

MINISTRY OF HEALTH OF UKRAINE
DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY

SYLLABUS
for the discipline
"METHODODOLOGY OF EVIDENCE-BASED MEDICINE"
(Elective course)

of the second (master's) level of higher education
branch of knowledge 22 "Health Care"
specialty 222 "Medicine"



2023

1. General information	
Faculty	Foreign Students
Educational program	22 Healthcare, 222 Medicine, second (master's) level of higher education, full-time
Academic year	2023-2024
Name of discipline, code	Methodology of Evidence-Based Medicine, VB 1.49 https://new.meduniv.lviv.ua/kafedry/kafedra-sotsialnoyi-medytsyny-ekonomiky-ta-organizatsiyi-ohorony-zdorov-ya/
Department	Department of social medicine, economics and organization of health care Address: Zelena, 12 tel. +38(032)276-81-67 e-mail: kaf_socmed@meduniv.lviv.ua
Head of the Department	Associate professor Taras Hryhorovych Gutor taras_gutor@ukr.net
Year of study	4th year of study
Semester	7 or 8 semesters
Type of discipline / module	Selective
Teachers	Associate Professor Taras Gutor taras_gutor@ukr.net Associate Professor Oksana Kovalska oksanaromkov@ukr.net Assistant of the department Zaremba Natalia natalyazaremba@gmail.com Assistant of the department Irina Gupalo irahup@gmail.com Assistant of the department Natalia Timchenko timchenkonataliaf@ukr.net Assistant of the department Roman Lysuyk socmed_ES@i.ua
Erasmus Yes / No	Erasmus - No
The person responsible for the syllabus	Assistant Ruslan Ihorovych Litvinyak ruslanlitvinyak@gmail.com
Number of ECTS credits	2 credits
Number of hours	60 hours (26 hours of practical classes, 34 hours of self-guided study of students)
Language of study	English
Information on consultations	Consultations - according to the schedule for the course once a week from 3.30 p.m. till 5.00 p.m.
Address, telephone and regulations of the clinical base, bureau	A clinical base is not provided
2. Short description of the course	
The elective course "Methodology of Evidence-Based Medicine" involves mastering information on the problems of the evidence-based approach in the branch of health care, and disclosure of the potential of evidence-based medicine as a technology for maintaining health and improving quality of life.	
3. The purpose and objectives of the course	
<p>1. The purpose of the elective course "Methodology of Evidence-Based Medicine" is the formation of students' knowledge of evidence-based medicine as the basis of state policy of health care and medical provision and the acquisition by future physicians of practical skills and abilities that will allow them to critically evaluate medical information for its rational and effective use in further practical activity.</p> <p>2. Learning objectives:</p> <ul style="list-style-type: none"> • to form in future doctors' professional skills of observance of principles of evidentiary practice. • the acquisition of skills in the use of information resources of evidence-based medicine in decision-making on diagnosis, treatment, and prevention of diseases. • to master the basics of statistical analysis of medical data. <p>3. Competences and learning outcomes, the formation of which provides the study of the discipline:</p>	

General competences (GC):

- GC-1 – Ability to abstract thinking, analysis and synthesis.
 GC-2 – Ability to learn and master modern knowledge.
 GC-3 – Ability to apply knowledge in practical situations.
 GC-4 – Knowledge and understanding of the subject area and understanding of professional activity.
 GC-5 – Ability to adapt and act in a new situation.
 GC-6 – Ability to make informed decisions.
 GC-7 – Ability to work in a team.
 GC-8 – Ability to interpersonal interaction.
 GC-9 – Ability to communicate in a foreign language.
 GC-10 – Ability to use information and communication technologies.
 GC-11 – Ability to search, process and analyze information from various sources.
 GC-12 – Definiteness and perseverance in terms of tasks and responsibilities.
 GC-13 – Awareness of equal opportunities and gender issues.
 GC-14 – The ability to exercise their rights and responsibilities as a member of society, to be aware of the values of civil (free democratic) society and the need for its sustainable development, the rule of law, human and civil rights and freedoms in Ukraine.
 GC-15 – Ability to preserve and multiply moral, cultural, scientific values and achievements of society based on understanding the history and patterns of development of the subject area, its place in the general system of knowledge about nature, society and in the development of society, techniques and technologies. active recreation and leading a healthy lifestyle, use different types and forms of physical activity for active recreation and a healthy lifestyle

