

**SYLLABUS OF THE EDUCATIONAL COMPONENT
BIostatISTICS AND CLINICAL EPIDEMIOLOGY**

(title of the educational component)

Specialty: 221 «Dentistry»
Educational and professional program: Dentistry
Component code in the educational program: _EC 47
Higher education level: _ the second (master's degree)
Form of education: _ full-time _____
Year of study: __4
Semester(s): __VIII _____
Type of educational component: _ elective _____
Academic year: **2027-2028**

Volume: **_3,0_ credits ECTS (90 hours)**
Training sessions: practical, consultations
Final control: credit _____
Prerequisites: _ **MC 10** Life Safety.
Fundamentals of Bioethics and Biosafety.
Occupational Safety in the Industry **MC 17**
Medical Informatics **MC 32** Epidemiology.
MC 39 Social Medicine, Public Health and
Fundamentals of Evidence-Based Medicine
(course of the subject of general
education in high school or component(s) code(s) in
the EPP)

Department/Unit: _Epidemiology Department 12 Trinkler Street, 3rd Floor of the Red Building
Head of the educational component: __Viktoriiia Makarova
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Page of the educational component in the Distance Learning System of KhNMU (Moodle):
<https://distance.knu.edu.ua/course/view.php?id=662>
(link to the page of the educational component in the Distance Learning System of KhNMU)

DESCRIPTION OF THE EDUCATIONAL COMPONENT

Brief description of the content of the subject

The Discipline contributes to the formation of Knowledge about statistical and clinical Research at the current Stage of Development of medical Science, the Methodology of their Organization and Conduct, Analysis and critical Evaluation of the Results obtained, and the use of research Data in the Practice of a Doctor.

PURPOSE OF THE COURSE: Formation of Knowledge on the methodology of conducting scientific research to optimize the process of diagnosis, treatment and prevention of diseases and make informed clinical decisions when carrying out diagnostic, therapeutic and preventive measures for each patient

LEARNING OUTCOMES: *(in a language understandable to applicants)*

1. Formulate hypotheses about possible risk factors for the development and spread of diseases;
2. Conduct statistical processing of results obtained during epidemiological studies;
3. Conduct a critical assessment of the publication for its scientific validity and evidence;
4. Use databases to search for information
- 5.

CONTENT OF THE EDUCATIONAL COMPONENT

List of lecture topics (_0_ hours):

Lectures are not conducted

List of topics of practical / laboratory classes / seminars (__20_ hours):

1. Biostatistics as the basis of clinical epidemiology and evidence-based medicine.
2. Information component of epidemiological and clinical studies.
3. The role of official statistics in the analysis of population health.
4. Epidemiological data. Basic principles of planning clinical studies.
5. Statistical indicators and standardized coefficients used in epidemiological studies. Graphical presentation of epidemiological data. Analysis and interpretation of data.
6. Descriptive epidemiological research methods. Formation and testing of hypotheses regarding the causes of the disease.

7. Analytical epidemiological studies.
8. Experimental epidemiological studies.
9. Defense of individual independent work.
10. Credit

List of topics of independent work of the student (_70_ hours)

1. The main stages of the development of biostatistics. Outstanding scientists and their contribution to the development of biostatistics.
2. The place and role of biostatistics in the work of a doctor. Standardization of medical care: clinical protocols, standards and recommendations.
3. Clinical epidemiology. The main stages of its development. The main principles and provisions of clinical epidemiology. The purpose of clinical and epidemiological studies and the quality of their organization.
4. Medical information. Types of information services Theoretical foundations of medical statistics. Medical statistics: subject, content and objectives. Sections of medical statistics. Sources of statistical information: accounting and reporting documentation, databases, registers and directories.
5. Use of the survey method in the field of health care. Types of questionnaires, their characteristics. Modern approaches to the analysis and assessment of the quality of life. The role of official statistics in the analysis of population health, its advantages and disadvantages.
6. World health statistics. The role of the World Health Organization in information provision. European database "Health for All".
7. Types of epidemiological data. Collection of epidemiological data. Standard case definition. Classification. Confirmed, probable and suspected (possible) case.
8. Problems of sample studies. Sample size. Formation of samples. Clinical study protocol.
9. Indicators of central tendency (mode, median, arithmetic mean), calculation and interpretation of variance, standard deviation and confidence interval.
10. Graphical presentation of data - depiction of manifestations of morbidity. Methods of illustrating epidemiological data. Tables, rules of construction. Line graphs and diagrams, their comparative characteristics, scope.
11. Indicators of incidence and prevalence of morbidity. Calculation and interpretation of ratios, proportions, coefficients, incidence, prevalence, mortality, lethality. Intensity. Dynamics. Territorial characteristics. Description of the structure of morbidity and identification of risk groups.
12. Formation of hypotheses about possible risk factors. Evaluation of hypotheses about the causes and conditions of disease occurrence. Design of epidemiological studies.
13. Cohort epidemiological studies. Longitudinal (retrospective and prospective) studies. Advantages and disadvantages of cohort studies
14. Statistical processing of data obtained in cohort studies. Measurement of associations (effect of exposure). Absolute, relative and attributive risk.
15. Case-control studies. Stages of conduct, advantages and disadvantages. Odds ratio.
16. Controlled, uncontrolled and natural epidemiological experiments. Epidemiological trials. Modeling the epidemic process.
17. Organization of a randomized controlled trial. Pseudorandomization. Blinding (masking) of the study: blind, double, triple and quadruple blind trials.
18. Stages of drug development and implementation. Bioethical aspects of epidemiological studies. Participant consent. Assessment of the effectiveness and safety of prophylactic and medicinal products.
19. Preparation for the test

Consultations: online by prior arrangement with the department lecturer using the corporate email of the lecturer/Department of Epidemiology of KhNMU

Teaching methods: practical work, solving situational tasks and cases, narrative explanation, conversation, discussion, presentation, educational videos.

