PRIVATE HIGHER EDUCATIONAL INSTITUTION "INTERNATIONAL ACADEMY OF ECOLOGY AND MEDICINE" Department of social medicine and humanitarian disciplines

"APPROVED"

Head of Department
Lyudmila DUDARENKO
"31" August 2022

WORKING PROGRAM OF EDUCATIONAL DISCIPLINE

" Biostatistics and clinical epidemiology " (Elective course)

LEVEL OF HIGHER EDUCATION Second (master's) level DEGREE OF HIGHER EDUCATION Master's degree BRANCH OF KNOWLEDGE 22 Healthcare SPECIALTY 222 Medicine

Reviewed and approved at the meeting of the department of social medicine and humanitarian disciplines Protocol No. 1 dated August 31, 2022 Working program of educational discipline **Biostatistics and clinical epidemiology** for the preparation of students of higher education of the second (master's) level of higher education in specialty 222 Medicine.

Developer: V.M. Kovalenko, Phd in medicine.

Agreed

The first vice-rector

Oleksandra SOROKA

INTRODUCTION

The program in the academic discipline "Biostatistics and clinical epidemiology" is compiled in accordance with the educational and professional program for training specialists of the second (master's) level of the specialty 222 Medicine, fields of knowledge 22 Health care, the Law of Ukraine "On Higher Education" dated 07.01.2014 No. 1556-VII (Article 13, Clause 7), the provision "On the organization of the educational process at the International Academy of Ecology and Medicine" PVZ, methodical recommendations approved by the Central Methodical Office of Higher Medical Education of the Ministry of Health of Ukraine regarding the development of programs of educational disciplines in accordance to industry standards of higher education. The discipline "Safety of life" belongs to the Professional training section of the training plan for students of higher education of the second educational (master's) level.

Description of the academic discipline

2 escription of the academic discipline					
Name of indicators	Field of knowledge, specialty. level of higher	Characteristics of the academic discipline			
	education	full-time education			
. C 1'4. ' . 1 5	Branch of knowledge:				
of credits is 1.5	22 Healthcare				
Sections - 1		Year of preparation:			
Content sections - 1	Specialty:	1st			
	222 Medicine	Semester			
of hours is 45		I - th			
		Lectures			
		10 hours			
		Seminary			
		10 hours			
	Educational level: Master of				
	Medicine	Independent (individual)			
	iviculence	work			
		25 hours			
		Type of control: current and final			
		control			

The subject of study of the academic discipline is modern principles of evidence-based medicine, theoretical and methodological foundations of biostatistics.

Interdisciplinary connections: educational the discipline is integrated with such disciplines as biophysics with a course of higher mathematics, medical informatics and computer technology.

1. PURPOSE AND OBJECTIVES OF THE EDUCATIONAL DISCIPLINE

- 1.1. The goal of teaching the academic discipline "Biostatistics and Clinical Epidemiology" is to train specialists who would have sufficient knowledge and skills to generalize and analyze medico-biological, clinical and environmental data.
 - 1.2. The main tasks of studying the academic discipline "Biostatistics and clinical epidemiology" are:
- mastering the theoretical foundations of biostatistics;
- mastering modern principles of evidence-based medicine;
- familiarization with methods of definition and analysis of basic biostatistical indicators and criteria;
- mastering the methodological and theoretical foundations of the formation of statistical aggregates for their further adequate analysis;
- mastering the principles of analysis and evaluation of results according to individual criteria and in relation to the factors affecting them.
 - 1.3. According to the requirements of the educational and professional program, students must:

know:

- definition of biostatistics as an educational discipline and its role in the system of evidence-based medicine;
- theoretical and methodological foundations of biostatistics;
- basic organizational elements of statistical research;
- methodological bases and criteria for choosing the main adequate methods of analysis for testing statistical hypotheses;
- theoretical and methodical bases of analysis of statistical results, their evaluation and description in order to form reasonable conclusions;

be able:

- to determine the tactics of statistical research organization, experiment planning;
- determine the necessary methods of statistical processing of research data;
- calculate statistical indicators, parameters of statistical aggregates;
- prevent, diagnose and correct statistical errors;
- determine the methods of graphic representation of the results of statistical analysis;
- evaluate and analyze statistical indicators and parameters of statistical aggregates;
- use applied methods of biostatistics for data analysis;
- determine strategies for searching for medical information; organization and conduct of meta-analysis;
- to develop plans for statistical analysis of the activity of the medical institution.

Students are recommended to keep records of completed tasks.

45 hours, 1.5 ECTS credits are allocated to the study of the academic discipline.

