

MINISTRY OF HEALTH OF UKRAINE  
KHARKIV NATIONAL MEDICAL UNIVERSITY

Department of Public Health and Health Management  
Academic year 2020-2021

**SYLLABUS**

**EDUCATIONAL DISCIPLINE**

« METHODOLOGY OF EVIDENCE MEDICINE »

(назва освітнього компоненту)

Selective educational component

Form of education \_\_\_\_\_ full-time form \_\_\_\_\_  
(full-time, external: distance learning)

Field of knowledge \_22 "Health care"  
(code and name of the field of knowledge)

Specialty \_222 "Medicine"  
(code and name of the specialty)

Specialization (if available) \_\_\_\_\_

Educational-professional program (educational-scientific program)  
OPP "Medicine"

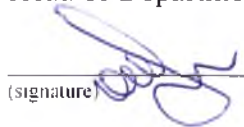
Second / master / level of higher education (choose required)

Course 4

The syllabus of the discipline was approved at  
a meeting of the Department of Public Health  
and Health Management

Protocol from.  
"27" August 2021 № 13  
Head of Department

(signature)

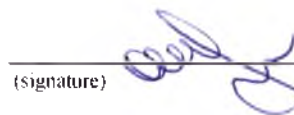


prof. V.A. Ognev  
(surname and initials)

Approved by the methodical commission of  
KhNMU on public health problems

Protocol from.  
"1" September 2021 № 2  
Head of Department

(signature)



prof. V.A. Ognev  
(surname and initials)

## **SILABUS COMPILERS:**

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(last name, first name and patronymic, position, academic title, scientific degree)
2. **Pomogaybo Katerina Georgievna, Associate Professor of Public Health and Health Management, Ph.D.**  
(last name, first name and patronymic, position, academic title, scientific degree)
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4. **Tregub Pavlo Olegovich, Associate Professor of Public Health and Health Management, Ph.D.**  
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**INFORMATION ABOUT TEACHERS  
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Consultations	Tuesday 15.30-17.00
Professional interests	Public health, biostatistics, evidence-based medicine
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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Consultations	Wednesday 15.30-17.00
Professional interests	Public health, biostatistics, evidence-based medicine
Location	Audience of the Department of Public Health and Health Management

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Professional interests	Public health, biostatistics, evidence-based medicine
Location	Audience of the Department of Public Health and Health Management

## INTRODUCTION

**The syllabus of the discipline** "Methodology of Evidence-Based Medicine" is compiled in accordance with the Educational-Professional Program "Medicine" and the draft Standard of Higher Education of Ukraine (hereinafter - the Standard), second (master's) level, field of knowledge 22 "Health", specialty 222 "Medicine».

### **Description of the discipline (abstract)**

Discipline "Methodology of evidence-based medicine" includes information on the basic concepts and terms of evidence-based medicine, the history of formation and development of evidence-based medicine, the concept of randomization, prerequisites and foundation of evidence-based medicine, purpose, objectives of evidence-based medicine, basic principles and importance of evidence-based medicine practices; features of the organization and carrying out of epidemiological researches, studying of prevalence and a natural course of certain diseases in groups of the population, revealing of scales of the problems connected with these diseases; identification of external and internal environmental factors that contribute to or prevent the occurrence and spread of these diseases; identification of priority problems in the field of public health; development of measures to eliminate or minimize the effects of adverse factors, as well as the study of types of epidemiological studies: descriptive, analytical, experimental. Acquaintance with the Convention for the Protection of Human Rights and Human Dignity in connection with the application of advances in biology and medicine and with such concepts as errors of epidemiological research, pseudorandomization, positive effects of intervention.

Mastering the technology of evidence-based medicine will allow to apply 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 summarize the results of epidemiological studies, critically evaluate the evidence, their reliability and usefulness (clinical application), implement the results of evidence-based medicine in medical practice, develop clinical guidelines, standards, guidelines and clinical protocols, evaluate social, medical and economic effectiveness 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, who has a systematic understanding of the basics of evidence-based medicine and is able to apply this knowledge to 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 links: the discipline** "Methodology of Evidence-Based Medicine" is integrated with the disciplines: "Principles of Public Health", "Health Care Organization in Ukraine", "Informatization in Public Health", "Epidemiological Surveillance and Health Assessment" I and the well-being of the population", " Biostatistics ", " Organization of medical and social research ", as well as with elective courses: " International organizations in health care ", " Formation of a healthy lifestyle ", " Legal aspects of medical activities ", " Ethical standards in public health ".

