Ministry of Education and Science of Ukraine

V.N. Karazin Kharkiv National University

Department of General Practice-Family Medicine

**“APPROVED”**

Vice-president for research

and education work

A.V. Panteleimonov

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Working educational program on discipline

**SAFETY OF VITAL FUNCTIONS,**

**FUNDAMENTALS OF BIOETHICS AND BIOSAFETY**

The program for the 1nd year students of medical faculty

Educational qualification level Master

Direction of training 22 Health care

Specialty: 222 "Medicine"

Educational program Medicine

Type of discipline Required

School of Medicine

2019/2020

The program is recommended for approval by the academic council of the faculty

“28” August 2019, protocol № 12

Authors:

Nikolenko E. Y., MD, Professor, Head of General Practice – Family Medicine Department

Vlasenko O. O., PhD, A**ssociate Professor** of General Practice – Family Medicine Department

Belyaeva L.V., PhD, A**ssociate Professor** of General Practice – Family Medicine Department

The program was approved on the meeting of General Practice – Family Medicine Department

Protocol № 1 dated 27.08.2019

Head of the department of General Practice – Family Medicine Department

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Nikolenko E.Y.

Scientific and methodological commission of the Medical School agreed the program

Protocol № 11 dated 28.08.2019

Head the scientific and methodological commission of the Medical School

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INTRODUCTION

The program on the discipline " Safety of vital functions, fundamentals of bioethics and biosafety" was compiled in accordance to the educational and professional (educational and scientific) program for training specialists approved by order of the Ministry of Education and Science of Ukraine No. 239 of April 16, 2003 "On approving the components of industry standards for higher education in the field of preparation Educational qualification level Master Direction of training Health care, Specialty: 222"Medicine", Specialization: doctor.

1. Description of the academic discipline

1.1. The purpose of teaching the academic discipline

As a result of studying the discipline, the student should:

*- Theoretical knowledge:* the principles of safety of health and life in modern society; rules for the safety of the professional activities of a medical professional; human rights as a source of bioethical principles and criteria of behavior; the relationship between the medical staff, the patient and his family; the concept of biosafety and risk of biomedical technologies; bases bioethical assessment of the moral status of the fetus and the beginning of life.

*- Practical knowledge:* to predict the consequences of violations of the valeological foundations for the formation of a healthy lifestyle and their impact on human life safety; to analyze and evaluate dangerous for the life, health and professional activity of the situation and independently take a decision on holding urgent actions; to create safe conditions for the professional work of a medical worker; to assess and monitor bases of biotic genetic technologies; bases biotic problems of pain, suffering, rehabilitation and euthanasia, bases biotic aspects of transplantology and blood transfusion, bases of bioethical issues of HIV-infection and other socially dangerous infections, bases of bioethical issues biopsychosocial medicine, psychology and psychiatry.

1.2. The main tasks of studying the discipline

The purpose of studying the course "Safety of vital functions, fundamentals of occupational safety" is to achieve the basic final goals of training specialist of 222"Medicine", and provides for the acquisition of such skills by the student:

* Define the basic principles of safety in ensuring the normal life of a person.
* Recognize the relationship between health status and the impact of harmful and dangerous factors.
* To predict the negative consequences of the influence of hazardous factors on the human body.
* To make a conclusion about the presence of factors of negative influence on the medical worker during the performance of his professional activity.
* Explain the requirements for ensuring the safe professional activity of a doctor in modern conditions.
* Explain key issues of legislative acts and regulations on the safety of the professional activities of a medical worker.
* To make a conclusion about professional medical ethics, Bioethics
* To learn about human rights as a source of bioethical principles and criteria of behavior.
* To make a conclusion about Cost of human life and health.
* To learn about bioethics of biomedical experimentsl; bioethical committees, history of creation, organization methods, models, rights and obligations, prospects of activity.

1.3. Number of credits - 3 credits

1.4. The total number of hours is 90 hours.

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| **1.5. Characteristics of the academic discipline** |
| Normative |
| Full-time education |
| **Year of preparation** |
| **1** |
| **Semester** |
| **2** |
| **Lectures** |
| **20** |
| **Practical lessons** |
| **20** |
| **Laboratory exercises** |
| **-** |
| **Independent work** |
| **50** |
| **Individual tasks** |
| **-** |

1.6. Planned learning outcomes

Students should know:

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| --- | --- |
| 1. Definition of concept «safety of ability to live», a subject and object of studying the safety of vital activity. Concept of safety, danger, risk. | |
| 1. Definition and examples of dangerous, harmful, menacing, neutral and necessary factors. Classification of dangerous factors. | |
| 1. Principles, methods and means of providing life safety. | |
| 1. Internal and external influence on a human organism. Dependence of psychophysical condition on external and internal factors level. | |
| 1. Natural physiological systems of organism protection. Immunity, adaptation. | |
| 1. Typical models of psychological reactions to extreme situations. Stress, phobia. | |
| 1. Classification of negative factors of the environment and their characteristics. A maximum allowable level of the factors. | |
| 1. Influence of meteorological conditions on human vital activity, concept of meteosensitivity. | |
| 1. Electromagnetic fields and radiation influence on a human, means of protection from them. | |
| 1. Ionizing radiations influence. Principles of providing radiation security. | |
| 1. Chemical factors, their classification, the routes of hazardous chemicals into a human body. Principles of chemical security. | |
| 1. Concept of information danger and new kinds of dangers which are generated by scientific and technical progress. | |
| 1. Human health, its definition and parameters. | |
| 1. Risk factors and groups of risk of diseases occurrence. | |
| 1. Health improving systems and ways of organism training. | |
| 1. The mechanism of alcohol influence effects on a human and threat to personal and public life caused by it. | |
| 1. The mechanism of influence of smoking on a human organism and the danger to health caused by it. | |
| 1. Concept of drug addiction, ways of quitting. | |
| 1. Influence of food on human life. Routes of harmful substances getting into food. | |
| 1. Consequences of entering pesticides, food additions and growth factors into food. | |
| 1. Genetically modified products and their hazard for human health. | |
| 1. Danger of entering radionuclides into food products. Food in conditions of radiating pollution. | |
| 1. Work peculiarity of a medical worker with HIV infected patients. Concept of «industrial disaster» and the order of actions in case of its occurrence. | |
| 1. Work peculiarity of a medical worker with patients infected by virus hepatitis. Prevention of infecting by hepatitis virus. | |
| 1. Preventive actions in professional work of a phthisiatrician. The national program of tuberculosis control. | |
| 1. Professional danger in work of a radiologist, roentgenologist. 2. Job descriptions which regulate safety of a doctor’s professional work for these specialities. 3. Creation and test of genetically modified organisms: danger to a doctor and the society. Laws which regulate genetic engineering activities. 4. Bioethics: the subject, purpose and objectives of the health care system. 5. History of professional medical ethics,nooethics. 6. Bioethics and the formation of a national health care system in Ukraine. 7. Human Rights as a source of bioethical principles and criteria of conduct. 8. The cost of human life and health. The dignity and inviolability of human life from the moment of conception to natural death. 9. International documents on bioethics and human rights. 10. Bioethics of biomedical experiments. The modern concept of evidence-based medicine. 11. Bioethical committees, history of creation, organization methods, models, rights and obligations, business prospects 12. Social justice, issues of transcultural ethics and socioethical obligations. Social justice and socioethical obligations. 13. Bioethical and legal problems of the coexistence of "traditional" and "alternative" medicine. 14. Development of respect for healthy life. Health, philosophical, biological and ethical determination. WHO definition of health. Healthy lifestyle as a condition of its duration, physical and spiritual development. 15. Human and disease. The disease as an experience and a behavior of human beings. 16. The relationship between the medical staff, the patient and his family. 17. The concept of biosafety and risk of biomedical technologies. 18. Bioethical aspects and biosafety ofenvironmental influence on a people. Bioethical aspects of agricultural technologies. 19. Bases bioethical assessment of the moral status of the fetus and the beginning of life, conflict between mother and fetus. 20. Bases biotic assessment and monitoring of genetic technologies. 21. Bases biotic problems of pain, suffering, rehabilitation and euthanasia. 22. Bases biotic aspects of transplantology and blood transfusion. 23. Bases of bioethical issues of HIV-infection and other socially dangerous infections. 24. Bases of bioethical issues biopsychosocial medicine, psychology and psychiatry 25. **Thematic plan of the academic discipline**   **Module 1**. **Basics of life safety, health and activity of the medical worker in modern society.**  *The content of the module:*  Basic foundations for health and life safety in the modern society.  Creation of safe conditions in professional work of a medical worker and their legislative maintenance.  Studying of the elective course «Safety of vital activity» is carried out according to the curriculum as class trainings in the form of lectures and seminars, as well as independent work of students. Lectures and practical trainings of students are formed in a sequence of lectures followed by corresponding seminars. Seminars lasting 2 hours are built in the form of discussions, debates on a . To be prepared for such kind of work students have to pay great attention to individual work with literature and other sources of information that allows a student to participate in discussion actively, to give the point of view on an investigated problem.  Mastering of a current is controlled during the seminar classes. It is recommended to use the following means for defining the preparation level: the test control to check the theoretical knowledge, the mastering and the salvation of the tasks, to determine the ability to apply them in specific professional situations.  