Special (professional, subject) competences (PC):

- PC-1 – Ability to collect medical information about the patient and analyze clinical data.
 PC-11 – Ability to solve medical problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility.
 PC-13 – Ability to carry out sanitary and hygienic, preventive measures.
 PC-14 – Ability to plan and carry out preventive and anti-epidemic measures against infectious diseases.
 PC-15 – Ability to conduct an examination of working capacity.
 PC-16 – Ability to keep medical records, including electronic forms.
 PC-17 – Ability to assess the impact of the environment, socio-economic and biological determinants on the health state of the individual, family, population.
 PC-18 – Ability to analyze the activities of a doctor, subdivision, health care institution, ensure the quality of medical care and improve the efficiency of the use of medical resources.
 PC-19 – Ability to organize and integrate the provision of medical care to the population and the marketing of medical services.
 PC-20 – Ability to conduct epidemiological and medical-statistical studies of public health; processing of social, economic and medical information.
 PC-21 – Clearly and unambiguously convey their own knowledge, conclusions and arguments on health care issues and related issues to specialists and non-specialists, in particular to students.
 PC-22 – Ability to manage workflows, in the field of health care, which are complex, unpredictable and require new strategic approaches
 PC-23 – Ability to develop and implement scientific and applied projects in the field of health care.
 PC-24 – Adherence to ethical principles when working with patients, laboratory animals.
 PC-25 – Adherence to professional and academic integrity, to be responsible for the accuracy of the obtained scientific results

4. Prerequisites of the course

The elective course "Methodology of Evidence-Based Medicine" as an educational discipline:

- is based on the study of academic disciplines: history of medicine, medical informatics, ethics, hygiene and ecology, epidemiology, sociology, and medical sociology;
- lays the foundations for the study of evidence-based practice in Ukraine and world experience;
- promotes the formation of skills with the use of an evidence-based medicine database in the practical activity of the doctor.

5. Program learning results**List of learning results**

Codes of Learning Results	Description of the learning result	Reference to the code of the competence matrix of the Program learning result in the Standard of higher education

<i>K-1</i>	Knowledge of statistical and epidemiological methods. Knowledge of the requirements for diagnostic tests which can be used in screening studies.	<i>PR-1, PR-2, PR-3, PR-19, PR-20, PR-21, PR-22</i>
<i>K-2</i>	Knowledge of the sources of evidence-based medicine, the scale of gradations of the strength of evidence	<i>PR-1, PR-2, PR-3, PR-19, PR-28</i>
<i>K-2</i>	Knowledge of socio-economic and biological determinants which affect public health	<i>PR-1, PR-2, PR-3, PR-16, PR- 21. PR-23</i>
<i>K-2</i>	Knowledge of the main indicators which characterize the activity of the main types of institutions and subdivisions of health care.	<i>PR-1, PR-2, PR-3, PR-25, PR-26, PR-28</i>
<i>S-1</i>	To own the standard methods of descriptive, analytical, epidemiological, medical, and statistical research. Ability to calculate risks.	<i>PR-21, PR-22, PR-26</i>
<i>S-2</i>	Be able to determine the source and location of the required information depending on its type. Be able to process information and analyze the received information.	<i>PR-21, PR-22, PR-25, PR-27</i>
<i>S-3</i>	Ability to analyze the obtained results, to compare them with existing ones.	<i>PR-21, PR-22</i>
<i>S-3</i>	Be able to calculate and evaluate the main indicators of activity of the doctor, subdivision, and medical care institution.	<i>PR-16, PR-24, PR-26, PR-28</i>
<i>C-1</i>	Conducting epidemiological, medical, and statistical studies of public health.	<i>PR-19, PR-20, PR-29</i>
<i>C-2</i>	Decision-making is based on data from evidence-based medicine.	<i>PR-21, PR-22, PR-25, PR-27</i>
<i>C-1</i>	Assessment of the impact of risk factors on health status.	<i>PR-15, PR-19, PR-23, PR-24, PR-29</i>
<i>C-2</i>	Conducting statistical analysis of the activity of the doctor, subdivision, and health care institution.	<i>PR-15, PR-16, PR-24, PR-26, PR-28</i>
<i>AR-1</i>	Ability to formulate conclusions based on the data of medical and epidemiological research.	<i>PR-21, PR-22, PR-25, PR-27, PR-29</i>
<i>AR-2</i>	Responsibility for the completion and quality of analysis of the information and conclusions based on its analysis.	<i>PR-20, PR-21, PR-22, PR-27</i>
<i>AR-2</i>	Responsibility for the justification of the assessment of risk factors on the public health status.	<i>PR-15, PR-19, PR-23, PR-24</i>
<i>AR-3</i>	Responsibility for the justification of reasonable decisions as to the improvement of the activities of a physician, institution/subdivision, and health care facilities.	<i>PR-16, PR-24, PR-26, PR-28</i>