The structure	Num	ber of hou	rs, of them				
of the	hours in	classrooms		Year of	type of control		
academic	general/	Lastumas	practical	S.S.	study	type of control	
discipline	ECTS credits	lectures	classes				
Module 1	45/1.5	10	20	15	4th	current, final	

Note: 1 ECTS credit – 30 hours Auditory load – 66.7%, S.S. – 33.3%.

2. INFORMATION VOLUME OF THE EDUCATIONAL DISCIPLINE

TOPIC 1. The concept and role of biostatistics as the main component of the evidence-based medicine system.

Definition of the terms "biostatistics", "evidence-based medicine", "clinical epidemiology". The main stages of the development of biostatistics. Outstanding scientists and their contribution to the development of biostatistics.

Basic principles of evidence-based medicine. Triad of evidence-based medicine. Theory and practice of evidence-based medicine. Evidence-based medicine and quality of clinical research. Concept of final results. Evidence-based medicine and quality of medical care. Standardization of medical care: clinical protocols, standards and recommendations.

The place and role of biostatistics in medical education and the work of a practicing physician.

TOPIC 2. Methodological foundations of the organization of statistical research in the health care system.

Organization of statistical research. Principles of forming statistical populations for analysis. Concept of general and selective population.

Classification of data types. Quantitative and qualitative data. Characteristics of measurement scales. General characteristics of methods of statistical analysis, features of their use. Generalization of statistical research results. Assessment of the probability of the obtained results. Concept of null and alternative hypothesis. Hypothesis testing. Error of the 1st and 2nd kind.

Typical mistakes at the stages of conducting research. Random and systematic error. Databases for analysis of statistical material, aspects of working with data. Statistical research software .

TOPIC 3. Epidemiological studies in health care, their characteristics and analysis. Risk factors.

The goals and objectives of epidemiology. History of epidemiology. Modern concept of epidemiology. Classification of epidemiological studies. Comparative characteristics of various types of research, assessment of the degree of evidence of their results. Retrospective and prospective studies.

Empirical studies. Descriptive epidemiology: description of a single case and case series. Analytical epidemiological studies. Cohort and case-control studies. Screening and requirements for screening tests. Sensitivity and specificity of the screening test.

Risk factors. Risk indicators: absolute, relative and additional population risk. Odds. Odds ratio indicator.

TOPIC 4. Clinical epidemiology. Modern principles and rules of clinical research.

Definition of the concept of clinical epidemiology. The main stages of its development. Basic principles and provisions of clinical epidemiology. The purpose of clinical and epidemiological studies and the quality of their organization.

Design of clinical studies. Types of designs. Research ethics. Inclusion and exclusion criteria from the study. Types of control. Blinding of the study. The role of a biostatistics specialist in the organization and conduct of research. Clinical research protocol.

Controlled clinical trials. Randomization and stratification. A randomized controlled clinical trial is the gold standard of research. Generalization of clinical research results. Analytical reviews. The concept of meta-data. Systematic reviews and meta-analysis. The Cochrane Collaboration: History and Activities.

TOPIC 5. Information provision of epidemiological and clinical studies. The role of official statistics in the analysis of population health.

Medical information. Types of information service. A doctor is a consumer and supplier of medical information. Information provision of epidemiological and clinical studies. Scientific and medical libraries.

Theoretical foundations of medical statistics. Medical statistics: subject, content and tasks. Sections of medical statistics. The system of the medical and statistical service in Ukraine: construction principles, activities, information flows. Information and analytical activity of health care institutions. Sources of statistical information: accounting and reporting documentation, databases, registers and directories.

Using the questioning method in the field of health care. Types of questionnaires, their characteristics. Modern approaches to the analysis and evaluation of the quality of life. The role of official

statistics in the analysis of population health, its advantages and disadvantages. Development prospects. Electronic document accounting. Telemedicine.

World health statistics. The role of the World Health Organization in information provision. European database "Health for all".

TOPIC 6. Planning and organization of statistical research.

Theory and concept of statistical observation, stages of its implementation. Methodological foundations, forms and methods of statistical observation and data collection. Accuracy of observations. Use of different measurement scales: absolute, ordinal, interval, ratios.

Sources of statistical information. Types of statistical data, statistical reporting. Marketing and sociological surveys, types of questions in questionnaires, problems of organizing surveys in health care. Types of sample research. Requirements for the formation of a sample population. Concepts of randomization and stratification. Design of clinical studies.

Grouping of statistical data, methods, values. Types of groupings, principles of building statistical groupings and classifications. Comparison of statistical groupings. Concept of multidimensional classifications. Statistical tables, their characteristics, types, construction rules. Methodical basics of reading and analyzing tables. The concept of non-numerical data, qualitative characteristics.

TOPIC 7. Relative values (statistical coefficients). Graphic methods of analysis.

