**MINISTRY OF HEALTHCARE OF UKRAINE**

**KHARKIV NATIONAL MEDICAL UNIVERSITY**

**Department of Public Health and Health Management**

**SYLLABUS**

**EDUCATIONAL DISCIPLINE**

**METHODOLOGY OF EVIDENCE**-**BASED MEDICINE**

(name of the discipline)

academic year **2020-2021**

field of knowledge **22 "Healthcare"**

(code and name of the field of knowledge)

specialty **222 "Medicine"**

(code and name of the specialty)

**"Master"**

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| The syllabus of the discipline was approved at a meeting of the Department of public health and health managementProtocol from “28” аugust 2020 № 13Head of Department \_\_\_\_\_\_\_\_\_\_\_\_\_\_ V.A. Ognev  (signature) (surname and initials) “28” аugust 2020  |  | Approved by the methodical commission of KhNMU on public health problems Protocol from “31” аugust 2020 № 12Head of Department \_\_\_\_\_\_\_\_\_\_\_\_ V.A. Ognev (signature) (surname and initials) “31” аugust 2020  |

1. **Data on teachers who teach the discipline**

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| **Surname, name, patronymic of the teacher** | **Ognev Victor Andreevich** |
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| Consultations | Tuesday 15.30-17.00 |
| Location | Audience of the Department of Public Health and Health Management |

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| **Surname, name, patronymic of the teacher** | **Pomogaybo Katerina Georgievna** |
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| Location | Audience of the Department of Public Health and Health Management |

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| Location | Audience of the Department of Public Health and Health Management |

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**SYLABUS DEVELOPERS:**

MD, prof. Ognev V.A.

Candidate of Medical Sciences, Associate Professor Pomogaybo K.G.

Ph.D., Assist. Nesterenko V.G.

assistant. Tregub P.O.

**COURSE ANNOTATION**

***The discipline "Methodology of Evidence-Based Medicine" includes information about the basic concepts and terms of evidence-based medicine, the history of the formation and development of evidence-based medicine, the concept of randomization, the preconditions for the emergence and foundation of evidence-based medicine, goals, objectives of evidence-based medicine, the basic principles and significance of evidence-based medicine for medical practice; features of organizing and conducting epidemiological studies, studying the prevalence and natural course of certain diseases in population groups, identifying the scale of problems associated with these diseases; determination of the factors of the external and internal environment that contribute or prevent the occurrence and spread of these diseases; identification of priority problems in the field of public health protection; the development of measures to eliminate or the maximum possible weakening of the effect of adverse factors, as well as the study of types of epidemiological studies: descriptive, analytical, experimental. Familiarization with the Convention for the Protection of Human Rights and Human Dignity in connection with the application of the achievements of biology and medicine and with such concepts as: errors of epidemiological studies, pseudo-randomization, positive effects of intervention.***

***Mastering the technology of evidence-based medicine will allow applying the methodological foundations of evidence-based medicine in practice: GCP standards - good clinical practice, GMP - good manufacturing practice, GLP - good laboratory practice, GDP - good distribution practice, as the basis of modern evidence-based medicine, meta-analysis and systematic reviews.***

***The study of the discipline will allow to summarize research results, critically evaluate the evidence found, their reliability and usefulness (clinical use), introduce the results of evidence-based medicine into medical practice, develop clinical guidelines, standards, guidelines and clinical protocols, evaluate the social, medical and economic efficiency of evidence-based medicine.***

The study of this discipline is one of the integral components of the training of a highly qualified specialist in the field of public health, has a systematic understanding of the basics of evidence-based medicine and is able to apply this knowledge to carry out professional activities in the field of public health.

The subject of study of the discipline is modern approaches to finding reliable and effective information for solving health problems based on evidence-based medicine.

**Interdisciplinary connections:** discipline "Methodology of evidence-based medicine" **is integrated with disciplines*:*** "Fundamentals of Public Health", "Health Organization in Ukraine", "Informatization in the Sphere of Public Health", "Epidemiological Surveillance and Assessment of the State of Health and Well-being of the Population", "Biostatistics", "Organization of Medical and Social Scientific Research", as well as with selected disciplines: "International organizations in ensuring health care", "Formation of a healthy lifestyle of the population", "Legal aspects of medical activity", "Ethical standards in public health".

The discipline belongs to the elective disciplines.

The syllabus is organized with the application of modern pedagogical principles of organization of the educational process of higher education.

**General approach:** studying the discipline provides for the mastery of theoretical knowledge and practical skills in the history of the formation of evidence-based medicine; the basic principles and the importance of evidence-based medicine for clinical practice; the importance of epidemiological research in disease prevention; determination of the factors of the external and internal environment that contribute or prevent the onset and spread of diseases; design of epidemiological studies, its types and their characteristics; stages of an epidemiological study: defining priorities, setting goals and objectives, formulating a hypothesis, defining a population, choosing a design, organizing a study, forming a sample, collecting data, analyzing and processing data; types of epidemiological studies: descriptive and analytical; experimental epidemiological research methods; history of implementation of randomization; types and purposes of blinding; principles of Cochrane cooperation; rules for the formation of clinical issues and topical problems in the formulation of questions, its structure; sources of medical information; electronic databases; requirements for screening tests; concept of ROC analysis; main approaches to critically evaluating publications in medical journals and other sources of information; advantages and disadvantages of clinical guidelines, manuals, etc. and requirements for them; quality criteria for clinical guidelines; indicators and criteria of medical efficiency of health care institutions.

To successfully complete the course, applicants for higher education need to complete all the tasks of the teacher in a timely manner, if questions or problems with their implementation are identified, contact the teacher in advance.

The study of the discipline ends with a test, so in the process of studying various topics, it is advisable for applicants to pay attention to the issues submitted for credit.