6. Format and scope of the course

Course Format	<i>Full-time</i>	
Type of academic classes	Number of hours	Number of groups
lectures	0	-
practical	26	23
seminars	0	-
self-study	34	23

7. Topics and description of the course

Code of occupation type	Topic	Content of learning	Code of learning result	Teacher
<i>P-1</i>	The history of development and the international experience of the evidence-based medicine	The notion of evidence-based medicine. The prerequisites of origin and foundation of evidence-based medicine. The aim and tasks of evidence-based medicine. The history of the development of evidence-based medicine. The evidence-based medicine in the clinical practice of Ukraine and countries of the world. The international experience of usage of evidence-based medicine.	<i>PR-1, PR-2, PR-15, PR-22</i>	according to the schedule of the groups
<i>P-2</i>	The basics of the statistical analysis of the medical data	The requirements for statistical data. The methods of research in evidence-based medicine. The statistical processing of data (the calculation of the average and relative values, criteria of their reliability). The statistical research. The main stages of the statistical research.	<i>PR-2, PR-3, PR-22, PR-25</i>	according to the schedule of the groups
<i>P-3</i>	The design of the	The types of the design and their characteristics. The aim and tasks of the epidemiological research. The	<i>PR-2, PR-3,</i>	according to the schedule of the

	epidemiological research	peculiarities of carrying out epidemiological research. Continuous research. The sample (randomized) studies. The representativeness of a sample. The principles of randomization. The mechanical selection. The typological (typical) selection. The serial (cluster) selection. The method of the directed selection. Accident-control. The supervisory study. The experimental study. The scientific (special) research. The routine research. The synchronous (transverse/diametrical) research. The dynamic research. The field research.	PR-22 , PR-25	groups
P-4	The epidemiological research in the health care system, their classification	The experimental research. The descriptive (estimated, uncontrolled). The analytical (controlled). The description of separate cases. The description of a series of cases. Retrospective research. Prospective research.	PR-2 , PR-21, PR-22 , PR-25	according to the schedule of the groups
P-5	The randomized controlled trial	The analysis of articles and their critical assessment. The randomized controlled investigation/trial (PCI). The double-blind trial. The drawback of the randomized controlled investigation. The systematized review and meta-analysis.	PR-3, PR-21, PR-22	according to the schedule of the groups
P-6	ROC analysis in medicine	A model of ROC-curves selection of decision rules for diagnostic tests and optimal values of diagnostic indicators of medical and biological information is proposed and substantiated. Standard criteria were used to assess the quality of diagnostic test prediction: sensitivity and specificity. To assess the significance of factor characteristics and compare the prognostic characteristics of the models used the method of constructing ROC curves and mathematical modeling. The definition of the optimal value of the diagnostic indicator at which the sensitivity of the test is equal to its specificity is found.	PR-3, PR-22, PR-25 , PR-26, PR-28	according to the schedule of the groups
P-7	Multiple regression analysis as an element of predicting the impact of risk factors	Regression analysis to predict risk factors. Types of regression analysis. Methods for verifying the reliability of the forecasting model. Factor and effective features. Graphic image of the analysis.	PR-3, PR-19, PR-20, PR-22, PR-29	according to the schedule of the groups
P-8	Modern programs for statistical analysis of medical research	Use of modern statistical programs in the field of health care. The role of official statistics in the analysis of public health, its advantages and disadvantages. The Statistica program as an open system. The SPSS program. The package of statistical programs R. Comparison of calculations and methods of graphic image in programs.	PR-3, PR-22	according to the schedule of the groups
P-9	The International Cocraine cooperation, its role in the efficiency of the medico-social intervention	The organization of the activity of the Cocraine cooperation. The logotype of the Cocraine cooperation. The basis of evidence-based medicine - randomized controlled clinical investigations - is the gold standard. The centers (groups) of the Cocraine reviews. The electronic publications of the Cocraine library. The principles of the Cocraine cooperation, the concept of three «E ».	PR-2, PR-3, PR-21 , PR-22	according to the schedule of the groups
P-10	The evidence-based prophylactics	The definition of the term «evidence-based prophylactics». The notion of dynamic observation. The system of prevention is based on the principles of evidence-based medicine. The instructions for the working group as to USPSTF prophylactics. The register of the medico-technological documents as to standardization of the medical care in the health care system (HC) of Ukraine.	PR-16, PR-19 , PR-20, PR-29, PR-21, PR-22, PR-26	according to the schedule of the groups
P-11	The screening -	The screening. The assessment of screening results.	PR-2,	according to the