The final control of the module mastering is carried out in the final modular lesson. The estimation of student’s success is rating and is exposed on a points scale taking into account the current progress, marks of the current modules and the final modular control and is defined according to the ECTS system and to the traditional scale used in Ukraine.  Faculties where the elective course «Safety of vital activity» is given, have the right to make changes to the curriculum within the limits of 15 %.  The PURPOSE of STUDYING the elective course «Safety of vital activity» is achievement of the main basic ultimate goals of preparation of the specialist by a speciality 7.110101 «Medical business» and provides a student’s obtaining of the following skills:  1. To define key principles of human life safety.  2. To predict consequences of violation of valeological bases of healthy lifestyle forming and their impact on safety of human vital activity.  3. To analyze and estimate hazardous situations for life, health and professional activity and to make a decision independently concerning urgent actions required.  ***Topic 1.* Theoretical basics of** «Safety of vital activity»  The vital activity as a physiological and structural concept. Interrelation of vital activity with an environment in the system of "person - environment - activity". The basic concepts and definitions of the safety of vital activity. Dangerous, harmful, menacing, neutral and necessary factors. Concept of safety, danger, risk and their interrelation. Classification of negative factors and definition of their level in individual activity. Forecasting methods of possible dangerous factors occurrence. Principles, methods and means of providing the safety of vital activity.  ***Topic 2.* Physiological and psychological factors of the safe life of a modern person.**  Internal and external influence on a human organism. Dependence of a psychophysical condition on a level of external and internal factors. A role of receptors, effectors, CNS in ensuring safety of human life. Natural physiological systems of protection, organism reserves. Influence of biorhythms on an individual risk level. Immunity. Adaptation. Possible violation of organism activity which are caused by life conditions and a person’s activity. Influence of character and temperament of the person on a security. External stimuli and their influence on psychophysical condition of a person. Stress. Phobias. Typical models of psychological reactions of a person under extreme situations.  ***Topic 3.* Negative factors of the environment and their influence on human health.**  Classification of negative factors of the environment and their characteristics. A maximum allowable level of factors. Adverse meteorological factors and their influence on organism functioning. Concept of meteorological sensitivity. Electromagnetic fields and radiation influence on a human. Ways and methods of protection. Ionizing radiations influence. Principles of providing radiation security. Chemical factors, their classification, and the routes of hazardous chemicals into a human body. Principles of chemical security. Biologically dangerous factors and protection from them. Modern information technologies, information danger. New kinds of dangers which are generated by scientific and technical progress.  ***Topic 4.* Valeological and sanological basics of health and life safety formation. Harmful habits and dangers connected with them**  Human health as a medical, biological and social category. Spiritual, mental, physical and social aspects of human health. Health and pathology. Valeology and sanology; definition, essence and a subject of their studying. Parameters of individual health of а person. Factors which provide health stability. Risk factors and groups of risk. Concept of lifestyle, its features in modern conditions. Health improving traditional and nontraditional systems and methods. Ways of organism training. Necessary physical and intellectual work of a person and a state of person’s health. Definition and varieties of harmful habits. The mechanism of destructive effects of alcohol, smoking and drugs. Threat to personal and public life caused by them. Methods of counteraction of addiction and ways of quitting.  ***Topic* 5. Safe foods as a component of life safety.**  The influence of food on human life. Requirements to quality and safety of food. Routes of harmful substances getting into food. Concept of toxic substances forming in the process of cooking food. Food additions as possible contaminants. Consequences of contamination of the food due to pesticides. Growth stimulators and other chemical substances which are applied in agriculture. Genetically modified foods and their hazard for human health. Radionuclides in food. Food in conditions of radiating pollution. Amount of toxic substances in food: the background allowable amount, possible allowable level of the toxic substances in food. Methods of reducing the amount of contaminants in food.  ***Topic* 6. Dangerous and vitally hazardous infectious diseases in a medical worker’s practice.**  Concept of vitally dangerous diseases. A HIV and AIDS in a doctor’s practice. Possible ways of a HIV-infected biological material getting into the organism of a medical worker. Concept of «industrial disaster» and the emergency appeal to in the Center of AIDS / the Institute of infectious diseases. The Antiretroviral 28-day-program. Virus hepatitis and probability of penetration into a doctor’s organism. Preventive measures against infection of hepatitis virus and immunization by the contact of patient’s biological materials of the person infected by hepatitis. The developing program of the services of the donor’s blood and its components. A tuberculosis and its spreading in Ukraine and in the world. Potential professional danger for the doctor - phthisiatrician and carrying out of preventive actions. The national program of tuberculosis control.  ***Topic 7.* Professional hazards in a doctor’s life.