**PURPOSE OF THE COURSE:**

***mastering by applicants of higher education modern knowledge on the basics of evidence-based medicine and, on its basis, optimizing the quality of medical care to the population in terms of safety, efficiency, cost and other important factors, as well as mastering the skills of using this knowledge in the implementation of professional activities in public health. In particular, applicants have:***

– need to know: the history of the formation of evidence-based medicine; basic principles and importance of evidence-based medicine for clinical practice; the importance of epidemiological research in disease prevention; determine the factors of the external and internal environment that contribute or prevent the onset and spread of diseases; design of epidemiological studies, its types and their characteristics; stages of an epidemiological study: setting priorities, setting goals and objectives, formulating a hypothesis, defining a population, choosing a design, organizing a study, forming a sample, collecting data, analyzing and formatting data; types of epidemiological studies: descriptive and analytical; experimental epidemiological research methods; history of implementation of randomization; types and purposes of blinding; principles of Cochrane cooperation; the rule for the formation of clinical questions and topical problems in the formulation of questions, its structure; sources of medical information; electronic databases; requirements for screening tests; concept of ROC analysis; basic approaches to critically evaluating publications in medical journals and other sources of information; advantages and disadvantages of clinical guidelines, manuals, etc. and requirements for them; quality criteria for clinical guidelines; indicators and criteria of medical efficiency of health care institutions.

– need to learn: to identify priority problems in the field of public healthcare; develop measures to eliminate or as much as possible weaken the effect of adverse factors; conduct analytical research, determine their goals and objectives; organize and conduct a randomized epidemiological study; planning the experiment; determine the level of credibility of evidence; interpret and critically evaluate the results of clinical trials; identify research flaws and their design; conduct systematic reviews and meta-analyzes; determine risk indicators in case-control studies; conduct meta-analysis, make systematic examinations; assess the social, medical and economic efficiency of evidence-based medicine results.

**COMPETENCIES**

According to the requirements of the standard and the educational and professional program, the discipline ensures the acquisition of **competencies** by applicants for higher education**:**

* *integral****:***

The ability to solve complex problems and problems in the field of public health or in the learning process involves research, the application of scientific theories and analytical methods, and is characterized by the complexity and uncertainty of conditions.

* *common****:***
* ability for abstract thinking, analysis and synthesis;
* ability to apply knowledge in practical situations;
* ability to communicate in a foreign (English) language;
* skills in the use of information and communication technologies;
* ability to conduct research at an appropriate level;
* the ability to learn and acquire modern knowledge;
* ability to search, process and analyze information from various sources;
* ability to work in an international context;
* ability to be critical and self-critical;
* ability to make informed decisions;
* the ability to act in a socially responsible and conscious manner;
* the ability to preserve and increase moral, cultural, scientific values ​​and achievements of society on the basis of understanding the history and patterns of development of the subject area, its place in the general system of knowledge about nature and society and in the development of society, technology and technology, to use various types and forms of physical activity for outdoor activities and a healthy lifestyle;
* ability to act on the basis of ethical considerations (motives)
* ability to be aware of equal opportunities and gender issues.
* *special (professional, subject):*
* the ability to assess, interpret, compare and predict key public health indicators;
* the ability to determine public health priorities, to assess the needs of the public health sector in a specific situation;
* the ability to develop and propose evidence-based options for strategies, policies and measures aimed at maintaining and improving the health of the population, as well as to assess their effectiveness;
* ability to organize public health surveillance activities using a multisectoral approach;
* the ability to analyze the impact of various determinants on public health and justify appropriate measures to prevent them;
* ability to assess risks and justify appropriate responses to public health emergencies;
* the ability to analyze public health strategies, policies and interventions and propose measures to improve the efficiency of the use of available funds;
* the ability to use ethical principles and legal norms in planning research, collecting information and using it;
* the ability to apply different methodologies, strategies and models of public health teaching;
* the ability to apply scientific approaches to research design planning, data collection, dissemination and use of research results in public health;
* the ability to teach the basics of public health in educational institutions of various levels, to plan and implement activities aimed at developing an appropriate level of human resources for public health;
* the ability to mentor and facilitate the continuing professional development of public health professionals.

**INFORMATION SCOPE OF THE COURSE**

The study of the discipline is given 90 hours, 3 ECTS credits.

**Topic 1. Introduction to evidence-based medicine. The history of the formation and development of evidence-based medicine.**

Evidence-based medicine as a science. Entry into evidence-based medicine. The history of the development of evidence-based medicine. World development experience. Evidence-based medicine in clinical practice in Ukraine and around the world. Basic principles and importance of evidence-based medicine for clinical practice.

**Topic 2. Modern epidemiology and biostatistics as a science and ideology of evidence-based medicine.**

Research methods in evidence-based medicine. Five stages of the evidence-based medicine process. Research types in clinical epidemiology. The hierarchy of evidence-based medicine research: from case reports to multicenter randomized controlled trials.

The concept of transverse and longitudinal studies, the advantages and disadvantages of various types of studies. Randomized controlled trial (RCT) as the gold standard of evidence-based medicine. Basic statistics for RCTs. Conditions for conducting RCTs. A critical analysis of RCTs. Formulation of the clinical problem.

**Topic 3. Design of epidemiological studies. Types of design and their characteristics. The purpose and objectives of epidemiological research. Capabilities of epidemiological study designs.**

Design of epidemiological studies. Types of design and their characteristics. The purpose and objectives of epidemiological research. Capabilities of epidemiological study designs. Stages of an epidemiological study: setting priorities, setting goals and objectives, formulating a hypothesis, defining a population, choosing a design, organizing a study, sampling, collecting data, analyzing and formatting data.

