

**MINISTRY OF SCIENCE AND HIGHER EDUCATION
RUSSIAN FEDERATION**

**FEDERAL STATE AUTONOMOUS EDUCATIONAL INSTITUTION OF
HIGHER EDUCATION
NORTH-CAUCASUS FEDERAL UNIVERSITY**

Methodological Guidelines
for Students on arranging and performing independent work
in the Discipline of "Evidence-Based Medicine"
for Students majoring (Specialty) in 31.05.01 General Medicine

introduction

The aim of mastering the discipline is the acquisition of new knowledge on the issues of diagnosis, prevention and treatment, as well as improving the prognosis of diseases in medical practice from the standpoint of evidence-based medicine, the acquisition of knowledge in evidence-based medicine, and the improvement of practical skills in working with sources of medical information.

The objectives of mastering the discipline are:

- the mastery by students of the main issues of examining a patient for the purpose of establishing a diagnosis, its substantiation, conducting a differential clinical diagnosis, and prescribing treatment in accordance with evidence-based recommendations;
- the formation in students of knowledge and skills in the field of searching for medical information on the Internet and in electronic resources (PubMed, the Cochrane Library, Medscape), conducting an expert assessment of a medical history and a medical article in accordance with methodological recommendations, standards of examination and treatment based on the principles of evidence-based medicine;
- the acquisition by students of basic statistical knowledge necessary for interpreting data from the medical literature;
- the study and mastery of the main methods of pharmacoepidemiological and pharmaco-economic analysis;
- the acquisition by students of knowledge about the planning and conduct of randomized clinical trials; levels of evidence and classes of recommendations;
- the formation of skills necessary for solving individual research and applied scientific tasks in the field of clinical pharmacology using knowledge of the main requirements of information security;
- the formation in students of skills of communication and interaction with the team, partners, patients, and their relatives.

Methodological Recommendations for Studying Theoretical Material

When performing the independent study of theoretical material, the student must follow the rules as set below. The working curriculum of the respective academic discipline shall be recommended to be used as the basis for such activity. According to the schedule of classroom lessons and independent work, a different number of hours is to be allocated for studying individual topics. A significant portion of the student's independent work should be allocated to mastering the material on the covered topic, writing a summary (notes) on the specified theoretical blocks, and searching for additional literature based on the NCFU library and via the Internet system. The lecture material shall not cover all theoretical material; the greater part of it must be mastered through independent work. Given the above, working with the recommended literature is mandatory. Special attention must be paid to the content of the main provisions and conclusions, the explanation of phenomena and facts, and the understanding of the practical application of the theoretical issues under consideration. In the process of this work, the student should strive to understand and memorize the main provisions of the material being considered, the examples illustrating it, as well as to understand the illustrative material. Preparation should be completed by drawing up a plan (summary/notes) on the material (issue) being studied. This allows for the creation of a concentrated, concise representation of the issues being studied. First, studying the recommended literature is to be done. Special attention must be paid to the content of the main provisions and conclusions, the explanation of phenomena and facts, and the understanding of the practical application of the theoretical issues under consideration.

During this work, the student should strive to understand and memorize the main provisions of the material being considered, the examples illustrating it, as well as to understand the illustrative material. Preparation should be completed by drawing up a plan (summary/notes) on the material (issue) being studied. This allows for the creation of a concentrated, concise representation of the issues being studied. If necessary, one should seek (advice) consultation from the instructor. When going to a consultation, it is necessary to thoroughly think through the

questions that require clarification. Keeping records contributes to turning reading into an active process, mobilizing motor memory along with visual memory. The following should be born in mind: a student who systematically keeps records creates their own individual stock of auxiliary materials for a quick review of what has been read and for the mobilization of accumulated knowledge. Records are especially important and useful when they reflect the thoughts that arose during independent work.

It is important to develop the students' capacity to compare sources and to think through the material being studied.

Improving note-taking skills among students is of great importance.