**Prerequisites** for studying the discipline involves mastering theoretical knowledge and practical skills in the history of evidence-based medicine; basic principles and importance of evidence-based medicine for clinical practice; the importance of epidemiological research in disease prevention; identification of external and internal environmental factors that contribute to or prevent the occurrence and spread of diseases; design of epidemiological studies, its types and their characteristics; stages of epidemiological research: prioritization, goal setting and objectives, hypothesis formulation, population determination, design selection, research organization, sampling, data collection, analysis and data design; types of epidemiological research: descriptive and analytical; experimental epidemiological research methods; history of randomization implementation; types and purposes of blinding; principles of Cochrane cooperation; rules of formation of a clinical question and actual problems at formulation of questions, its structure; sources of medical information; electronic databases; requirements for screening tests, the concept of ROC-analysis; basic approaches in critical evaluation of publications in medical journals and other sources of information; advantages and disadvantages of clinical recommendations, manuals, etc and requirements to them; quality criteria for clinical guidelines; indicators and criteria of medical efficiency of health care facilities.

**Postrequisites.** The discipline "Methodology of Evidence-Based Medicine" includes information on the main theoretical and methodological issues of evidence-based medicine as a science and practice and a methodological basis for the analysis and assessment of public health and the health care system. Knowledge and skills of evidence-based medicine are a prerequisite for conducting scientifically sound research in public health, understanding the processes taking place in public health and carrying out the professional activities of a public health specialist.

## **1. PURPOSE AND TASKS OF THE COURSE**

**1.1. The purpose of the discipline** is to master higher education in modern knowledge of the basics of evidence-based medicine and on its basis to optimize the quality of medical care in terms of safety, efficiency, cost and other important factors, as well as mastering the skills of using this knowledge in professional activities, public health.

## **1.2. The main tasks of studying the discipline are**

– to know the history of the formation of evidence-based medicine; basic principles and significance of evidence-based medicine for clinical practice; the importance of epidemiological research in disease prevention; identify external and internal environmental factors that contribute to or prevent the occurrence and spread of diseases; design of epidemiological studies, its types and their characteristics; stages of epidemiological research: setting priorities, goal setting and objectives, hypothesis formulation, population definition, design selection, research organization, sampling, data collection, analysis and data design; types of epidemiological research: descriptive and analytical; experimental epidemiological research methods; history of randomization implementation; types and purpose of blinding; principles of Cochrane cooperation; the rule of formation of a clinical question and actual problems at formulation of questions, its structure; sources of medical information; electronic databases; requirements for screening tests, the concept of ROC-analysis; basic approaches in critical evaluation of publications in medical journals and other sources of information; advantages and disadvantages of clinical guidelines, manuals, etc. and requirements to them; quality criteria for clinical guidelines; indicators and criteria of medical efficiency of health care facilities.

– learn to: identify priority issues in the field of public health; develop measures to eliminate or minimize the effects of adverse factors; to conduct analytical research, determine their goals and objectives; organize and conduct a randomized epidemiological study; to plan the experiment; determine the levels of reliability of evidence; interpret and critically evaluate the results of clinical trials; identify the shortcomings of the study and their design; conduct systematic reviews and meta-analysis; determine risk indicators in the case-control study; conduct meta-analysis, make systematic reviews; to evaluate the social, medical and economic effectiveness of the results of evidence-based medicine.

**1.3. Competences and learning outcomes**, in accordance with the requirements of the standard and educational-professional program, the discipline provides the acquisition of higher education by competencies:

- integral:

ability to solve typical and complex specialized problems and practical problems in professional activity in the field of health care, or in the process of training, which involves research and / or innovation and is characterized by complexity and uncertainty of conditions and requirements.

- general:

CL1 - Ability to abstract thinking, analysis and synthesis, ability to learn and be modernly trained

CL2 - Ability to apply knowledge in practical situations

CL3 - Knowledge and understanding of the subject area and understanding of professional activity

LC4 - Ability to adapt and act in a new situation

LC5 - Ability to make informed decisions; work in a team; skills of interpersonal interaction

LC7 - Skills of information and communication technologies

LC9 - Ability to act socially responsibly and consciously

- special (professional, subject):

FC1 - Skills survey

FC2 - Ability to determine the required list of laboratory and instrumental studies and evaluate their results

FC11 - Ability to plan and conduct sanitary, preventive and anti-epidemic measures, including infectious diseases

FC12 - Ability to determine the tactics of management of persons subject to dispensary supervision

FC13 - Ability to conduct an examination of working capacity

FC14 - Ability to maintain medical records

FC15 - Ability to conduct epidemiological and medical -statistical surveys of public health; processing of state, social, economic and medical information

FC17 - Ability to analyze the activities of a doctor, department, health care institution, to take measures to ensure the quality and safety of medical care and improve the efficiency of medical resources

FC18 - Ability to conduct activities for the organization and integration of medical care, and marketing of medical services

**1.3.2.** The study of the discipline provides students with the acquisition of the following program learning outcomes:

Knowledge and understanding:

PRN 1 – have general and special fundamental and professionally-oriented knowledge, skills, abilities, competencies necessary to perform typical professional tasks related to activities in the medical field in the relevant position