**  Concept of professional harm, the list of dangerous medical professions and positions. Professional harm in the work of a radiologist, roentgenologist, doctor of ultrasonic diagnostics. Prevention of dangerous effects on a doctor’s organism in professional work. Job descriptions which regulate safety of a doctor’s professional work. Process of creation and test of genetically modified organisms: danger to a researcher and to the society. Regulation of genetic engineering activity. The Ukrainian law “Of the National Biosafety System used in generating, testing, transportation and use of Genetically Modified Organisms”.  **Module 2**  **Fundamentals of bioethics and biosafety**  ***Topic 1.* Bioethics: the subject, purpose and objectives of the health care system. The history of professional medical ethics, nooethics. Bioethics and the formation of a national health care system in Ukraine**.  Directions and methods of bioethics. History of professional medical ethics, neo-ethics Bioethics and the formation of a national health care system in Ukraine. Subject, definition, content and functions of bioethics. Functions of bioethics and its transcultural dimension. Prerequisites for the development of bioethics. Stages of development of professional medical ethics. Bioethical stage of medical ethics. The nooetic degree of bioethics development.  ***Topic 2.* Bioethical basis of professional activity of the doctor. Relationships between medical staff, the patient and his family in the context of transcultural bioethics. The bioethical principle of equity in the distribution of health resources.Bioethical and legal evaluation of medical errors and iatrogenics.** The role of the family in the decisions taken. Social justice, problems of transcultural ethics and socioeconomic commitments. The bioethical principle of equity in the distribution of health resources. Bioethical and legal problems of coexistence of "traditional" and "nontraditional" medicine. Models of relations between a doctor, a pharmacist and a patient. Principles of informed consent and confidentiality. Protection of patient rights at the international and national levels. Model of integrated medicine in the field of interprofessional relationships. Conflict of interests in the professional activity of the doctor.  ***Topic 3.* Human rights as a source of bioethical principles and behavioral criteria. Cost of living and health of a person. International Documents on Bioethics and Human Rights. WHO Health Determination.**  A healthy lifestyle as a condition of its duration, physical and spiritual development. International Code of Medical Ethics. Universal Declaration of Human Rights. Convention on the Protection of Human Rights and Dignity in Connection with the Advancement of Biology and Medicine. Ethical code of the doctor of Ukraine. Lisbon Declaration on Patient Rights. Convention on the Rights of Persons with Disabilities. Declaration on the rights of mentallyretarded persons. WHO Health Determination. A healthy lifestyle as a condition of its duration***,*** physical and spiritual development. Man and disease. Disease as an experience and behavior of a human person***.***  Ethical, moral, deontological and legal dimensions in different spheres of their application. Ethics and morality.Deontology Differences between descriptive and normative ethics. Ethics and moral law, law and legal law. Principles of medical deontology. Levels of responsibility of health care workers.12. Development of respect for healthy life. Health, philosophical, biological and ethical determination.  ***Topic 4.* Bioethical and legal problems of human reproduction, genetictechnologies, transplantation and blood transfusiology. General Declaration on the Human Genome and Human Rights. Genetic counseling and genetic engineering**. Fundamentals of bioethical assessment of the moral status of the fetus and the beginning of life, conflicts between mother and fetus. Declaration on family planning. Statement on the rights of women to use contraception. Application for artificial insemination and embryo transplantation. Law of Ukraine on organs transplantation and other anatomical materials of a person.  ***8*. *Topic* 5. Bioethical and legal problems of HIV infection and other socially dangerous infections, medical psychology and psychiatry. Major bioethical conflicts in the context of HIV infection, medical care and prevention.** International and national regulation of HIV infection. Bioethical problems of clinical trials and research in the context of HIV infection. Programs to combat HIV infection in Ukraine in the context of human rights protection. Psychosomatic concept of medicine. Bioethical problems of medical psychology. The main problems in psychiatry that are subject to bioethical and legal assessment. The Law of Ukraine on Psychiatric Aid. Bioethical aspects of abuse, stigma and discrimination in psychiatry.  ***Topic 6.*** **Bioethical problems of pain, suffering, rehabilitation and euthanasia. Bioethics of the final phase of life. Bioethical problems of palliative and rehabilitation medicine.** Statement of Persistent Vegetative Condition. Statement on a policy on the treatment of deadly patients with chronic pain. Venice Declaration of Terminal Condition. The Sydney Declaration Concerning the Detection of the Death.  ***T Topic 7.* Bioethics of medical and biological experiments and clinical researches. Ethical assessment of biosafety and risks of biomedical technologies.**The Helsinki Declaration of the World Medical Association "Ethical Principles of Medical Investigations involving Human Rights as a Research Object". Provisions on the use of animals in biomedical research. Ethical assessment of biosafety and risks of biomedical technologies. | |