**Topic 4. Empirical methods of surveillance of epidemiological studies. Features of descriptive research. Description of individual cases and description of a series of cases.**

Types of epidemiological studies: descriptive and analytical. Descriptive research. Goals and objectives. The types of graphs are most commonly used in descriptive analysis. Histogram (Freguency plot, Bar chart). Error bar plot. Box whisker plot. Scatter plot. Catego-rized plots. Research types. Environmental research and mapping.

**Topic 5. Analytical methods of observation of epidemiological studies. Case-control studies, cohort studies and environmental studies.**

Analytical. Goals and objectives. Study types: case-control, cross-sectional study, cohort study, randomized clinical trial. Analytical retrospective study (case-control study). Analytical reproducibility. Systematic errors of retrospective studies. Statistical analysis of the study (reliability criterion, compliance rate, relative risk ratio, regression analysis, methods of correlation analysis).

**Topic 6. Experimental epidemiological studies. Uncontrolled and controlled research. Randomized and nonrandomized studies. Pseudorandomization.**

Experimental epidemiological research methods. The purpose of experimental research. Convention for the Protection of Human Rights and Human Dignity with regard to the Application, Advances in Biology and Medicine. Organization and conduct of a randomized epidemiological study. Errors in epidemiological studies. Pseudorandomization. Benefits of the intervention.

**Topic 7. Randomization and blinding in epidemiological research. The Gold Standard in Epidemiology.**

Randomization. The main goal of the randomized trial. The history of the introduction of randomization. Random number table. The value of Austin Bradford Hill (1897-1991rr), British epidemiologist and statistician, pioneer of randomized clinical trial. Conditions supporting randomized trials. Blind types (Open label) Single-blind; Double-blind; Triple-blind; Complete blinding. Target of blinding.

**Topic 8. Evidence-based medicine as a new style of activity in the patient's health care system. The main goal and objectives of evidence-based medicine. Rule 4 "A" in evidence-based medicine.**

General concept, goals, main tasks (stages) of evidence-based medicine. Definition, basic principles. Methodological foundations of evidence-based medicine GCP standards are good clinical practice, GMP is good manufacturing practice, GLP is good laboratory practice, GDP is good distribution practice, as the basis of modern evidence-based medicine. Definition of evidence-based medicine. Epidemiology and Biostatistics as the Foundation of Evidence-Based Medicine. Degree of medical evidence. Evidence of studies of etiology, diagnosis, treatment and prognosis. The role of randomized controlled trials. Experiment planning. Study design. Methods that increase objectivity (control groups, randomization, blind method). General concepts, goals, main tasks (stages) of evidence-based medicine.

**Topic 9. The importance of the largest world organization – International Kokreinivske cooperation in the formation and assessment of the effectiveness of medical and social interventions.**

Founder of the largest world organization - The Cochrane Collaboration Oxford, (University of Oxford), 1992 Archie Cochrane (1909-1988). Cocrane cooperation logo. Evidence-based medicine - randomized controlled clinical trials - the gold standard. Centers (groups) of Cochrane examinations. Cochrane Library. Principles of Kokreinivskoi cooperation, the concept of three "E".

**Topic 10. Information needs of the health care system. Problem statement to be found reliably proven solution. PICO Formula.**

The rule for the formation of clinical questions, topical problems in the formulation of questions. The structure of the clinical question. Patient or clinical situation. Interventions. Comparison of interventions Results. Types of questions. PICO Formula.

**Topic 11. Identifying the best evidence for answering the questions.**

Sources of medical information. Significance, search for scientific evidence, independence and transparency, reliability and objectivity of data. Publications. Kokreinivska library. The Internet. Peer-reviewed and unverified data sources. Determination of confidence levels of evidence, types of research and their role in presenting evidence. Interpretation and critical evaluation of the results of clinical trials. Identifying research flaws and design. Electronic databases. Electronic versions of medical journals. Scientific evidence-based medical sites. Professional medical association websites. Clinical guidelines databases.

**Topic 12. Medical databases. Sources of analytical information. Electronic versions of medical journals with leading positions in the citation index.**

 The content of scientific medical literature. Advantages and Disadvantages of Various Sources of Medical Information. Search for information on the Internet using evidence-based medicine filters. The structure and content of a scientific publication. The main sections of the scientific publication. Analysis of articles and their critical assessment. Systematic review and meta-analysis. Cochrain Library. Putting scientific evidence into practice - implementation. Collection and dissemination of scientific data. Introduction to clinical practice guidelines. Definition, the need for development and implementation. The link between evidence-based medicine, the development of practice tools and quality assessment for change.

**Topic 13. Screening - a source of information about the health status of the population in epidemiological studies.**

Screening. Evaluation of screening results. Requirements for screening tests. Sensitivity and specificity of the screening test. The relationship between sensitivity and specificity. Concept of ROC analysis. Determination of risk indicators in a case-control study. Absolute, relative and additional population risk: calculation methodology and assessment. The concept of odds in epidemiology. Determination of the odds ratio in a cohort study: calculation method and assessment.

**Topic 14. Critical assessment of the found evidence for its reliability and usefulness.**

Critical assessment of the found evidence (literature data), their reliability (closeness to the truth) and usefulness (clinical application) (3rd stage). Basic approaches to critically evaluate publications in medical journals and other sources of information. The hierarchy of evidence in medicine. Systematic error. Types of systematic error. Qualitative characterization of evidence: a summary measure of the methodological quality of all available studies. Quantitative characterization (volume) of evidence: effect size, number of studies, total sample size of patients. Confidence level of evidence. Sample size (power), duration of observation and completeness of observation. Consistency of Evidence: The degree to which the results of different studies agree

**Topic 15. Systematic review and review with meta-analysis, features of preparation and use.**

Systematic reviews and reviews with meta-analysis. Conducting meta-analysis, compiling systematic reviews. Cochrane Systematic Reviews. Key features of the Cochrane Systematic Review. Development of the Cochrane Review: an introduction. Aims and structure of Cochrane examinations. Logistics development review. Determination of the question of inspection. Development of a systematic review protocol. Search for studies. Selection of studies. Assessing the risk of bias in the included studies. The value of Cochrane systematic reviews in finding and presenting evidence for the effectiveness of medical interventions. Kokreinivski and no Kokreinivski systematic reviews. Determination of an algorithm for the development of a systematic examination and conducting a meta-analysis.