Concept of statistical indicators, their types, form of presentation. Absolute data, relative values, their practical significance. Types of relative values, methods of their calculation and methodical bases of application for data analysis.

Concepts and types of structure of medical and biological data, structural changes, features of their analysis. Graphic methods of data analysis. Types of diagrams, rules for their construction.

TOPIC 8. Characterization and analysis of a statistical population. Average values and indicators of variation.

Average values in clinical and epidemiological studies, their practical significance. Elements and characteristics of variational series. Average values: their types, methods of calculation, features of use.

The concept of variation, its meaning. Variability of population parameters, assessment methods. Absolute indicators of variation (amplitude, mean square deviation) and relative indicators of variation (coefficients of variation and determination), their assessment.

Measures of variation, concepts of distribution laws, their types, characteristics. Estimation of normality of distribution, "jumping out" options. The rule of "three sigma", its practical use.

TOPIC 9. Method of standardization.

Problems of comparison of statistical indicators in heterogeneous populations. Types of standardization methods: direct, indirect, reverse. Characteristics of the stages of the standardization method.

Formulation of the null hypothesis. Selection and calculation of the standard. Calculation of expected numbers. Calculation of standardized indicators. Null hypothesis testing, evaluation of results. Practical significance of the standardization method.

TOPIC 10. Parametric methods of evaluation and analysis of statistical hypotheses .

Selective observation as a source of statistical information. Null and alternative hypotheses. Errors of the first and second kind. The level of significance of statistical criteria. Average error of mean and relative value, confidence interval.

Estimation of the probability of difference: t - Student's criterion, calculation method, its evaluation, typical errors of use. Paired and multiple comparisons. Newman-Keuls criterion, Tukey's criterion.

TOPIC 11. Non-parametric methods of evaluation and analysis of statistical hypotheses.

Justification of cases of use of non-parametric assessment methods, their significance. Types of compared populations, their characteristics. Analysis and evaluation of results in related populations, sign test, Wilcoxon test.

Statistical hypothesis testing for independent samples, Kolmogorov-Smirnov test. Analysis of qualitative features. Conjugation tables. Chi-square criterion, its evaluation and practical application. Fisher's exact test. Peculiarities of using other non-parametric criteria: Mann-Whitney, Kruskal-Wallis.

TOPIC 12. Analysis of the relationship between the studied parameters of statistical populations .

Studying the relationship between quantitative variables. The concept of functional and correlational connection. Strength and direction of communication. Types of correlation coefficients. Pearson's linear correlation coefficient, its evaluation, characteristics.

Non-parametric methods of relationship assessment - Spearman's rank correlation coefficient. Pair and multiple correlation coefficients. Regression analysis, regression coefficient, regression equation. Using regression analysis for forecasting.

TOPIC 13. Screening: evaluation of the accuracy of screening tests. Risk factors: method of calculating and assessing risks.

Screening: general scheme and purpose of conducting. Screening tests. Assessment of sensitivity and specificity of screening tests.

Concept of risk factors. Practical use of risk assessment techniques in epidemiological studies. Cohort and case-control studies. Risk indicators, methods of their calculation and analysis. Absolute, additional risk. Relative risk, additional population risk. Odds ratio.

TOPIC 14. Series of dynamics and their analysis.

Basic rules of construction and analysis of dynamic series when studying the dynamics of medical and biological phenomena. Series levels. Types of dynamics series: simple and complex, interval and instantaneous. The main indicators of dynamic series analysis: absolute growth, growth/decrease rate, growth rate.

The main methods of processing a dynamic series in order to determine the trend. Dynamic series alignment methods: least squares; variable mean, averaging on the left and right sides; increasing intervals.

Study and measurement of seasonal fluctuations in series of dynamics. Correspondence of dynamic series. Interpolation and extrapolation in series of dynamics. Forecasting based on extrapolation of dynamics series.

TOPIC 15. Final modular control.