	the source of information as to the public health status in epidemiological research	The screening test requirements. The sensitivity and specificity of the screening test. The sensitivity and specificity of communication. The detection of risk factors in research «accident-control». The absolute, relative, and additional population risk: the calculation method and rating. The concept of chances in epidemiology. The detection of the ratio indicator of chances in the cohort study: the calculation method and rating.	PR-3, PR-19, PR-20, PR-22, PR-29	schedule of the groups
P-12	The evidence-based medicine and marketing	The evidence-based medicine as means of promoting medical preparations. The signs of the incorrect advertising of medicines. The information that misleads the consumer. The unfair competition. The notion of the endpoint surrogate point. The development of the National medical (pharmaceutical) policy.	PR-2, PR-16, PR-21, PR-25	according to the schedule of the groups
P-13	The critical assessment of the evidence found its reliability and usefulness	The critical assessment of the evidence found (literature data), its reliability (proximity to truth), and usefulness of (clinical application); (the 3-rd stage). The main approaches in critical assessment of publications in the medical journals and other sources of information. The hierarchy of evidence in medicine. The systematic mistake. The types of systematic mistakes. The qualitative characteristics of evidence: The total/summary indicator of the methodological quality of the all-available research. The quantitative characteristics of the evidence. (volume) the size of the effect, the number of investigations, and the summary size of the selection of patients. The levels of reliability of evidence.	PR-3, PR-21, PR-22, PR-25, PR-28	according to the schedule of the groups
IWS-1	The key notions of the clinical epidemiology	The term «clinical epidemiology». The regulations of clinical epidemiology. The essence of clinical epidemiology. Death. Disease. Discomfort. Disability. Dissatisfaction. The Methodology of the evidence-based medicine. The epidemiological method. The interconnection between evidence-based medicine and clinical epidemiology and biological statistics.	PR-1, PR-2	according to the schedule of the groups
IWS-2	The ethical problems in epidemiology	The ethical standards in epidemiology. The regulations of research ethics. The ethical consideration in the study. The phenomenon of accidental discovery. The ethical problems of the placebo application in clinical trials. The International guides the ethical expert examination in epidemiological research.	PR-1, PR-2, PR-24, PR-25, PR-28	according to the schedule of the groups
IWS-3	The stages of the evidence-based medicine	The formulation of the clinical question. The systematic search of the evidence-based data. The reliability assessment of the evidence-based data, and their clinical significance. The application of the obtained results in practice.	PR-2, PR-3, PR-21, PR-22, PR-26	according to the schedule of the groups
IWS-4	The 4-component PICO system	The types of clinical questions. Anatomy of formulating questions. The meaning of the term PICO. The components of PICO: a patient, intervention, comparison, and result. The matrix for the formulation of the clinical questions. The assessment criteria of the results.	PR-2, PR-3, PR-21, PR-22	according to the schedule of the groups
IWS-5	The formulation of the clinical problem by using the PICO principle	The sphere of the clinical problem. The types of the formulated questions. The composing of the clinical questions. The shortcomings (drawbacks) of the formulated clinical question. The factors necessary for the effective solution of the clinical problem.	PR-3, PR-21, PR-28	according to the schedule of the groups
IWS-6	The advantages and disadvantages of different sources of the medical information	The content of the scientific medical literature. The search of information on the Internet by using the filters of evidence-based medicine. The structure and content of the scientific publication. The main sections of the scientific publication. The database of the public health status (the European and domestic databases	PR-2, PR-21	according to the schedule of the groups