**Topic 16. Implementation of the results of evidence-based medicine in clinical practice. Development of clinical guidelines, standards, clinical protocols.**

Implementation of evidence-based medicine results into clinical practice. Development of clinical guidelines, standards, guidelines and clinical protocols. How materials are created to implement their goals, objectives and opportunities. AGREE questionnaire. Classes of recommendations. Advantages and disadvantages of clinical guidelines, manuals, etc. Their legal status. How to improve implementation materials. Requirements for clinical guidelines, instructions, etc. Unified clinical protocol for medical care. Adapted clinical guidelines. Local protocols. Quality criteria for clinical guidelines.

**Topic 17. Assessment of the social, medical and economic efficiency of the results of the implementation of evidence-based medicine in clinical practice.**

Assessment of social, medical and economic efficiency of evidence-based medicine results. Indicators and criteria of medical efficiency of health care institutions. Social efficiency, its criteria. Determination and analysis of the economic efficiency of health care institutions. Study of economic losses in case of temporary disability caused by morbidity of the population and injuries. Economic effect and economic efficiency. Direct costs and indirect losses associated with morbidity and disability of the population.

**ORGANIZATION OF EDUCATION**

|  |  |  |
| --- | --- | --- |
| Name оf indicators | Field of knowledge, direction of training, educational and qualification level | Characteristics of the discipline |
| **full-time education** |
| Number of credit – 3 | Field of knowledge22 «Healthcare» (code and name) | **Selective** |
| The total hours – 90 | Specialty:222«Medicine»(code and name) | **Year:** |
| 4 |
| **Semester** |
| 7,8 |
| Hours for correspondence learning:classroom - 30independent student work - 60 | Education level:Master's degree | **Lectures** |
| 4 h. |
| **Practical, seminar** |
| 26 h. |
| **Individual tasks** |
| 60 h. |
| **Type of control:** |
| credit |
|  |

**The structure of the discipline**

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| --- | --- |
| The name of the sections of the discipline and topics | **Number of hours** |
| **Form of study (correspondence)** |
| **total** | **including** |
| **lec** | **p** | **i.w.** |
| 1 | **2** | **3** | **4** | **5** |
| **1.** | Introduction to evidence-based medicine. The history of the formation and development of evidence-based medicine | 4 | 2 | 2  | 2 |
| **2.** | Modern epidemiology and biostatistics as a science and ideology of evidence-based medicine | 4 | 2 | 2  | 2 |
| **3.** | Design of epidemiological studies. Types of design and their characteristics. The purpose and objectives of epidemiological research. Capabilities of epidemiological study designs | 5 | -  | 2 | 2 |
| **4.** | Empirical methods of surveillance of epidemiological studies. Features of descriptive research. Description of individual cases and description of a series of cases | 4 | -  | 2 | 2 |
| **5.** | Analytical methods of observation of epidemiological studies. Case-control studies, cohort studies and environmental studies. | 4 | -  | 2 | 2 |
| **6.** | Experimental epidemiological studies. Uncontrolled and controlled research. Randomized and nonrandomized studies. Pseudorandomization. | 3 | -  | 2 | 2 |
| **7.** | Randomization and blinding in epidemiological research. The Gold Standard in Epidemiology | 5 | -  | 2 | 2 |
| **8.** | Evidence-based medicine as a new style of activity in the patient's health care system. The main goal and objectives of evidence-based medicine. Rule 4 "A" in evidence-based medicine | 4 | - | 2 | 2 |
| **9.** | The importance of the largest world organization – International Kokreinivske cooperation in the formation and assessment of the effectiveness of medical and social interventions | 4 | - | 2 | 4 |
| **10.** | Information needs of the health care system. Problem statement to be found reliably proven solution. PICO Formula | 4 | - |  2 | 4 |
| **11.** | Identifying the best evidence for answering the questions | 7 | - | 1 | 4 |
| **12.** | Medical databases. Sources of analytical information. Electronic versions of medical journals with leading positions in the citation index. | 7 | - | 1 | 6 |
| **13.** | Screening – a source of information about the health status of the population in epidemiological studies. | 8 | - | 2  | 6 |
| **14.** | Critical assessment of the found evidence for its reliability and usefulness | 5 | - | 1 | 4 |
| **15.** | Systematic review and review with meta-analysis, features of preparation and use | 6 | - | - | 4 |
| **16.** | Implementation of the results of evidence-based medicine in clinical practice. Development of clinical guidelines, standards, clinical protocols. | 4 | - | 1 | 4 |
| **17.** | Assessment of the social, medical and economic efficiency of the results of the implementation of evidence-based medicine in clinical practice | 7 | - | 1 | 4 |
|  | **Final lesson** | 5 | - | 1 | 4 |
| **Total** | **90** | **4** | **26** | **60** |

**Lecture topics**

|  |  |  |
| --- | --- | --- |
| № | Name topics | Number of hours |
| 1 | Introduction to evidence-based medicine. The history of the formation and development of evidence-based medicine | 2 |
| 2 | Modern epidemiology and biostatistics as a science and ideology of evidence-based medicine | 2 |
|  | Total hours | 4 |