| |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Name of modules and topics | Number of hours | | | | | | | | | | | | | full-time education | | | | | |  | | | | | | | Total | including | | | | |  |  | | | | | | L | Sem | Lab | Ind | SW |  |  |  |  |  | | 1 | 2 | 3 | 4 | 5 | 6 | 7 |  |  |  |  |  |  | | Module 1. Basics of life safety, health and activity of the medical worker in modern society. | | | | | | | | | | | | | |  | | | | | | | | | | | | | | *Topic 1.* Theoretical basics of «Safety of vital activity» | 6 | 2 |  |  |  | 4 |  |  |  |  | - | - | | *Topic 2.* Physiological and psychological factors of the safe life of a modern person. | 8 | 2 | 2 |  |  | 4 |  |  |  |  |  |  | | *Topic 3.* Negative factors of the environment and their influence on human health. | 6 |  | 2 |  |  | 4 |  |  |  |  |  |  | | *Topic 4.* Valeological and sanological basics of health and life safety formation. Harmful habits and dangers connected with them | 8 | 2 | 2 |  |  | 4 |  |  |  |  |  |  | | *Topic* 5. Safe foods as a component of life safety. | 3 | 2 |  |  |  | 1 |  |  |  |  |  |  | | *Topic* 6. Dangerous and vitally hazardous infectious diseases in a medical worker’s practice.  медичного працівника | 8 | 2 | 2 |  |  | 4 |  |  |  |  |  |  | | *Topic 7.* Professional hazards in a doctor’s life | 6 |  | 2 |  |  | 4 |  |  |  |  |  |  | | Total– 45 | 45 | 10 | 10 |  |  | 25 |  |  |  |  |  |  | | **Module 2**  Fundamentals of bioethics and biosafety | | | | | | | | | | | | | | *Topic 1.* Bioethics: the subject, purpose and objectives of the health care system. The history of professional medical ethics, nooethics. Bioethics and the formation of a national health care system in Ukraine. | 4 | 2 |  | - | - | 4 | - | - | - | - |  |  | | *Topic2.* Bioethical basis of professional activity of the doctor. Relationships between medical staff, the patient and his family in the context of transcultural bioethics. The bioethical principle of equity in the distribution of health resources.Bioethical and legal evaluation of medical errors and iatrogenics.. | 8 | 2 | 2 | - | - | 4 |  |  |  |  |  |  | | *Topic3.* Human rights as a source of bioethical principles and behavioral criteria. Cost of living and health of a person. International Documents on Bioethics and Human Rights. WHO Health Determination. | 6 | 2 |  | - | - | 4 | - | - | - | - | - | - | | *Topic 4.* Bioethical and legal problems of human reproduction, genetictechnologies, transplantation and blood transfusiology. General Declaration on the Human Genome and Human Rights. Genetic counseling and genetic engineering | 4 | - | 2 | - | - | 4 |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  | | *Topic 5*. Bioethical and legal problems of HIV infection and other socially dangerous infections, medical psychology and psychiatry. Major bioethical conflicts in the context of HIV infection, medical care and prevention | 6 | 2 | 2 | - | - | 2 | - | - | - | - | - | - | | *Topic 6.* Bioethical problems of pain, suffering, rehabilitation and euthanasia. Bioethics of the final phase of life. Bioethical problems of palliative and rehabilitation medicine. | 4 | - | 2 | - | - | 2 | - | - | - | - | - | - | | *Topic 7.* Bioethics of medical-biological experiments and clinical researches. Contemporary concept of evidence-based medicine. Ethical assessment of biosafety and risks of biomedical technologies.. | 9 | 2 | 2 |  |  | 5 |  |  |  |  |  |  | | Total content module 2 | 45 | 10 | 10 |  |  | 25 | - | - | - | - | - | - | | Total | 90 | 20 | 20 |  |  | 50 |  |  |  |  |  |  |   **4.** **Topics of lectures**   |  |  |  | | --- | --- | --- | | № |  | Hours | |  | **Module 1**. **Basics of life safety, health and activity of the medical worker in modern society*».*** |  | | 1. | Theoretical basics of «Safety of vital activity» | 2 | | 2. | Physiological and psychological factors of the safe life of a modern person | 2 | | 3. | Valeological and sanological basics of health and life safety formation. | 2 | | 4. | Safe food as a component of life safety | 2 | | 5. | Dangerous and vitally hazardous infectious diseases in practice of a medical worker. | 2 | |  | **Module 2**  **Fundamentals of bioethics and biosafety** | 2 | | 6. | Bioethics: the subject, purpose and objectives of the health care system. The history of professional medical ethics, nooethics. Bioethics and the formation of a national health care system in Ukraine | 2 | | 7. | Bioethical basis of professional activity of the doctor. |  | | 8. | Human rights as a source of bioethical principles and behavioral criteria. Cost of living and health of a person. International Documents on Bioethics and Human Rights. WHO Health Determination. | 2 | | 9. | Bioethical and legal problems of HIV infection and other socially dangerous infections, medical psychology and psychiatry |  | | 10. | Bioethics of medical-biological experiments and clinical researches. Contemporary concept of evidence-based medicine. Ethical assessment of biosafety and risks of biomedical technologies. | 2 |   **5. Topics of seminars**   |  |  |  | | --- | --- | --- | | № |  | Hours | |  | **Module 1**. **Basics of life safety, health and activity of the medical worker in modern society** |  | | 1. | Physiological and psychological factors of the safe life of a modern person | 2 | | 2. | Negative factors of the environment and their influence on human health | 2 | | 3. | Valeological and sanological basics of health and life safety formation. | 2 | | 4. | Dangerous and vitally hazardous infectious diseases in practice of a medical worker. | 2 | | 5. | Professional hazards in a doctor’s life | 2 | |  | **Module 2**  **Fundamentals of bioethics and biosafety** |  | | 6. | Bioethical basis of professional activity of the doctor. Relationships between medical staff, the patient and his family in the context of transcultural bioethics. The bioethical principle of equity in the distribution of health resources.Bioethical and legal evaluation of medical errors and iatrogenics.. | 2 | | 7. | Bioethical and legal problems of human reproduction, genetictechnologies, transplantation and blood transfusiology. General Declaration on the Human Genome and Human Rights. Genetic counseling and genetic engineering. | 2 | | 8. | Bioethical and legal problems of HIV infection and other socially dangerous infections, medical psychology and psychiatry. Major bioethical conflicts in the context of HIV infection, medical care and prevention | 2 | | 9. | Bioethical problems of pain, suffering, rehabilitation and euthanasia. Bioethics of the final phase of life. Bioethical problems of palliative and rehabilitation medicine.. | 2 | | 10. | Bioethics of medical and biological experiments and clinical researches. Ethical assessment of biosafety and risks of biomedical technologie | 2 | |  |  |  | |