The instructor may recommend the following main forms of recording to students: a plan (simple and detailed), excerpts, and theses (abstracts).

The results of note-taking can be presented in various forms.

1. A plan is an outline of the read material, a brief (or detailed) list of questions reflecting the structure and sequence of the material.
2. A detailed plan fully replaces a summary.
3. A summary (notes) is a systematized, logical presentation of the source material. Four types of summaries are distinguished:
4. Outline-summary (Plan-notes) – this is an expanded, detailed plan in which sufficiently detailed records are provided for those points of the plan that need explanation.
5. Textual summary – this is the reproduction of the most important provisions and facts of the source.
6. Free summary – these are clearly and briefly formulated (stated) main provisions resulting from a deep understanding of the material. It may contain excerpts, quotations, and theses; part of the material may be represented by a plan.
7. Theme-based summary – this is compiled on the basis of studying a number of sources and gives a more or less exhaustive answer according to a certain scheme (issue).

Methodological Guidelines for the Preparation for Practical Activities

When preparing for practical activities, the recommendation implies studying the control questions for the given lesson and the theoretical material from one's own notes.

The main form of work during the lessons is an interview (discussion). Each student must be ready to speak on all issues raised in the plan and demonstrate maximum activity during their consideration.

The speech must be constructed freely, convincingly, and with arguments. The instructor ensures that the speech is not reduced to a reproductive level (simple reproduction of the text); simple reading of the summary is also not allowed.

It is necessary for the speaker to show their own attitude towards what they are talking about, express their personal opinion and understanding, substantiate it, and be able to draw the correct conclusions from what has been said. In doing so, the student may refer to the entries in the summary, directly to the primary sources, use knowledge of previously studied disciplines, etc. In addition, to obtain a grade at an advanced level, students solve situational tasks based on the results of the mastered topics.

During the execution of practical works, a defense of practical skills is provided, the full list of which is specified in the fund of assessment tools.

Methodological Recommendations for the Preparation of Presentations and Reports

The report must contain elements of novelty; along with the fundamental aspect, an analysis of the current state of the problem under study must be carried out, as well as inclusion in regional issues. The report must include an introduction, a theoretical part, a conclusion, a list of literature, and a presentation that reveals the essence of the topic in graphs, pictures, diagrams, and formulas.

The report is recommended to be submitted on 1 printed sheet. The text of the work must be printed with 1.5 line spacing on one side of a standard sheet (A4) of white paper.

The text and other printed elements of the work must be black, and the contours of letters and signs must be clear, without halos and shading. The font must be Times New Roman, size 14. The titles of chapters and paragraphs are highlighted in bold. The sheet with text must have margins: left – 30 mm, right – 10 mm, top – 20 mm, bottom – 20 mm.

Page numbering of the text is done in the lower right corner of the sheet. It is necessary to number pages starting from the page where the Introduction is printed, on which the number 3 is placed. After that, all pages, including appendices, are numbered.

A space equal to two intervals is placed between the title of the chapter and the title of the paragraph of this chapter, and the title of the paragraph must not be separated from the text of this paragraph by a space. The titles of paragraphs shall be separated from the text of the previous paragraph by a space equal to two intervals. Each chapter, as well as the introduction, conclusions, appendices, and the list of used literature, begin on a new page. The word Chapter is not to be written. Chapters have ordinal numbers within the entire work, designated by Arabic numerals (for example: 1, 2, 3), followed by a period.

The word **PARAGRAPH** or the paragraph symbol (§) is not placed in the title. Paragraphs have ordinal numbers within the chapters, designated by Arabic numerals (for example: 1.1. and 1.2.).

Headings of chapters and paragraphs in the text must be centered; a period shall not be placed at the end of the title of the chapter and paragraph. It is not allowed to hyphenate (transfer) a part of a word in a heading. 4.5. The numbering of tables and figures can be running (continuous) or relate to the number of the chapter and paragraph. For example, if a table or a figure is included in the text of the first paragraph of the second chapter, the numbering is as follows: Table 2.1.1., Fig. 2.1.1.