PRN 2 - have knowledge of psychophysiological characteristics of man, human health, health support, disease prevention, human treatment, public health

Application of knowledge and understanding:

PRN 3 - apply the acquired knowledge, skills and understanding to solve typical tasks of a physician, the scope of which is provided by lists of syndromes and symptoms, diseases, emergencies, laboratory and instrumental studies, medical manipulations

PRN 4 - to collect information about the patient

PRN 9 - to determine the tactics of contingent of persons, subject to dispensary supervision

PRN 10 - to diagnose emergencies, determine the tactics of emergency medical care

PRN 11 - to carry out sanitary and hygienic and preventive measures

PRN 12 - to plan preventive and anti-epidemic measures on infectious diseases

PRN 13 - to carry out medical and evacuation measures

PRN 17 - to be able to keep medical records, process state, social and medical information

Formations of judgments:

PRN 18 - to assess the state of human health and provide its support taking into consideration the impact of the environment and other health factors { {1}}

PRN 19 - to assess the sanitary and hygienic condition of the environment in order to determine the sanitary and hygienic and preventive measures

PRN 20 - to apply the acquired knowledge about the existing health care system to optimize their professional activities and participation in solving practical problems of the field

PRN 21 - adhere to the code of ethics of the doctor, which ensures the formation of a specialist with appropriate personal qualities

**1.3.3.** The study of the discipline provides students with the following social skills (**Soft skills**):

tolerance, empathy, the ability to cooperate with the patient / client, colleagues, to show leadership, work in critical conditions and think logically and systematically.

## 2. INFORMATION SCOPE OF THE COURSE

Name of indicators	Field of knowledge, direction of training, educational and qualification level	Characteristics of the discipline
		<b>Full-time education</b>
Number of credits – 3	Field of knowledge: 22 "Health care" (code and name)	<b>Selective</b>
Total number of hours - 90	Specialty: 222 "Medicine" (code and name)	<b>Year of preparation:</b>
		4th
		<b>Semester</b>
Hours for distance learning: classroom – 18 individual work of the student - 72	Educational - qualification level: master's degree	8th
		<b>Lectures</b>
		4 hours
		<b>Practical, seminar</b>
		14 hours
		<b>Individual work</b>
		72 hours.
		<b>Individual tasks</b>
hours		
<b>Type of control</b>	Credit	

### 2.1 Description of the discipline

#### 2.2.1 Lectures

№ 3/II	Name of the topics	Total hours
1	Introduction to evidence-based medicine. History of formation	2



	and development of evidence-based medicine.	
2	Modern epidemiology and biostatistics as sciences and ideologies of evidence-based medicine.	2
	Total lecture hours	4

### 2.2.2 Practical training

№ 3/II	Name topics	Total hours
1	Epidemiological research design. Types of design and their characteristics. The purpose and objectives of epidemiological research. Possibilities of epidemiological research designs.	1
2	Empirical research methods of observation of epidemiological researches. Features of descriptive studies. Description of individual cases (case report) and description of a series of cases (case series).	4
3	Analytical study methods of observation of epidemiological researches. Case control study, cohort study, and environmental studies.	4
4	Experimental epidemiological studies. Uncontrolled and controlled research. Randomized and nonrandomized Pseudorandomization studies.	4
5	Randomization and blindness in epidemiological studies (open-label study, simple blindness, double blindness, triple blindness, and complete blindness). The gold standard in epidemiology.	2
6	Evidence-based medicine as a new style of activity in the patient care system. The main purpose and objectives of evidence-based medicine. Rule 4 "A" in evidence-based medicine.	1
7	Identifying the best evidence to answer the questions.	1
8	Medical databases. Sources of analytical information. Electronic versions of medical journals that take leading positions in the citation index.	3

9	Critical evaluation of the evidence found for their reliability and usefulness.	2
10	Implementation of the results of evidence-based medicine in clinical practice. Development of clinical guidelines, standards, guidelines, clinical protocols.	1
11	Evaluation of social, medical and economic efficiency of the results of the introduction of evidence-based medicine in clinical practice.	2
12	Final control	1
	Total hours of practical training	26

### 2.2.3. Individual work

№ 3/Π	Name topics	Total hours
1	<b><i>Introduction to evidence-based medicine. History of formation and development of evidence-based medicine.</i></b>  Elaboration of educational literature. Drawing up a detailed plan of answers to questions of the topic. Variable performance of individual tasks.	2
2	<b><i>Modern epidemiology and biostatistics as sciences and ideologies of evidence-based medicine.</i></b>  Elaboration of educational literature. Drawing up a detailed plan of answers to questions of the topic. Work with legal documents. Variable performance of individual tasks.	2
3	<b><i>Epidemiological research design. Types of design and their characteristics. The purpose and objectives of epidemiological research. Possibilities of epidemiological research designs.</i></b>  Elaboration of educational literature. Drawing up a detailed plan of answers to questions of the topic. Work with legal documents. Variable performance of individual tasks.	2
4	<b><i>Empirical research methods of observation of epidemiological researches. Features of descriptive studies.</i></b>	2

