of science.

CP7. - Promoting and ensuring the prestige of the medical profession and raising the professional level.

✓ **Transversal competences (TC)**

CT1. - Autonomy and responsibility in the activity.

CT4. - Achieving interaction skills and social responsibility.

✓ **Study outcomes**

The student at the end of the course will be able:

- to understand how the results of clinical research should be presented correctly according to the principles EBM.
- to acquire basic knowledge and develop the absolutely necessary skills for a doctor-researcher.
- to use different types of studies to get valid results.
- to demonstrate the spirit in organizing a scientific study.
- to apply contemporary methods of searching for correct scientific information.

Note. Study outcomes (are deduced from the professional competencies and formative valences of the informational content of the discipline).

IX. STUDENT'S SELF-TRAINING

No.	Expected product	Implementation strategies	Assessment criteria	Implementation terms
1.	**Searching for scientific information**	Applying different ways of searching for scientific information	Working skills in: Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, PsycINFO (a database of psychological literature) CINAHL.	During the module

2.	**Report / Essay**	Analysis of bibliographic sources and production of a paper on a topic of interest, additional to the program	1. The quality of the systematization and analysis of the informational material obtained through own activity. 2. The concordance of the information with the proposed topic.	During the module
3.	**Critical analysis of a scientific article**	Students will individually select one published article in medical journals to analyze.	1. Critical assessment of the validity and relevance of scientific research. 2. Number of gaps and errors identified in the structure and content of the articles.	During the module

X. METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-ASSESSMENT

- ***Teaching and learning methods used*** - Interactive lecture, guided discussion, role play, brainstorming, brainwriting, group work, Venn diagram, individual study, debate.
- ***Applied teaching strategies / technologies*** *(specific to the discipline)* - Strategies focused on the teacher's activity and on the teaching action: 1) Discursive and conversational strategies; 2) Discursive and demonstrative strategies.
- ***Methods of assessment*** *(including the method of final mark calculation)*

Current:

The current assessment during the semester includes a midterm test (the theoretical part) and a practical part (Practical part). The latter represent the assessment of the practical skills of a student.

Theoretical part:

- Midterm test – computerised grid-test

Practical part:

- Critical analysis of a scientific article, Case study analysis + attendance of the theoretical lectures.

The mark of the practical part of the current assessment is complex and consists of two components: the mark for the practical problem (coefficient 0.9) and the mark for the attendance of the theoretical lectures (coefficient 0.1).

The semester mark is calculated as the average of the midterm test and the mark for solving a practical problem.

Final: examination.

The examination for the discipline "Evidence-Based Medicine: the critical assessment of medical articles" represents a computerised grid-test. It includes 30 random questions from each of the studied themes with 40% single-choice questions and 60% multiple-choice questions. The student has at his/her disposal 30 minutes to answer to the grid-test.

Those students who gained less than 5.0 and / or did not recover their absence(s) for the practical seminars and theoretical lectures will not be admitted to the final examination.

The subjects for the final examination are approved at the chair meeting, while students will be notified one month before the exam.

The **final mark** is calculated as the average of the semester mark (coefficient is 0.5) and the test-grid obtained score at the exam (coefficient is 0.5).

The knowledge evaluation is made with marks from 1.00 to 10.00, according to the table:

Method of mark rounding at different assessment stages

Intermediate marks scale (annual average, marks from the examination stages)	National Assessment System	ECTS Equivalent
1.00-3.00	**2**	**F**
3.01-4.99	**4**	**FX**
5.00	**5**	**E**
5.01-5.50	**5.5**	
5.51-6.0	**6**	
6.01-6.50	**6.5**	**D**
6.51-7.00	**7**	
7.01-7.50	**7.5**	**C**
7.51-8.00	**8**	
8.01-8.50	**8.5**	**B**
8.51-8.00	**9**	
9.01-9.50	**9.5**	**A**
9.51-10.0	**10**	

The average annual mark and the final examination score (computer-assisted, test, oral) - are expressed in numbers according to the mark scale (following the table), and the final mark obtained is expressed in number with two decimals, which is transferred to student's record-book.