6. Methods of control

The forms of control and the evaluation system are carried out in accordance with the requirements of the course program and instructions on the system for assessing the educational activity of students approved by the Ministry of Health of Ukraine.

The assessment based on the course " Safety of vital functions, fundamentals of bioethics and biosafety " is a rating and is defined as the sum of the assessments of the current training activity (points) and the evaluation of the final modular control (points) that are presented when assessing the student's knowledge in accordance with the list of issues identified by the program course.

The forms of control and the system of evaluation are carried out in accordance to the requirements of the program of the discipline "Life safety, the fundamentals of labor protection", instructions on the system for evaluating student learning activities in the credit-module system of the organization of the educational process (Ministry of Health of Ukraine, 2005) and the Order of the Ministry of Health of Ukraine dated July 23, 2007 . No. 414 "On Amendments to the Order of the Ministry of Health of Ukraine from 31.01.2005. №52 ».

Score in the discipline "Safety of vital functions, fundamentals of occupational safety", which includes two modules, is a rating and is defined as the sum of the marks of the current learning activity (points) that is exposed when assessing a student's knowledge in accordance with the list of questions identified by the course program.

The maximum number of points is assigned to students with the mastering of the module (credit) is 200 and consists of the sum of assessments for the current training activity and in case of its successful implementation.

The current control is carried out in accordance with specific objectives at each of the seminars. For monitoring, it is recommended to use such means of diagnosing the level of students' preparation: test tasks (for monitoring the theoretical preparation of the student), situational problems (for assessing the ability to apply theoretical knowledge in specific situations), standardized questions for written and verbal control. Current monitoring is also carried out through oral and written interview of students and analysis of their participation in the general discussion for seminars.

The current assessment of students on relevant topics is carried out according to the traditional 4-point system ("excellent", "good", "satisfactory", "unsatisfactory") with subsequent recalculation in a multi-scale scale.

Evaluation of «Excellent». A student attended all lectures and seminars. Has written lectures and seminars. When classes are missed (no more than 2) for valid reasons (to confirm the dean) and must be worked out.

Student is aware of general scientific and theoretical foundations of learning discipline, can make definitions, can make differentiate subject matter and its structuring on the basis of science. A student has extensive knowledge of the system of disciplines and recognizes them as a system of knowledge. The answers are complete, the material is put in full logical and literary language.

Evaluation of «Good». A student attended all lectures and seminars. Has written lectures and seminars. Student has strong fundamental knowledge discipline of teaching, but can have minor inaccuracies in the structuring and content of educational material.

Evaluation of «Satisfactory». A student attending seminars and seminars. Has written lectures and seminars. A student knows basic topics of the course, but his knowledge is general and student has difficulty to explain the phenomena and laws, has minor errors which are not corrected after the instructions of the teacher.

Evaluation of «Unsatisfactory» is exhibited in cases when the knowledge and skills of the student do not meet the requirements of a "satisfactory" assessment; the student passively follows the discussion of the thematic issues without taking part in it, has obvious difficulties in answering the direct questions of the teacher.

Recalculation of the assessment of a multi-scale scale is carried out based on the total number of practical classes in the module that the course is presented to.

**Tasks for conducting semester control**

1. With what structures of the brain does a person adapt in the external environment?

a) using the function of the cerebral cortex

b) using the function of the brain stem.

2. How many analyzers are there in the human body?

а)10;

б) 8;

в) 5.

3. Which analyzers are the main ones in detecting danger?

a) visual;

b) auditory;

c) motor.

4. What are the peripheral parts of the analyzers that perceive the stimuli called?

a) receptors;

b) sensitive neurons;

c) synapses.

5. What are the basic hazardous environmental factors?

a) physical, chemical, biological;

b) physical, chemical, biological, psychological;

c) physical and chemical;

d) anthropogenic, natural, social.

6. Maximum amount of a toxic substance which has no effect on human health is defined as:

a) deadline;

b) latent effect;

c) the maximum possible concentration;

d) the maximum permissible concentration.

