

Federal State Autonomous Educational Institution of Higher Education
«Peoples' Friendship University of Russia»

Medical Institute

Recommended MCSD

SYLLABUS
(STUDY GUIDE)

Subject

Evidence-Based Medicine

Recommended for the direction of training (specialty)

31.05.01 General Medicine

Program (profile, specialization)

General Medicine

1. Goals and objectives of the discipline

Goal: to create acknowledgement and understanding of the concept of «Evidence-based medicine» (EBM), training to use approach in medical science and practice, in which the decision to the evaluation and use of preventive, diagnostic and therapeutic measures are taken on the basis of the available evidence of their effectiveness and safety and such evidence are searched, compared, summarized and widely disseminated to patients' benefit.

Objectives:

- Familiarization with the concept, principles and methodological foundations of evidence-based medicine;
- Formation of students' skills in the field of searching for medical information on the Internet in top indexing systems for professional publications (Scopus, Web of Science, PubMed, eLIBRARY.RU) and on specialized electronic resources (Cochrane Library, Medscape);
- Increased knowledge in the field of biomedical statistics, acquiring and reinforcement of skills to evaluate evidence base of medical and biological information, a critical interpretation of the results of clinical studies, publications in professional medical literature;
- Familiarity with the principles of good clinical and laboratory practice and the fundamentals of modern practice in clinical trials of medicinal products and medical devices;
- Studying and mastering the main methods of pharmacoepidemiological and pharmaco-economic analysis, the formation of skills necessary for solving individual research and scientific and applied problems in the field of clinical pharmacology;
- Acquisition of knowledge about the place of evidence-based clinical recommendations in the examination of a patient in order to establish a diagnosis, justify it, conduct a differential clinical diagnosis and prescribe therapeutic measures from the standpoint of evidence-based medicine;
- Acquiring skills in expert assessment of case history, medical article in accordance with clinical guidelines, examination and treatment standards based on the principles of evidence-based medicine.

2. Place of discipline in the structure of Educational Program of Higher Education

«Evidence-based medicine» is a discipline of the mandatory part of Block 1 of the curriculum.

The Table №1 shows preceding and subsequent disciplines involved in forming competences, for which the discipline «Evidence-based medicine» serves as continuation and base, respectively, in accordance with the competence matrix of Basic Educational Program of Higher Education.

Table №1

Preceding and subsequent disciplines involved in forming competencies

| №№ | Code and name of competence | Preceding disciplines | Subsequent disciplines |
|--------------------------|-----------------------------|---|--|
| Professional competences | | | |
| 1. | PC-5. | Immunology; Hygiene; Ophthalmology; Urology; | Hospital therapy; Hospital surgery, pediatric surgery; |

| №№ | Code and name of competence | Preceding disciplines | Subsequent disciplines |
|----|-----------------------------|---|--|
| | | Organization of special patient care; Neurology, medical genetics, neurosurgery | Outpatient therapy; Clinical Pharmacology; Allergology; Pediatrics |

3. Requirements for the results of completion the discipline

The discipline «Evidence-Based Medicine», among a number of the above-mentioned components of the Basic Educational Program of Higher Education, participates in the formation of the following specialist' competencies (Table №2).

Table №2

Formed competencies

| Competencies | Competency name | Competence achievement indicators |
|--------------------------------|---|--|
| <i>Professional competence</i> | | |
| PC-5 | Being able to carry out preventive measures and measures to promote a healthy lifestyle and sanitary and hygiene education among population and monitor their effectiveness | <p>PC-5.1. Being able to organize and conduct medical examinations taking into account age, health status, profession in accordance with applicable legislative acts and other documents.</p> <p>PC-5.2. Being able to organize and monitor the immunization of the adult population against infectious diseases in accordance with the current procedures for the provision of medical care, clinical guidelines (treatment protocols) on the provision of medical care taking into account the standards of medical care.</p> <p>PC-5.3. Being able to carry out medical examination of the adult population aimed at early detection of chronic noncommunicable diseases and the main risk factors for their development in accordance with the current legislative acts and other documents.</p> <p>PC-5.5. Being able to prescribe preventive measures to patients taking into account risk factors in accordance with the current procedures for the provision of medical care, clinical guidelines (treatment protocols) on the provision of medical care taking into account the standards of medical care.</p> <p>PC-5.6. Being able to monitor observing preventive measures.</p> <p>PC-5.11. Being able to assess the effectiveness of preventive patient care.</p> |

As a result of completion of the discipline «Evidence-based medicine», the student must:

Know:

- the principles and methodological foundations of EBM;
- levels of evidence in scientific research;