	<p><b><i>Case report and case series description.</i></b></p> <p>Study of educational literature. Drawing up a detailed plan of answers to questions of the topic. Variable performance of individual tasks.</p>	
5	<p><b><i>Analytical study methods of observation of epidemiological researches. Case control study, cohort study, and environmental research.</i></b></p> <p>Drawing up a detailed plan of answers to questions of the topic. Variable performance of individual tasks.</p>	2
6	<p><b><i>Experimental epidemiological studies. Uncontrolled and controlled research. Randomized and nonrandomized studies Pseudorandomization.</i></b></p> <p>Study of educational literature. Drawing up a detailed plan of answers to questions of the topic. Variable performance of individual tasks.</p>	2
7	<p><b><i>Randomization and blindness in epidemiological studies (open-label study, simple blindness, double blindness, triple blindness, and complete blindness). The gold standard in epidemiology.</i></b></p> <p>Study of educational literature. Drawing up a detailed plan of answers to questions of the topic. Variable performance of individual tasks.</p>	2
8	<p><b><i>Evidence-based medicine as a new style of activity in the patient care system. The main purpose and objectives of evidence-based medicine. Rule 4 "A" in evidence-based medicine.</i></b></p> <p>Elaboration of educational literature. Drawing up a detailed plan of answers to questions of the topic. Variable performance of individual tasks.</p>	4
9	<p><b><i>The value of the world's largest organization - International Cochrane cooperation in the formation and evaluation of the effectiveness of medical and social interventions.</i></b></p> <p>Development of educational literature. Drawing up a detailed plan</p>	4

	of answers to questions of the topic. Variable performance of individual tasks.	
10	<b><i>Information needs of the health care system. Statement of a problem for which it is necessary to find a reliably proven solution. PICO formula.</i></b>  Elaboration of educational literature. Drawing up a detailed plan of answers to questions of the topic. Variable performance of individual tasks.	4
11	<b><i>Identifying the best evidence to answer the questions.</i></b>  Elaboration of educational literature. Drawing up a detailed plan of answers to questions of the topic. Variable performance of individual tasks.	4
12	<b><i>Medical databases. Sources of analytical information. Electronic versions of medical journals that occupy leading positions in the citation index.</i></b>  Study of educational literature. Drawing up a detailed plan of answers to questions of the topic. Work with legal documents. Variable performance of individual tasks.	6
13	<b><i>Screening is a source of information about the state of health of the population in epidemiological studies.</i></b>  Development of educational literature. Drawing up a detailed plan of answers to questions of the topic. Variable performance of individual tasks.	6
14	<b><i>Critical evaluation of the found evidence for their reliability and usefulness.</i></b>  Elaboration of educational literature. Drawing up a detailed plan of answers to questions of the topic. Working with the electronic system. Variable performance of individual tasks.	4
15	<b><i>Systematic review and review with meta-analysis, features of preparation and use.</i></b>  Elaboration of educational literature. Drawing up a detailed plan of answers to questions of the topic. Working with the	4

	electronic system. Variable performance of individual tasks.	
16	<b><i>Implementation of the results of evidence-based medicine in clinical practice. Development of clinical guidelines, standards, guidelines, clinical protocols.</i></b>  Development of educational literature. Drawing up a detailed plan of answers to questions of the topic. Working with the electronic system. Variable performance of individual tasks.	4
17	<b><i>Evaluation of social, medical and economic efficiency of the results of the introduction of evidence-based medicine in clinical practice.</i></b>  Drawing up a detailed plan of answers to questions of the topic. Working with the electronic system. Variable performance of individual tasks.	2
	<b><i>Final control</i></b>  Preparation for the final control of the discipline and passing the test.	4
	Total	60

**Teaching methods:** story-explanation, conversation, lecture, illustration, demonstration, presentation, discussion,, business, role-playing, game, modeling of processes and situations, delegation of powers, project method, debate, brainstorming method.

**Methods of control** (only those used in teaching the discipline are given):

**Current control:** oral examination (individual and frontal); written survey; test control; creative tasks; individual tasks; abstracts; self-control; report; speech on a given topic;.

**Final control:** credit.

### **3. EVALUATION CRITERIA**

**3.1.** The current educational activity of higher education students is controlled by the teacher of the academic group, after students master each topic of the discipline and grades are set using a 4-point (national) system. At the end of the semester, the teacher automatically receives the average grade (to the nearest hundredth) for IPA using an electronic journal of the ACS system.