7. What means are used for protection from local vibration?

a) vibroprotection respirators;

b) medical gowns;

c) vibroprotection gloves, kneecaps;

d) lead aprons.

8. The ionizing radiation sources are:

a) X-rays;

b)radioactive materials;

c) cosmic rays;

d) all answers right.

1. Regular physical exercise:

a) reduce the amount of cholesterol in the blood;

b) improve the oxygenation of nerve cells of the brain;

c) reduce blood sugar levels.

1. What is the main goal of valeology:
2. public health monitoring;
3. b) monitoring and strengthening the health of the individual;
4. c) preservation of mental health;

d) stop the violation of homeostasis.

1. Sanology is:

a) the section of medicine in which the mechanisms and processes of restoring impaired functions are studied - restoration after diseases, injuries and other pathological conditions arising at the public level;

b) monitoring and strengthening human health.

1. Health is:

a) state of complete physical and mental well-being;

b) a state of complete physical, mental and social well-being.

13. Occupational diseases of doctors often develop under the action of:

a) biological factors;

b) chemical factors;

c) physical factors.

14. AIDS is transmitted:

a) hematogenous;

b) sexually;

c) by airborne droplets.

15. Postexposure prophylaxis with antiretroviral drugs includes:

a) 1 drug;

b) 2 drugs;

c) 3-4 drugs.

16. The duration of postexposure prophylaxis with antiretroviral drugs is:

a) 2 weeks;

b) 4 weeks;

c) more than 6 weeks.

1. The factors of the chemical exposure are:

a) vaccines;

b) substances for anesthesia;

c) radiation

18. Effects of laser relate to:

a) chemical harmful factors

b) biological factors

c) physical factors

19. The maximum permissible radiation dose is:

a) 50 mSv(5 rem).

b) 70 mSv(7 rem).

c) 100 mSv(10 rem).

20. Most exposed to ionizing radiation are:

a) therapist

b) dermatologist

c) radiologist

21.What is the doctor-patient relationship?

a) Professional interaction between the doctor and the patient.

b) Sexual interaction between the doctor and the patient.

22. The active-passivity model of doctor-patient relationship its:

1. The doctor do not accepts responsibility for the treatment;
2. The patient accepts complete responsibility for the treatment;
3. The doctor accepts complete responsibility for the treatment.

23. Medical paternalism and the principle of autonomy:

1. Patient autonomy was never violated by paternalism.
2. Paternalism is always a violation of patient autonomy.

24. Effective doctor-patient communication helps to:

1. Drink a glass of wine with medical staff.
2. Enhance patient compliance to treatment.
3. Avoid patient to do hard work.

25. Whether donors have a right to informed consent for every use of their cells?

1. Yes.
2. No.

26. Whether human donors of cells receive money profit from their use?

1. Yes.
2. No.

27. Are the use of prosthesis and implants violated of human identity?

1. Yes.
2. No.

28. Should whether agricultural animals be kept in cages on farms?

1. Yes.
2. No.

29. Does GM plants limit the biodiversity?

1. Yes.
2. No.

30.Reproductive human cloning is currently

1. not legal in the world.
2. legal in the world.

31. Unethical source of stem cells is

1. miscarried or stillborn fetuses.
2. umbilical cord blood.
3. preimplantation embryos.

32. Does cloning prevent gene diversity?

1. Yes.
2. No.

33. AIDS (Acquired Immune Deficiency Syndrome) is a disease. IS it true?

1. yes.
2. no.

34. Autonomy of persons with HIV/AIDS and other socially dangerous infections can be violated in case:

1. if patient is unwilling to be an active participant in the treatment process.
2. if patient does not understand the cause of the his disease.

35. What can violate of human rights to freedom of movement if a person has an infectious disease?

1. Imprisonment.
2. Quarantine.
3. Fuel price.

36. If patient has infectious disease and treatment of this disease can expose the doctor to personal risk, the doctor:

1. Should refuse treatment of patient.
2. Cannot refuse treatment of patient.

37. Autonomy patients with terrible pain may be violated in situations:

1. patients may not be able to carefully analyze the risks and benefits of treatments,
2. patients may not be able to escape from a hospital.

38. If risks and beneficence of pain medication are comparable (close), the a clinical decision must take by:

1. only a doctor.
2. doctor and patient.

39. Opioids, used to treat pain, have:

1. only useful effects.
2. useful and side effects.

