



SYLLABUS OF THE EDUCATIONAL COMPONENT LIFE SAFETY; BASICS OF BIOETHICS AND BIOSAFETY; OCCUPATIONAL SAFETY IN THE INDUSTRY

(name of the educational component)

Speciality: 221 "Dentistry"

Educational and professional program: **Dentistry**

Component code in the educational program: **MC10**

Higher education level: **second (master's degree)**

Form of education: **full-time**

Year of study: **1**

Semester(s): **I (autumn), II (spring)**

Type of educational component: **mandatory**

Academic year: **2024-2025**

Volume: **1 credits ECTS (30 hours)**

Training sessions: **lectures, seminars, consultations**

Final control: **credit**

Prerequisites: "Latin language and medical terminology", "Medical biology", "Medical and biological physics; medical information technologies", "Medical chemistry", "Bioorganic chemistry", "Human anatomy".

Department/Unit: **Department of Propedeutics of Internal Medicine, Nursing and Bioethics**, Aerospace Avenue, 137. Communal non-commercial enterprise "City Clinical Hospital № 13" of Kharkiv City Council, Trinklera Street 3, Regional Clinical Hospital.

Head of the educational component: **Professor Ambrosova Tetiana Mykolayivna**

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Page of the educational component in the Distance Learning System of KhNMU (Moodle):

<https://distance.knu.edu.ua/course/index.php?categoryid=857>

DESCRIPTION OF THE EDUCATIONAL COMPONENT

"Fundamentals of Bioethics and Biosafety" introduces students to the moral, legal, and safety aspects of modern medicine and biotechnology. It develops future physicians' understanding of ethical professional principles, as well as skills for safe handling of biological materials and technologies.

PURPOSE OF THE COURSE: The course aims to provide students with a comprehensive system of knowledge regarding medical ethical principles and the rules for safe handling of biological objects. It focuses on cultivating professional responsibility, humanistic values, and a biosafety culture essential for modern medical practice.

LEARNING OUTCOMES: To know and understand the basic concepts, principles and history of the formation of bioethics and biosafety; international documents and ethical codes regulating medical and scientific activities; principles of biosafety, levels of biological protection, rules for working with pathogens and biomaterials.

To be able to analyze and justify ethical decisions in professional situations; to apply the principles of bioethics in relationships with patients, colleagues and society; to comply with biosafety rules during clinical practice and scientific research.

Possess the skills to argumentatively resolve ethical and safety dilemmas in medicine and biotechnology; work with biological materials in accordance with safety requirements; have a responsible attitude to professional activities that takes into account the interests of humans, society, and the environment.

CONTENT OF THE EDUCATIONAL COMPONENT

List of lecture topics (10 hours):

1. Bioethics: History, Terminology, and Debatable Issues
2. Goals and Principles of Evidence-Based Medicine, Clinical Trials, and Good Practices
3. Bioethical Issues of Euthanasia, Palliative, and Rehabilitative Medicine
4. Medical-Ethical and Legal Aspects of Transplantology, Donation, and Cloning
5. Medical-Ethical Aspects of Biosafety and Biological Risk

List of topics of practical / laboratory classes / seminars (10 hours):

1. The Concept of Evidence-Based Medicine as the Basis for Modern Scientific Medical Knowledge: Core Terminology. Principles of clinical trials involving human subjects: assessment of evidence and quality. The doctrine of informed consent as a bioethical and legal aspect of interaction between healthcare professionals and patients. The concept of Good Practices (GxP).
2. Ethical, Moral, and Legal Issues of Euthanasia in the Context of Incurable Diseases. Arguments "for" and "against" euthanasia. International legal regulation of euthanasia: historical and contemporary aspects. Concepts of palliative medicine and the hospice movement. Ethical issues in intensive care medicine. Ethical and legal aspects of transplantology. The concepts of "presumed consent" and "opt-out" versus "informed consent" in organ and tissue donation. National and international regulatory documents on transplantation (Ukrainian and global experience). Hemotransfusiology: ethical and legal issues. Ethical, legal, and medical components of stem cell application in medicine. Cloning of living beings: medical and ethical aspects.
3. Ethical and Legal Aspects of Assisted Reproductive Technologies: artificial insemination and in-vitro fertilization (IVF). Abortion as a social, medical, and moral-ethical problem. The status of the embryo. Surrogacy: ethical and legislative aspects.
4. Biosafety and Biological Risk. Modern biotechnology and genetic engineering: history and terminology. Fields of application for genetic engineering. Genetic diagnostics and gene therapy: risks, efficiency, and prospects.