3. STRUCTURE OF THE EDUCATIONAL DISCIPLINE

1. The concept and role of biostatistics as the main component of the evidence-based medicine system. 2. Methodological foundations of the organization of statistical research in the health care system. 3. Epidemiological studies in health care, their characteristics and analysis. Risk factors. 4. Clinical epidemiology. Modern principles and rules of clinical research. 5. Information provision of epidemiological and clinical studies. The role of official statistics in the analysis of population health. 6. Planning and organization of statistical research 7. Relative values (statistical coefficients). Graphic methods of analysis. 8. Characteristics and analysis of statistical data. Average values and indicators of variation. 9. Method of standardization. 10. Parametric methods of estimation and analysis of statistical hypotheses. 11. Non-parametric methods of estimation and analysis of statistical hypotheses. 12. 1 13. Analysis of the relationship between the studied parameters of statistical populations. 14. Dynamics series and their analysis. 15. Final modular control 16. Pinal modular control 17. Pinal modular control 18. Correcting: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks. 19. Dynamics series and their analysis. 10. Correcting: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks. 19. Dynamics series and their analysis. 10. Dynamics series and their analysis. 11. Total hours - 45 11. ECTS credits - 1.5	No	Topics	Lectures	Practical training	S.S.
2	1.		2	-	0.5
3. factors.2-0.54. Clinical epidemiology. Modern principles and rules of clinical research.2-0.55. Information provision of epidemiological and clinical studies. The role of official statistics in the analysis of population health.2-0.56. Planning and organization of statistical research-217. Relative values (statistical coefficients). Graphic methods of analysis218. Characteristics and analysis of statistical data. Average values and indicators of variation219. Method of standardization2110. Parametric methods of estimation and analysis of statistical hypotheses2111. Non-parametric methods of estimation and analysis of statistical hypotheses2112. Analysis of the relationship between the studied parameters of statistical populations2113. Screening: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks2114. Dynamics series and their analysis2115. Final modular control-22Implementation of S.S1.5Total hours - 45102015	2.		2	1	0.5
5.Information provision of epidemiological and clinical studies. The role of official statistics in the analysis of population health.2-0.56.Planning and organization of statistical research-217.Relative values (statistical coefficients). Graphic methods of analysis218.Characteristics and analysis of statistical data. Average values and indicators of variation219.Method of standardization2110.Parametric methods of estimation and analysis of statistical hypotheses2111.Non-parametric methods of estimation and analysis of statistical hypotheses2112.Analysis of the relationship between the studied parameters of statistical populations2113.Screening: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks2114.Dynamics series and their analysis2115.Final modular control-22Implementation of S.S1.5Total hours - 45102015	3.	• •	2	ı	0.5
3.statistics in the analysis of population health.2-0.56.Planning and organization of statistical research-217.Relative values (statistical coefficients). Graphic methods of analysis218.Characteristics and analysis of statistical data. Average values and indicators of variation219.Method of standardization2110.Parametric methods of estimation and analysis of statistical hypotheses2111.Non-parametric methods of estimation and analysis of statistical hypotheses2112.Analysis of the relationship between the studied parameters of statistical populations2113.Screening: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks2114.Dynamics series and their analysis2115.Final modular control-22Implementation of S.S1.5Total hours - 45102015	4.	Clinical epidemiology. Modern principles and rules of clinical research.	2	ı	0.5
7.Relative values (statistical coefficients). Graphic methods of analysis218.Characteristics and analysis of statistical data. Average values and indicators of variation219.Method of standardization2110.Parametric methods of estimation and analysis of statistical hypotheses2111.Non-parametric methods of estimation and analysis of statistical hypotheses2112.Analysis of the relationship between the studied parameters of statistical populations2113.Screening: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks2114.Dynamics series and their analysis2115.Final modular control-22Implementation of S.S1.5Total hours - 45102015	5.		2	-	0.5
7.Relative values (statistical coefficients). Graphic methods of analysis218.Characteristics and analysis of statistical data. Average values and indicators of variation219.Method of standardization2110.Parametric methods of estimation and analysis of statistical hypotheses2111.Non-parametric methods of estimation and analysis of statistical hypotheses2112.Analysis of the relationship between the studied parameters of statistical populations2113.Screening: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks2114.Dynamics series and their analysis2115.Final modular control-22Implementation of S.S1.5Total hours - 45102015	6.	Planning and organization of statistical research		2	1
8. variation 2 1 9. Method of standardization 2 1 10. Parametric methods of estimation and analysis of statistical hypotheses 2 1 11. Non-parametric methods of estimation and analysis of statistical hypotheses 2 1 12. Analysis of the relationship between the studied parameters of statistical populations 2 1 13. Screening: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks 2 1 14. Dynamics series and their analysis 2 1 15. Final modular control - 2 2 Implementation of S.S 1.5 Total hours - 45	7.		_	2	1
10.Parametric methods of estimation and analysis of statistical hypotheses2111.Non-parametric methods of estimation and analysis of statistical hypotheses2112.Analysis of the relationship between the studied parameters of statistical populations2113.Screening: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks2114.Dynamics series and their analysis2115.Final modular control-22Implementation of S.S1.5Total hours - 45102015	8.		1	2	1
11.Non-parametric methods of estimation and analysis of statistical hypotheses2112.Analysis of the relationship between the studied parameters of statistical populations2113.Screening: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks2114.Dynamics series and their analysis2115.Final modular control-22Implementation of S.S1.5Total hours - 45102015	9.	Method of standardization.	-	2	1
11.Non-parametric methods of estimation and analysis of statistical hypotheses2112.Analysis of the relationship between the studied parameters of statistical populations2113.Screening: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks2114.Dynamics series and their analysis2115.Final modular control-22Implementation of S.S1.5Total hours - 45102015	10.	Parametric methods of estimation and analysis of statistical hypotheses.	-	2	1
populations. Screening: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks. 14. Dynamics series and their analysis. 15. Final modular control Implementation of S.S. Total hours - 45	11.		-	2	1
13. calculating and assessing risks. - 2 1 14. Dynamics series and their analysis. - 2 1 15. Final modular control - 2 2 Implementation of S.S. - - 1.5 Total hours - 45 10 20 15	12.		-	2	1
15. Final modular control - 2 2 Implementation of S.S. - - 1.5 Total hours - 45 10 20 15	13.		-	2	1
Implementation of S.S.	14.		-	2	1
Total hours - 45 10 20 15	15.	Final modular control	-	2	2
		Implementation of S.S.	-	-	1.5
ECTS credits – 1.5			10	20	15
		ECTS credits – 1.5			