**Topics of practical classes**

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| --- | --- | --- |
| № | Name topics | Number of hours |
| 1 | Design of epidemiological studies. Types of design and their characteristics. The purpose and objectives of epidemiological research. Capabilities of epidemiological study designs | 2 |
| 2 | Empirical methods of surveillance of epidemiological studies. Features of descriptive research. Description of individual cases and description of a series of cases | 2 |
| 3 | Analytical methods of observation of epidemiological studies. Case-control studies, cohort studies and environmental studies. | 2 |
| 4 | Experimental epidemiological studies. Uncontrolled and controlled research. Randomized and nonrandomized studies. Pseudorandomization. | 4 |
| 5 | Randomization and blinding in epidemiological research. The Gold Standard in Epidemiology | 2 |
| 6 | Evidence-based medicine as a new style of activity in the patient's health care system. The main goal and objectives of evidence-based medicine. Rule 4 "A" in evidence-based medicine | 2 |
| 7 | Identifying the best evidence for answering the questions | 2 |
| 8 | Medical databases. Sources of analytical information. Electronic versions of medical journals with leading positions in the citation index. | 2 |
| 9 | Critical assessment of the found evidence for its reliability and usefulness | 2 |
| 10 | Implementation of the results of evidence-based medicine in clinical practice. Development of clinical guidelines, standards, clinical protocols. | 2 |
| 11 | Assessment of the social, medical and economic efficiency of the results of the implementation of evidence-based medicine in clinical practice | 2 |
| 12 | Final lesson | 2 |
|  | Total hours | 26 |

**Independent work**

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| --- | --- | --- |
| № | Name topics | Number of hours |
| 1 | ***Introduction to evidence-based medicine. The history of the formation and development of evidence-based medicine.***Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Variable performance of individual tasks. | 2 |
| 2 | ***Modern epidemiology and biostatistics as a science and ideology of evidence-based medicine.***Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Working with regulatory documents. Variable performance of individual tasks. | 2 |
| 3 | ***Design of epidemiological studies. Types of design and their characteristics. The purpose and objectives of epidemiological research. Capabilities of epidemiological study designs.***Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Working with regulatory documents. Variable performance of individual tasks. | 2 |
| 4 | ***Empirical methods of surveillance of epidemiological studies. Features of descriptive research. Description of individual cases and description of a series of cases.***Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Variable performance of individual tasks. | 2 |
| 5 | ***Analytical methods of observation of epidemiological studies. Case-control studies, cohort studies and environmental studies.***Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Variable performance of individual tasks. | 2 |
| 6 | ***Experimental epidemiological studies. Uncontrolled and controlled research. Randomized and nonrandomized studies. Pseudorandomization.*** Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Variable performance of individual tasks. | 2 |
| 7 | ***Randomization and blinding in epidemiological research. The Gold Standard in Epidemiology.*** Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Variable performance of individual tasks. | 2 |
| 8 | ***Evidence-based medicine as a new style of activity in the patient's health care system. The main goal and objectives of evidence-based medicine. Rule 4 "A" in evidence-based medicine.*** Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Variable performance of individual tasks. | 2 |
| 9 | ***The importance of the largest world organization – International Kokreinivske cooperation in the formation and assessment of the effectiveness of medical and social interventions.*** Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Variable performance of individual tasks. | 4 |
| 10 | ***Information needs of the health care system. Problem statement to be found reliably proven solution. PICO Formula.*** Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Variable performance of individual tasks. | 4 |
| 11 | ***Identifying the best evidence for answering the questions.***Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Variable performance of individual tasks. | 4 |
| 12 | ***Medical databases. Sources of analytical information. Electronic versions of medical journals with leading positions in the citation index.*** Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Working with an electronic system. Variable performance of individual tasks. | 6 |
| 13 | ***Screening – a source of information about the health status of the population in epidemiological studies.*** Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Working with an electronic system. Variable performance of individual tasks.  | 6 |
| 14 | ***Critical assessment of the found evidence for its reliability and usefulness.*** Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Working with an electronic system. Variable performance of individual tasks. | 4 |
| 15 | ***Systematic review and review with meta-analysis, features of preparation and use.***Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Working with an electronic system. Variable performance of individual tasks. | 4 |
| 16 | ***Implementation of the results of evidence-based medicine in clinical practice. Development of clinical guidelines, standards, clinical protocols.***Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Working with an electronic system. Variable performance of individual tasks. | 4 |
| 17 | ***Assessment of the social, medical and economic efficiency of the results of the implementation of evidence-based medicine in clinical practice.***Processing of educational literature. Drawing up a detailed plan of answers to the questions of the topic. Working with an electronic system. Variable performance of individual tasks. | 4 |
|  | ***Final lesson***Preparation for the final lesson of the discipline and passing the test. | 4 |
|  | Total | 60 |

Individual tasks

Individual work of applicants for higher education under the guidance of a teacher in the discipline "Evidence-based medicine methodology" is carried out during the semester in the form of: study of literary sources recommended for the development of topics and problems and preparation of reports; study of normative documents recommended for the study of various topics of the discipline; work with an electronic system; fulfillment of individual tasks.

Applicants for higher education by correspondence form of study must complete an individual task and send it to the teacher for verification (by e-mail) no later than 10 days before the start of the study session.

Applicants choose the task (topics) for individual work from the proposed list. Also, applicants can independently propose a topic for completing an individual assignment, based on the field of scientific interests or practical activities, while they must agree on it with the teacher.

Assessment criteria for an individual assignment. The work should have a volume of 10-16 pages of standard text (sheet size A4, font - Times New Roman, size - 14, line spacing - 1.5, paragraph - 1.25, alignment in width, between paragraphs - absent) and completely disclose the content of selected questions. The work should be structured and contain a list of used literary sources, drawn up in accordance with existing requirements. The work must be submitted for review on time.

Inconsistency of content, too large or small amount of work, inadequacy of formal requirements for design, lack of a list of sources used or its incorrect design, insufficient structure of the work, untimely submission of work for verification as reasons for lowering the grade or returning the work for revision.