Recalculation of the average grade for current activities is carried out in accordance with the "Instructions for evaluating the academic performance of higher education at the Kharkiv National Medical University", approved by the order of KhNMU № 181 from 21.08.2021.

The final score for IPA in the semester is defined as the arithmetic mean of national grades for each lesson and software, rounded to 2 decimal places. The amount of points for IPA also includes an assessment for individual work performed. According to the specified Instruction, recalculation of an average estimation for current educational activity (PND) in a multi-point scale, for the disciplines coming to the end of credit is carried out according to the table.

Table 2

**Recalculation of the average grade for current activities in a multi-point scale (for disciplines ending with credit)**

4-бальна шкала	200-бальна шкала	4-бальна шкала	200-бальна шкала	4-бальна шкала	200-бальна шкала
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	<b>Less than 3</b>	<b>It is not enough</b>
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		

The final lesson (SO) is conducted according to the schedule, during the last lesson.

During the assessment of the applicant's knowledge included in this final lesson (SO), a grade is given on a national scale, which is considered as a grade on the IPA.

### **3.2. Test questions:**

1. History of modern epidemiology.
2. Modern definitions of epidemiology, the main purpose and objectives. Types of epidemiology.
3. Clinical epidemiology as a new branch of medical knowledge. The concept of "clinical information". Quality assessment of clinical information and its interpretation.
4. Clinical epidemiology, goals, objectives, functions. Job descriptions of a clinical epidemiologist.
5. Epidemiological research is the methodological basis of evidence-based medicine.
6. Planning clinical trial programs: basic principles.
7. The main stages of descriptive epidemiological research.
8. Basic methods of epidemiological surveillance.
9. The concept of screening. Its role in the formation of the hypothesis of origin pathological process.
10. Fundamentals of analytical research. Identification of risk factors for the development of the disease.
11. The role of epidemiological experiment and mathematical modeling for research.
12. The concept of true clinical outcome and indirect evaluation criteria.
13. Evaluation of potential efficacy and safety of prophylactic and therapeutic drugs.
14. Evaluation of the potential effectiveness of diagnostic and screening tests.
15. Statistical programs used in the scientific activities of the epidemiologist. Using statistical software packages.
16. Test statistical hypotheses.
17. Forecasting the results of epidemiological studies.
18. Legal bases of epidemiological research.
19. Ethical principles of epidemiological research.
20. Modern methodological requirements for authors of medical publications devoted to the evaluation of the effectiveness of epidemiological research.
21. Relationship between design and structure of epidemiological research.
22. Principles of planning and compiling clinical trial programs.
23. Stages of development of evidence-based medicine.
24. 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.

28. The role of Cochrane's work in the development of evidence-based medicine.
29. Types of clinical trials.
30. Cohort studies. Cohort types.
31. Prognostic studies. Risk and prognosis.
32. Case-control study: characteristics, advantages and disadvantages.
33. Randomized controlled trial: design features, advantages and disadvantages.
34. Types of randomized trials. Pseudorandomized clinical trial.
35. Clinical significance. Statistical significance.
36. The main characteristics of a systematic review.
37. Types of control during controlled clinical trials.
38. Cochrane cooperation: characteristics of the organization and main activities.
39. Goals and objectives of Cochrane.
40. Principles of cooperation of Cochrane.
41. Cochrane structure. Cochrane groups.
42. Evidence Cochrane: development, presentation, availability.
43. Cochrane Library: A Review of Databases.
44. Key characteristics of the Cochrane systematic review.
45. Objectives of the development of Cochrane systematic reviews.
46. The structure of the Cochrane systematic review.
47. Steps in the development of the Cochrane systematic review.
48. Defining the review question.
49. Research search: stage characteristics.
50. Resources needed to develop the Cochrane Review.
51. Evaluation of the quality of evidence in Cochrane systematic reviews.
52. Ways to minimize bias in the development of the Cochrane Review.
53. Evaluation of the results. Types of results.
54. Meta-analysis: basic steps.
55. Possibilities and ways of implementing the principles of evidence-based medicine in health care practice.
56. Key principles for developing evidence-based clinical guidelines and guidelines.
57. Innovative ways to deliver evidence to health practice.
58. Basic approaches in the critical evaluation of publications in medical journals, and other sources of information.
59. Sources of medical information: evaluation criteria, search for evidence.

### **3.3. Questions of control**

1. Epidemiological research - the methodological basis of evidence-based medicine.
2. Planning clinical trial programs: basic principles.
3. The main stages of descriptive epidemiological research.
4. Basic methods of epidemiological surveillance.
5. The concept of screening. Its role in the formation of the hypothesis of the pathological process.