Audit. work – 66.7%, S.S. – 33.3%

4. THEMATIC PLAN OF LECTURES ON THE DISCIPLINE

No	Topic name	Number of hours
1.	The concept and role of biostatistics as the main component of the evidence-based medicine system.	2
2.	Methodological foundations of the organization of statistical research in the health care system.	2
3.	Epidemiological studies in health care, their characteristics and analysis. Risk factors.	2
4	Clinical epidemiology. Modern principles and rules of clinical research.	2
5	Information provision of epidemiological and clinical studies. The role of official statistics in the analysis of population health.	2
	In total	10

5. THEMATIC PLAN OF PRACTICAL CLASSES IN THE DISCIPLINE

No	Topic name	Number of hours
1.	Planning and organization of statistical research	2
2.	Relative values (statistical coefficients). Graphic methods of analysis.	2
3.	Characteristics and analysis of statistical data. Average values and indicators of variation.	2
4.	Method of standardization.	2
5.	Parametric methods of estimation and analysis of statistical hypotheses.	2
6.	Non-parametric methods of estimation and analysis of statistical hypotheses.	2
7.	Analysis of the relationship between the studied parameters of statistical populations.	2
8.	Screening: assessing the accuracy of screening tests. Risk factors: method of calculating and assessing risks.	2
9.	Dynamics series and their analysis.	2
10.	Final modular control	2
	In total	20

6. THEMATIC PLAN OF STUDENTS' INDEPENDENT WORK

No	TOPIC	Number of hours	type of control
1.	Preparation for practical classes – theoretical preparation and development of practical skills	9	Current control. Checking tasks.
2.	Independent processing of lecture topics	2.5	Current control Final modular control
3.	Implementation of S.S. on the selected topic	1.5	Checking the work
4.	Preparation for the final modular control	2	Final modular control
	In total	15	

EXECUTION OF INDEPENDENT (INDIVIDUAL) STUDENT WORK

Students are invited to do **independent (individual) work (S.S.)** on one of the proposed topics, that are not included in the plan of classroom lessons (in writing or in printed form, at least 10 pages with pictures, tables), using the knowledge obtained from the discipline, statistical data, scientific literature, Internet resources. The structure of the S.S. should be similar to a scientific article, that is, it should contain: the plan, relevance and purpose of the study, the main results of the study, conclusions, a list of references, as well as examples of the use of statistical methods. Completion of S.S. is not mandatory. A list of topics for performing S.S. is attached.