List of topics of independent work of the student (10 hours)

1. Clinical, Social, and Global Bioethical Issues in the Context of HIV Infection. Bioethical foundations of the socio-legal aspects of HIV-positive patients. Consequences of the HIV/AIDS epidemic. Ukraine's regulatory and legal framework on HIV infection.
2. Valeology as a Science. Sources and history of development. Human as a system. Health and its mechanisms from a systems approach perspective. Diagnosis and prognosis of individual health. Human health. Healthy lifestyle: environmental, sociological, and socio-psychological aspects.
3. Ethical and Legal Aspects of Biomedical Experiments. Use of living beings in biomedical research. Alternative models for experimental research. Legal aspects of conducting biomedical experiments.
4. Bioethical Issues in the Interaction between Medicine and Pharmacy. Advertising in medicine and pharmacy. Freedom of research and the necessity of its ethical and legal control. Monitoring and prevention of adverse drug reactions. The system of pharmacological monitoring and surveillance in Ukraine.
5. Biosafety and Biological Risk. Biological terrorism as a social phenomenon. Genetically Modified Organisms (GMOs). Biological and medical risks of using genetically modified organisms.

The IWS is aimed at deepening and consolidating the theoretical knowledge gained during classroom training and contributing to the formation of professional competencies. The results of the IWS are subject to control and are included in the final control of knowledge.

Consultations: online, with prior registration on the course page in the Distance Learning System of the course.

Teaching methods: lecture, performing exercises and practical work, solving situational tasks and cases, the standardized patient method

EVALUATION

Current Learning Activities (CLA). Assessment of the success of education seekers is carried out in accordance with the Instructions for assessing the educational activity of higher education seekers at KhNMU (https://knmu.edu.ua/doc_block_type/instrukczyi-navchalnogo-proczesu/). The grade for a practical or final lesson is from 2 to 5 points. Submitting 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 posted in the electronic journal. Unsatisfactory grades are worked out in accordance with the Regulations on the procedure for working out academic classes by KhNMU students (chrome-extension://efaidnbnmnibpcjpcglclefindmkaj/https://knmu.edu.ua/wp-content/uploads/2021/05/pol_por-vidprac-zaniat.pdf)

At the end of the semester, the average grade for the semester is converted into a multi-point grade (70 - 120 points) in accordance with Table 1 of the Assessment Instructions (see above). The arithmetic average of the PND for both semesters constitutes **the total educational activity (TEA)**.

Individual tasks (IT) are evaluated up to 10 points.

Final control. The condition for admission to the exam is to score 70 points of the final examination. The grade for the exam is from 50 to 80 points.

Grade in subject (GS). $OG = TEA + IT + \text{credit}$

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: actively participate in all forms of work in classes, devote 1-2 hours daily to independent work and preparation for classes, ask questions during classes, attend consultations, submit assignments on time and complete all forms of control.

Attending classes. Attendance at lectures and practical classes is mandatory. The uniform for offline classes is a white medical gown. If a student is more than 5 minutes late for a lecture or practical class, he/she may not be admitted to the class. Missed classes are made up in accordance with the Regulations on the procedure for students of KhNMU to complete classes (chrome-extension://efaidnbnmnibpcjpcglclefindmkaj/https://knmu.edu.ua/wp-content/uploads/2021/05/pol_por-vidprac-zaniat.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. is permitted only with the instructor's permission.

Policy on persons with special educational needs. Students with special educational needs should contact the instructor 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
- *other requirements of the department*

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

RECOMMENDED SOURCES

1. Beauchamp T. L., Childress J. F. Moral Norms // Beauchamp T. L., Childress J. F. Principles of Biomedical Ethics. – New York: Oxford University Press, 2019. – P. 1-30.
2. Bryant J., Velle L. Ethics and Bioethics // Bryant J., Velle L. Introduction to Bioethics. – Wiley-Blackwell, 2018. – P. 23-38.



3. Talbot M. Biotechnology and Bioethics: What it is All about? Ethical theories: virtue, duty and happiness // Talbot M. Bioethics. An Introduction. – Cambridge University Press, 2012. – P. 3-47.
4. Veatch R., Guidry-Grimes L. The Hippocratic Oath and Its Challengers: A Brief History // Veatch R., Guidry-Grimes L. The basics of bioethics. – London, New York: Routledge, 2019. – P. 18-36.
5. Biosafety and the environment [Електронний документ]. – Доступ: <https://www.cbd.int/doc/press/presskits/bs/cpbs-unep-cbd-en.pdf>

Head of Department, Professor _____ (*signature*)

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