The last digit means the ordinal number of the table (or figure) in this paragraph.

The table is to be placed as the next page after the first mention of it in the text.

Recommended literature.

Main literature:

1. Begun D. N., Borshchuk E. L., Ekimov A. K., Bayanova N. A. Vvedenie v statisticheskiy analiz meditsinskikh dannykh [Introduction to Statistical Analysis of Medical Data] [Electronic resource]: uchebnoe posobie dlya aspirantov. Orenburg: Orenburgskaya gosudarstvennaya meditsinskaya akademiya, 2014. 118 p. Available at: <https://www.iprbookshop.ru/54283.html> (in Russian).
2. Goryushkin A. P. Matematicheskaya logika i teoriya algoritmov [Mathematical Logic and Theory of Algorithms] [Electronic resource]: uchebnik. Saratov: Vuzovskoe obrazovanie, 2022. 499 p. ISBN 978-5-4487-0808-4. Available at: <https://www.iprbookshop.ru/117296.html> (in Russian).
3. Degtyareva I. N. Teoriya statistiki [Theory of Statistics] [Electronic resource]: uchebnik. Moscow: Ay Pi Ar Media, 2021. 248 p. ISBN 978-5-4497-1212-7. Available at: <https://www.iprbookshop.ru/109498.html> (in Russian).

Additional literature:

1. Aleksandrovskaya, Yu. P. (2019). Information Technologies for Statistical Data Analysis [Electronic resource]: study guide. Kazan: Kazan National Research Technological University. 152 p. ISBN 978-5-7882-2636-1. Available at: <https://www.iprbookshop.ru/100535.html>
2. Gorelov, V. I., & Ledashcheva, T. N. (2015). Analysis of Statistical Data [Electronic resource]: practical course. Moscow: Russian International Academy of Tourism, Universitetskaya Kniga. 120 p. ISBN 978-5-98699-151-1. Available at: <https://www.iprbookshop.ru/70537.html>

3. Korovin, V. N. (2021). Methods for Solving Optimization Problems in Medicine [Electronic resource]: textbook. Moscow: IPR Media. 82 p. ISBN 978-5-4497-1204-2. Available at: <https://www.iprbookshop.ru/108368.html>
4. Rybchinskaya, I. I. (2012). Case History in Propaedeutic Therapy [Electronic resource]: textbook. K. M. Ivanov (Ed.). Orenburg: Orenburg State Medical Academy. 22 p. Available at: <https://www.iprbookshop.ru/31822.html>
5. Chung, K. L., & AitSahlia, F. (2021). Elementary Course of Probability Theory. Stochastic Processes and Financial Mathematics [Electronic resource]. Transl. by M. B. Lagutin. 4th ed. Moscow: Laboratoriya Znaniy. 456 p. ISBN 978-5-93208-572-1.

Online resources:

1. <http://rudocor.net> - Medical Portal
2. <http://www.e-reading.club> / - Great Online Library
3. <https://dic.academic.ru> / - Dictionaries and Encyclopedias
4. <https://roszdravnadzor.gov.ru> / - Federal Service for Supervision of Healthcare
5. <https://www.rmj.ru> / - Russian Medical Journal

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Methodological guidelines for the discipline "Evidence-Based Medicine" (specialty 31.05.01 General Medicine) are aimed at developing skills in searching, critically evaluating, and applying scientific data in clinical practice. The discipline includes the study of the principles of evidence-based medicine, clinical guidelines, levels of evidence, and methods of statistical analysis.

Key sections of the methodological guidelines:

Fundamentals of evidence-based medicine (EBM): Definition, key principles (scientific validity, transparency, consideration of patient preferences).

Critical appraisal of evidence: Study of the hierarchy of evidence (from expert opinion to systematic reviews), analysis of the quality of studies, assessment of the risk of systematic errors.

Statistical indicators: Study of methods for evaluating treatment effectiveness (relative risk, absolute risk, NNT — number needed to treat).