Absence on an exam without a good reason is recorded as "absent" and is corresponding to 0 (zero). The student has the right to have two reappraisals.

XI. RECOMMENDED LITERATURE:

A. Compulsory:

1. Gareth Hagger-Johnson. Introduction to Research Methods and Data Analysis in the Health Sciences. 2014, 328 p. https://www.routledge.com/Introduction-to-Research-Methods-and-Data-Analysis-in-the-Health-Sciences/Hagger-Johnson/p/book/9780273763840
2. Thomas Rice, Karen Y. Matsuoka. Book Review: The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors. https://doi.org/10.1177/1077558704269498
3. Israel Barbara A., Eng Eugenia, Schulz Amy J., Parker Edith A. Methods in Community-Based Participatory Research for Health. John Wiley & Sons, 2005, 480 p. https://books.google.md/books?hl=ro&lr=&id=fN6I3_IJW-wC&oi=fnd&pg=PR5&dq=books+Methods+of+research+and+analysis+of+health+status&ots=

HZrDi4CxkK&sig=ml6QvKm3-ngubmzv3CViVSRP958&redir_esc=y#v=onepage&q=books%20Methods%20of%20research%20and%20analysis%20of%20health%20status&f=false

4. Elizabeth DePoy, Laura N. Gitlin. Introduction to Research E-Book: Understanding and Applying Multiple Strategies. Elsevier Health Sciences, 2019, 416 p.

B. Additional

1. Apostoleris NH. Review of Integrating narrative medicine and evidence- based medicine: The everyday social practice of healing. Fam Syst Health. 2012; 30(1), pp. 82-83.
2. Bergman NG, Parker RA. Meta-analysis: neither quick nor easy. BMC Medical Research Methodology. 2002, pp. 2. http://www.biomedcentral. com/1471-2288/2/10.
3. Giménez-Pérez G. Dissemination of "patient-oriented evidence that matters" on the Internet: the case of Type 2 diabetes treatment. Diabet. Med. 2005; 22(6), pp. 688-692.
4. Ginsburg KR, Carlson EC. Resilience in action: an evidence-informed, theoretically driven approach to building strengths in an office-based setting. Adolesc. Med State Art Rev. 2011; 22(3), pp. 458-481.
5. Delgado-Rodríguez M. Glossary on meta-analysis. Journal of Epidemiology and Community Health. 2001, 55, pp. 534-536.
6. Hirsch O. Arriba-lib: association of an evidence-based electronic library of decision aids with communication and decision-making in patients and primary care physicians. Int J Evid Based Health. 2012;10(1):68-76.
7. Layde PM. A model to translate evidence-based interventions into com- munity practice. Am J Public Health. 2012;102(4):617-624.
8. Oxman A. Levels of evidence and strength of recommendations in clinical practice guidelines. Tidskr Nor Laegeforen. 2000; 120, pp. 1791-1795.
9. Sackett D. Applying overviews and meta-analyses at the bedside. Clin Epidemiol. 1995; 48, pp. 61-66.
10. Thies H. Correspondence (letter to the editor): Poor Evidence Based Medicine. Dtsch. Arztebl Int. 2012; 109(6), p. 112.
11. Truman B. Developing the Guide to Community Preventive Services - Overview and Rationale. Am. Prev. Med. 2000; 18, pp. 18-27.
12. Van Rijswijk L, Gray M. Evidence, research, and clinical practice: a patient - centered framework for progress in wound care. J Wound Ostomy Continence Nurs. 2012; 39(1), pp. 35-44.
13. Bacârea V., Sabău M., Mărușteri M., Bacârea A. Metodologia cercetării științifice medicale. Târgu Mureș, 2009.
14. Spinei L. Metode de cercetare și de analiză a stării de sănătate. Chișinău, 2012, 511 p.