		«Health for all»): design, filling, potentialities.		
IWS-7	The use of the obtained data in clinical practice	The use of the obtained data in practice. The introduction to the guide of the clinical practice. The definition, the need for development, and implementation. The obstacles to changing the practice. The standards of medical care to the population. The clinical recommendations are based on data from evidence-based medicine. The clinical protocols.	PR-3, PR-16, PR-18, PR-21, PR-25, PR-26, PR-28	according to the schedule of the groups
IWS-8	The principles and practice of carrying out a medical audit	The medical audit: the definition, purpose, and appointment. The principles and practice. The process of planning and conducting the audit. The clinical audit. The audit of the effectiveness of medical care. The analysis of mistakes.	PR-2, PR-3, PR-21, PR-22, PR-26, PR-28	according to the schedule of the groups
IWS-9	The role of patients in the scientific research	The adherence to the principles in carrying out the medico-biological experiment. The clinical investigations as the processing stage of the administrative decisions. The types of clinical investigations. The design of the clinical investigations. The duration of the clinical investigations.	PR-2, PR-22, PR-24, PR-25	according to the schedule of the groups
IWS-10	The rights of patients in the scientific research	How to participate in the clinical trials. The ethics of the clinical trials. The obligations of the parties. Accidents. The Helsinki declaration of the World medical association «The ethical principles of the medical investigations with human participation as the object of study».	PR-1, PR-2, PR-15, PR-24, PR-28, PR-29	according to the schedule of the groups

8. Verification of learning results

Current control

is carried out during academic classes and aims to check the knowledge of learning material by students. Forms of assessment of current educational activities include control of theoretical and practical skills. The final grade for the current academic activity is based on a 4-point (national) scale

Code of learning result	Code of occupation type	Method of verifying learning results	Evaluation criteria
AR-1, AR-2, AR-3	P-1-13	Checking a written task for extracurricular self-preparation for a practical lesson	passed / not passed
AR-1, AR-2, AR-3	IWS-1-10	Checking a written task for self-study	passed / not passed
Kn-1, Kn-2 S-1, S-2, S-3 C-1, C-2	P-1-13, IWS-10	Oral control during a practical class on topic of practical lesson and independent work	"2" - <60% of correct answers; "3" - 60-69%, "4" - 70-89%, "5" - 90-100%.
Kn-1, Kn-2 S-1, S-2, S-3 C-1, C-2	P-1-13, IWS-10	Test control during a practical lesson	"2" - <70% of correct answers; "3" - 70-79%, "4" - 80-89%, "5" - 90-100%.
Kn-1, Kn-2 S-1, S-2, S-3 C-1, C-2	P-1-13, IWS-1-10	Demonstrating practical skills of calculation of indicators	"2" - <60% of correct answers; "3" - 60-69%, "4" - 70-89%, "5" - 90-100%.
Kn-1, Kn-2 S-1, S-2, S-3 C-1, C-2	P-1-13, IWS-1-10	Demonstrating practical skills of evaluation and analysis of the study results	"2" - <60% of correct answers; "3" - 60-69%, "4" - 70-89%, "5" - 90-100%.