6. Fundamentals of the organization of analytical research. Identification of risk factors for the development of the disease.
7. The role of epidemiological experiment and mathematical modeling for research.
8. The concept of true clinical outcome and indirect evaluation criteria.
9. Evaluation of potential efficacy and safety of prophylactic and therapeutic drugs.
10. Evaluation of the potential effectiveness of diagnostic and screening tests.
11. Statistical programs used in the scientific activities of the epidemiologist. Using statistical software packages.
12. Test statistical hypotheses.
13. Forecasting the results of epidemiological studies.
14. Legal bases of conducting epidemiological researches.
15. Ethical principles of epidemiological research.
16. Modern methodological requirements for authors of medical publications devoted to the evaluation of the effectiveness of epidemiological research.
17. Relationship between design and structure of epidemiological research.
18. Principles of planning and compiling clinical trial programs.

**3.4. Individual tasks** (the list approved at the meeting of the department with the determination of the number of points for their performance, which can be added as incentives):

1. The role and place of modern epidemiology in the study of public health.
2. Methods of epidemiological research and methods of their conduct.
3. Screening as a source of information about public health in epidemiological research.
4. Clinical epidemiology as a scientific basis for clinical decision making.
5. Risk factors: their role in epidemiological studies and features of the study.
6. Features of epidemiological research.
7. Systematic reviews and reviews with meta-analysis, their preparation and use.
8. Clinical guidelines, protocols and recommendations. Introduction of evidence-based medicine and evaluation of the results of the work done.
9. Formation of a clinical question in evidence-based medicine to solve a problem in the field of health care.
10. Identification of the best substantiated evidence to address the issue from the standpoint of evidence-based medicine.
11. Critical evaluation of the found evidence (literature data), their reliability and usefulness.
12. Working with databases of medical literature that have passed expert assessment.
13. Systematic reviews and reviews with meta-analysis, their preparation and use.
14. Clinical guidelines, protocols and guidelines.

15. Introduction of evidence-based medicine and evaluation of the results of the work performed.

### **3.6. Rules for appealing the assessment**

The rules for appealing the assessment are regulated in the "Regulations on the appeal of the results of the final control of students of Kharkiv National Medical University", approved by the order of KhNMU № 252 from 30.09.2020

Reference:

[http://www.knmu.kharkov.ua/index.php?option=com\\_content&view=article&id=1226%3A2013-03-25-12-07-55&catid=4%3A2011-05-04-07-20-12&Itemid=19&lang=uk](http://www.knmu.kharkov.ua/index.php?option=com_content&view=article&id=1226%3A2013-03-25-12-07-55&catid=4%3A2011-05-04-07-20-12&Itemid=19&lang=uk)

## **4. DISCIPLINE POLICY**

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

In accordance with the current "Instructions for the evaluation of educational activities at 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 the training session, he must complete it in accordance with the "Regulations on the procedure for training of students of the Kharkiv National Medical University." Practices are carried out daily by the next teacher of the department.

If the applicant did not pass the individual task on time for a good reason, it is necessary to inform the teacher about this situation and set a new deadline. If the applicant does not have time to complete an individual task, he can ask the teacher to postpone the deadline justifying the reason for late performance (the teacher decides in each situation whether it makes sense to extend the deadline and for how long).

In case of non-fulfillment of tasks during training sessions, or non-fulfillment of a part of such lesson, the teacher gives an unsatisfactory grade, which the applicant should reassign to the teacher in his / her free time. lesson outline and maintain a sufficient level of silence.

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

The following are important during classes:

- respect for colleagues, politeness and politeness,
- tolerance for others and their experience,
- receptivity and impartiality,
- ability not to agree with the opinion, but respect the personality of the opponent,
- careful argumentation of his opinion and the courage to change his position under the influence of evidence,
- self-statement, when a person avoids unnecessary generalizations,

describes his feelings and formulates his wishes based on their own thoughts and emotions,

- mandatory acquaintance with the original sources, readiness for the lesson.

A creative approach in its various manifestations is welcome. Higher education students are expected to be interested in participating in various scientific and communicative activities in the subject profile.

Successful completion of the course requires academic integrity, knowledge and ability to use in preparation for classes and tasks documents - dissertations, research reports, scientific publications, materials of scientific forums, educational literature, educational publications and teaching aids for the presence of textual borrowings.

## **5.5. ACADEMIC INTEGRITY**

### **The policy of academic integrity**

5.1. Academic integrity is a set of ethical principles and statutory rules that should guide the participants in the educational process during training, teaching and conducting scientific (creative) activities in order to ensure confidence in learning outcomes and / or scientific (creative) achievements.

**5.2. Observance of academic integrity by pedagogical, scientific-pedagogical and scientific workers provides:**

5.2.1. objective and impartial assessment of knowledge and skills of students (graduates);

5.2.2. compliance with the rules of reference to sources of information in the case of borrowing ideas, statements, writing materials, research papers, etc. ;

5.2.3. monitoring the observance of academic integrity by applicants for higher education,

5.2.4. compliance with the legislation on copyright and related rights;

5.2.5. informing applicants for higher education about the main criteria for detecting plagiarism and responsibility for its use,

5.2.6. conducting activities among students to prevent cases of plagiarism.