7. INDIVIDUAL TASKS FOR PERFORMING S.S.

- 1. Concept of accuracy of statistical observation. Measurement scales (absolute, ordinal, interval, ratios). Use in medical practice.
- 2. Survey method. Rules for compiling questionnaires, types of questions. Sociological and marketing surveys. Problems of organizing surveys in health care.
- **3.** Types of groupings. Principles of construction of statistical groupings and classifications. Comparison of statistical groupings. Concept of multidimensional classifications.
- 4. The concept of non-numerical data, qualitative characteristics. The specifics of the analysis of point estimates.
- 5. Concepts and types of structure of medical and biological data, structural changes, features of their analysis.
- **6.** Practical use of risk assessment methods in medicine.
- 7. Problems of comparison of statistical indicators.
- **8.** The main methods of processing a dynamic series in order to determine the trend. Correspondence of dynamic series. Interpolation and extrapolation in series of dynamics.
- 9. Relative indicators of variation: coefficients of variation and determination, their use in medical research.
- 10. The concept of laws of distribution, their types, characteristics. The role of distribution estimation for statistical analysis of medical research data.
- 11. Methods of assessing the normality of the distribution. The importance of assessing the normality of the distribution in clinical research.
- 12. Null and alternative hypotheses. Errors of the first and second kind, their significance for evaluating research results in medicine.
- **13.** Typical errors in the use of the dent criterion in medical research.
- **14.** Problems of using statistical methods for processing data obtained in a small sample (on a small number of observations) in medical practice.
- 15. Justification of cases of use of non-parametric methods of assessing the probability of research results in medicine.
- **16.** Regression analysis, regression coefficient, regression equation. Using regression analysis to predict health status.
- 17. Concept of cluster analysis. Examples of use in medical practice.
- **18.** The concept of variance and multivariate analysis (ANOVA/MANOVA). Examples of use in medical practice.
- 19. Modern problems of organization and conduct of clinical research.
- **20.** Implementation of evidence-based medicine in clinical practice (on the example of a separate clinical discipline).
- 21. The importance of assessing the sensitivity and specificity of methods used in clinical research.
- 22. Meta-analysis. Modern examples of use in clinical medicine.
- 23. The "gold standard" of conducting clinical research: history and modernity.
- **24.** Biostatistical approaches to the design of a journal publication in the field of medicine: requirements, quality criteria, typical errors.

8. CONTROL METHODS

Current control is carried out at each practical lesson in accordance with the specific goals of the topic, during the individual work of the teacher with the student for those topics that are not included in the structure of the practical lesson and which the student works on independently. It is recommended to apply types of objective (standardized) control of theoretical and practical training of students.

The final module control is credited to the student, if he has demonstrated mastery of practical skills and scored at least 50 points while learning theoretical training.

List of questions for preparing students for the final module control

- 1. Theory and concept of statistical observation, stages of its implementation.
- 2. Design of clinical studies. Sources of statistical information.
- 3. Design of clinical studies. Control group. Blinding of the study.
- **4.** Types of clinical research design. Research ethics.
- **5.** Required sample size. Inclusion and exclusion criteria.
- **6.** Selection of the research object, concepts of randomization and stratification.
- 7. Grouping of statistical data. Types of groupings. Coding and encryption of statistical data.
- **8.** Statistical tables, their characteristics, types, construction rules.
- **9.** Selective observation as a source of statistical information. Sampling requirements.
- 10. Types of statistical observation over time. Prospective and retrospective studies.
- 11. Types of statistical monitoring of the completeness of accounting. Concept of general and selective population.
- 12. Methods of collecting statistical material. Rules for compiling questionnaires. Open and closed questions.
- 13. Absolute data, relative values, their practical significance.
- 14. Graphic methods of data analysis. Types of diagrams, rules for their construction.
- 15. Indicators of ratio and transparency, their calculation method and methodical basis of application for data analysis.
- **16.** Intensive and extensive indicators, methods of their calculation and methodical basis of application for data analysis.
- 17. Average values in clinical and epidemiological studies, their types, practical significance, calculation methods.
- 18. The concept of variation, its meaning. Variability of population parameters, assessment methods.
- 19. Indicators of variation: mean square deviation, coefficient of variation.
- 20. Normal distribution of numbers. The rule of three sigma. Amplitude of the variation series.
- 21. Analysis and evaluation of results in related populations, sign test, Wilcoxon test.
- 22. Statistical hypothesis testing for independent samples. Chi-square correspondence criterion, its evaluation and practical application.
- 23. Justification of cases of use of non-parametric methods of probability assessment, their significance.
- **24.** Estimation of the probability of difference: Student's criterion, calculation method, its evaluation, typical errors of use.
- 25. Average error of mean and relative value, confidence interval.
- **26.** Functional and correlational connection. Types of correlation coefficients.
- **27.** Correlation-regression relationship. Direction and strength of connection.
- 28. Correlation-regression relationship. Pair and multiple correlation coefficients.
- **29.** Regression analysis, regression coefficient, regression equation. Using regression analysis for forecasting.
- 30. Linear correlation coefficient, its evaluation, characteristics and features of use .
- 31. Rank correlation coefficient, its assessment, characteristics and features of use.
- 32. Methods of standardization, stages of the direct method of standardization.
- 33. Practical significance of the standardization method, assessment of standardized indicators.
- **34.** Stages of the direct method of standardization. Rules for choosing and calculating the standard.
- **35.** Types of dynamics series. Basic rules of construction and analysis of dynamic series. Alignment of dynamic series. The moving average method.
- **36.** Alignment of dynamic series. Method of averaging on the left and right halves.
- 37. The main indicators of dynamic series analysis. Methodology of calculation and assessment.