Application in clinical practice: Integration of the best evidence with clinical experience and patient preferences, study of the principles of developing clinical guidelines.

Forms of control and training:

Practical classes: Solving situational tasks, discussing clinical cases from the EBM standpoint, analyzing publications.

Independent work: Preparation of essays, work with databases, formulation of a clinical question.

Final control:

Pass/fail exam, testing on the principles of evidence-based medicine.

Topic 4. Observational Studies Characteristics. Advantages. Principles

Observational studies in evidence-based medicine are scientific research methods where the researcher does not intervene in the treatment process but only observes the natural course of events, analyzing the relationships between risk factors and outcomes. They occupy an important step in the hierarchy of evidence (above case descriptions, below RCTs), allowing the study of rare diseases, long-term effects, and real clinical practice.

1. Characteristics of observational studies

Lack of intervention: The researcher does not prescribe treatment, does not change the medication regimen, but records the data.

Types of studies:

Cohort studies: Observation of a group of individuals (a cohort) with and without a risk factor over time (prospectively or retrospectively) to identify outcomes.

Case-control studies: Comparison of people with a disease ("case") and healthy people ("control") to identify the causes of the disease in the past.

Cross-sectional studies: Assessment of the prevalence of a disease and risk factors at a single point in time.

Level of evidence: Most often correspond to levels II-III (depending on the design and quality), inferior to randomized controlled trials (RCTs) in determining cause-and-effect relationships.

Cardiovascular therapy and prevention

2. Advantages

Study of real practice: They show how drugs work in a broad population, not just in specially selected patients.

Ethical aspects: The ability to study harmful factors that cannot be deliberately assigned to patients.

Efficiency and cost: Usually cheaper and faster to conduct.

Duration: They allow the identification of rare or delayed side effects years later.

Cardiovascular therapy and prevention

3. Principles in evidence-based medicine

Transparency: A clear description of the design, methods of patient selection, and statistical analysis.

Minimization of systematic errors: Special attention is paid to confounders (interfering factors) that can distort the results (e.g., the use of multivariate analysis methods or pseudo-randomization).

Protocol registration: Preliminary registration of the study design to increase reliability.

Questions for the interview

1. Main stages of the development of epidemiology.
2. Modern structure of epidemiology.
3. Main goals of epidemiology.
4. Tasks of epidemiology.
5. Clinical epidemiology.
6. Evidence-based medicine.
7. Epidemiological data.
8. Characterize descriptive and analytical studies.
9. What are their advantages and disadvantages?
10. Main indicators of descriptive epidemiology.
11. List the main tasks of analytical studies.
12. What types of analytical studies do you know?
13. What does the correlation coefficient show?

14. Disadvantages of correlational studies.
15. What types of epidemiological data do you know?
16. Measures of central tendency characterize...
17. Median. Advantages and disadvantages.
18. Mode. Advantages and disadvantages.
19. Arithmetic mean. Advantages and disadvantages.
20. What is included in the concept of "description of the morbidity of the population with a certain disease"?
21. The significance of statistical indicators for studying the morbidity of the population.
22. What refers to intensive indicators?
23. Which indicators refer to extensive indicators?
24. What is the purpose of the descriptive method in epidemiology?
25. In what values are morbidity indicators expressed?
26. What do absolute values of morbidity characterize?
27. How are relative values (intensive and extensive indicators) calculated?
28. What dimensions are used in intensive indicators?
29. What dimensional signs of intensive indicators are used?
30. What is the incidence rate?
31. The formula for calculating the incidence rate?
32. What is the prevalence rate?
33. What does the point prevalence rate (PRM) characterize?
34. What does the period prevalence rate (PRM) characterize?
35. For which diseases is the prevalence rate used?
36. What do intensive indicators reflect?
37. What do extensive indicators reflect?
38. The formula for calculating an extensive indicator?
39. How is data grouping carried out?
40. Types of graphs.
41. What types of scales are used when designing linear graphs?
42. The rule of the "golden ratio" when constructing linear diagrams?
43. Varieties of bar charts.
44. By what parameters is the long-term dynamics of morbidity assessed?
45. Characterize analytical studies.
46. What are their advantages?
47. Stages of organizing an analytical study. Definition of a risk factor.
48. What types of analytical studies do you know?
49. What are "cohort studies"? What are their advantages and disadvantages?
50. What are "case-control studies"? What are their advantages and disadvantages?
51. Characterize cross-sectional (snapshot, one-time) studies. What are their areas of application?
52. What are the principles of constructing four-field tables?
53. Provide formulas for calculating "relative risk" and "odds ratio."
54. What types and sources of errors in analytical studies do you know?
55. What are the ways to prevent them?
56. Define attributable risk.
57. Characterize a cohort study.
58. Definition of diagnostic and screening tests.
59. Main characteristics of diagnostic tests, their calculation.
60. Bayes' theorem.
61. Calculations of the predictive value of test results.
62. Characterize experimental studies.
63. When are they conducted?
64. What types of experimental studies do you know?