**Topics of individual tasks**

1. The role and place of modern epidemiology in the study of public health.

2. Methods of epidemiological research and methodology for their implementation.

3. Screening as a source of information about the health of the population during epidemiological studies.

4. Clinical epidemiology as a scientific basis for making clinical decisions.

5. Risk factors: their role in epidemiological research and study features.

6. Features of conducting epidemiological studies.

7. Systematic reviews and reviews with meta-analysis, their preparation and use.

8. Clinical guidelines, protocols and recommendations. Implementation of evidence-based medicine and assessment of the results of the work done.

9. Formation of a clinical question in evidence-based medicine for solving problems in the health sector.

10. Identification of the best evidence-based evidence to address the issue from the standpoint of evidence-based medicine.

11. Critical assessment of the found evidence (literature data), their reliability and usefulness.

12. Working with databases of medical literature that have passed the expert assessment.

13. Systematic reviews and reviews with meta-analysis, their preparation and use.

14. Clinical guidelines, protocols and recommendations.

15. Implementation of evidence-based medicine and assessment of the results of the work done.

**\*** **Note.** Performing independent work involves preparing a presentation on this topic with a mandatory presentation (defense of the work) in a practical lesson.

**Teaching methods**

Problematic, multimedia and lecture-conversation; creative and problematic discussions, visual illustrations, discussions, oral questioning, written tests, test assignments, written creative works, independent work, game methods, solving situational and practical problems, as well as students' independent work with information sources and normative documents.

**Types of control:** current and final.

**EVALUATION**

The form of the final control of the discipline is the credit, which is carried out by the teacher of the academic group at the last lesson in the discipline.

**Assessment of current learning activities**

The current educational activity of applicants for higher education is monitored by the teacher of the academic group, after the students have mastered each topic of the discipline, and grades are given using a 4-point (national) system. For applicants for part-time studies, the grade for the completed individual assignment also belongs to the current grades. At the end of the semester, the teacher automatically receives the average grade (to the nearest hundredths) according to the current educational activityusing the electronic journal of the ACS system.

The recalculation of the average assessment of current activities is carried out in accordance with the "Instructions for the assessment of educational activities under the European credit and transfer system for organizing the educational process", approved by order of KhNMU No. 52 of 23.02.2016.

The final score for the current academic activity in the semester is determined as the arithmetic mean of national grades for each lesson, rounded to 2 decimal places. The total score for the current educational activity also includes an assessment for the completed individual work. According to the specified Instructions, the recalculation of the average mark for the current educational activity into a multi-point scale, for disciplines completed with an exam, is carried out in accordance with the table.

**Recalculation of the average assessment of current activities into a multi-point scale**

**(For disciplines, completed by credit)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 4-point scale | 200-point scale |  | 4-point scale | 200-point scale |  | 4-point scale | 200-point scale |
| 5 | 200 | 4.22-4,23 | 169 | 3.45-3,46 | 138 |
| 4.97-4,99 | 199 | 4.19-4,21 | 168 | 3.42-3,44 | 137 |
| 4.95-4,96 | 198 | 4.17-4,18 | 167 | 3.4-3,41 | 136 |
| 4.92-4,94 | 197 | 4.14-4,16 | 166 | 3.37-3,39 | 135 |
| 4.9-4,91 | 196 | 4.12-4,13 | 165 | 3.35-3,36 | 134 |
| 4.87-4,89 | 195 | 4.09-4,11 | 164 | 3.32-3,34 | 133 |
| 4.85-4,86 | 194 | 4.07-4,08 | 163 | 3.3-3,31 | 132 |
| 4.82-4,84 | 193 | 4.04-4,06 | 162 | 3.27-3,29 | 131 |
| 4.8-4,81 | 192 | 4.02-4,03 | 161 | 3.25-3,26 | 130 |
| 4.77-4,79 | 191 | 3.99-4,01 | 160 | 3.22-3,24 | 129 |
| 4.75-4,76 | 190 | 3.97-3,98 | 159 | 3.2-3,21 | 128 |
| 4.72-4,74 | 189 | 3.94-3,96 | 158 | 3.17-3,19 | 127 |
| 4.7-4,71 | 188 | 3.92-3,93 | 157 | 3.15-3,16 | 126 |
| 4.67-4,69 | 187 | 3.89-3,91 | 156 | 3.12-3,14 | 125 |
| 4.65-4,66 | 186 | 3.87-3,88 | 155 | 3.1-3,11 | 124 |
| 4.62-4,64 | 185 | 3.84-3,86 | 154 | 3.07-3,09 | 123 |
| 4.6-4,61 | 184 | 3.82-3,83 | 153 | 3.05-3,06 | 122 |
| 4.57-4,59 | 183 | 3.79-3,81 | 152 | 3.02-3,04 | 121 |
| 4.54-4,56 | 182 | 3.77-3,78 | 151 | 3-3,01 | 120 |
| 4.52-4,53 | 181 | 3.74-3,76 | 150 | **Less than 3** | **Not enough** |
| 4.5-4,51 | 180 | 3.72-3,73 | 149 |  |  |
| 4.47-4,49 | 179 | 3.7-3,71 | 148 |
| 4.45-4,46 | 178 | 3.67-3,69 | 147 |  |  |
| 4.42-4,44 | 177 | 3.65-3,66 | 146 |  |
| 4.4-4,41 | 176 | 3.62-3,64 | 145 |  |  |
| 4.37-4,39 | 175 | 3.6-3,61 | 144 |  |  |
| 4.35-4,36 | 174 | 3.57-3,59 | 143 |  |  |
| 4.32-4,34 | 173 | 3.55-3,56 | 142 |  |  |
| 4.3-4,31 | 172 | 3.52-3,54 | 141 |  |  |
| 4,27-4,29 | 171 | 3.5-3,51 | 140 |  |  |
| 4.24-4,26 | 170 | 3.47-3,49 | 139 |  |  |

**Conducting and evaluating the final lesson.**

The final lesson is held according to the schedule, during the last lesson.