EVALUATION

Current Learning Activities (CLA). Assessment of the success of education seekers is carried out in accordance with the Instructions for assessing the educational activities of higher education seekers at KhNMU (https://knmu.edu.ua/doc_block_type/instrukcziyi-navchalnogo-proczesu/)

Grades for practical classes are given according to the traditional 4-point system: “excellent”, “good”, “satisfactory” or “unsatisfactory” in accordance with the criteria for assessing knowledge and skills. Submission of assignments late for unwarranted reasons entails a reduction in the grade in accordance with the percentage of delay in time from the time of completing the assignment. Assignments are checked within 24 hours. Grades are given in the electronic journal. Unsatisfactory grades are worked out in accordance with the Regulations on the procedure for working out academic classes by students of KNMU chrome-extension://efaidnbmninnibpcjpcglclefindmkaj/https://knmu.edu.ua/wp-content/uploads/2021/05/pol_por-vidprac-zaniat.pdf).

At the end of the semester, the semester average grade is converted into a multi-point grade (120 – 200 points) in accordance with Table 2 of the Assessment Instructions (see above). The arithmetic average of the PND with the addition of points for completed individual tasks (performed at will) constitutes the total learning activity (TLA).

Individual tasks (IT) are evaluated up to 10 points. Individual student tasks (hereinafter referred to as ITS) are not a mandatory element, but if the student wishes, they can be completed and are evaluated in ECTS points (no more than 10), which are added to the sum of points scored for current educational activities. At the meeting of the department, a list of individual tasks (participation with reports in student conferences, specialized Olympiads, preparation of analytical reviews with presentations with plagiarism check) was approved, specifying the number of points for their completion, which can be added as incentives.

Final control. Credit

Grade in subject (GS). $GS=CLA+IT$

Appealing the results of the final control is carried out in accordance with the procedure established in KhNMU (https://knmu.edu.ua/wp-content/uploads/2021/05/polog_apel_kontrol.pdf).

POLICIES OF THE EDUCATIONAL COMPONENT

Recommendations for working on the course: take an active part in all forms of work in classes, devote the hours allocated for independent work, to completing the necessary tasks, namely, "Analysis of a scientific publication", "Analysis of the incidence of a certain infectious disease" to preparing for classes, ask questions during classes, attend consultations, submit assignments on time and perform all forms of control. Explanations regarding the completion of tasks assigned to the applicant's independent work are provided by the teacher in the 1st class.

Attendance at classes. Attendance at lectures and practical classes is mandatory. The dress code during offline classes is a medical gown. If you are more than 5 minutes late, you may not be allowed to class. Missed classes are made up in accordance with the Regulations on the procedure for completing classes by students of KhNMU https://knmu.edu.ua/wp-content/uploads/2021/05/polog_ad-1.pdf

Academic integrity. KhNMU stands on the positions of zero tolerance to manifestations of academic dishonesty. Any violations of the principles of academic integrity entail responsibility in accordance with the procedure established by KhNMU (https://knmu.edu.ua/wp-content/uploads/2021/05/polog_ad-1.pdf).

Use of electronic gadgets and artificial intelligence tools. allowed for educational activities, subject to teacher permission.

Policy on persons with special educational needs. Applicants with special educational needs should contact a teacher to develop an individual educational trajectory.

Teacher Response Time: 24 hours.

Technical requirements for the course:

- access to a computer, laptop, tablet or smartphone

- Corporate Google account with your own photo
- skills in working with Google Workspace (Google Meet, Docs, Sheets, Slides, Forms) and Moodle

Technical support: ASM (ev.shevtsov@knmu.edu.ua), Google (tehotdelknmu@gmail.com), Moodle (al.korol@knmu.edu.ua)

RECOMMENDED SOURCES

1. Fletcher R. H., Fletcher S. W., Fletcher G. S. Clinical Epidemiology: The Essentials. 6th ed. Philadelphia : Wolters Kluwer, 2020. 288 p.
2. Elmore J. G., Wild D. M., Nelson H. D., Katz D. L. Jekel's Epidemiology, Biostatistics, Preventive Medicine, and Public Health. 5th ed. Philadelphia : Elsevier, 2020. 432 p.
3. Webb P., Bain C., Page A. Essential Epidemiology: An Introduction for Students and Health Professionals. 4th ed. Cambridge : Cambridge University Press, 2020. 438 p.
4. Motulsky H. Intuitive Biostatistics: A Nonmathematical Guide to Statistical Thinking. 4th ed. Oxford : Oxford University Press, 2021. 592 p.
5. Katz M. H. Multivariable Analysis: A Practical Guide for Clinicians and Public Health Researchers. 4th ed. Cambridge : Cambridge University Press, 2021. 280 p.
6. Bland M. An Introduction to Medical Statistics. 4th ed. Oxford : Oxford University Press, 2021. 464 p.
7. Bender R., Lange S. Statistical Methods in Epidemiology. Berlin : Springer, 2022. 300 p.

Head of Department of Epidemiology

(signature)

Tatyana Chumachenko