65. Define RCT.
66. What errors are possible when conducting an RCT? What are the ways to prevent them?
67. Stages of organizing an experimental study.
68. Define the null and alternative hypotheses.
69. What indicators are used to evaluate the results of an RCT?
70. Criteria for assessing the significance of results?
71. List the documents regulating the ethical principles of conducting clinical trials.
72. What is informed consent? How is it formalized?
73. Search engines in databases; Boolean algebra operators used when searching for information.
74. What are the strategies for forming a search query in various search engines and databases depending on the type of clinical question?
75. What are the principles of working with the MEDLINE database hosted on the website www.pubmed.com?
76. Use of information search filters depending on the research methodology: Clinical Queries and Special Queries.
77. What are the features of searching databases containing information on evidence-based medicine?
78. What is the sensitivity and specificity of the search when using methodological filters on the PubMed website?
79. Formulate one question on any topic that interests you (or may become a topic for a systematic review of standard practice). Break it down into the maximum (of 4 possible) PICO components. Determine the type of your question. Determine the type of epidemiological study that will find the answer to this question.
80. Name 5 foreign or domestic periodicals publishing primary medical information.
81. Name 5 sources of medical information publishing secondary materials (summaries of RCTs and systematic reviews, systematic reviews).
82. Indicate the advantages and disadvantages of various sources of medical information:
83. Journals of primary information;
84. List the main search capabilities in PubMed.
85. Indicate the principles of searching for scientific articles in the Clinical Queries system on the PubMed MEDLINE website?
86. Information systems in medicine. Models of information systems.
87. Medical servers. Examples of information systems in epidemiology (WHOSIS (WHO Statistical Information System), Health Metrics Network, VAERS, etc.)
88. Databases: definition, classification. Two types of databases: relational and post-relational (document-oriented).
89. Information technologies. Data exchange. Information flows. Management of information flows.
90. Electronic sources of evidence-based information. Media. Networks. Access. Subscription. Update. Search for information.
91. Search engines (OVID, Silver Platter). Headings (MeSH).
92. Strategies for forming a search query in various search engines and databases depending on the type of clinical question.
93. Strategies for searching for randomized clinical trials, systematic reviews, diagnostic tests, etiological factors, disease prognosis, treatment outcomes of clinical guidelines, prevention programs with proven effectiveness, developed by evidence-based medicine centers in the UK, Canada, the USA, and other countries.
94. The Cochrane Collaboration (Cochrane). Characteristics of the organization. History of development.
95. Goals and tasks of Cochrane's activities. Types of activities of the Cochrane Collaboration.
96. Archie Cochrane's challenge. Vision and mission of the Cochrane Collaboration. Principles of the Cochrane Collaboration's work.