40. What euthanasia is illegal worldwide?

1. Passive voluntary euthanasia.
2. Active voluntary euthanasia.
3. Involuntary euthanasia.

**Right answers:**

1. а 21. a

2. b 22. c

3. а,b 23. b

4. а 24. b

5. а 25. a

6. d 26. a

7. c 27. b

8. d 28. b

9. a,b 29. a

10. b 30. a

11. a 31. c

12. b 32. a

13. a,b,c 33. a

14. a,b 34. a

15.c 35. b

16. b 36. b

17. a,b 37. a

18. c 38. a

19. a 39. b

20. c 40. c

1 correct answer - 2 points

7. Scheme of calculation of points

Example for the final semester control in the form of a credit without performing the test work:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Current testing, questioning | | | | | | | | | | | | | | | Number of points for individual work | Number of points for a final test | Sum |
| Lecture module1/modul2 | | | | | Content module 1 | | | | | Content module 2 | | | | |
| L1  L1 | L2  L2 | L3  L3 | L4  L4 | L5  L5 | T1 | T2 | T3 | T4 | T5 | T1 | T2 | T3 | T4 | T5 | 10 | 40 | 200 |
| 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |

Т1, Т2 ... – topics of modules

8. Scale of assessment

|  |  |  |
| --- | --- | --- |
| The sum of points for all types of educational activity  during the semester | Score | |
| for a four-level rating scale | for a two-level rating scale |
| 180 - 200 | "excellent" | - |
| 150 - 179 | "good" | - |
| 120 - 149 | "satisfactorily" | - |
| < 120 | "Unsatisfactory" | - |

Recalculation of the current student's progress in the study of the module "Safety of vital functions, fundamentals of occupational safety"

"Excellent" ratings - 10 points;

The score is "good" - 7 points;

The rating is "satisfactory" - 6 points;

The rating is "unsatisfactory" - 0 points

Assessment of independent work: an assessment of the independent work of students, which is provided in the topic next to the classroom work, is carried out during the current monitoring.

The maximum number of points that a student can earn for current academic activity is 200 points. It is calculated by multiplying the number of points corresponding to the score "5" by the number of topics in the module with the addition of points for individual independent work (10 x 20 = 200).

The minimum number of points a student can gain while studying a module is calculated by multiplying the number of points corresponding to the "3" score by the number of topics in the module (6 x 20 = 120).

Since the form of final control in the discipline "Safety of vital functions, fundamentals of occupational safety" is credit, which is assessed on a two-point system ("accepted", "not accepted ") after graduation studying the topic students are announced the sum of points that each of them scored according to the results of the current monitoring and for the performance of individual works. A student gets a score "credited" if the number of points scored by him is not less than 120 and he visited all the training sessions (seminars) or worked on them in time. If the number of points is less than 120, he receives a "not accepted" rating.

For a student who received an "unsatisfactory" grade, the dean of the faculty gives a direction for the elimination of academic debt in discipline. The training of classes and increase of students' points in the direction of the dean's office must take place in due course during workings on the schedule of the department and the individual consultative work of the teacher. After working off the missed classes, the dean's office gives a student permission paper. These students form the basic questions (verbally or in writing) on ​​the academic discipline during the individual consultative work of the teacher of the corresponding academic (semester) group. Taking of the test is allowed no more than 2 times with permission of the dean's office.

9. Recommended literature

9.1. Main literature

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11. Operational Guidelines for Ethics Committees that Review Biomedical Research. - Geneva: WHO, 2000.-31P.

**9.2. Additional literature**

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2. Безпека життєдіяльності: Навч. посібник / За ред. М. На-зарука. - Львів: За вільну Україну, 1997
3. Постанова Кабінету Міністрів України від 10.01.2002 № 14 «Про затвердження Міжгалузевої комплексної програми «Здоров'я нації» на 2002-2011 роки».
4. Методичні розробки практичних занять та тези лекцій.
5. Періодичні видання за тематикою (перелік систематично оновлюється).
6. Risk assessment — roles and responsibilities / European Agency for Safety and Health at Work European Agency for Safety and Health at Work, ‘Facts 80, 2008.
7. Including gender issues in risk assessment / European Agency for Safety and Health at Work, ‘Facts 43’.
8. Snyder, R. (2000). Overview of the toxicology of benzene. *Psychological Review, 105,* 83-107.
9. The Safety of Genetically Modified Foods Produced through Biotechnology, Toxicol Sci (2003) 71 (1): 2-8.
10. Bloodborne Pathogens and Needlestick Injuries. OSHA Safety and Health Topics Page.
11. European Agency for Safety and Health at Work, Risk assessment

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**9.3. References to information internet resources**

# <https://www.osha.gov/dsg/hospitals/documents/1.2_Factbook_508.pdf>

# <http://osha.europa.eu/en/topics/riskassessment>

1. <https://www.osha.gov/SLTC/bloodbornepathogens/index.html>
2. <https://books.google.com.ua/books?id=Ceuq9P4hLJMC&pg=RA1-PA1991&lpg=RA1-PA1991&dq=Physiological+and+psychological+factors+of+the+safe+life&source=bl&ots=NLkxVQMffM&sig=l_PABh5nvn4tIRERwf5-afUw_Z8&hl=en&sa=X&ved=0ahUKEwj39YT_h5_SAhUHEiwKHe5lDq84ChDoAQgkMAI#v=onepage&q&f=false>