- the main stages and methodology of scientific research;
- sources of scientific data;
- the procedures for collecting, storing, searching, processing, transforming, distributing information in medical and biological systems, using information computer systems in medicine and healthcare;
- the concept of clinical guidelines, protocols and standards for diagnosis and treatment, the stages of their development and adoption, their place in the healthcare system;
- basics of biomedical statistics;
- stages of the development and implementation of medicinal and immunobiological products in practice;
- modern principles of planning and conducting clinical trials of medicinal products and medical devices;

Be able to:

- perform search for scientific publications, clinical guidelines, standards for the diagnosis and treatment of diseases of internal organs, in accordance with the principles of evidence-based medicine;
- compose an algorithm for examining a patient in accordance with current clinical guidelines based on the principles of evidence-based medicine;
- compose an algorithm for treating a patient in accordance with current clinical guidelines based on the principles of evidence-based medicine;
- perform an expert assessment of a scientific article, case history in accordance with clinical guidelines, diagnostic and treatment standards based on the principles of evidence-based medicine;
- independently formulate conclusions based on the stated purpose of the study, the results obtained and the evaluation of potential risks of errors and bias;
- use information technology and medical information systems for statistical analysis of data obtained in a clinical trial;

Possess:

- the skills of searching, analyzing and evaluating the evidence-based level of research protocols and their results in scientific publications;
- basic skills in choosing a research design in accordance with the goals set and the necessary research tools to comply with the ethical standards of their conduct;
- the basics of pharmacoepidemiological and pharmacoeconomic analysis;
- skills in the application of current clinical guidelines, standards for the diagnosis and treatment of diseases of internal organs, corresponding to the principles of evidence-based medicine, in preventive and diagnostic-treatment medical activities.

4. Discipline study load and types of educational activities

The total study load of the discipline is **2 academic credits**.

| Type of educational work | Total hours | Semester |
|---------------------------------|-------------|-----------|
| | | 7 |
| Contact classes (total) | 36 | 36 |
| Including: | | |
| Practice classes (PC) | 36 | 36 |
| Independent work (total) | 36 | 36 |
| Total study load | ac.hrs. | 72 |
| | ac.cred. | 2 |

5. Content of the discipline

5.1. Content of the discipline sections

| № | The name of the discipline section | Section content (topics) |
|----------|---|---|
| 1. | An introduction to evidence-based medicine. Evidence levels. | <p>1. Evidence-based medicine as the main way to improve the quality of medical care to the population. The history of the development of evidence-based medicine.</p> <p>2. Basic concepts and methods. Objectives of evidence-based medicine, role in the training of a doctor.</p> <p>3. Levels of evidence (A, B, C) and grades of recommendation (I, IIa, IIb, III). Systematic review. Meta-analysis.</p> |
| 2. | Statistics in Evidence-Based Medicine. Analysis of publications from the standpoint of evidence-based medicine. | <p>1. Basic statistical knowledge required to interpret evidence-based medicine data.</p> <p>2. Graphic presentation of statistical data.</p> <p>3. Sources of professional information. Search – methods, tools, algorithms.</p> <p>4. Analysis of publications from the standpoint of evidence-based medicine. Conflict of interest.</p> |
| 3. | Pharmacoepidemiology. Pharmacoeconomics. | <p>1. Definition. Types of pharmacoepidemiological studies.</p> <p>2. Basic methods of pharmacoepidemiological analysis and modeling.</p> <p>3. Analysis of drug consumption.</p> |

| № | The name of the discipline section | Section content (topics) |
|----------|---|--|
| 4. | Clinical research. Formular system. Adverse drug reactions. | 1. Clinical trials of medicines: phases, GCP, ethical and legal norms. 2. Formular system: principles of construction, methods of choosing medicines. The system for the rational use of medicines in Russia. 3. Classification of ADR. Monitoring methods. Pharmacovigilance. |
| 5. | Application of the principles and methods of evidence-based medicine in the health care system. | 1. Uniform standards for the presentation of the results of randomized controlled trials. 2. The concept of GLP. 3. Development and implementation of clinical guidelines, standards and protocols. 4. Clinical thinking and logic of diagnosis, specific patient management tactics in the era of evidence-based medicine. |

5.2. Discipline sections and types of classes

| № | Discipline sections | Lect. | Pract. class | Lab. class | Sem. | ISW | Total, ac.hrs. |
|----------|--|--------------|---------------------|-------------------|-------------|------------|-----------------------|
| 1. | An introduction to evidence-based medicine. Evidence levels. | - | 4 | | - | 4 | 8 |
| 2. | Statistics in Evidence-Based Medicine. Analysis of publications from the perspective of evidence-based medicine. | - | 8 | | - | 8 | 16 |
| 3. | Pharmacoepidemiology. Pharmacoconomics. | - | 8 | | - | 8 | 16 |
| 4. | Clinical research. Formular system. Adverse drug reactions. | - | 8 | | - | 8 | 16 |
| 5. | Application of the principles and methods of evidence-based medicine in the health care system. | - | 8 | | - | 8 | 16 |
| | TOTAL, ac.hrs. | - | 36 | | - | 36 | 72 |