97. Strategy 2020 of the Cochrane Collaboration. Cochrane logo. The significance of Cochrane's activities in developing evidence of the effectiveness of interventions in medicine.
98. The Cochrane Collaboration in the Russian Federation.
99. Cochrane Russia: history of development, development strategy, achievements, and prospects.
100. Systematic reviews. Key characteristics of a Cochrane systematic review.
101. Development of a Cochrane review: introduction. Goals and structure of Cochrane reviews. Logistics of review development.
102. Defining the review question.
103. Development of a systematic review protocol. Defining PICO.
104. Search for studies. Search strategies. Sources of search for studies.
105. Selection of studies. Assessment of the risk of bias in included studies.
106. The significance of Cochrane systematic reviews in finding and presenting evidence of the effectiveness of interventions in medicine.
107. Cochrane and non-Cochrane systematic reviews.
108. Systematic reviews: how to read, understand, and use in healthcare practice.
109. Risk of bias in systematic reviews and its significance in the interpretation and reliability of results. Assessment of sources of bias. Assessment of the risk of bias in studies. Ways to minimize bias when developing a Cochrane systematic review.
110. Quality of evidence. Assessment of the quality of evidence in Cochrane systematic reviews.
111. Meta-analysis: steps, presentation and interpretation of results, the significance of meta-analysis.
112. The concept of continuous and dichotomous outcomes. Analysis of dichotomous outcomes.
113. Table for assessing the effect of interventions. Expressing probability: risks and odds. Difference between the concepts.
114. Measures of effect for comparison groups: relative risk, odds ratio, risk difference (absolute risk). Examples of calculations.
115. Choice of effect measure. Factors influencing the choice of effect measure: communication of information about the effect, consistency (sequence), mathematical properties.
116. Number needed to treat to obtain one additional positive outcome (NNT), interpretation of the indicator.
117. Other data formats that can also be used.
118. Necessary measure of variability (variance): standard deviation, confidence interval. Data collection for dichotomous outcomes.
119. Sensitivity and specificity. Factors determining sensitivity and specificity.
120. Likelihood ratios.
121. Requirements for tests. Application of multiple diagnostic tests.
122. The ability of a test to detect changes in the measured parameter.
123. Practice of evidence-based medicine.
124. Electronic databases of primary and secondary evidence-based information.
125. How to read medical literature.
126. Analysis of clinical decisions.
127. Achievements and barriers to the implementation of evidence in clinical practice.
128. Pharmaceutical marketing and evidence-based medicine.
129. Clinical guidelines dedicated to treatment tactics as a tool for introducing the results of the best scientific research into clinical practice.
130. The process (methodology) of developing clinical guidelines.
131. The significance of Cochrane systematic reviews.
132. Analysis of clinical decisions. Decision tree.
133. The quality of existing clinical guidelines. Conflict of interest as a source of bias in clinical guidelines.

134. Evaluation of clinical guidelines. Have all categories of patients with a certain disease, all interventions, and clinical outcomes been considered? Is there a systematic review on the clinical question under consideration? Has a list of preferences and life values been determined that are taken into account when considering possible clinical outcomes?
135. The degree of reliability of clinical guidelines.
136. Sensitivity analysis. Correlating information on evidence of the effectiveness and safety of an intervention with other factors important to the patient. Assessment of the initial risk. Decision making.

Recommended literature.

Main literature:

4. Begun D. N., Borshchuk E. L., Ekimov A. K., Bayanova N. A. Vvedenie v statisticheskiy analiz meditsinskikh dannykh [Introduction to Statistical Analysis of Medical Data] [Electronic resource]: uchebnoe posobie dlya aspirantov. Orenburg: Orenburgskaya gosudarstvennaya meditsinskaya akademiya, 2014. 118 p. Available at: <https://www.iprbookshop.ru/54283.html> (in Russian).
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3. <https://dic.academic.ru> / - Dictionaries and Encyclopedias
4. <https://roszdravnadzor.gov.ru> / - Federal Service for Supervision of Healthcare
5. <https://www.rmj.ru> / - Russian Medical Journal