The methodology for conducting the final lesson provides for the assessment of the development of theoretical knowledge and practical skills (assessment criteria - “fulfilled” or “did not fulfill”). When assessing the knowledge of the applicant included in this final lesson, an assessment is given on a national scale, which is considered as an assessment according to the current educational activity.

**Correspondence of grades on the 200-point scale,**

**four-point (national) scale and the ECTS scale**

|  |  |  |
| --- | --- | --- |
| Score on a 200-point scale | Score on the ECTS scale | Score on a four-point (national) scale |
| 180–200 | А | Perfectly |
| 160–179 | В | Fine |
| 150–159 | С | Fine |
| 130–149 | D | Satisfactorily |
| 120–129 | E | Satisfactorily |
| Less than 120 | F, Fx | Unsatisfactorily |

The grade in the discipline is given only to students who have passed all the final classes, credits.

Grades "**FX**" or "**F**" ("unsatisfactory") are given to students who are not credited with the study of the discipline, the form of control of which is credit.

After completing the study of the discipline responsible for the organization of educational and methodical work at the department or the teacher puts the student's grade on the scales in the record book and fill in the progress of students in the discipline forms: U-5.03A – **credit**.

**COURSE POLICY**

The policy of the course is to comply with the Code of Ethics, concluded by the university community, which defines the basic moral principles (the Code of Corporate Ethics of KhNMU is presented on the website http://knmu.edu.ua)

According to the current "Instructions for the assessment of educational activities under the European credit transfer system of the organization of the educational process" applicants for higher education must receive an assessment for each topic of the discipline. If the applicant missed a class, he worked it out in accordance with the "Regulations on the procedure for working out by students of the Kharkov National Medical University of study". Practicing is carried out daily by the next teacher of the department.

In the event that the applicant did not pass the individual assignment on time for a good reason, it is necessary to inform the teacher about such a situation and set a new deadline. If the applicant does not have time to complete the individual task, he can ask the teacher to postpone the deadline with a justification for the reason for the untimely performance (the teacher decides in each specific situation it makes sense to extend the deadline and for how long).

In case of non-fulfillment of tasks during training sessions, or failure to complete part of such a lesson, the teacher gives an unsatisfactory mark, which the applicant has to retake to the teacher in the teacher's free time and the applicant, who should be pre-assigned.

During the lecture, higher education applicants are encouraged to take notes of the lesson and maintain a sufficient level of silence.

During practical classes, a sufficient level of preparedness of applicants for them is expected and active participation in the work and implementation of the tasks set by the teacher. In particular, active participation in the discussion in the audience is expected, applicants must be ready to understand in detail the material, ask questions, express their point of view, and discuss. During class, are important:

* respect for colleagues, politeness and good manners,
* tolerance towards others and their experiences,
* sensitivity and impartiality,
* the ability to disagree with opinions, but respect the personality of the opponent / s,
* careful argumentation of your opinion and the courage to change your position under the influence of evidence,
* I-statements, when a person avoids unnecessary dressing, describes his feelings and formulates his wishes based on his own thoughts and emotions,
* compulsory acquaintance with primary sources, readiness for the lesson.

Creative approach in its various forms is encouraged. Applicants for higher education are expected to be interested in participating in various scientific and communication events in the subject profile.

Successful completion of the course requires observance of academic virtue, knowledge and ability to use in preparation for classes and performing tasks Regulations on the procedure for checking text documents at Kharkiv National University - dissertations, research reports, scientific publications, materials from scientific forums, educational literature, educational and methodological publications and teaching aids for the presence of text borrowings.

**Audience behavior**

**Basic “yes” and “no”**

It is important for applicants for higher education to follow the rules of proper university conduct. These rules are general for everyone, they also apply to the entire faculty and staff / -ts, and do not fundamentally differ from generally accepted norms. During classes, applicants must wear medical gowns (professional clothing).

It is allowed during classes:

* leave the audience for a short time if necessary and with the permission of the teacher;
* drink water;
* photograph presentation slides;
* actively participate in the class.

forbidden:

* eating (except for persons whose special medical condition requires another – in this case, medical confirmation is required)
* smoking, consume alcoholic and even low-alcohol drinks, other drinks besides water, as well as drugs;
* use obscene language or use words that offend the honor and dignity of colleagues and faculty;
* playing gambling;
* harm the material and technical base of the university (damage inventory, equipment; furniture, walls, floors, litter premises and territories)
* make noise, shout or listen to loud music in classrooms and even corridors during class.

**Occupational health**

In the first lesson of the course, the basic principles of labor protection will be explained by conducting appropriate instructions. Everyone is expected to know where the nearest emergency exit is, where the fire extinguisher is located, how to use it, etc.

**RECOMMENDED BOOKS**

***Basic literature***

1. Гринхальх, Т. Основы доказательной медицины / Т. Гринхальх. –

М. : ГЭОТАР-МЕДРоссия, 2015. – 336 p.

2. Общая эпидемиология с основами доказательной медицины. Руководство к практическим занятиям : учеб. пособие / под ред. В. И. Покровского, Н. И. Брико. – М. : ГЭОТАР - Медиа, 2010. – 400 p.

3. Основы доказательной медицины : учеб. пособие для системы послевузовского и дополнительного профессионального образования врачей / под общ. ed. Р. Г. Оганова. – М. : Силицея-Полиграф, 2010. – 136 p.

4. Ушаков, Е. В. Биоэтика : учебник и практикум для вузов / Е. В. Ушаков. – М. : Издательство Юрайт, 2018. – 306 p.