5.2.7. providing reliable information about research methods and results, sources of information used and own pedagogical (scientific-pedagogical, creative) activity;

**5.3. The academic integrity of higher education seekers includes:**

5.3.1. use in teaching or research activities only verified and reliable sources of information and correctly refer to them.

5.3.2. compliance with the rules of reference to sources of information in the case of borrowing ideas, statements, writing materials, research papers, etc.

5.3.3 independent implementation of educational tasks, tasks of current and final control of learning outcomes (for people with special educational needs this

requirement is applied taking into account their individual needs and possibilities);

5.3.4. compliance with the legislation on copyright and related rights;

5.3.5. providing reliable information about the results of their own educational (scientific, creative) activities, used research methods and sources of information.

#### **5.4. Violation of academic integrity is:**

- *academic plagiarism* - publication (partially or completely) of scientific (creative) results obtained by other persons as the results of own research (creativity) and / or reproduction of published texts (published works of art) of other authors without indication of authorship;

- *self-plagiarism* - publication (in part or in full) of one's own previously published scientific results as new scientific results;

- *fabrication* - the fabrication of data or facts used in the educational process or research;

- *falsification* - a deliberate change or modification of existing data relating to the educational process or research;

- *write-off* - performance of written works with the involvement of external sources of information, other than those permitted for use, in particular during the evaluation of learning outcomes;

- *deception* - providing knowingly false information about their own educational (scientific, creative) activities or organization of the educational process ;

- *bribery - the provision* (receipt) of a participant in the educational process or a proposal to provide (receive) funds, property, services, benefits or any other material or intangible benefits in order to obtain an illegal advantage in the educational process, receiving payment for settlement in dormitories, permission to use the material and technical base of the University (if it does not provide a list of paid services);-

- *biased assessment* - deliberate overestimation or underestimation of the assessment of learning outcomes of students.

- *involvement of fictitious persons* in the list of authors of scientific (creative) or educational work, participation of such persons in the current or final assessment of knowledge;

- *forced charitable contributions and forced labor* - forcing participants in the academic process to pay money or perform certain work under the threat of intentionally harming the interests and rights of the learner in education or other matters.

- *the emergence of situations that caused a conflict of interest* - the real and potential conflict between personal, property, non-property interests of the person

or persons close to him and his powers, the presence of which may affect the objectivity of decision-making, as well as actions or omissions the time of performance of the powers granted to her;

*-Excess of authority* - the use of official position, family ties to obtain benefits in the educational, scientific or administrative field.

**5.5. For violation of academic integrity, pedagogical, scientific-pedagogical and scientific staff of educational institutions may be held liable for such academic liability:**

5.5.1. refusal to award a scientific degree or confer a scientific title;

5.5.2. deprivation of the awarded scientific (educational and creative) degree or awarded academic title;

5.5.3. refusal to assign or deprivation of the assigned pedagogical title, qualification category,

5.5.4. deprivation of the right to participate in the work of statutory bodies or to hold statutory positions.

**5.6. For violation of academic integrity, students may be held subject to the following academic liability:**

5.6.1 re-assessment (test, exam, test, etc.)

5.6.2. re-passing the relevant educational component of the educational program;

5.6.3. deductions from educational institutions (except for persons receiving general secondary education)

5.6.4. deprivation of an academic scholarship;

5.6.5. deprivation of tuition benefits provided by the educational institution.

**5.7. Types of academic responsibility** (including additional and / or detailed) participants of the educational process for specific violations of academic integrity are determined by special laws and / or internal regulations of the educational institution, approved (agreed) by the Academic Council of the university and agreed with the relevant self-governing bodies of students.

**5.8. The procedure for identifying and establishing the facts of violation of academic integrity.**

Every person in respect of whom the fact of violation of his academic integrity has been established has the following rights:

- to read all the materials of the inspection to establish the fact of violation of academic integrity, to submit comments to them,

- in person or through a representative to provide oral and written explanations or refuse to provide any explanations, ;

- to know about the date, time and place and to be present during the consideration of the issue of establishing the fact of violation of academic integrity and bringing it to academic responsibility;

- to appeal the decision to bring to academic responsibility to the body, authorized to consider appeals, or to court.

5.9. Forms and types of academic responsibility of educational institutions are determined by special laws.

5.10. For actions (inaction) recognized as a violation of academic integrity, a person may be held liable for other types of liability on the grounds and in the manner prescribed by law.