- **38.** Analysis of the dynamics of medical and social phenomena for further forecasting, concepts of extrapolation and interpolation.
- **39.** Concept of risk in epidemiological studies. Concept of risk factors. About the main risk factors affecting public health.
- **40.** Absolute and relative risk indicators, methods of their calculation and analysis.
- 41. The concept of chance in epidemiological studies. Odds ratio indicator, method of calculation and analysis.
- **42.** Clinical epidemiology. Basic principles and provisions. Hierarchy of clinical research evidence.
- **43.** Concept of null hypothesis. Statistical hypothesis testing. Errors of the first and second kind.
- 44. Screening. Basic characteristics of screening tests. Specificity and sensitivity of the screening test.
- 45. Empirical and experimental epidemiological studies. Cohort and case-control studies.
- **46.** Evidence-based medicine. History, main provisions, areas of application. Triad of evidence-based medicine. Cochrane collaboration.
- **47.** Data types. The concept of measurement scales. Meta data. The concept of systematic reviews and meta-analysis.
- **48.** The subject and tasks of medical statistics. Organization of the medical statistics service in Ukraine. Tasks of the information and analytical department of the health care institution. The concept of accounting and reporting documentation.

9. DISTRIBUTION OF POINTS RECEIVED BY STUDENTS

Assessment of current educational activities. During the assessment of mastery of each topic for the current educational activity, the student is given grades on a 4-point (national) grading scale. At the same time, all types of work provided for by the discipline program are taken into account. The student must receive a grade in each topic. Estimates given on a traditional scale are converted into points. The final grade for the current educational activity is recognized as an arithmetic average (the sum of grades for each class is divided by the number of classes in the semester) and is converted into points according to Table 1.

Table 1. Recalculation of the average grade for the current activity into a multi-point scale (for disciplines ending with a differential credit)

4-	120	4-	120	4-	120	4-	120-point
point	-point	point	-point	point	-point	point	scale
scale	scale	scale	scale	scale	scale	scale	
5	120	4.45	107	3.91	94	3.37	81
4.95	119	4.41	106	3.87	93	3.33	80
4.91	118	4.37	105	3.83	92	3.29	79
4.87	117	4.33	104	3.79	91	3.25	78
4.83	116	4.29	103	3.74	90	3.2	77
4.79	115	4.25	102	3.7	89	3.16	76
4.75	114	4.2	101	3.66	88	3.12	75
4.7	113	4.16	100	3.62	87	3.08	74
4.66	112	4.12	99	3.58	86	3.04	73
4.62	111	4.08	98	3.54	85	3	72
4.58	110	4.04	97	3.49	84	Les	Not
4.54	109	3.99	96	3.45	83	s than 3	enough
4.5	108	3.95	95	3.41	82		

The maximum number of points that a student can score for the current educational activity for admission to the diff. credit is 120 points.

The minimum number of points that a student must score for the current educational activity for admission to the diff. the credit is 72 points. The calculation of the number of points is carried out on the basis of the grades received by the student on a 4-point (national) scale during the study of the discipline, by calculating the arithmetic mean (CA), rounded to two decimal places.

Assessment of individual student tasks. Points for individual tasks are awarded only under conditions of their successful completion and defense. The number of points awarded for different types of individual tasks depends on their volume and importance, but no more than 10-12 points. They are added to the sum of points scored by the student in classes during the current educational activity. In no case can the total amount for the current activity exceed 120 points.

Assessment of students' independent work. Students' independent work, which is provided for by the topic of the lesson along with classroom work, is evaluated during the current control of the topic in the corresponding lesson. The mastery of topics that are presented only for independent work is checked during the final control.

The maximum number of points that a student can score while taking the diff. credit is 80 points.

The evaluation of the final control is considered passed if the student scored at least 60% of the maximum number of points (for a 200-point scale – at least 50 points).

Determination of the number of points scored by the student in the discipline: the number of points scored by the student in the discipline is defined as the sum of points for the current educational activity and for the final control (dif. credit).

Conversion of the number of points from the discipline into grades on the ECTS scale and on the four-point (traditional) scale

Subject scores are independently converted to both the ECTS scale and the national grading scale, but not vice versa. Table 2.

Criteria for setting the assessment according to the traditional 4-point and ECTS scale for taking the exam:

Score in points	Rating by national scale	Rating according to the ECTS scale
180-200	Perfectly	A
160-179	Fine	В
150-159	rine	С
130-149	Satisfactorily	D
120-129		E
50-119		FX
0-49	Unsatisfactorily	F

Evaluation criteria.