Final control

General evaluation system	Academic performance during the semester – 100% on a 200-point scale
Rating scales	Traditional 4-point scale, multi-point (200-point) scale, ECTS rating scale

Conditions of admission to the final control	The student attended all practical classes and received at least 120 points for classroom academic performance	
Type of final control	Methods of final control	Criteria of Evaluation
Credit	Students have to pass all topics by the thematic schedule. Grades by the 4-point scale are converted into points on a multi-point (200-point) scale following the Regulation "Criteria, rules and procedures for evaluating the results of student academic performance"	<i>The maximum number of points is 200.</i> <i>The minimum number of points is 120</i>
<p><i>The maximum number of points</i> that a student can score for the current academic performance for the semester to pass is 200 points.</p> <p><i>The minimum number of points</i> that a student has to score for the current academic performance to pass the discipline is 120 points.</p> <p><i>The calculation of the number of points</i> is based on the grades received by the student by a 4-point (national) scale during the discipline, by calculating the arithmetic mean (A), rounded to two decimal places. The resulting value is converted into points on a multi-point scale as follows:</p> $x = \frac{CA \times 200}{5}$		
9. Course policy		
During the course, teachers promote a policy of academic integrity.		
10. Literature		
<p>Basic</p> <ol style="list-style-type: none"> Gruzeva T.S., Lekhan V.M., Ognev V.A., Galienko L.I., Kryachkova L.V., Palamar B.I., Grechishkina N.V., Litvynova L.O., Gutor T.G. [etc.]. Biostatistics: a textbook for the training of specialists of the second (master's) level of higher education / edited by Prof. T.S. Gruzeva. Vin-nytsia: New Book, 2020. 384 p. The public health: textbook for students of higher educational establishments. Vinnytsia: «New book/Nova Knyha », pub. 3. 2013. 560 p. Workshop for preparation for practical classes in the academic discipline "Public Health". Lviv, 2020. Jekel's Epidemiology, Biostatistics, Preventive Medicine, and Public Health: With Student Consult. Joann G. Elmore, Dorothea Wild, Heidi D. Nelson, David L. Katz. Elsevier; 5th edition. 2020. 464 p. Oxford Textbook of Global Public Health, 6 edition. / Edited by Roges Detels, Martin Gulliford, Quarraisha Abdool Karim and Chorh Chuan Tan. Oxford University Press, 2018. 1728 p. <p>Additional</p> <ol style="list-style-type: none"> Brigitte Baldi, David S. Moore Practice of Statistics in the Life Sciences Fourth Edition. W. H. Freeman; Fourth edition. 2018. 768 p. Board Review in Preventive Medicine and Public Health. Gregory Schwaid. Elsevier, 2017. 450 p. Liam J. Donaldson, Paul Rutter. Donaldson`s Essential Public Health, Fourth Edition. CRC Press, Taylor&Francis Group, 2017. 374 p. The Legislation of Ukraine. The electronic resource: zakon.rada.gov.ua/ The medical legislation of Ukraine. The electronic resource: http://mozdocs.kiev.ua/ The statistical data of Ukraine. The electronic resource: http://www.ukrstat.gov.ua/ The statistical data of the Lviv region. The electronic resource: https://www.lv.ukrstat.gov.ua/ The center of public health WHC of Ukraine (Ministry of Health of Ukraine): https://phc.org.ua/ The Ukrainian database of medico-statistical information «Health for all»: http://medstat.gov.ua/ukr/news.html?id=203 The World Health Organization www.who.int The European Regional Bureau of WHO www.euro.who.int/ru/home The Kokhranivsky centre of evidence-based medicine www.cebm.net The Kokhranivsky library www.cochrane.org The National medical library of the USA – MEDLINE PubMed www.ncbi.nlm.nih.gov/PubMed The Canadian evidence-based centre of public care www.cche.net The Centre of control and disease prevention www.cdc.gov The Journal British Medical Journal www.bmj.com The Journal Evidence-Based Medicine www.evidence-basedmedicine.com 		
11. Equipment, logistics, and software of the course		
<ul style="list-style-type: none"> Curriculum, thematic schedules of lectures, seminars, and independent extracurricular activities Educational and methodical recommendations on the topic of the lesson (theoretical presentation of the topic of the lesson, control questions, situational tasks for independent work, and a list of recommended references); Textbooks and manuals from the library Computer and multimedia projector. 		
12. Additional information		
All the necessary information for the educational process – thematic schedules of classes and extra classes, guidelines for		

practical classes, independent work of students, and test control of knowledge are available in Misa.

Syllabus compiler

Asst. Litvinyak Ruslan Ihorovych

Head of the department

Assoc. Prof., Ph.D. Gutor T.H.