6. Laboratory workshop not provided.

7. Practice classes

| № п/п | Section name | Practice class name | Total ac. hrs. |
|-------|--|--|----------------|
| 1. | An introduction to evidence-based medicine. Evidence levels. | 1. Evidence-based medicine as the main way to improve the quality of medical care to the population. The history of the development of evidence-based medicine. 2. Basic concepts and methods. Objectives of evidence-based medicine, role in the training of a doctor. 3. Levels of evidence (A, B, C) and grades of recommendation (I, IIa, IIb, III). Systematic review. Meta-analysis. | 4 |
| 2. | Statistics in Evidence-Based Medicine. Analysis of publications from the perspective of evidence-based medicine. | 1. Basic statistical knowledge required to interpret evidence-based medicine data. 2. Graphic presentation of statistical data. 3. Sources of professional information. Search – methods, tools, algorithms. 4. Analysis of publications from the standpoint of evidence-based medicine. Conflict of interest. | 8 |
| 3 | Pharmacoepidemiology. Pharmacoeconomics. | 1. Definition. Types of pharmacoepidemiological studies. 2. Basic methods of pharmacoepidemiological analysis and modeling. 3. Analysis of drug consumption. | 8 |
| 4 | Clinical research. Formular system. Adverse drug reactions. | 1. Clinical trials of medicines: phases, GCP, ethical and legal norms. 2. Formular system: principles of construction, methods of choosing medicines. The system for the rational use of medicines in Russia. 3. Classification of ADR. Monitoring methods. Pharmacovigilance. | 8 |
| 5 | Application of the principles and methods of evidence-based medicine in the health care system. | 1. Uniform standards for the presentation of the results of randomized controlled trials. 2. The concept of GLP. 3. Development and implementation of clinical guidelines, standards, and protocols. 4. Clinical thinking and logic of diagnosis, specific patient management tactics in the era of evidence-based medicine. | 8 |

8. Discipline technical requirements and support

To teach the discipline «Evidence-based medicine», the Department of Evidence-Based Medicine of the RUDN Medical Institute is provided with:

- sufficient classroom fund on the clinical base of the department – GBUZ «Morozovskaya DGKB DZM»;
- modern and sufficient IT infrastructure for classroom training (modern computer and multimedia equipment with the necessary list of system and office software, Internet connection);
- educational-methodical complex of discipline, enabling electronic learning and

electronic information resources (demos, presentations, etc.), providing classroom training with students.

9. Discipline informational requirements and support

a) Software:

Teaching the discipline «Evidence-Based Medicine» does not require special or specialized software. For classroom lessons Windows-computers with MS Office are used.

б) Databases, information and referral and search engines:

- RUDN Electronic library system (lib.rudn.ru);
- The Cochrane Collaboration (cochrane.org), The International Cochrane Collaboration;
- Cochrane Library (thecochranelibrary.com);
- Scopus (scopus.com), the indexing system of citations and abstracts database;
- Web of Science (webofscience.com/wos/woscc/basic-search), the indexing system of citations and abstracts database;
- PubMed (ncbi.nlm.nih.gov/PubMed), universal system designed to find citations including MEDLINE;
- UpToDate (uptodate.com), evidence-based decision support system;
- eLIBRARY.RU Scientific electronic library;
- Medscape (medscape.com), an information web-resource for professionals;
- official web-resources of the largest publishers/journals in the specialized field: The Lancet (thelancet.com), The New England Journal of Medicine (nejm.org), British Medical Journal (bmj.com), Annals of Internal Medicine (annals.org), etc.;
- web-resource of the Interregional Public Organization «Society of Evidence-Based Medicine Specialists» (osdm.org).

10. Educational and methodological support of the discipline

a) Main textbooks:

- Basics of Evidence-Based Medicine: A textbook for the system of postgraduate and additional professional education of doctors / MG Bubnova, EK Butina, VA Vygodin [and others]. - MOSCOW: LLC «Silicea-Polygraph», 2010. - 135 p.;
- Petrov, V.I. Medicine based on evidence: a textbook for students of medical universities and postgraduate education of doctors / V.I. Petrov, S.V. Nedogoda; V.I. Petrov, S.V. Nedogoda. - Moscow: GEOTAR-Media, 2009. - 141p.
- Grinhalkh, T. Basics of evidence-based medicine: translation from English / T. Grinhalkh; ed. I.N. Denisova, K.I. Saitkulova. - 3rd ed. - Moscow: GEOTAR-Media, 2009. - 282p.;
- Henegan, K. Evidence-based medicine / K. Henegan; Karl Henegan, Douglas Badenoch; per. from English ed. V.I. Petrov. - Moscow: GEOTAR-Media, 2011. - 125 p. - (Pocket Guide);

b) Additional literature:

- Petrov, V.I. *Medicine based on evidence: a textbook* / V.I. Petrov, S.V. Nedogoda. - Moscow: Limited Liability Company Publishing Group «GEOTAR-Media», 2012. - 144 p.;
- *Evidence-based medicine: a textbook for students of medical universities* / IP Artyukhov, A.V. Shulmin, V. V. Kozlov [and others]. - Krasnoyarsk: Krasnoyarsk State Medical University named after Professor V.F. Voino-Yasenetsky, 2012. - 206 p.;
- *General epidemiology with the basics of evidence-based medicine: a guide to practical exercises* / Edited by V.I. Pokrovsky, N.I. Bricaud. - 2nd edition, revised and enlarged. - Moscow, 2012. - 496 p.;
- *Evidence-based medicine: how to practice EBM. How to Teach EBM* / Sharon E. Straus, W. Scott Richardson, Paul Glaceio, R. Brian Haynes; transl. from English ed. V.V. Vlasova, K.I. Saitkulova. - Moscow: Publishing group «GEOTAR-Media», 2010. - 309 p.;
- *Moiseev, V.S. Internal diseases with the basics of evidence-based medicine and clinical pharmacology: a guide for doctors* / V.S. Moiseev; V.S. Moiseev, J.D. Kobaleva, S.V. Moiseev; ed. V.S. Moiseeva. - Moscow: GEOTAR-Media, 2010. - 832 p.;
- *Vorobyova, N.A. Evidence-based medicine in modern clinical practice: achievements and problems: a tutorial* / N.A. Vorobyova, A.A. Schapkov. - Arkhangelsk: Northern State Medical University, 2020. - 167 p.;
- *Basics of evidence-based medicine: Study guide* / MP Khokhlov, AB Peskov, IR Kerova [and others]; Ulyanovsk State University. - Ulyanovsk: Ulyanovsk State University, 2020. - 52 p.;
- *Naumova, E.A. Introduction to evidence-based medicine: a textbook* / E.A. Naumova, Yu.G. Schwartz, O.N. Semenova. - Moscow: Publishing House «Academy of Natural Sciences», 2019. - 76 p.;
- *Topical issues of evidence-based medicine: a practical guide for doctors* / Ministry of Health and Social Development of the Samara Region, Samara State Med. un-ty, Samara regional medical information and analytical center; [comp. L. V. Kveder]. - Samara: SSMU, 2012. - 117 p.;
- *Bashchinsky, S.E. Development of clinical practice guidelines from the standpoint of evidence-based medicine: textbook. manual for doctors and healthcare organizers* / S.Ye. Bashchinsky; S.E. Bashchinsky; Centr. SciRes Inst. Of Healthcare Management of Ministry of healthcare of Russia, Interregional Public Organization «Society of Evidence-Based Medicine Specialists». - Moscow: Publishing house Media Sphere, 2004. - 135 p.

11. Guidelines for organizing the study of the discipline

The course of the discipline «Evidence-Based Medicine» is composed of classroom activity in the form of contact laboratory classes with the teaching staff and independent work of students in an extracurricular format.

Contact study is conducted using a problem-oriented approach to mastering the subject of the curriculum of the discipline. In this second part of the students need regular training to exercise using basic and additional recommended literature, visits and active work in the classroom with teachers.

Extra-curricular activity of students in mastering the discipline is based on acquaintance

with the main and additional recommended literature, work on the assignments of teachers. At the disposal of students is the use of department teaching and educational materials, electronic information and educational resources. It occupies an important place of work and with the relevant Institute formational Internet resources.

The current control of the development of the discipline is carried out through interactive polls and interviews during classroom sessions with students.

Textbooks in electronic form on several topics studied are posted in the TUIS of the RUDN University, as well as on the local resources of the electronic library system of the RUDN University.

12. Fund of assessment tools for intermediate examination of students in the discipline «Evidence-based medicine»

Materials for assessing the level of mastering the educational material of the discipline «Evidence-based medicine» (evaluation materials), including a list of competencies with an indication of the stages of their formation, a description of indicators and criteria for evaluating competencies at various stages of their formation, a description of the assessment scales, standard control tasks or other materials, necessary for the assessment of knowledge, abilities, skills and (or) experience of activities that characterize the stages of the formation of competencies in the process of mastering the educational program, methodological materials defining the procedures for assessing knowledge, skills, skills and (or) experience of activities, characterizing the stages of formation of competencies, have been developed in full and are available for students on the discipline page at TUIS RUDN.

The program was arranged in accordance with the requirements of the Federal State Educational Standard of Higher Education.

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