During the evaluation of the mastery of each topic for the current educational activity, the higher education applicant is given grades according to the national (traditional) scale, taking into account the approved evaluation criteria:

- grade "excellent" (5) the student perfectly mastered the theoretical material of the topic of the lesson, demonstrates deep and comprehensive knowledge of the relevant topic, the main provisions of scientific primary sources and recommended literature, thinks logically and constructs an answer, freely uses the acquired theoretical knowledge when analyzing practical material, expresses his attitude to certain problems, demonstrates a high level of assimilation of practical skills;
- grade "good" (4) the student has well mastered the theoretical material of the lesson, has the main aspects from primary sources and recommended literature, explains it in a reasoned way; possesses practical skills, expresses his thoughts on certain problems, but certain inaccuracies and errors are assumed in the logic of the presentation of theoretical content or in the performance of practical skills;
- grade "satisfactory" (3) the student has basically mastered the theoretical knowledge of the subject, orients himself in primary sources and recommended literature, but answers unconvincingly, confuses

concepts, additional questions cause the student uncertainty or lack of stable knowledge; when answering questions of a practical nature, reveals inaccuracies in knowledge, does not know how to evaluate facts and phenomena, connect them with future activities, makes mistakes when performing practical skills;

rating "unsatisfactory" (2) - the student has not mastered the educational material of the topic, does not know scientific facts, definitions, hardly orients himself in primary sources and recommended literature, lacks scientific thinking, practical skills are not formed.

Estimates given on a traditional scale are converted into points. The minimum number of points that a student must score for the current academic activity per semester for admission to the exam is 120 points.

10. RECOMMENDED LITERATURE

Basic literature

- 1. Biostatistics / in general ed. V.F. Moskalenka K.: Book Plus, 2019. 184 p.
- 2. Social medicine and organization of health care '(for students of stomatological faculties of higher medical educational institutions of Ukraine IV level of accreditation) / by general ed. Moskalenko V.F. K.: Book plus, 2018. 328 p.
- 3. Social medicine and the organization of health care '/ under general ed. Yu.V. Voronenko, V.F. Moskalenka Ternopil: Ukrmedknyga, 2020. 680 p.
- 4. Program test questions on social medicine and health care organization / edited by Yu.V. Voronenka Ternopil: Ukrmedknyga, 2019. 316 p.
- 5. Handbook of social medicine and health care organization / edited by Yu.V. Voronenko K.: "Health", 2020. 359 p.

Supporting literature

- 1. Public health / edited by V.F. Moskalenka Vinnytsia, "New Book". 2012. 560 p.
- 2. Albom A., Norell S. Introduction to modern epidemiology. Tallinn, 1996. 122 p.
- 3. Vlasov V.V. Introduction to evidence-based medicine. M.: Media Sphere, 2001. 392 p.
- 4. Gerasimov A.N. Medical statistics. M.: LLC "Medical Information Agency", 2007. 480 p.
- 5. Glantz S. Medical and biological statistics. M.: Practice, 1999. 459 p.
- 6. Zaitsev V.M., Liflyandskyi V.G., Marynkin V.I. Applied medical statistics. St. Petersburg: LLC "Izdatelsto FOLIANT", 2003. 432 p.
- 7. Lakin G.F. Biometrics: Textbook. manual for biol. special University 4th ed., revised. and additional M.: Vyssh. Shk., 1990. 352 p.
- 8. Lekhan V.M., Voronenko Yu.V. etc. Epidemiological methods of studying non-infectious diseases (for VMNH III IV levels of accreditation). Dnipropetrovsk, Kyiv, 2004.
- 9. General theory of statistics: Textbook / Ed. member-correspondent RAN I.I. Eliseeva 4th ed., revised. and additional Moscow: Finance and Statistics, 2000. 480 p.
- 10. Basics of epidemiology: Introduction to applied epidemiology and biostatistics / Science. ed. trans. I. Solonenko K.: Osnovy, 1997. 501 p.
- 11. Basics of evidence-based medicine / edited by M.P. Racer. Ternopil: Ukrmedknyga, 2005. 244 p.
- 12. Rebrova O.Yu. Statistical analysis of medical data. Application of the package of application programs STATISTICA. Moscow: Media Sphere, 2002. 312 with.
- 13. V.I. Sergiyenko, I.B. Bondareva Mathematical statistics in clinical research. M.: GEOTAR-MED, 2001. 256 p.
- 14. Theory of statistics: Textbook / Ed. Prof. R.A. Shmoilovoy. 3rd ed., revised. M.: Finance and Statistics, 2001. 560 p.
- 15. Fletcher R., Fletcher S., Wagner E. Clinical epidemiology. Fundamentals of evidence-based medicine.- M.: Media Sphere, 1998. 352 p.