## **6 RECOMMENDED BOOKS**

### *Basic literature*

1. Гринхальх, Т. Основы доказательной медицины / Т. Гринхальх. – М. : ГЭОТАР-МЕДРоссия, 2015. – 336 с.
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 с.
3. Основы доказательной медицины : учеб. пособие для системы послевузовского и дополнительного профессионального образования врачей / под общ. ред. Р. Г. Оганова. – М. : Силиция-Полиграф, 2010. – 136 с.
4. Ушаков, Е. В. Биоэтика : учебник и практикум для вузов / Е. В. Ушаков. – М. : Издательство Юрайт, 2018. – 306 с.
5. Методичні рекомендації кафедри
6. Лекційний курс кафедри.

### *Допоміжна література*

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

### *Інформаційні ресурси*

1. Всесвітня організація охорони здоров'я. – URL: [www.who.int](http://www.who.int)
2. Европейская база даних «Здоровье для всех». – URL: [www.euro.who.int/ru/home](http://www.euro.who.int/ru/home)
3. Кохрейнівський центр доказової медицини. – URL: [www.cebm.net](http://www.cebm.net)
4. Кохрейнівська бібліотека. – URL: [www.cochrane.org](http://www.cochrane.org)
5. Національна медична бібліотека США. – MEDLINE. – URL: [www.ncbi.nlm.nih.gov/PubMed](http://www.ncbi.nlm.nih.gov/PubMed)
6. Канадський центр доказів в охороні здоров'я. – URL: [www.cche.net](http://www.cche.net)
7. Центр контролю та профілактики захворювань. – URL: [www.cdc.gov](http://www.cdc.gov)
8. Центр громадського здоров'я МОЗ України. – URL: [www.phc.org.ua](http://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](http://www.bmj.com)
11. Журнал Evidence-Based Medicine. – URL: [www.evidence-basedmedicine.com](http://www.evidence-basedmedicine.com)

### **8. ІНШЕ**

Useful links:

Положення про запобігання, попередження та врегулювання випадків, пов'язаних із сексуальними домаганнями і дискримінацією у ХНМУ  
[http://files.knmu.edu.ua:8181/upload/redakt/doc\\_uchproc/polog-sex.doc](http://files.knmu.edu.ua:8181/upload/redakt/doc_uchproc/polog-sex.doc)

Положення про академічну доброчесність та етику академічних взаємовідносин в Харківському національному медичному університеті  
[http://files.knmu.edu.ua:8181/upload/redakt/doc\\_uchproc/polog\\_ad\\_etyka\\_text.pdf](http://files.knmu.edu.ua:8181/upload/redakt/doc_uchproc/polog_ad_etyka_text.pdf)

Порядок проведення занять з поглибленого вивчення студентами Харківського національного медичного університету окремих дисциплін понад обсяг навчального плану  
[http://files.knmu.edu.ua:8181/upload/redakt/doc\\_uchproc/nak-poriad-poglyv-dysc.docx](http://files.knmu.edu.ua:8181/upload/redakt/doc_uchproc/nak-poriad-poglyv-dysc.docx)

Положення про Комісію з академічної доброчесності, етики та управління конфліктами ХНМУ  
[http://files.knmu.edu.ua:8181/upload/redakt/doc\\_uchproc/polog\\_komis\\_ad\\_t\\_ext.pdf](http://files.knmu.edu.ua:8181/upload/redakt/doc_uchproc/polog_komis_ad_t_ext.pdf)

Положення про визнання результатів неформальної освіти в Харківському національному медичному університеті  
[http://files.knmu.edu.ua:8181/upload/redakt/doc\\_uchproc/polog\\_neform\\_osv.pdf](http://files.knmu.edu.ua:8181/upload/redakt/doc_uchproc/polog_neform_osv.pdf)

ІНКЛЮЗИВНА ОСВІТА:

[http://www.knmu.kharkov.ua/index.php?option=com\\_content&view=article&id=7108%3A2021-03-10-14-08-02&catid=12%3A2011-05-10-07-16-32&Itemid=33&lang=uk](http://www.knmu.kharkov.ua/index.php?option=com_content&view=article&id=7108%3A2021-03-10-14-08-02&catid=12%3A2011-05-10-07-16-32&Itemid=33&lang=uk)

АКАДЕМІЧНА ДОБРОЧЕСНІСТЬ:

[http://www.knmu.kharkov.ua/index.php?option=com\\_content&view=article&id=2520%3A2015-04-30-08-10-46&catid=20%3A2011-05-17-09-30-17&Itemid=40&lang=uk](http://www.knmu.kharkov.ua/index.php?option=com_content&view=article&id=2520%3A2015-04-30-08-10-46&catid=20%3A2011-05-17-09-30-17&Itemid=40&lang=uk)

[http://files.knmu.edu.ua:8181/upload/redakt/doc\\_uchproc/kodex\\_AD.docx](http://files.knmu.edu.ua:8181/upload/redakt/doc_uchproc/kodex_AD.docx)