5. Methodical recommendations of the department

6. Lecture course of the department.

***Supporting literature***

1.Актуальные вопросы доказательной медицины : практ. рук. / под ред. Г. П. Котельникова, Г. Н. Гридасова. – Самара : Глагол, 2012. – 118 p.

2.Власов В. В. Время доказательной медицины [Электронный ресурс]. – 2013. – Режим доступа: http://www.strana-oz.ru/2006/2/vremya-dokazatelnoy-mediciny. – Дата доступа – 14.05.2018.

3.Медицина, основанная на доказательствах. Как практиковать ДМ. Как обучать ДМ : практикум : пер. с англ. / Е. Шарон [и др.]; под ред. В. В. Власова, К. И. Сайткулова. – М. : ГЭОТАР-Медиа, 2010. – 320 p.

4.Спасов, А. А., Черников М. В. Основы доказательной медицины [Электронный ресурс]. – 2013. – Режим доступа: http: // www.volgmed.ru/publishmg/lv/ about. php. – Дата доступа – 14.05.2018.

5.Хенеган, К. Доказательная медицина : справ. / К. Хенеган,

Д. Баденоч ; пер. с англ.; под ред. В. И. Петрова. – Москва : ГЭОТАР-Медиа, 2011. - 144 p.

***Information resources***

1. Всесвітня організація охорони здоров’я. – URL: www.who.int
2. Европейская база данных «Здоровье для всех». – URL: www.euro.who.int/ru/home
3. Кохрейнівський центр доказової медицини. – URL: www.cebm.net
4. Кохрейнівська бібліотека. – URL: www.cochrane.org
5. Національна медична бібліотека США. – MEDLINE. – URL: ww.ncbi.nlm.nih.gov/PubMed
6. Канадський центр доказів в охороні здоров'я. – URL: www.cche.net
7. Центр контролю та профілактики захворювань. – URL: www.cdc.gov
8. Центр громадського здоров’я МОЗ України. – URL: www.phc.org.ua
9. Українська база медико-статистичної інформації «Здоров’я для всіх». – URL: http://medstat.gov.ua/ukr/news.html?id=203
10. Журнал British Medical Journal. – URL: www.bmj.com
11. Журнал Evidence-Based Medicine. – URL: www.evidence-basedmedicine.com

**LIST OF QUESTIONS FOR CREDIT:**

1. The history of the development of modern epidemiology.

2. Modern definitions of epidemiology, the main goal and objectives. Types of epidemiology.

3. Clinical epidemiology as a new branch of medical knowledge. The concept of "clinical information". Assessment of the quality of medical information and its interpretation.

4. Clinical epidemiology, goals, objectives, functions. Job descriptions of a clinical epidemiologist.

5. Epidemiological research - the methodological basis of evidence-based medicine.

6. Clinical Trials Program Planning: Basic Principles.

7. The main stages of descriptive epidemiological studies.

8. receptions of epidemiological surveillance.

9. The concept of screening. Its role in the formation of the hypothesis of the onset of the pathological process.

10. Basics of organizing analytical research. Identification of risk factors for the development of the disease.

11. The role of epidemiological experiment and mathematical modeling for research work.

12. The concept of true clinical outcome and indirect evaluation criteria.

13. Assessment of the potential efficacy and safety of preventive and therapeutic drugs.

14. Assessment of the potential effectiveness of diagnostic and screening tests.

15. Statistical programs that are used in the scientific activities of the epidemiologist. Use of statistical software packages.

16. Testing statistical hypotheses.

17. Forecasting the results of epidemiological studies.

18. Legal basis for conducting epidemiological research.

19. Ethical principles for conducting epidemiological research.

20. Modern methodological requirements for authors of medical publications devoted to assessing the effectiveness of epidemiological studies.

21. Relationship between the design and structure of epidemiological studies.

22. Principles of planning and programming clinical trials.

23. Stages of development of evidence-based medicine.

24. The hierarchy of evidence in medicine.

25. The main questions posed by clinical epidemiology and evidence-based medicine.

26. Systematic error. Types of systematic error.

27. Levels of evidence confidence.

28. The role of Cochrane labor in the development of evidence-based medicine.

29. Types of clinical trials.

30. Cohort studies. Cohort types.

31. Predictive research. Risk and prognosis.

32. Study "case-control": characteristics, advantages and disadvantages.

33. Randomized controlled trial: design features, advantages and disadvantages.

34. Types of randomized trials. A pseudo-randomized clinical trial.

35. Clinical relevance. Statistical significance.

36. Main characteristics of the systematic review.

37. Types of control during controlled clinical trials.

38. Kokreinivske cooperation: characteristics of the organization and main activities.

39. Goals and objectives of Cochrane.

40. How the Cochrane Collaboration Works.

41. Cochrane structure. Cochrane groups.

42. Cochrane Evidence: Design, Presentation, Accessibility.

43. Kokreynivska library: an overview of databases.

44. Key characteristics of the Cochrane systematic review.

45. Objectives for the development of Cochrane systematic reviews.

46. ​​Structure of the Cochrane Systematic Review.

47. Steps for developing the Cochrane Systematic Review.

48. Determination of the issue of inspection.

49. Research search: characteristics of the stage.

50. Resources required for the development of the Cochrane survey.

51. Assessment of the quality of evidence in Cochrane systematic reviews.

52. Ways to minimize displacement in the development of Kokreynivsky inspection.

53. Evaluation of results. Types of results.

54. Meta-analysis: basic steps.

55. Opportunities and ways of introducing the principles of evidence-based medicine into healthcare practice.

56. Key principles for the development of evidence-based clinical guidelines and recommendations.

57. Innovative ways of delivering evidence to healthcare practice.

58. The main approaches in the critical assessment of publications in medical journals and other sources of information.

59. Sources of medical information: evaluation criteria, search for evidence.